

IDMA BULLETIN

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WEEKLY PUBLICATION



Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

- ★ **Union Budget 2021-22: Highlights** (Page No. 4)
- ★ **IDMA and BDMAI joint Submission on Environmental Approvals – regarding Bulk Drug Industry** (Page No. 32)
- ★ **MoEF amendment brings APIs and intermediates under single category** (Page No. 37)
- ★ **DCG(I) calls for suggestions from industry to reduce compliance burden** (Page No. 37)
- ★ **Union Budget 2021-22: Vaccine-focus a shot in the arm** (Page No. 39)

UNWAVERING ATTENTION TO DETAIL. FOR ABSOLUTE **PRECISION.**

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NATURAL FLAVOURS
NATURAL COLOURS



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- COMPACTCEL (Co-processed Excipients for Tableting)

Signet

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IDMA ACTIVITIES:

Union Budget 2021-22: Highlights.....	4
Direct Tax Highlights-Finance Budget 2021-22.....	18
Pharma sector reacts to Union Budget 2021-22	25
IDMA and BDMAI joint Submission on Environmental Approvals – regarding Bulk Drug Industry.....	32
IDMA Members donate Medicines to Shanti Avedna Sadan for the Care of the Advanced and Terminally ill Cancer Patients	33

NEW DEVELOPMENTS:

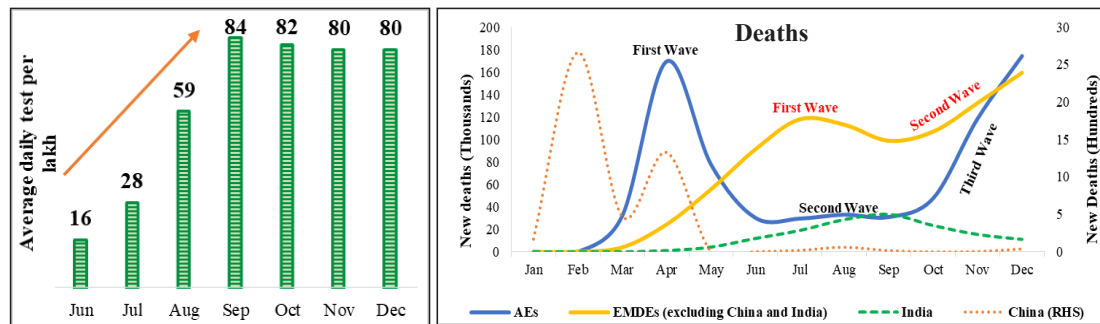
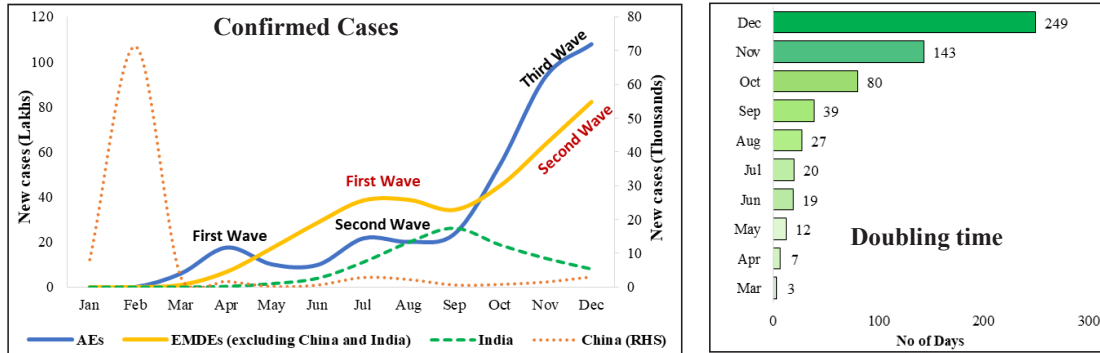
Drugs, vaccines less effective vs new virus variants antibody cocktail may protect patients' contacts	34
Researchers trying tapeworm, vertigo and pancreatitis drugs to fight COVID-19.....	35

NATIONAL NEWS:

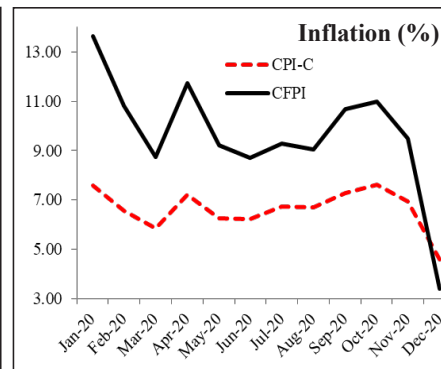
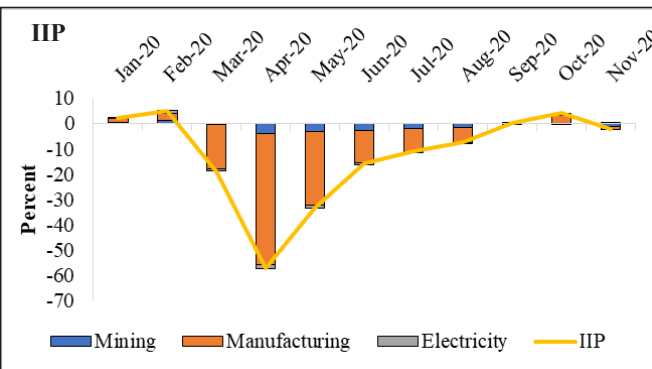
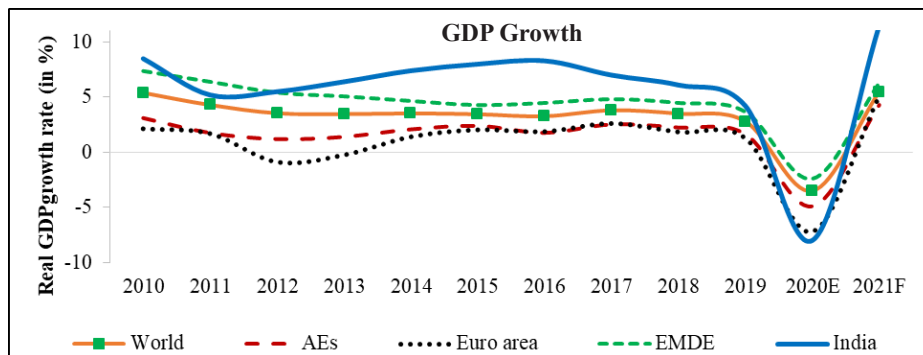
Covid shadow on Budget 2021: Health gets a vaccine shot, water in new 'well-being' category	36
DCG(I) calls for suggestions from industry to reduce compliance burden	37
MoEF amendment brings APIs and intermediates under single category	37
Covid blessing? Finally, biotech gets booster shot.....	38
Union Budget 2021-22: Vaccine-Focus a shot in the arm.....	39
IDMA & APTAR joint webinar on “Accelerating and De-Risking Your Product Development”: Announcement	41
IDMA Bulletin Advt. Tariff Card.....	42
Advertisements.....	2, 40, 43, 44 & 45

Union Budget 2021-22: Highlights

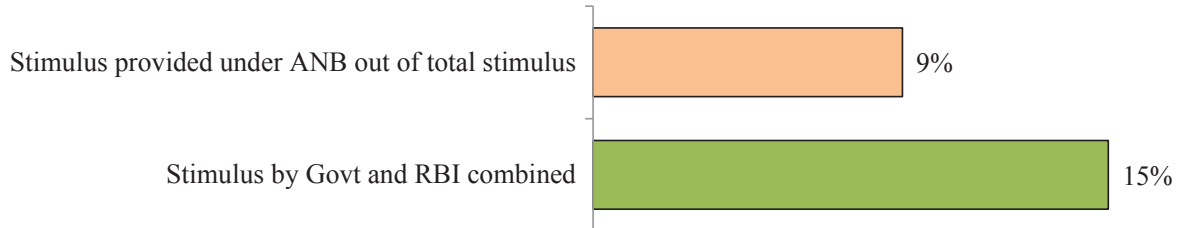
Resilience in face of Once in a Century Crisis



V Shaped Recovery



Atma Nirbhar Bharat Abhiyan



GOVERNMENT REFORMS

- Increase in borrowing limits of state governments
- Privatisation of Public Sector Enterprise



ENERGY

- Liquidity support for discoms
- Elimination of Regulatory Assets
- Commercial coal mining
- Reduction in cross-subsidy

MSMEs AND INDUSTRY

- Collateral free loans for businesses
- Fund of funds will be set up for MSMEs
 - PM Garib Kalyan Yojana
 - Subordinate debt for MSMEs
- Disallowing global tenders of up to Rs 200 crore
- Change in definition of MSMEs



SOCIAL SECTOR

- ❖ National Digital Health Blueprint
- ❖ Additional Allocation for MGNREGS
- ❖ Technology driven education: PM eVidya, National Foundational Literacy and Numeracy Mission

MIGRANT WORKERS

- ✓ One Nation One Card
- ✓ Free food grain Supply to migrants

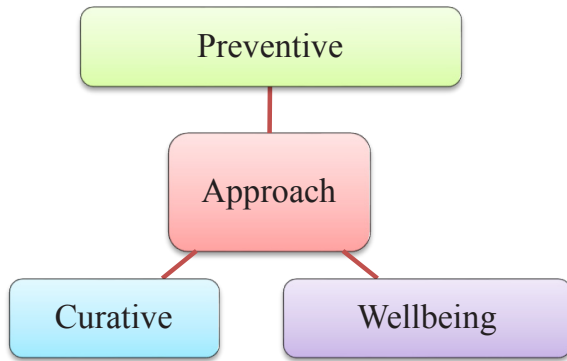


AGRICULTURE AND ALLIED SECTORS

- Concessional Credit Boost to farmers
 - Agri Infrastructure Fund
- Emergency working capital for farmers
- Animal Husbandry infrastructure development
- Amendments to the Essential Commodities Act
 - Agriculture marketing reforms



Holistic Approach to Health



Supplementary Nutrition Programme and Poshan Abhiyan to be merged and launched as Mission Poshan 2.0

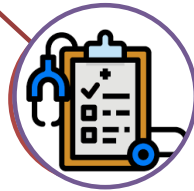


- ❖ Outlay ₹64180 crore over 6 years
- ❖ Support for Health and Wellness centres

PM AtmaNirbhar Swasth Bharat Yojana

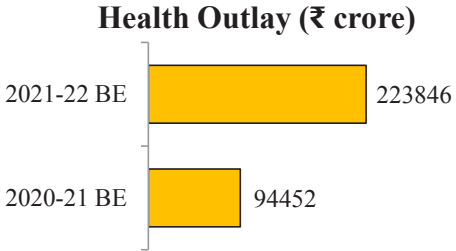
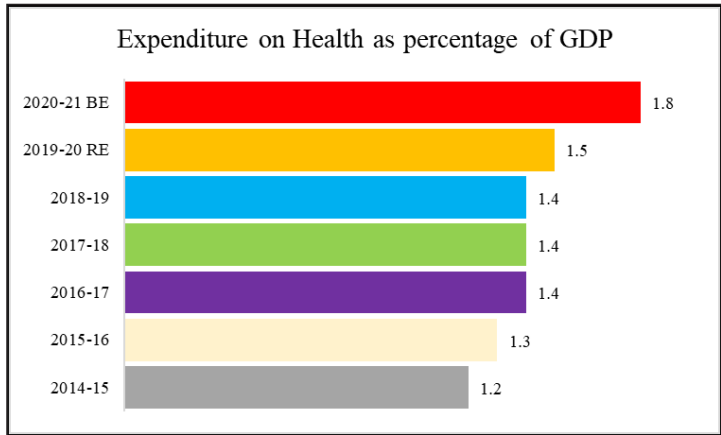


- ❖ Setting up of Integrated Public Health Labs
- ❖ Establishing critical care hospital blocks



- ❖ Strengthening NCDC
- ❖ Expanding integrated health information portal

- Pnuemococcal vaccine to be rolled across the country
- ₹35000 crore for Covid-19 Vaccine in 2021-22



Introduction of National Commission for Allied Healthcare Professionals Bill

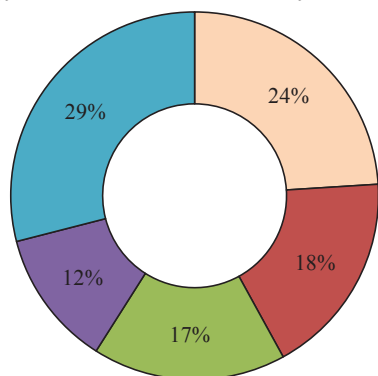
Industry

PLI launched to create manufacturing global champions across 13 sectors with amount committed nearly ₹1.97 lakh crore in next 5 years starting FY2021-22



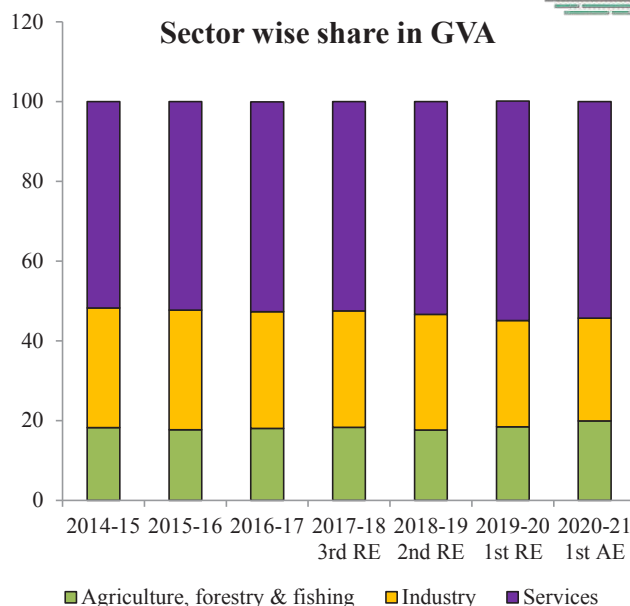
NIP projects by sector

Energy Road Urban Railways Others



NIP Project pipeline expanded to 7400 projects

Sector wise share in GVA

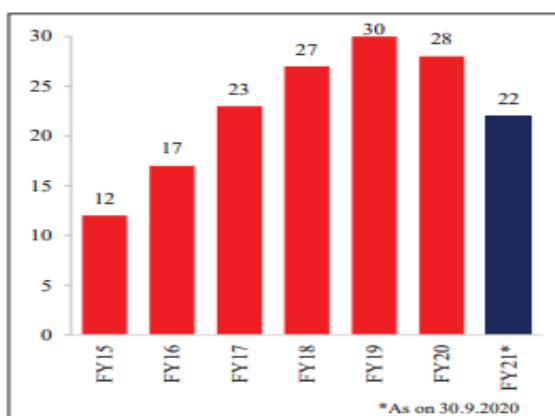


MITRA Scheme to create world class infrastructure for global champions in textile sector leading to creation of 7 textile parks over 3 years.

Infrastructure



Road Construction Per Day in km

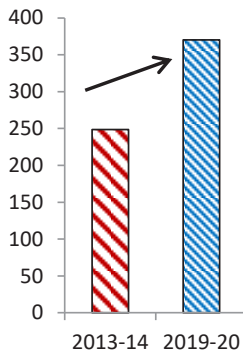


National Rail Plan

- Aims at developing adequate rail infrastructure by 2030 to cater to the projected traffic requirements up to 2050.
- The objective is to increase the modal share of rail in freight from the current level of 27 per cent to 45 per cent.

- 100% electrification of Broad Gauge Routes by 2023
- Indigenously developed automatic train protection system to be launched

Installed Plant Capacity (GW)



- ✓ 139 GW of installed capacity was added during 6 years connecting additional 2.8 crore households with addition of 1.41 lakh circuit km of transmission lines
- ✓ Revamped reforms-based result-linked power distribution sector scheme will be launched with an outlay of ₹3,05,984 crore over 5 years
- ✓ Hydrogen energy mission will be launched



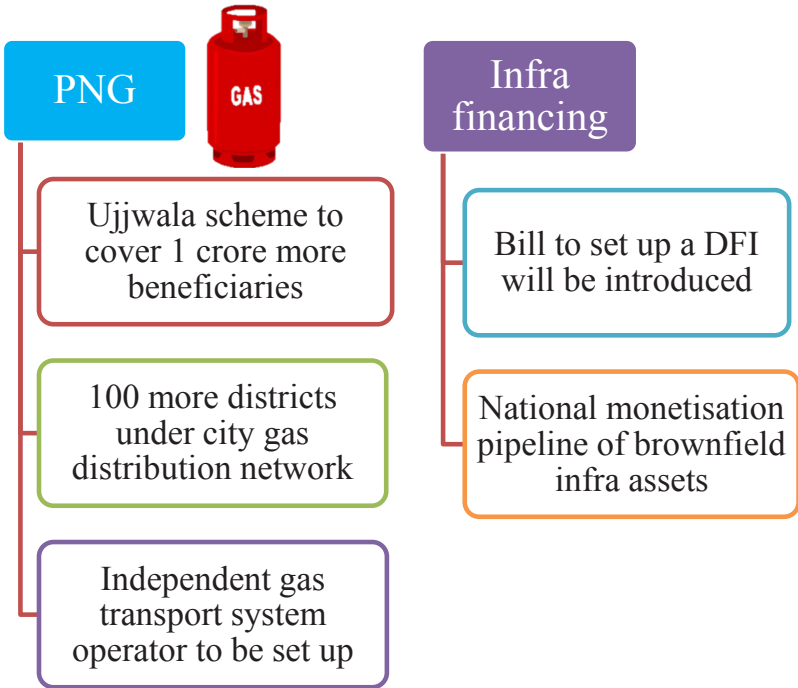
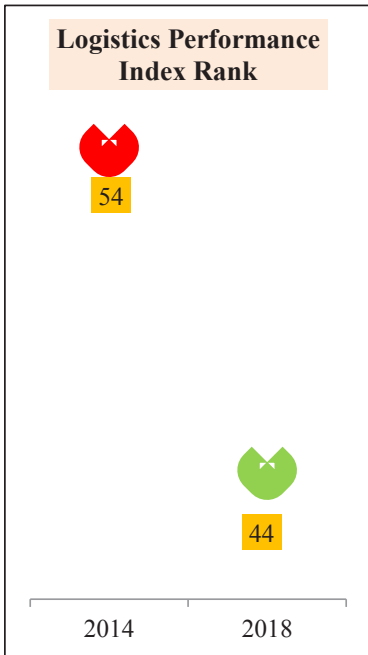
Ports, Shipping, Waterways



PPP mode to be utilised for managing operational services of major ports

Subsidy support to promote flagging of merchant ships

Recycling of Ships Act, 2019 enacted and recycling capacity to be doubled by 2024



Urban Development

Jal Jeevan Mission (Urban) for universal water supply in all ULBs



Urban Swachh Bharat Mission with outlay ₹1,41,678 crore over 5 years

₹2,217 crore for 42 urban centres to tackle air pollution



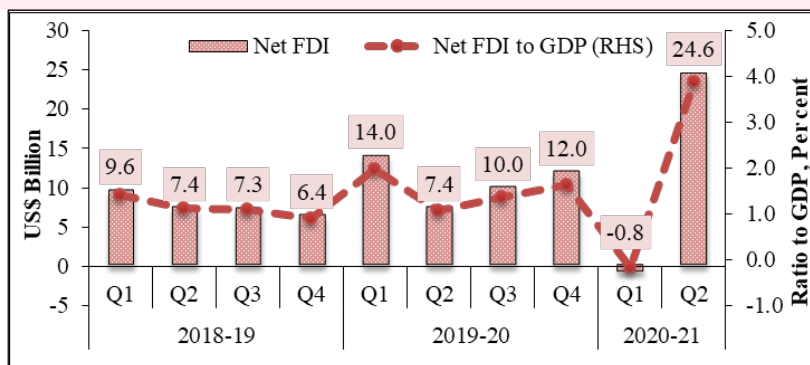
Voluntary Vehicle Scrapping policy

Innovative PPP models to augment public bus transport



MetroLite and MetroNeo for tier 2 and peripherals of tier 1 cities

Financial Reforms



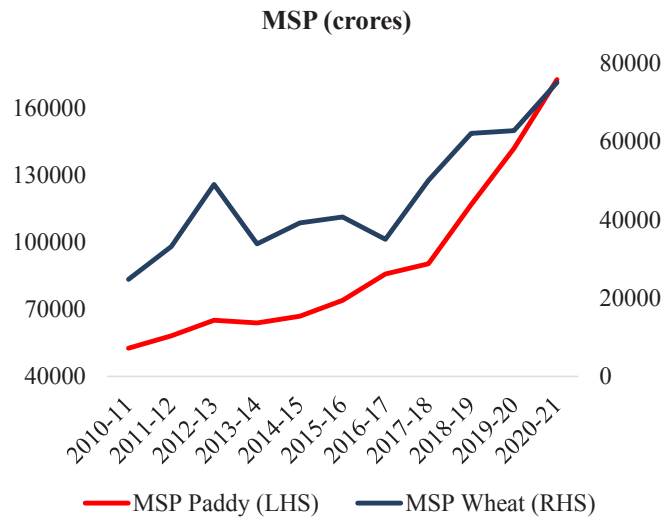
- ❖ Rationalised single Securities Markets Code by 2022
 - ❖ World class fintech hub at GIFT IFSC
- ❖ Permanent institutional framework for Corporate bond market
- ❖ SEBI as regulator and greater role for WDRA for development of commodity market ecosystem
 - ❖ Investor charter as a right across all financial products
- ❖ Amending the Insurance Act, 1938 to increase the FDI limit with safeguards
- ❖ Asset Reconstruction Company Limited and Asset Management Company to resolve stressed assets problem of PSBs.

Inclusive Development

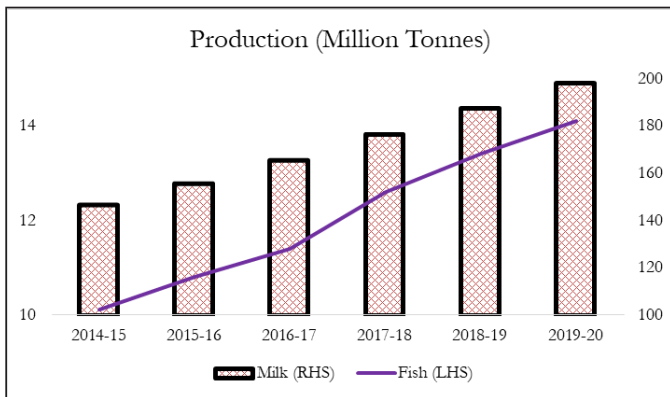


AGRICULTURE

- ❑ Extending coverage of SWAMITVA Scheme to all states/UTs
- ❑ Expansion of Operation Green scheme to include 22 perishable products
- ❑ 1000 more mandis to be integrated with e-NAM



FISHERIES

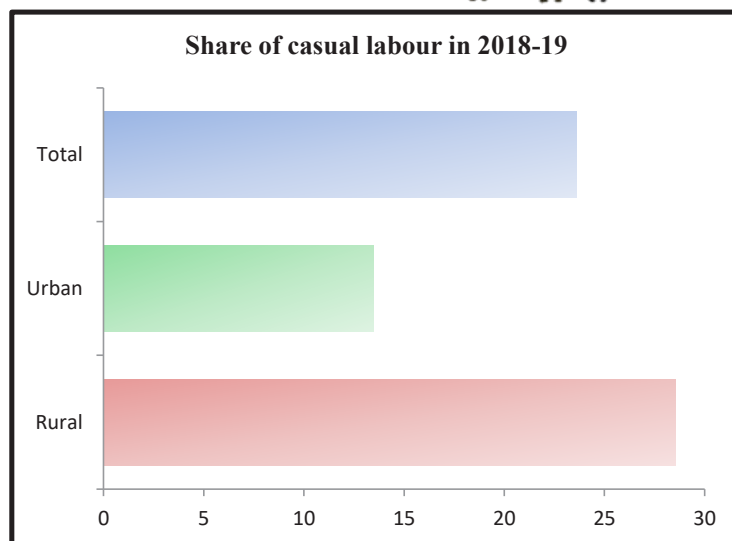


- Development of modern fishing harbours and fish landing centres
- Multipurpose Seaweed Park to be set up in Tamil Nadu

MIGRANT WORKERS AND LABOURERS



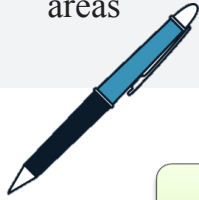
- One nation one ration card scheme under implementation in 32 states and UTs.
 - A portal to be launched for gig, building and construction workers
 - Social security benefits will be extended to gig and platform workers



Human Capital

EDUCATION

- Revamped Post Matric Scholarship Scheme for welfare of SCs
- 100 new Sainik schools
- 750 Eklavya schools in tribal areas

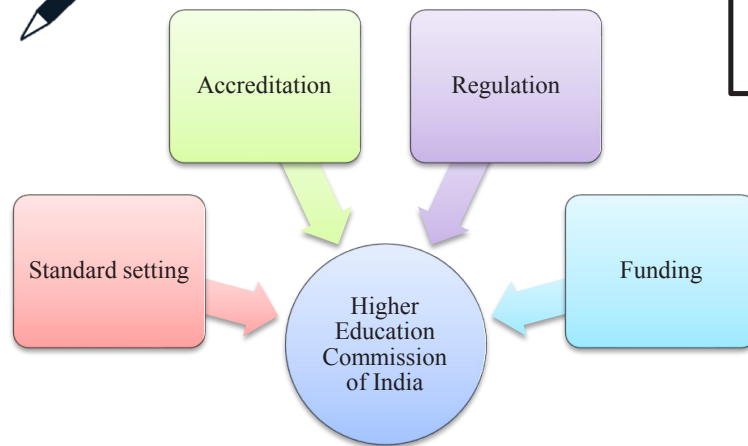
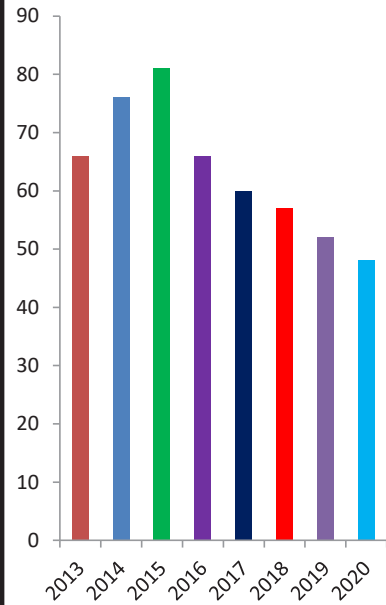


SKILLS

- ❖ Realigning National Apprenticeship Training scheme for graduates and diploma holders in Engineering
- ❖ Partnership with UAE and Japan in area of skill development and recognition



GII Rank

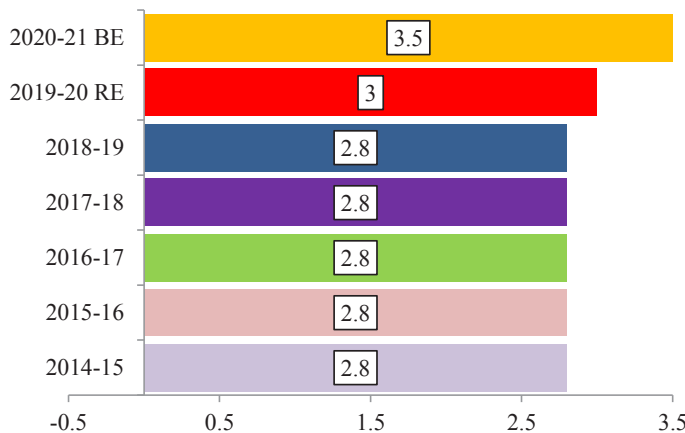


R&D

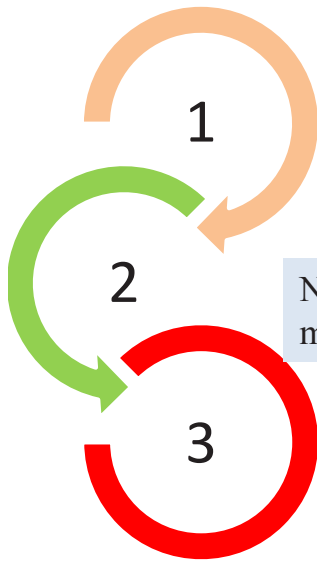
- ✓ National Research Foundation with outlay of ₹50,000 crore over 5 years
- ✓ National Language Translation Mission to boost internet access
- ✓ Deep Ocean Mission for ocean exploration and biodiversity conservation



Expenditure on Education as per cent of GDP



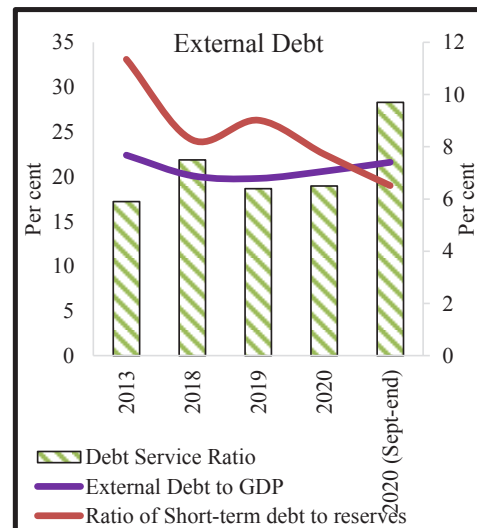
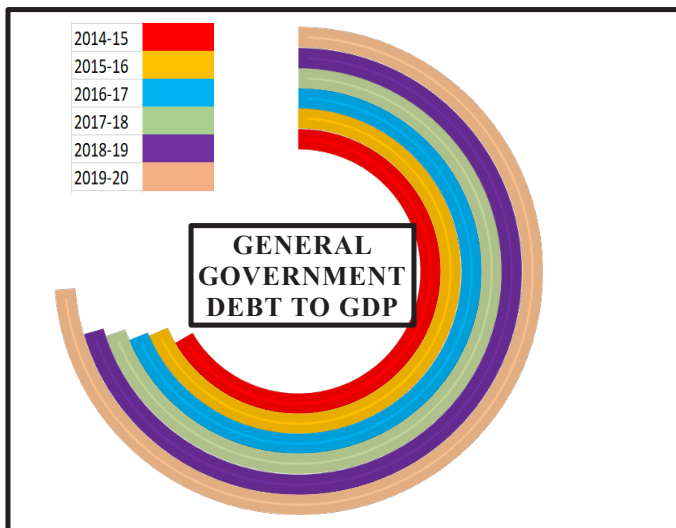
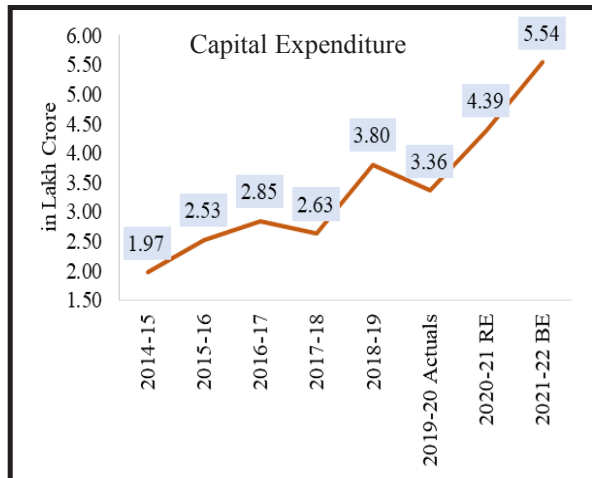
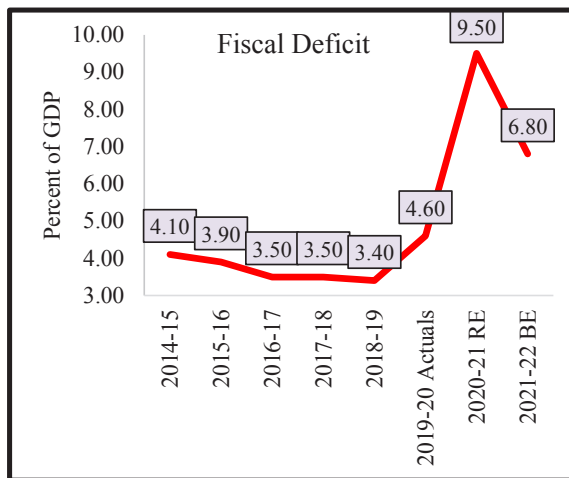
Fiscal Position



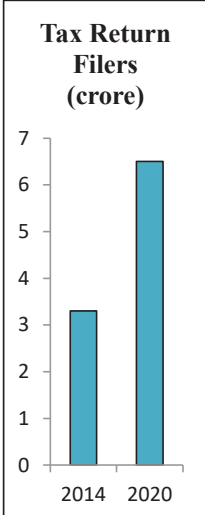
- Allowing a normal ceiling of net borrowing for the states at 4% of GSDP for 2021-22
- Additional Borrowing ceiling of 0.5% of GSDP subject to conditions

NSSF loan to FCI for food subsidy to be replaced by making budget provisions

₹1,18,452 crore as Revenue Deficit grant to 17 states in 2021-22



Tax proposals

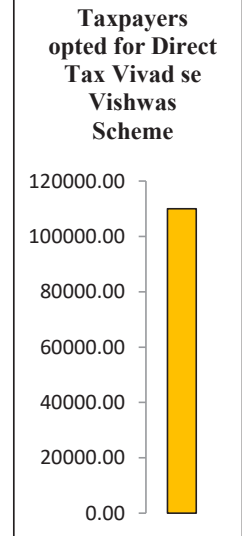


Exemption from filing income tax returns for senior citizens (75 years and above) who only have pension and interest income. The paying bank will deduct the necessary tax on their income.

Reducing time limit for reopening of income tax assessment

Constitution of a Dispute Resolution Committee for small tax payers

Income Tax Appellate Tribunal to be made faceless



Increase in limit for tax audit for persons who carry out 95% of their transactions digitally

Dividend payment to REIT/InvIT to be exempted from TDS

Additional deduction of ₹1.5 lakh shall be available for loans taken up till 31 March 2022 for purchase of affordable house

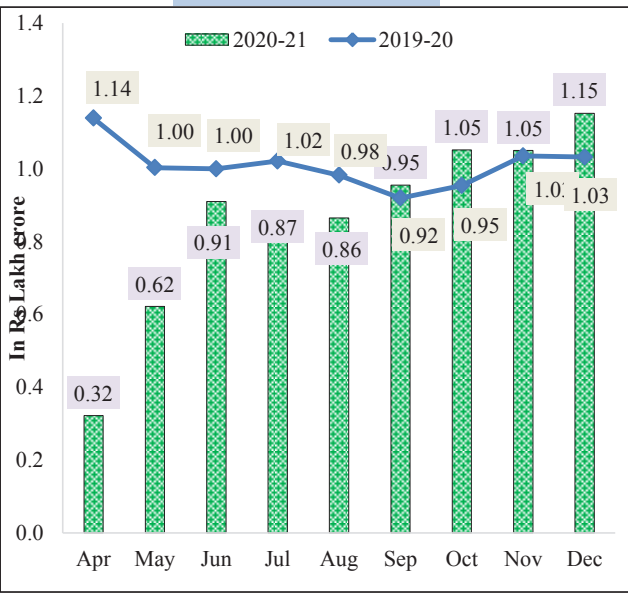
Pre filling of returns will also cover capital gains from listed securities, dividend income, etc.

Eligibility for claiming tax holiday for start ups proposed to be extended by one more year



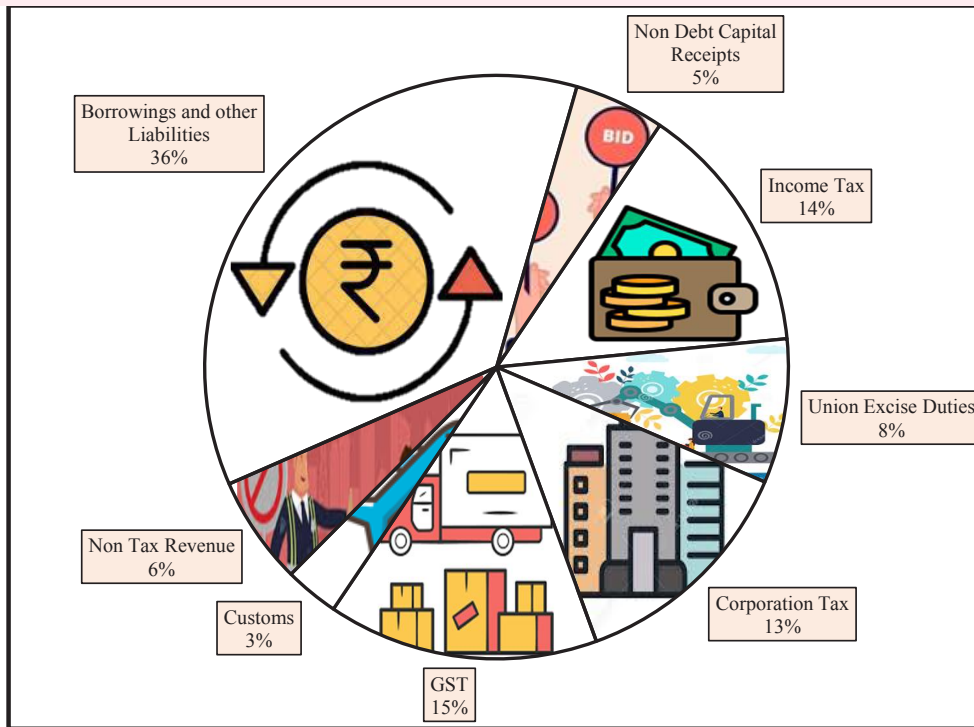
Indirect Tax

GST Collection

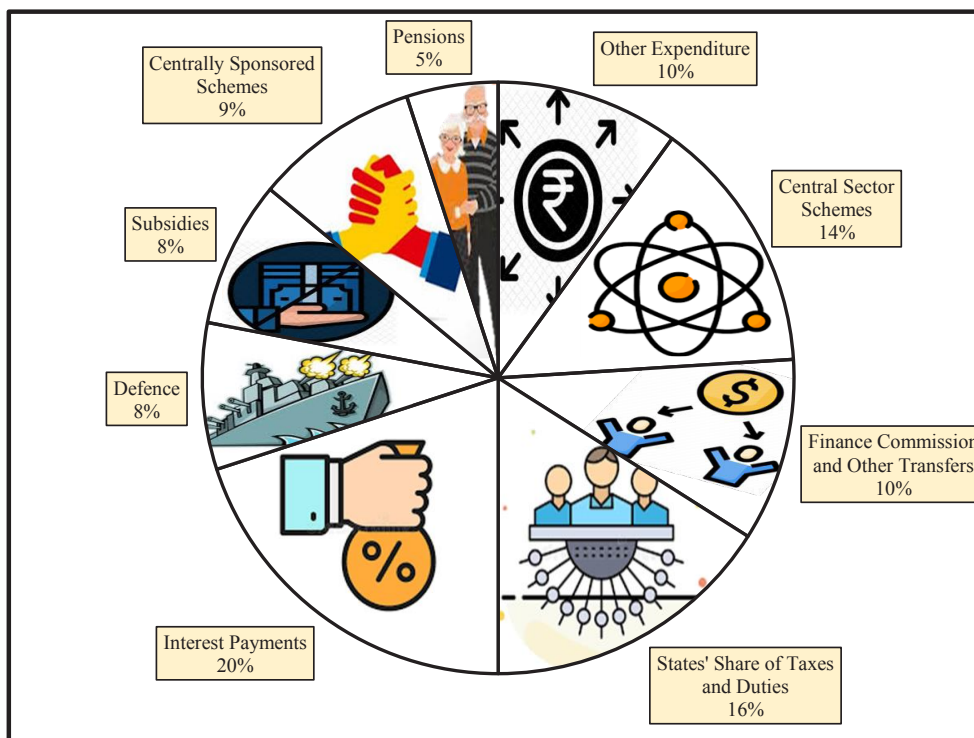


- ❖ Rationalisation of customs duty structure by eliminating outdated exemptions
- ❖ Support to MSMEs hit by recent sharp rise in iron and steel prices and relief to metal recyclers
- ❖ Rationalisation of duties on raw material inputs to man made textiles
- ❖ Rationalisation of custom duty on gold and silver
- ❖ Increase in duty on solar invertors and lanterns to promote domestic production
- ❖ Agriculture Infrastructure and Development Cess on small number of items

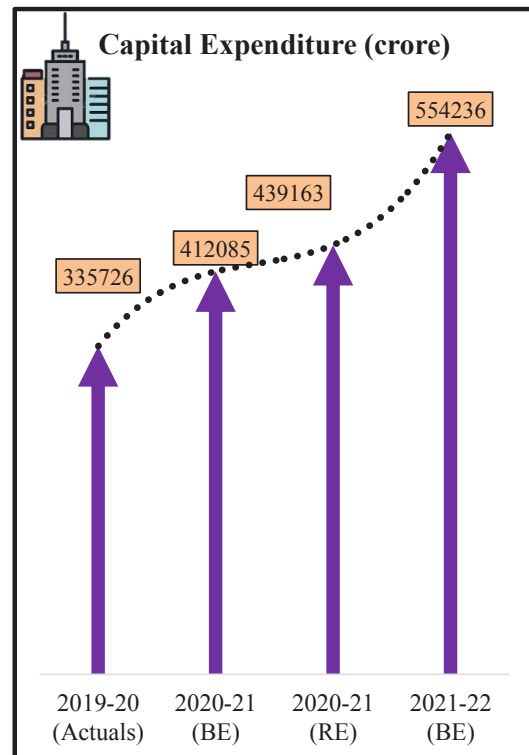
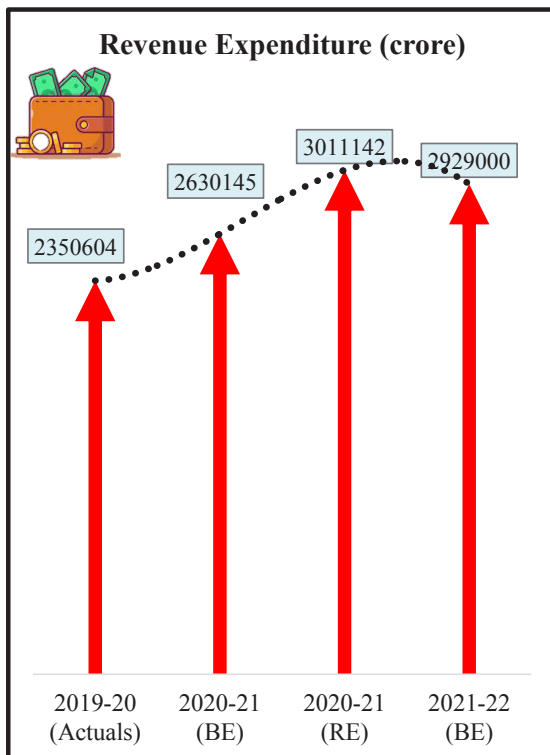
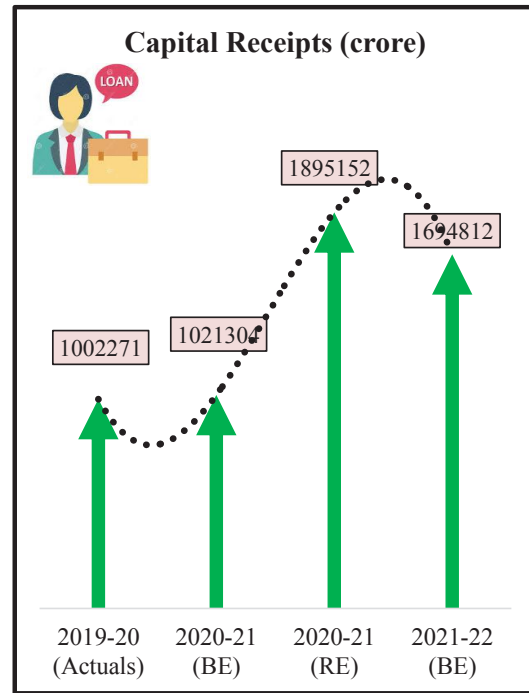
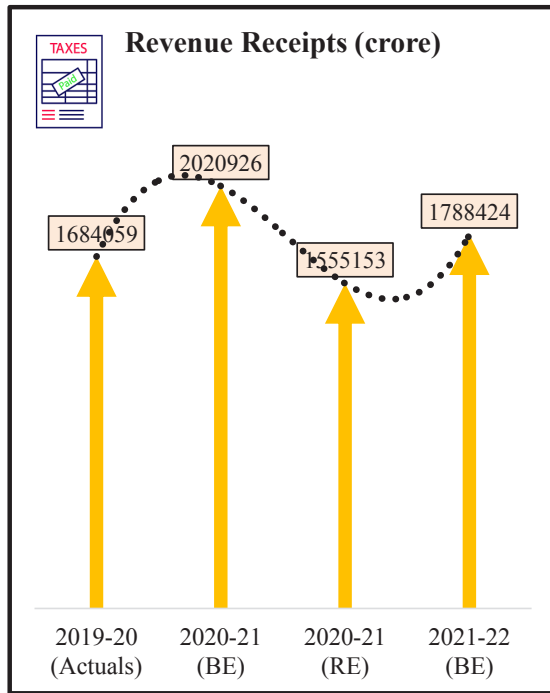
Rupee comes in



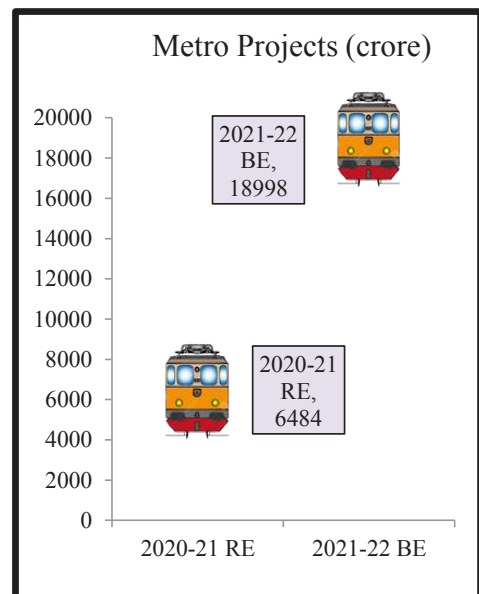
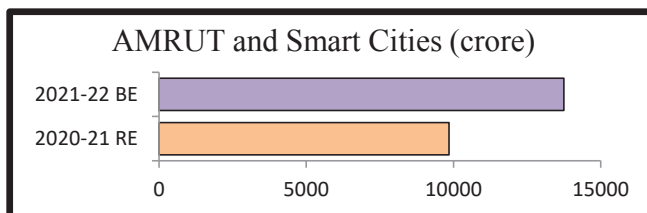
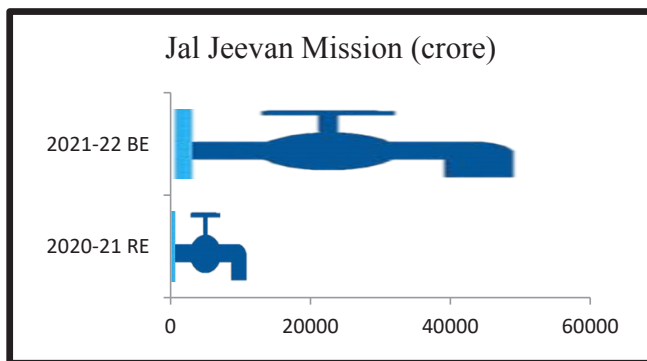
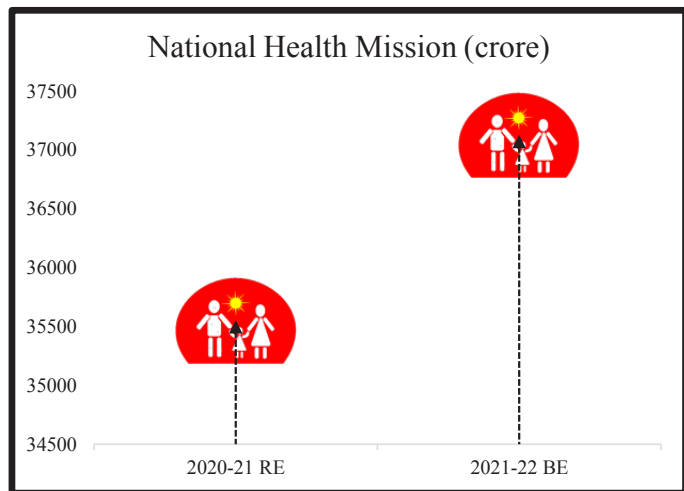
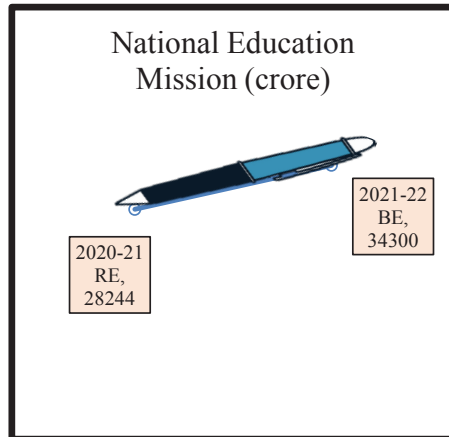
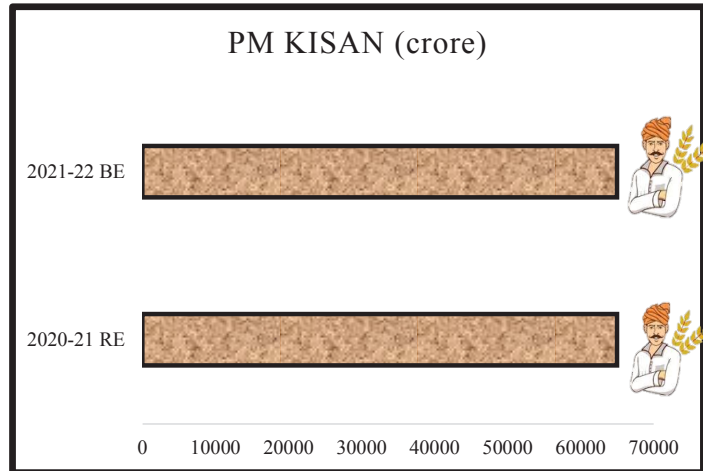
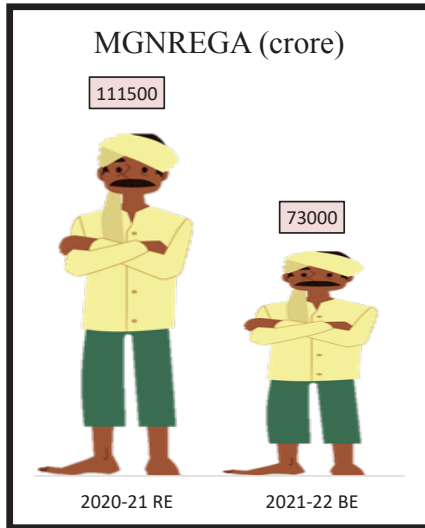
Rupee goes out



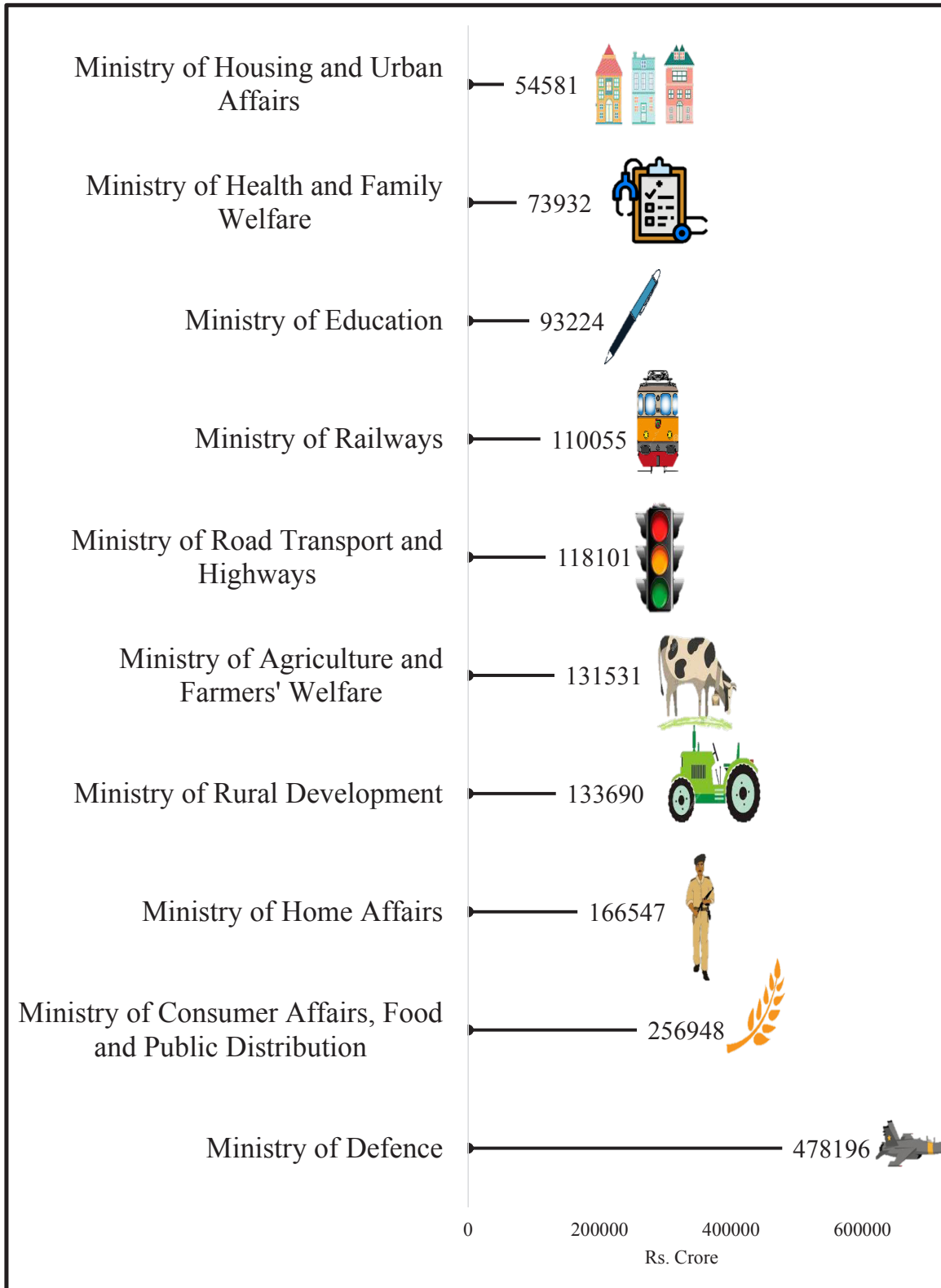
Budget at a Glance



Allocation to major schemes



Major Allocations



Direct Tax Highlights-Finance Budget 2021-22

Courtesy: Mr B G Barve, Chairman, IDMA Excise and Taxation Committee

CORPORATES

➤ Depreciation on goodwill

It is proposed that:

- The block of asset shall not include goodwill of a business or profession and therefore it will not be eligible for depreciation.
- Goodwill will be construed as a capital asset giving rise to capital gains in case of its sale/transfer.
- In a case where goodwill of a business or profession formed part of a block of asset on which depreciation has been claimed until Assessment Year 2020-21, the written down value of that block of asset and short-term capital gains, if any, shall be determined in the prescribed manner in the year of transfer of such goodwill.
- In case of goodwill of business or profession acquired by way of purchase and depreciation has been claimed, then, the cost of acquisition of such goodwill will be the purchase price as reduced by the depreciation so claimed until Assessment Year 2020-21.

➤ Late deposit of employee's contribution by employer to various funds will be disallowed to the employer

It is proposed to clarify that the employees' share of various funds will be allowed as a deduction only if it is paid on or before the due date mentioned in the respective Acts and not the due date of filing of return of income.

It is also proposed to clarify further that this was always the intention of the Act and the reference to due date being the due date of filing of return was incorrectly interpreted.

(This amendment will take effect retrospectively from 01.04.2020)

➤ Relief from applicability of MAT provisions on Dividend Income earned by Foreign Companies

It is proposed to extend the above relief from applicability of MAT provisions to dividend income accruing or arising to a foreign company and credited to its profit and loss account. Correspondingly,

provision is also made requiring the adding back of expenditure related to such dividend income if debited to the profit and loss account.

(This amendment will take effect retrospectively from 01.04.2020)

TAX DEDUCTED AT SOURCE/TAX COLLECTED AT SOURCE/ADVANCE TAX

➤ Tax Deduction at Source (TDS) on purchase of goods

Section 194Q is introduced to levy a TDS of 0.1% on purchase of goods from resident exceeding Rs. 50 lakhs during financial year only if the buyer's total sales/ gross receipts from business exceeds Rs. 10 crore during immediately preceding financial year.

If a transaction is liable to TCS u/s 206C(1H) of the Act, as well as TDS under this section, then as per second proviso to section 206C(1H) only TDS under this section shall be deducted on such transaction. Hence, now, a payer needs to first check whether TDS is deductible under normal provisions of the Act. If no, then whether TDS is deductible under this new provision. Again, if no, then the seller would need to collect TCS on the same as per the provisions of section 206C(1H).

Further, if the seller, fails to provide his PAN or Aadhar, provisions of section 206AA would become applicable. However, the rate of TDS in this case has been amended to be at 5% instead of 20%.

(This amendment will take effect from 01st July 2021)

➤ TDS/TCS on non-filer at higher rates

It is proposed that any sum or income paid, or payable, by a person to a person who does not file return of income, the person paying the amount would be liable to deduct TDS u/s 206AB at higher of following rates:

- twice the rate specified in the Act; or
- twice the rates in force; or
- the rate of 5%

(This section shall not apply where the tax is required to be deducted under sections 192, 192A, 194B, 194BB, 194LBC or 194N of the Act)

Similarly with respect to TCS, It is proposed that any sum or amount received by a person to a person from a person who is non-filer of income tax return, would be liable to collect TCS u/s 206CCA at higher of following rates:

- twice the rate or rates in force; or
- the rate of 5%

The non-filer person who has not filed income tax returns for the two immediate previous years in which tax deducted or collected, aggregated to Rs. 50,000 or more in each of these two previous years.

(This amendment will take effect from 01st July 2021)

[Action to be taken - w.e.f 01st July, 2021, *deductor will have to collect declaration alongwith copy of last 2 years ITR acknowledgement and Form 26AS from each person whose TDS is to be deducted*]

➤ **TDS on payments to Foreign Institutional Investors (FII)**

Income on securities earned by FII shall be subject to TDS at the lower of the following rates:

- at the rate of 20%; or,
- the rate of income-tax provided in the DTAA provided the FII furnishes tax residency certificate

➤ **Exemption of deduction of tax at source on payment of Dividend to business trust in whose hand dividend is exempt**

TDS is not required to be deducted to such income credited or paid to a business trust by a special purpose vehicle.

(This amendment will take effect retrospectively from 1st April, 2020)

➤ **Advance tax liability on dividend** will arise only after declaration/payment of dividend.

If the shortfall of advance tax is on account of dividend income earned from domestic companies, the tax-payer will not be liable to pay the interest amount on such shortfall provided adequate tax thereon has been paid in the subsequent instalments. It is also provided that the above mentioned concession will not extend to deemed dividend.

(This amendments will take retrospective effect from 01.04.2020)

➤ **Dividend payment to REIT/ InvIT** will be **exempt from TDS**

INDIVIDUAL

➤ **Taxability of Interest on various funds in case of large contributions:**

Interest income accrued during the year on the employee's contribution to various provident funds to the extent attributable to contribution exceeding ₹ 2.5 lakh in a financial year shall be taxable.

(This amendment will take effect from 01.04.2021)

➤ **Exemption for Leave Travel Concession Cash Scheme**

Under the existing provisions, an employee is eligible for exemption for travel concession or assistance received from his employer in connection with his leave to any place in India.

In view of the situation arising out of outbreak of COVID pandemic, it is proposed to provide tax exemption for cash allowance in lieu of travel concession subject to the fulfilment of the following conditions :

- The employee exercises an option for the deemed LTC fare in lieu of the applicable LTC in the block year 2018-2021;
- The amount of exemption shall not exceed Rs. 36,000 per person or 1/3rd of specified expenditure, whichever is less;
 - "Specified expenditure" means expenditure incurred by an individual or a member of his family during the specified period on goods or services which are liable to tax at an aggregate rate of 12% or above under various GST Laws and goods are purchased or services procured from GST registered vendors/service providers;
 - "Specified period" means the period commencing from 12th October, 2020 and ending on 31st March, 2021;
- The payment to GST registered vendor/service provider is made by an account payee cheque or account payee bank draft or ECS and tax invoice is obtained from such vendor or service provider;
- If the amount received by an employee from his employer, in relation to himself and his family, for the LTC is more than what is allowable to such person, the exemption would be available

only to the extent of exemption admissible under above listed provisions.

(This amendments will apply retrospectively from 01.04.2020)

➤ **Rationalisation of taxation of Unit Linked Insurance Plan (ULIP)**

Restricted Tax exemption for maturity proceeds of the ULIP having annual premium up to Rs. 2.5 lakh. However, the amount received on death shall continue to remain exempt without any limit on the annual premium. The cap of ₹ 2.5 lakh on the annual premium of ULIP shall be applicable only for the policies taken on or after 01.02.2021. Further, in order to provide parity, the non-exempt ULIP shall be provided same concessional capital gains taxation regime as available to the mutual fund.

➤ **Relief to senior citizen (75 years and above)** having only pension and interest income from pension bank account are **exempted from filing income tax returns**. However, the paying bank will deduct the necessary tax on their income.

➤ Tax incentive of affordable rental housing project for migrant workers extended till 31.03.2022 for 100% deduction of profits u/s 80-IBA.

➤ Incentives of deduction in respect of interest, up to Rs. 1.50 lakhs, on housing loans in respect of residential house property having stamp duty value not exceeding threshold of Rs. 45 lakhs, has been extended to loans sanctioned till 31st March 2022.

➤ Tax incentives u/s 80-IAC for entrepreneurs embarking on new journeys of setting up their own start-ups and Sec 54GB of the Income tax act exemption on transfer of residential property for investment in start-ups taken place are extended till 31st March 2022.

➤ Government to **notify rules to eliminate double tax for NRIs on foreign retirement funds**

➤ **New section 2(29A) is inserted to define the term “liable to tax”**

It means that there is a liability to tax on such person “under any law for the time being in force” in any country and will include a case where subsequent to imposition of such tax liability, an exemption has been provided.

(This amendment will take effect from 1st April, 2020)

➤ **Addressing mismatch in taxation of income from overseas retirement**

Presently, there is a mismatch in the year of taxability of withdrawal from overseas retirement funds by residents who had opened such fund when they were non-resident in India and resident in foreign country. At present the withdrawal from such funds may be taxed on receipt basis in such foreign countries, while on accrual basis in India.

In order to address this mismatch, it is proposed that the income of a specified person from specified account shall be taxed in the manner and in the year as prescribed by the Central Government

➤ **Equalisation Levy - An anomaly removed**

The exemption section 10(50) is amended which will now apply to e-commerce supply or services provided ‘on or after April 1, 2020’. Consequently, for FY 20-21 also, in cases where Equalisation Levy is leviable, income tax won’t be leviable.

➤ **Equalisation Levy on “ROYALTY” or “FEES FOR TECHNICAL SERVICES” – Not Leviable**

Where there is an overlap between application of EL and application of income-tax on either royalty or fees for technical services, then, the relevant income will be taxed as royalty or fees for technical services either under the Act or under the relevant tax treaty; and Such income will not be subject to EL

➤ **Equalisation Levy – Meaning of “ONLINE SALE OF GOODS” and “ONLINE PROVISION OF SERVICES”**

This aspect is now sought to be clarified by insertion of new Explanation to S. 164 which states that the expressions “online sale of goods” and “online provision of service” shall include one or more of the following online activities:

- (a) Acceptance of offer for sale; or
- (b) Placing of purchase order; or
- (c) Acceptance of purchase order; or
- (d) Payment of consideration; or
- (e) Supply of goods or provision of services, partly or wholly.

➤ **New Definition – “CONSIDERATION RECEIVED OR RECEIVABLE FROM E-COMMERCE SUPPLY OR SERVICES”**

It is now proposed to insert a new definition of the expression “consideration received or receivable from e-commerce supply or services”. This expression shall include:

- Consideration for sale of goods irrespective of whether the e-commerce operator owns the goods;
- Consideration for provision of services irrespective of whether service is provided or facilitated by the e-commerce operator.

CHARITABLE INSTITUTIONS

➤ **Rationalisation to eliminate possibility of double deduction by charitable institutions**

Where the corpus fund has been exempted and its application has been claimed as application against the mandatory 85% application of non-corpus income results into unintended double deduction.

To ensure that there is no double counting while calculating application or accumulation, it has been proposed that:

- Voluntary contributions made with a specific direction, that it shall form part of the corpus shall be invested or deposited in specified investments maintained specifically for such corpus.
- Utilisation of funds out of corpus shall not be considered as application of income for charitable or religious purposes.
- However, when amounts are re-invested or re-deposited in specified investments maintained specifically for such corpus out of the income, then, such amount shall be allowed as application in the previous year in which it is re-deposited to corpus fund.

Similarly, it is also proposed that funds applied/ utilised out of loans and borrowings shall not be considered as application for charitable or religious purposes. However, when loan or borrowing is repaid from the income, then, such repayment shall be allowed as application in the previous year in which it is repaid to the extent of such repayment.

➤ **The blanket exemption for Educational Trusts and hospitals limit has been increased from Rs. 1 crore to Rs. 5 crore (Sec 10(23C))**

(This amendment will take effect from 1st April, 2021)

Procedure for Assessments, Appeals and other Resolution Mechanism

➤ **Pre-filled income tax return** will have pre-filled data regarding details of capital gains from listed securities, dividend income, and interest from banks, post office, etc.

➤ **Due date for filing of belated and revised ITR preponed**

Due date for filing of belated and revised ITR to be reduced by 3 months before the end of the relevant assessment year i.e.31st December of that assessment year or before completion of the assessment, whichever is earlier

➤ **Reduction of time limit for assessment proceedings**

Particulars	Existing Time Limits	Proposed Time Limits
Time limit for sending intimation u/s.143(1)	One year from the end of the FY in which the return is furnished.	Nine months from the end of the FY in which the return is furnished.
Time limit for issuance of notice u/s.143(2)	Six months from the end of the FY in which the return is furnished.	Three months from the end of the FY in which the return is furnished.
Time limit for passing Assessment Order u/s. 143(3) or 144	Twenty-one months from the end of the AY in which income was first assessable.	Nine months from the end of the AY in which the income was first assessable.

(This amendment will take effect from 01.04.2021)

➤ **Allowing prescribed authority to issue notice under section 142(1)(i)**

It is proposed to empower the prescribed income-tax authority besides the Assessing Officer to issue notice under the said clause.

➤ **Reassessment & Search Proceedings**

The provisions relating to reassessment and search assessments are proposed to be completely substituted as under:

- Provisions of Section 153A and Section 153C to be applicable only on search initiated u/s 132 or requisition made u/s 132A on or before March 31, 2021.

- Common new procedure to be followed in case of assessments, reassessments or re-computations in search initiated u/s 132 or requisition made u/s.132A after March 31, 2021 which are prescribed in substituted Section 147,148,148A of the Act.
- Section 147 to allow AO to assess/reassess or re-compute any income escaping assessment in any AY.
- Notice under substituted section 148 to be issued before assessment/reassessment/re-computation when the AO has “information” that income chargeable to tax has escaped assessment and after following procedure specified in proposed section 148A of the Act.
- “Information” which suggests that income is said to have escaped assessment has been defined to mean:
 - i. Information flagged by a computer based system in accordance with the risk management strategy formulated by CBDT.
 - ii. Final objection raised by CAG to the effect that assessment/reassessment has not been in accordance with the provisions of the Act.
 - iii. In case of search, survey, requisition or seizure after on or after April 1, 2021, the AO shall be deemed to have information which suggests that income has escaped assessment for 3 AY’s prior to year of search, seizure survey or requisition.
- Section 148A to be inserted to empower the AO to conduct enquires, if required, with prior approval of specified authority and give the Assessee an opportunity of being heard before issuance of notice u/s.148 and after obtaining due approval of “specified authority”. After considering the Assessee’s reply, the AO shall decide by passing an order whether it is a fit case for issuance of notice u/s 148 and serve a copy of such order along with the notice to the assessee. Aforementioned procedure of conducting enquiry, providing opportunity and passing order before issuing notice u/s 148 not applicable in search cases.
- Time limit for issuance of notice u/s.148:
 - i. Normally, three years from the end of the relevant AY;
 - ii. If AO has in his possession evidence, that income chargeable to tax, represented in the form of an asset, which has escaped assessment amounts to or is likely to amount to Rs.50,00,000/- or more for that year, then ten years from the end of the relevant AY.
- Section 151 is proposed to substituted to define the “specified authority” for the purpose of section 148 and 148A to mean as under

TIME PERIOD	DESIGNATION OF OFFICER
If less than 3 years	Principal Commissioner or Principal Director or Commissioner or Director
If more than 3 years	Principal Chief Commissioner or Principal Director General or Chief Commissioner or Director General

- Under the proposed amendments, once assessment/reassessment/re-computation has started the AO is empowered to assess/reassess the income in respect of any issue which has escaped assessment and which comes to his notice subsequently in the course of proceedings under this procedure notwithstanding that the procedure prescribed in section 148A was not followed before issuing such notice for such income.
(This amendment will take retrospective effect from 01.04.2020)
- **Due date for ITR filing for partners of a firm liable for Transfer Pricing Audit extended**
Due date for ITR filing for partners of a firm liable for Transfer Pricing Audit is being proposed to extend to 30th November of the assessment year, since the total income of such partner can be determined only after the books of accounts of such firm have been finalised.
- **Dispute resolution committee** for small taxpayers with **total income less than Rs.50 lakhs and disputed income less than ₹10 lakhs** can approach the committee which is **faceless**.
- **Establishment of National Faceless Income Tax Appellate Tribunal Centre** - All communication shall be electronic. Where personal hearing is needed, it shall be done through video-conferencing.
- **Discontinuation of Income-tax Settlement Commission (ITSC)** with effect from 01st February 2021 and to constitute Interim Board of settlement for pending cases

➤ **Re-opening of assessments on account of income escaping assessment**

Escapement of Income Liabile to Tax	Proposed Time Limit for Issuing Re-opening Notice
Escaped income up to Rs. 50 lakhs	Within 3 years of the end of the assessment year
Escaped income more than Rs. 50 lakhs	Within 10 years of the end of the assessment year

- The Income-tax Officer shall be empowered to assess/re-assessor re-compute any income escaping assessment for any assessment year (called relevant assessment year). But only after seeking approval of the Principal Commissioner or Principal Chief Commissioner or Principal Director General.
- Before initiating action, a notice shall be required to be issued under section 148 of the Act, which can be issued only when there is information with the Assessing officer which suggests that the income liable to tax has escaped assessment for the relevant assessment year.
- Any information which has been flagged in the Department's computer based system in accordance with the risk management strategy formulated by the Board shall be considered as `information`.
- Before issuance of the notice, the Income-tax Officer shall conduct enquiries, if required, and provide an opportunity of being heard to the tax-payer and after considering his reply, decide by passing an order, whether it is a fit case for issue of notice under section 148 of the Act.
- Once the assessment/reassessment or re-computation has been initiated, the Income-tax Officer is empowered to take into account any other income which comes to his notice subsequently during the course of such proceedings.

Others

- **No Tax Audit** for and assessee carrying on business having **turnover upto Rs.10 crores** provided 95% of the transactions are carried digitally i.e. cash receipts during the year does not exceed 5% of total receipts; and cash payments during the year does not exceed 5% of total payments
(This amendment will take retrospective effect from 1st April, 2020)

➤ **Rationalisation of the provision of presumptive taxation for professionals under section 44ADA**

It is being clarified that the presumptive taxation scheme for professionals under Sec 44ADA, is applicable only to an individual, HUF or partnership firm, however so not including LLP since an LLP is required to maintain books of accounts in any case under LLP Act.

(This amendment will take effect from 01.04.2020)

➤ **Rationalisation of provision of slump sale**

It is proposed to amend the scope of the definition of the term `slump sale` so that all types of transfer defined in the Act are included within its scope.

➤ **Provision of transfer of capital asset to partner on dissolution or reconstitution of a firm**

It is proposed to tax the firm under the head capital gains for the amount paid to the partner at the time of retirement or dissolution or reconstitution of the firm in excess of the balance in the partner's capital account (excluding balance arising out of re-valuation of assets or self-generated assets).

It is further provided that in computing capital gains in the hands of the firm:

- The amount of money paid to the partner and the fair market value of assets distributed to the partner shall be deemed to be the sale consideration.
- The cost shall be the balance in the capital account of the partner (excluding balance arising out of re-valuation of assets or self-generated assets) in the books of accounts of the firm at the time of its dissolution or reconstitution.

➤ **Provisional attachment in Fake Invoice cases**

It is proposed to enable the Assessing Officer to exercise the powers under this section during the pendency of proceedings for imposition of penalty of the Act on such person who makes a false entry or omit an entry from his books of accounts, if the amount or aggregate of amounts of penalty imposable is likely to exceed ₹ 2 Crores.

- Notified Infrastructure Debt Funds will be eligible to raise funds by issuing tax efficient Zero Coupon Bonds.

Note on GST amendments in Budget 2021-22

Courtesy: Mr B G Barve, Chairman, IDMA Excise and Taxation Committee

Mrs Nirmala Sitharaman presented Union Budget 2021 in Parliament on Monday, February 1st, 2021. Presenting the first ever digital Union Budget, she stated that India's fight against COVID-19 continues into 2021 and that this moment in history, when the political, economic, and strategic relations in the post-COVID world are changing, is the dawn of a new era – one in which India is well-poised to truly be the land of promise and hope.

We have analysed in detail the changes proposed under the GST Law – Section wise for easy digest and implementation when notified.

- 1. Scope of Supply (r.w.e.f. 01.07.2017):** A new clause (aa) in sub-section (1) of Section 7 of the CGST Act is proposed to be inserted, retrospectively with effect from the 1st July, 2017, so as to ensure levy of tax on activities or transactions involving supply of goods or services by any person, other than an individual, to its members or constituents or *vice-versa*, for cash, deferred payment or other valuable consideration.
- 2. Eligibility and conditions for taking input tax credit:** A new clause (aa) to sub-section (2) of the section 16 of the CGST Act is proposed to be inserted to provide that input tax credit on invoice or debit note may be availed only when the details of such invoice or debit note have been furnished by the supplier in the statement of outward supplies and such details have been communicated to the recipient of such invoice or debit note.
- 3. Audit by Chartered Accountant:** Sub-section (5) of section 35 of the CGST Act is proposed to be omitted so as to remove the mandatory requirement of getting annual accounts audited and reconciliation statement submitted by specified professional.
- 4. Annual return:** Section 44 of the CGST Act is proposed to be substituted so as to remove the mandatory requirement of furnishing a reconciliation statement duly audited by specified professional and to provide for filing of the annual return on self certification basis. It further provides for the Commissioner to exempt a class of taxpayers from the requirement of filing the annual return.
Proposed to empower the Central Government to provide by rules the time within which and the form
- 5. Interest on delayed payment of tax Section 50 (r.w.e.f 01.07.2017) -** Section 50 of the CGST Act is proposed to be amended, retrospectively, to substitute the proviso to sub-section (1) so as to charge interest on net cash liability with effect from the 1st July, 2017.
- 6. Determination of tax not paid or short paid or erroneously refunded or input tax credit wrongly availed or utilised by reason of fraud or any willful misstatement or suppression of facts:** Section 74 of the CGST Act is proposed to be amended so as make seizure and confiscation of goods and conveyances in transit a separate proceeding from recovery of tax.
- 7. Amendment in Section 75:** An explanation to sub-section (12) of section 75 of the CGST Act is proposed to be inserted to clarify that “self-assessed tax” shall include the tax payable in respect of outward supplies, the details of which have been furnished under section 37, but not included in the return furnished under section 39.
- 8. Provisional attachment to protect revenue in certain cases:** Section 83 of the CGST Act is proposed to be amended so as to provide that provisional attachment shall remain valid for the entire period starting from the initiation of any proceeding under Chapter XII, Chapter XIV or Chapter XV till the expiry of a period of one year from the date of order made thereunder.
Substituting sub-section (1) thereof, which empowers the Central Government to provide by rules the manner in which the Commissioner may attach provisionally any property, including bank account, belonging to the taxable person or any person specified in sub-section (1 A) of section 122.
- 9. Appeals to Appellate Authority (Section 107) -** A proviso to sub-section (6) of section 107 of the CGST Act is proposed to be inserted to provide that no

appeal shall be filed against an order made under sub-section (3) of section 129, unless a sum equal to twenty-five percent of penalty has been paid by the appellant.

- 10. Detention, seizure and release of goods and conveyances in transit (Section 129)** - Section 129 of the CGST Act is proposed to be amended to delink the proceedings under that section relating to detention, seizure and release of goods and conveyances in transit, from the proceedings under section 130 relating to confiscation of goods or conveyances and levy of penalty.

Sub-section (6) of the said section seeks to empower the Central Government to provide by rules the manner in which and the time within which the goods or conveyance detained or seized under that section shall be sold or disposed of.

- 11. Confiscation of goods or conveyances and levy of penalty (Section 130)** - Section 130 of the CGST Act is proposed to be amended to delink the proceedings under that section relating to

confiscation of goods or conveyances and levy of penalty from the proceedings under section 129 relating to detention, seizure and release of goods and conveyances in transit.

- 12. Power to collect statistics.** - Section 151 of the CGST Act is proposed to be substituted to empower the jurisdictional Commissioner to call for information from any person relating to any matter dealt with in connection with the Act.

- 13. Bar on disclosure of information (Section 152)** - Section 152 of the CGST Act is proposed to be amended so as to provide that no information obtained under sections 150 and 151 shall be used for the purposes of any proceedings under the Act without giving an opportunity of being heard to the person concerned.

- 14. Paragraph 7 of Schedule II to the CGST Act** Consequent to the amendment in section 7 of the CGST Act paragraph 7 of Schedule II to the CGST Act is being omitted retrospectively, with effect from the 1st July, 2017.

Pharma sector reacts to Union Budget 2021-22

Adopting the paperless culture, the Finance Minister Nirmala Sitharaman presented the Union Budget 2021-22 which is considered as a well balanced budget. With a considerable focus on healthcare the government's intention in driving the investment in advancements in biotechnology, smart medicines, virtual and augmented reality, AI & IoT in healthcare are likely to gain momentum. Although the Union Budget 2021-22 recorded higher budget allocation for COVID-19 vaccine, but the industry's expectations of increased weighted deduction on R&D upto 200 percent were absent in the announcement. Therefore, the industry experts have expressed that if the government could have waived off some taxes on the input material, its result would have cheered by consumer (patient) directly as medicines would have become more affordable. Besides this, the industry is overwhelmed with the government's recognition of the Health Sector as a First pillar amongst six pillars

'Overall, a reassuring Budget with no negative surprises' - Kiran Mazumdar Shaw, Executive Chairperson, Biocon:

Overall, a reassuring budget with no negative

surprises that has buoyed overall sentiment. Healthcare and well-being has received top priority in this budget, with more than doubling of the outlay to Rs. 223,846 crore, including the allocation of Rs. 35,400 crore towards COVID-19 vaccination and Rs. 64,184 Cr for a new scheme to strengthen the country's primary, secondary and tertiary health infrastructure.

Other positives include the higher spending on infrastructure, the push for bank privatisation, increased funding for strengthening the public sector R&D and innovation ecosystem, as well, as increasing the FDI cap in insurance from 49 per cent to 74 per cent. Monetisation of public sector assets including land is an important policy plan which must be implemented expeditiously to support the mega infra projects.

'Healthcare allocation as percentage of GDP dismal; many good measures' - Sharad Tyagi, President, OPPI:

The Organisation of Pharmaceutical Producers of India (OPPI) welcomes the Finance Minister's proposal to increase the Budget outlay for healthcare marginally

from last year's revised estimates of Rs. 69,234 crore to Rs. 71,269 crore. It is also a welcome step that Rs. 35,000 crores is allocated for COVID-19 vaccine and the assurance that any additional spending required would be allocated for vaccines.

It has been the demand of the healthcare and pharmaceutical sectors to increase the public spending on healthcare from the below one per cent of GDP level to at least 2.5 per cent of GDP. OPPI is glad to note the Rs. 64,180 crore PM *Atma Nirbhar Swasth Bharat Yojana* over six years to develop capacities of primary, secondary, and tertiary healthcare systems, strengthen existing institutions, new institutions, and focus on detection and cure of new diseases.

OPPI also welcomes the support to rural and urban health and wellness centers, public health labs, strengthening the National Centre for Disease Control (NCDC, connecting the Integrated Health Information Portal to public health labs, setting up new public health units at the borders and in the country, setting up emergency operation centers, bio-safety laboratories and regional virology centres.

OPPI also welcomes the proposal to amend the Insurance Act, 1938 to increase the permissible FDI limit in insurance sector from 49 per cent to 74 per cent to allow foreign ownership and control with safeguards. This would help global health insurance companies to have a focused interest in the country. However, it has been disappointing that the Finance Minister has not specifically laid out any modalities to improve bio-pharmaceutical research. OPPI hopes the five-year outlay of Rs 50,000 crores to strengthen the overall research ecosystem and to identify national-priority thrust areas would have a focused approach to improve bio-pharmaceutical research in the country.

'A well-rounded holistic budget' – Nikhil Chopra, CEO and Whole Time Director, JB Chemicals & Pharmaceuticals:

"A well-rounded holistic budget that embraces all sectors through various measures to boost economic activity. Against the backdrop of the pandemic and an economy facing an unprecedented contraction, the Finance Minister has met the challenge face-on with a budget that has a long term vision laid out in a strategic road map. The emphasis on an '*Aatmanirbhar Bharat*' with an increase in capital expenditure will

boost investment in infrastructure and fuel economic growth.

The significant increase in allocation for health and well-being augurs well for the nation and can be a driving force and strong foundation for accelerating essential drugs and health-related consciousness to the last mile of Indians. The allocation of funds for COVID-19 vaccination will fast track the inoculation drive and it is worth lauding the Government's commitment to provide further funds if deemed necessary.

The budget addresses the gaps in rural and urban healthcare that the pandemic exposed with the '*PM Atmanirbhar Swasth Bharat Yojana*' in addition to the National Health Mission. Along with the emphasis on nutrition, clean water, and clean environment, this will bolster health infrastructure and reach across India. The pharma industry is ready to contribute towards fortifying the health of the nation that is the cornerstone of development. JBCPL stands by the nation!

'We are encouraged with Government's renewed focus on preventive and curative health' – Rehan A Khan, Managing Director - India Region, MSD:

"We welcome the much-deserved attention on India's healthcare sector in the Union Budget 2021, and are glad to hear the increase in the total budget outlay for healthcare in this year. We are encouraged with the Government's renewed focus on preventive and curative health as well as the overall wellness and well-being of our citizens. The introduction of the *Aatmanirbhar Health Yojana* in addition to the National health Mission, along with other announcements in the healthcare and pharma sector- such as setting up health and wellness centres, integrated public health labs in each district, – are aimed at widening access to health and wellness while driving focus on preventive health. These patient centered initiatives will play a pivotal role in the success of the National Health Mission.

Healthcare in India is at the cusp of transformation. The advancements in biotechnology, smart medicines, virtual and augmented reality, AI & IoT in healthcare are likely to gain momentum. This calls for a patient-focused healthcare ecosystem wherein community health, mental health and other such critical areas are properly represented. The Government's focus on self-reliance, especially with the attention on scaling production capabilities of vaccines and other medicines, demonstrates its commitment to build a

healthy India. While 2020 has accelerated the foundation for a digital transformation and innovation of the healthcare system, 2021 will support in further widening access and increasing digital inclusion in the remotest corners of the country.

Having said this, there is a need to further bolster the research and innovation ecosystem in the country in order to ensure that Indian patients receive new treatments and cures. An increased collaboration between stakeholders from industry, academia, governments, non-governmental organisations (NGOs), regulators and patients' organisations is essential to promote a robust research framework which recognises and rewards innovation."

'It is a far-reaching budget announcement' – Dr Krishna Ella, Chairman and Managing Director, Bharat Biotech:

"It's a great step ahead, and far-reaching budget announcement, providing ₹35,000 crore for COVID-19 vaccination in 2021-22. The Finance Minister commitment providing more funds in order to contain the Coronavirus pandemic spread in the country and provide an effective, smooth path for the vaccination scheme will help contain, and lead our nation towards accomplishing a covid-19 disease free Bharat.

The lay out plan of a ₹64,180 crore spending plan for healthcare over the next six years to be spent on primary, secondary and tertiary healthcare, in addition to the National Health Mission is also a welcome move, which will strengthen public health services as 17,000 rural and 11,000 urban health and wellness centres and integrated public health labs to be set up in each district. The government focus, on three areas – preventive health, curative health and well-being, is also very reassuring.

Suchitra Ella, Joint Managing Director, Bharat Biotech

The new health infra schemes with significantly higher outlay of Rs 35,000 crore for Bharat's mega COVID-19 vaccination drive is a huge fiscal medicine to contain the pandemic, reduce disease burden for the population, and the economy. A record total outlay of Rs 2,23,846 crore for health and wellbeing aimed to boost the health and well-being of the nation, is also a well-thought announcement in this budget, with focus on preventive, and curative health.

It's encouraging to note the creation of 9 Bio Safety Lab (BSL) in the Budget, that will boost research and scientific discoveries.

'PM Atmanirbhar Swasth Bharat Yojna will boost healthcare infrastructure across primary, secondary and tertiary care'– Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance:

The FY22 Budget is in line to support recovery of Indian economy while keeping the overall policy stability and fiscal discipline in perspective. The COVID-19 pandemic is an unprecedented time and has brought importance to healthcare in India. The focus on healthcare infrastructure in FY22 Budget is a positive step towards growth with a 137 per cent increase in allocation to the sector at Rs 2,23,846 crore. The allocation of Rs 64k Cr (over 6 years) on the PM Atmanirbhar Swasth Bharat Yojna will help boost the healthcare infrastructure across primary, secondary and tertiary care and the Vaccination programme is well-funded with over Rs 35k, it will help the country address the pandemic. All these initiatives are pointers to increased investment in healthcare infrastructure and will strengthen the sector going forward.

'Union Budget 2021 is positive for Healthcare Industry'- S V Veeramani, Past National President – IDMA & Chairman and Managing Director, Fourrts India Laboratories

The announcement of Rs 64000 Cr for Atmanirbhar Health scheme is a welcome. As per the Finance Minister, the healthcare infrastructure fund will also be increased from Rs 94,000 crores to Rs 2,23,846 crores. Besides this, the already announced PLI scheme by the Government together with the proposed funding for COVID-19 vaccine and Pneumococcal vaccine augurs well for the healthcare industry in general.

Our expectations of increased weighted deduction on R&D upto 200 percent is absent in the announcement.

'A big gift to healthcare sector'- B R Sikri, Vice President, BDMA and Chairman FOPE

We welcome step of the Government for presenting Budget through Digital route i.e. paperless budget. Finance Minister presented her budget speech in six pillars and we are grateful to her as health sector was taken as the First pillar.

Scientific efforts to produce two domestic vaccines for COVID not only for India rather than to supply to 100 countries are remarkable achievements. Rs. 35000 crores allocated for vaccination of COVID is a welcome step by the Government of India. Due to serious health sector efforts during COVID, minimum deaths have taken place in India when compared with other countries seeing size of the population. Seriousness on the part of the Government towards the health sector itself proves because the government has increased the health budget from Rs.94 thousand crores to 2.23 Lakh Crores. As an Industry, we appreciate this great initiative taken by the Finance Minister in the Union Budget.

Particularly, from the pharmaceutical industry's point of view, we were hoping that the government will come forward to give some special relief for R&D and rationality of import duty was also expected. Similarly if the government has waived off some taxes on the input material, it would have given not only relief to the pharma industry rather to the consumers too because the medicines would have become more affordable for a common man.

'This is one of the most challenging budget'- Vivek Padgaonkar, Independent Healthcare Consultant Former-Director OPPI (Project and Policy), Former GSK (Sales and Marketing):

Global economy is in a very difficult phase in the last fifty years and India can be no exception to this so perhaps this is one of the most challenging budget for our Finance minister Nirmala Sitharaman.

At the back drop of shrinkage of the economy by 24% in the first quarter of 2020, due to global pandemic, the Union Budget proposal 2021-22 rests on six different pillars. The inclusion of Health and wellbeing, innovation and R&D, and the budget allocation increased by 137 per cent over the previous year, will have a significant contribution for the Indian life science sector.

The 'PM Atmanirbhar Swasth Bharat Yojana' which will be launched with a total outlay of Rs. 64,180 crore over a period of next six years, with a focus on developing capacities of healthcare systems, develop institutions for detection and cure of new and emerging diseases will boost Indian pharma industry.

'This year's budget is pragmatic, positive and committed to the healthcare sector' – Harshit Jain MD, CEO and Founder, Doceree:

This year's budget by the Finance Minister is pragmatic, positive and committed to the healthcare sector which needed a deliberate boost post unprecedented virus outbreak last year. The announcement of centrally funded scheme – *Aatmanirbhar Health Yojana* – with an outlay of Rs. 64,180 crore over six years in addition to National Health Mission is a welcome step towards strengthening primary, secondary and tertiary healthcare in the country.

Setting up of 15 Health Emergency Centres shows the government's intent to be future-ready to address any healthcare crises. It is commendable that the government has put healthcare on the forefront, putting focus on curative and preventive health and wellbeing. The allocation this year is likely to be around Rs. 2,23,846 crore which is a whopping over 130 per cent rise from the budget last year. The proposals would make quality healthcare accessible and affordable, besides standardizing healthcare infrastructure across the country.

'Gol is placing importance on the sector spurred by the COVID pandemic' – Rohitashwa Prasad, Partner, J Sagar Associates:

"For FY 21 Gol had budgeted Rs. 69,000 crore for healthcare, which was 1.6 per cent of GDP. The budgeted amount for FY 22 shows a significant increase. If this growth were to be extrapolated, the Gol should achieve the target of healthcare spend of 2.5 – 3 per cent of GDP (as envisaged in the National Health Policy 2017) well before its target date. This is quite promising and clearly illustrates the importance that the Gol is placing on the sector spurred by the COVID pandemic.

What is also very commendable is that the Gol has allocated Rs.35,000 crore for the COVID-19 vaccine as a separate line item. This shows that the Gol has avoided the pitfall of focusing all its resources on tackling communicable diseases at the cost of building healthcare systems generally because of the COVID-19 pandemic, which notwithstanding its materially adverse impact on the health and economy, is an extraordinary event. The Gol has thus avoided the saliency bias which the Economic Survey had warned against.

'Budget 2021 is realistic, positive, and holistic' – Akshay Daftary, Director, SIRO Clinpharm:

"In this year's budget, the Finance Minister considered the health and well-being sector as the first pillar, which

is very encouraging for healthcare and nutraceuticals sector professionals. The announcements made by the FM especially for the healthcare sector in terms of promised reforms and anticipated conducive measures to boost domestic manufacturing of the medical devices along with the emphasis on preventive care, PPP in Ayushman Bharat, expansion of *Jan Aushadhi Kendra* in all districts to provide medicines at affordable rates, etc. are very promising and will provide impetus to the growth of the sector in the long run. The allotment of Rs. 3000 crore funds under skill development is a positive move by the government in terms of recruiting people since the EMS (Emergency Medical Services) industry demands skilled individuals in paramedics as they are the ones driving the sector and hence play a vital role in saving lives.

The allocation of Rs. 35,000 crore for COVID-19 vaccines was much needed as it is the need of the hour. Additionally, the allocation of Rs. 69,000 crore to healthcare is again something that is commendable and a heartening measure announced by the FM for the development of the healthcare sector. Overall, Budget 2021 is realistic, positive, and holistic at the same time, centered around the common man and his needs.”

‘Launch of PM Aatmanirbhar Swasth Bharat Yojna includes multiple priorities’ – Dr Hari Natarajan Founder and Dr Karishma Shah, Director, Pronto Consult:

The first budget of the new decade saw the necessary boost required for Healthcare and India as a whole taking care of most of the stakeholders is the budget for New India.

The health sector has got a 2.24 L crore allocation and the increase in spending is as per the expectations of the healthcare sector, which as per the Finance Minister is a 137 per cent increase over last year.

The infusion of capital into multiple projects across transportation, railways, public service would help to give the necessary boost for employment generation and would facilitate the increase in money flow into the economy and would give a boost to the economy.

Gol has also provided Rs 35400 crore for COVID-19 vaccination in 21-22 and also the pneumococcal vaccine, Made in India product would be rolled across India from

just five states now and also from the currently available two vaccines, there would be two more vaccines which can be approved soon.

Healthcare got the much needed boost by strengthening the expenditure increase and also by expanding Virology institutes. The launch of *PM Aatmanirbhar Swasth Bharat Yojna* includes multiple priorities from supporting the Health and Wellness Centres, setting up critical care hospital blocks, strengthening of primary, secondary and tertiary healthcare centres.

As from the word of the Finance Minister “Three areas - preventive health, curative health and well-being to be strengthened during the current year fits well into the budget for this space.

‘An increase by 137 per cent in the budget outlays shows that the Government is serious’ - Sushant Raorane, Director and Co-founder Adroit Biomed:

An increase by 137 per cent in the budget outlays shows that the Government is serious. Just the symbolic placement of the sector in the first section of the budget speech shows the government’s commitment to enhance the health infrastructure for the wellness of all citizens. There is going to be a special thrust in natural medicines and therapy and this will give a boost to the nutraceutical segment. We welcome this budget for sure and aim to work hard for a self-confident and self-reliant India.

‘Aatmanirbhar Swastha Bharat Yojana have hit the bullseye’ – Sidharth Shankar, Partner, J Sagar Associates:

The experiences of COVID-19 have delineated the importance for emerging economies to invest in healthcare infrastructure at all levels – primary, secondary and tertiary. The budgetary announcements of the outlay of Rs. 64,180 crore under the **Aatmanirbhar Swastha Bharat Yojana** have hit the bulls eye in this area. The approach followed by the Indian government is a marked departure from existing practices of reduction of out-of-pocket expenditure of the citizens.

‘First time, the government has explicitly mentioned the emphasis on overall wellbeing’- Sanjaya Mariwala, Executive Chairman and Managing Director, Omni Active Health Technologies and Founder President of the Association of Herbal and Nutraceuticals Manufacturers of India (AHNM):

“Focus on both preventive and curative healthcare in the Nutrition Programme 2.0 is a great boost for the nutraceutical industry. For the first time, the government has explicitly mentioned the emphasis on overall wellbeing. Mission Poshan 2.0, which will be focused on strengthening nutritional content, delivery, and the outcome is a great initiative and a big boost for the nutraceutical industry.

Further extension of the PLI scheme and emphasis on manufacturing in India is also encouraging. We will look forward to further specifics especially the PLI scheme for the nutraceutical sector.

‘The budget proposals reflect an embolden India’- Chintan Gandhi, Managing Director – Millennium Herbal Care:

The budget proposals reflect an embolden India, possibly buoyed by the government’s overall handling of the pandemic relative to other countries. The ability to comfortably budget the deficit at 6.8 per cent is the need of the hour. In reference to the healthcare sector, just the symbolic placement of the sector in the first section of the budget speech shows the government’s commitment to enhance the health infrastructure for the wellness of all citizens. This shall be good for the Ayurvedic sector too, especially with the recent appreciation from consumers.

‘The government did not meet the industry’s expectations of taxation’ - Parvathavardhini Natarajan, Associate Director, Ratings, Brickwork Ratings:

On the taxation side, the government did not meet the expectations of the industry which looked forward to tax benefits on R&D investments in pharma and lower GST for life-saving drugs.

‘No mention of specific support and incentives for R&D and innovation’ - Charu Sehgal, Partner and Leader, Lifesciences and Healthcare, Deloitte India:

”The budget 2021 has provided the much expected increase in public expenditure on Healthcare. The FM has announced an outlay of Rs. 64,180 crores over six years though, on *Atma Nirbhar Swasthya Bharat* scheme in addition to the National Health Mission budget.

There appears to be an integrated approach whereby both the short term and immediate needs as well as the longer term measures have been proposed. While the

provision of Rs.35,000 crores for COVID-19 vaccine and focus on disease control and surveillance will help cope with the immediate needs brought forth by the pandemic, the setting up of National Institutes for virology and Integrated Health Labs, an updated Health Information portal will all prepare us for future such eventualities.

The pandemic had brought to the fore the stark shortage in infrastructure and medical and paramedical medical resources. The budget announced setting up and upgradation of primary, secondary and tertiary health units across districts and blocks as well as a focus on allied healthcare professionals and that is a welcome step.

What seems to be missing was the support and boost that was expected to encourage private investment in healthcare infrastructure as well in manufacture of medical devices. There was also no mention of specific support and incentives for R&D and innovation for Pharma and Medical technology.

It was the private sector that really rose to the challenge during the last year whether it was on innovation or manufacture of drugs, devices and vaccines or on testing and treatment and it was expected that it will be provided a boost.”

The budget is definitely aimed to make India a better place to do business’-Sumit Kumar, Vice President – NETAP, TeamLease:

The budget is definitely aimed to make India a better place to do business, to work for a common man and to massify quality education. The increased focus and impetus on infrastructure, manufacturing, financial sector and health sector will create employment opportunities which makes the case stronger for the skilling ecosystem to ensure productivity at execution. Skilling will step up in the automotive sector at both ground level for production and also at the macro level to boost R&D and prepare the workforce for Industrial Revolution 4.0.

The outlook to amend the Apprenticeship Act will lead to attractive incentives for Small and Medium Enterprises, especially in the auto ancillary segment and will further boost skilling through apprenticeships along with the OEMs which further creates employment opportunities.

Realignment of National Apprenticeship Training Scheme (NATS) and the allocation of Rs 3000 crores will

motivate organisations for providing apprenticeship training. Commencing degree and diploma apprenticeships in the non-technical stream will improve the employability factor for the youth and prepare a productive workforce in the country.

Additionally, the setting up of The Higher Education Commission will help us understand the ground realities of execution of policies like that of the National Education Policy among other education reforms, and will help in addressing challenges in execution as well. However, the budget's silence on the regulatory front especially for Skills Universities and relaxation of laws in online education licensing is a bit disappointing as these aspects are very crucial for improving affordability, accessibility and scalability of quality education in India.

'Overall it is an ambitious budget' – Suresh Pattathil, MD, Allergan India:

Overall, this is an ambitious, growth-oriented budget and the FM has tried to ensure that the economy receives the impetus it needs to go back to a respectable GDP growth level. We are glad that in line with the vision of 'Atmanirbhar Bharat', the FY22 budget identifies six pillars on which to build a future ready India. We are particularly glad that health and wellbeing and innovation and R&D are included here.

The significant increase in budgetary support for the health sector is most welcome. The additional outlay of Rs. 64,180 crore over the next six years is to be spent

to improve and fill gaps in the primary, secondary, and tertiary health segments. The hope is that this will make a measurable difference to the access and delivery of high quality healthcare for all.

However, India's health challenges are huge and require a high degree of collaboration between the public and private health sectors to improve healthcare access, increase insurance cover, bring down out of pocket expenses and ensure a good supply of new innovative drugs. The Indian pharmaceutical industry needs strong incentive to invest in making India a pharma research hub for the country and the world.

'Higher allocation to the MSME industry' – Mahendra Patel, Managing Director, Lincoln Pharmaceuticals:

Budget is in line to help recovery of Indian economy post COVID-19 while keeping taxation neutral, policy stability and fiscal discipline in perspective. Higher allocation to the MSME industry and 137 per cent rise in allocation to the health sector will further boost the health infrastructure in the country. Overall it is a good budget with higher allocation to infrastructure, agriculture which are need of the hour.

(With inputs from Viveka Roychowdhury and Lakshmi Priya Nair)

Source: Express Pharma, 02.02.2021



Have you renewed your **Membership** for the years

2019-2020 & 2020-2021

If not, please do so; kindly contact IDMA Secretariat at:
Email: actadm@idmaindia.com / accounts@idmaindia.com
Tel.: 022 - 2494 4624 / 2497 4308 / Fax: 022 - 2495 0723

IDMA and BDMAI joint Submission on Environmental Approvals – regarding Bulk Drug Industry

IDMA and BDMAI have made a joint submission on 1st February 2021 to Shri Rameshwar Prasad Gupta, IAS, Secretary, Ministry of Environment, Forest & Climate Change (MoEFCC), New Delhi with copy to Ms S Aparna, IAS, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi as below:

"We thank you for the MoEF&CC Office Memorandum F.No.22-33/2019-IA.III dated 28.01.2021, confirming future appraisals of all proposals for Environmental clearance under provisions of EIA Notification 2006 and subsequent amendments under the category of the schedule of EIA Notification 2006 for the "API and Intermediates" as single category instead of individual products. *(The Office Memorandum is published in IDMA Bulletin issue dated 30 January 2021 - page no.17)*

This was a long pending request of Pharma Industry and it is a very welcome step in the right direction, which will help accelerate growth of API industry. While the notification refers to only "Prior Environmental Clearance....and subsequent amendments", it is silent as to how currently valid/under renewal EC/ CTE / CTO mentioning individual products can be converted into single category documents. There are also no specific guidelines for SPCBs to this effect. As the wording stands, only a handful of new (greenfield) units, and those whose EC is up for amendment will get benefit of this notification while omitting most of the existing units with valid EC/CTE /CTO. Thus, our request for a corrigendum to this OM laying down simple procedure for existing / under renewal ECs / CTEs / CTOs for amendment from existing individual product names to a single category. Unless this is done, all the good intentions of MoEF will remain just on paper

with no immediate relief at the ground level to majority of API manufacturers.

Further, the OM is silent on issue of "removal of cap on Production quantity". It was agreed as per Minutes against Issue-1 (see below) that only the quantity and quality of effluent (pollution load) need to be regulated.

Decision: The Secretary, EF&CC has agreed in-principle and directed to initiate amendment in EIA Notification, 2006 regarding permitting the change in product mix or raw material mix including no cap on increase in the production quantity without prior environmental clearance as long as there is 'no increase in pollution load'.....

We assume that this will be covered in soon to be announced comprehensive amendment to EIA Notification 2006, if not we request that a separate OM be issued on this subject.

Some other issues were also discussed in this meeting regarding change of "Product Mix" for which we hope similar OMs are in the offing. As regards the simplification of application forms for ToR and EC, we have already shared our suggestions with Secretary, Pharmaceuticals and hope the same must have been forwarded to you by now. We look forward to a meaningful discussion on the same with your officials at their earliest convenience.

We once again thank you very much for your kind acceptance of our proposals for simplification of operating procedures without effecting the cause of environmental protection."



IDMA Members donate Medicines to Shanti Avedna Sadan for the Care of the Advanced and Terminally ill Cancer Patients



IDMA along with a few Lions (number restricted due to Covid-19 Pandemic) of Lions Club of Byculla on **26th January 2021** completed their annual contribution of medicines to *Shanti Avedna Sadan*, on a home for the continuing care of the **Advanced and Terminally ill Cancer Patients** located at Bandra (W), Mumbai.

Shanti Avedna Sadan is India's first Hospice, an Institution that takes care of the advanced terminally ill Cancer patients. It is neither a hospital nor a home, but is in fact both, offering the specialized care of a hospital together with the love of a home.



IDMA & Lions Club of Byculla had started this tradition of contributing medicines required by Shanti Avedna Sadan every year for the past several years and we are grateful and thankful to our IDMA Members for contributing every year for this noble cause.

IDMA, Lions Club of Byculla along with the Sisters and Patients at Shanti Avedna Sadan humbly thank our IDMA Members mentioned below for their generous contribution of medicines to *Shanti Avedna Sadan*:

1. **Ajanta Pharma Ltd**
2. **Alkem Laboratories Ltd**
3. **Cachet Pharmaceuticals Pvt Ltd**
4. **Cipla Ltd**
5. **Galpha Laboratories Ltd**
6. **Intas Pharmaceuticals Ltd**
7. **IPCA Laboratories Ltd**
8. **Micro Labs Ltd**



Drugs, vaccines less effective vs new virus variants antibody cocktail may protect patients' contacts

The following is a roundup of some of the latest scientific studies on the novel coronavirus and efforts to find treatments and vaccines for COVID-19, the illness caused by the virus.

Coronavirus variants escape effects of antibody drugs:

Antibody therapies and vaccines for treating or preventing COVID-19 are likely to be less effective against some of the new variants of the Coronavirus circulating around the world, a new study suggests. Of particular concern is the variant identified in South Africa and another one first found in Brazil with similar features. In lab tests, Eli Lilly and Co's antibody bamlanivimab was inactive against the South Africa strain, according to a report posted on Tuesday, 26.01.2021 on bioRxiv ahead of peer review. The drug just last week had shown an ability to cut the risk of COVID-19 by 80% for nursing home residents. The activity of one antibody in Regeneron Pharmaceuticals Inc's dual-antibody therapy was impaired by the South Africa variant, although the cocktail remained potent. And tests of blood from people who got either of the COVID-19 vaccines from Pfizer Inc or Moderna Inc showed antibodies generated by the shots were less effective against the South Africa variant, although Moderna has said it still believes its vaccine will provide protection.

"Mutationally, this virus is traveling in a direction that could ultimately lead to escape from our current therapeutic and prophylactic interventions," the researchers said. "If the rampant spread of the virus continues and more critical mutations accumulate, then we may be condemned to chasing after the evolving SARS-CoV-2 continually, as we have long done for influenza virus." Lilly and Regeneron said this week that they are working on new versions of their drugs to address the new variants.

Antibody cocktail may protect patients' household contacts:

A two-drug antibody cocktail from Regeneron Pharmaceuticals called REGEN-COV prevents COVID-19 in people exposed to an infected household member, preliminary data suggest. In an ongoing study,

REGEN-COV, containing the drugs casirivimab and imdevimab, has so far caused a 100% reduction in symptomatic infection and roughly 50% lower overall rates of infection, the company announced on Tuesday, 26.01.2021. The results suggest that the cocktail may not only reduce transmission of the virus but may also reduce disease severity in those who get infected, said Regeneron research chief and co-founder George Yancopoulos. The therapy, which would be given to those in close contact with an infected person, immediately delivers virus-fighting antibodies into the body as opposed to vaccines spur the body's immune system to develop its own antibodies over weeks. "This approach could protect patients receiving chemotherapy for cancer, enable control/prevention of outbreaks in an institutional setting and reduce pressure on health services," said Dr Penny Ward from King's College London. The initial data comes from the first 409 subjects of a trial that hopes to recruit 2,450 participants. Full data from the trial are expected in April.

Blood cancer drug shows promise against COVID-19:

A drug used in Australia to treat blood cancer might be a powerful treatment for COVID-19, new research suggests. The drug, plitidepsin - also known as aplidin - acts against a protein in cells the virus uses to replicate. In test tube experiments with human lung cells, plitidepsin was 27.5 - fold more potent than Gilead Sciences Inc's remdesivir at inhibiting the virus, researchers reported on Monday, 25.01.2021 in Science.

In mice with COVID-19, the drug produced a 99% reduction of viral loads in the lungs and reduced inflammation. Researchers have begun testing the drug in humans with COVID-19 and are working with regulatory agencies on plans for larger trials. Rather than targeting a protein in the virus, as many drugs do, plitidepsin targets a protein in patients' cells. This means that if the drug proves successful in humans, the virus could not easily gain resistance through mutation.

(Open tmsnrt.rs/3c7R3BI in an external browser for a Reuters graphic on vaccines in development. Reporting by Nancy Lapid and Christine Soares; Editing by Bill Berkrot)

Source: Nancy Lapid, Reuters, 28.01.2021 (Excerpts)



Researchers trying tapeworm, vertigo and pancreatitis drugs to fight COVID-19

The plan to vaccinate the global population against COVID-19 is a noble one, but the importance of treatment to the affected is of prime importance too

KEY HIGHLIGHTS

- *Could the common blood pressure medications, called angiotensin receptor blockers, help reduce the impact of Coronavirus?*
- *Some scientists in Australia are experimenting on nefamostat, an obscure drug that has been used to treat pancreatitis in Japan and Korea.*
- *Could inhaling a common cancer drug and anti-viral called interferon help will stop the COVID-19 virus from infecting people?*

Vaccines may not be the silver bullet that will end the COVID-19 pandemic, say, researchers. Since most vaccines aren't 100 per cent effective, it's not likely that they will fortify the entire community. It will be several months before the majority of the population will be vaccinated and till such day, effective treatments for COVID-19 will hold the day.

While we understand that vaccines are key to prevent COVID-19 infecting a person's body, it is treatments that will help us get better if we do acquire the infection. According to a report in the Australian website abc.net.au, the country's doctors and patients are at the forefront of global efforts to develop those treatments, and a number of treatments are under trial. In some critically ill patients, steroids like dexamethasone, along with hydrocortisone and prednisolone, have been able to save the lives of patients fighting COVID-19 in a safe, cheap and widely available protocol.

"It's the standard of care now," Infectious diseases physician Dr James McMahon told. Dr McMahon said some of the drop in case fatality rates globally could also be attributed to health professionals simply getting better at managing COVID-19. "They're better at identifying people who are becoming unwell. Better at identifying people who are vulnerable," he said. Several existing drugs with well-established safety profiles are the source of inspiration for some scientists who are now trying to repurpose those drugs to treat COVID-19.

Japanese pancreatitis drugs:

Scientists at the University of Melbourne are experimenting with a hemostat, an obscure drug that

has been used to treat pancreatitis in Japan and Korea. Nefamostat works by binding to one of the two receptors that allow the COVID-19 spike to enter human cells. Professor Josh Davis is from the Menzies School of Health Research, which is part of the study. "The likelihood is at least one or two of the interventions we're looking at will prove to be effective," Professor Davis told ABC. "But we don't think any one of these will be a magic bullet." There are more than 70 hospital and trial sites in Australia, India and Denmark.

Take heart, this medication might work:

Another major study by The George Institute for Global Health and the University of Sydney is looking at whether common blood pressure medications, called angiotensin receptor blockers, could help reduce the impact of coronavirus. The new phase four study led by Professor Meg Jardine is looking at common Angiotensin Receptor Blockers (ARBs) like candesartan (Atacand), irbesartan, losartan and telmisartan. It has been found that people already taking these medications do not get any sicker than the rest of the population if they get COVID-19.

Trials on inhalers, cancer drugs:

Scientists are also carrying out experiments to check if inhaling a common cancer drug and anti-viral called interferon will stop the COVID-19 virus from infecting people. The premise they are working on is the possibility that the medication can block the virus from entering the cells in the nose and upper respiratory tract. A Chinese claims that it found the method prevented healthcare workers from catching the virus, but in Australia, lead investigator Professor Monica Slavin warned that study was limited. "It wasn't a really well-conducted study, but it's promising," she said. Researchers are also looking at whether a cancer drug called selinexor can help.

Vertigo drug, anti-tapeworm medicine under scanner too:

The drug, called ifenprodil, is being tested by a Canadian drug company called Algernon Pharmaceuticals. It was developed in the 1970s and has been used to treat vertigo in Japan. The same report also states that South Korean firm Daewoong Pharmaceutical is looking to repurpose an antiparasitic drug that is used to treat patients suffering from tapeworms, also known as niclosamide. It's been turned into a long-acting injection and it's hoped it will prevent the virus from invading host cells by inhibiting a protein called SKP2.

Source: Kirti Pandey, www.timesnownews.com, 26.01.2021



Covid shadow on Budget 2021: Health gets a vaccine shot, water in new 'well-being' category

With covid infections **crossing the 1-crore mark**, and claiming nearly 1.54 lakh lives, the Government has allocated Rs. 64,180 crore in the **Union Budget presented Monday, 01.02.2021** to upgrade public health care infrastructure under a new flagship PM AtmaNirbhar Swasth Bharat initiative over six years — and unveiled a new expenditure head called “health and well-being”.

Spelling out medium and long term expenditure for the public health care system, which came under severe stress during the initial stages of the pandemic, Union Finance Minister Nirmala Sitharaman pegged the total expenditure for “health and well-being” at Rs 2,23,846 crore — an increase of 137 per cent — including Rs 35,000 crore for immunisation with Covid vaccines.

The Finance Minister underlined that the Government will take a “holistic approach” this time by strengthening three critical areas: “Preventive health, curative health and well-being.”

“Even at the outset, I would like to say that the investment on health infrastructure in this Budget has increased substantially. Progressively, as institutions absorb more, we shall commit more... the Budget outlay for ‘health and well-being’ is 2,23,846 crore in BE (Budget Estimates) 2021-22 as against this year’s BE of 94,452 crore, an increase of 137 percentage,” Sitharaman said.

The Rs. 2.23 lakh crore will include expenditure on six components in varying proportions: Department of Health & Family Welfare (31.83 per cent) with finance commission grant (5.89 per cent); Department of Drinking Water & Sanitation (26.81 per cent) with finance commission grant (16.09 per cent); vaccination (15.63 per cent); health research (1.89 per cent); Ministry of AYUSH (1.32 per cent); and, nutrition (1.20 per cent).

The allocation shows that drinking water and sanitation has received the biggest boost of 179 per cent, with funds for health and family welfare increasing by 9.62 percent while nutrition witnessed a drop of 27 per cent. Sitharaman said the Centre is “committed to provide further funds if required” for Covid vaccines and that the pneumococcal vaccine, presently limited to only five states, will be rolled out across the country.

Welcoming the allocation, Union Health Minister Dr Harsh Vardhan said: “The experiences of the country’s yearlong fight with Covid have shaped the Union Budget. This will give a tremendous boost to India’s health infrastructure... Investment on Health Infrastructure in Budget 2021 has increased 2.37 times or 137 per cent. The focus on strengthening three areas — Preventive health, curative health and well-being — with total allocation to the health sector being Rs. 2,23,846 crore will be of immense help to the country at this critical juncture.”

Sitharaman, meanwhile, emphasised that PM Atma Nirbhar Swasth Bharat will be implemented in addition to the National Health Mission — and provide “support” for 17,788 rural and 11,024 urban health and wellness centres. “This will develop capacities of primary, secondary, and tertiary care health systems, strengthen existing national institutions, and create new institutions to cater to detection and cure of new and emerging diseases,” she said.

Under the new scheme, five key interventions will be implemented, specifically catering to new and emerging diseases: integrated public health labs in all districts and 3,382 block units in 11 states; critical care hospital blocks in 602 districts and 12 central institutions; a strengthened National Centre for Disease Control (NCDC) and its five regional branches and 20 metro health surveillance units; and, a national institution for One Health, a regional research platform for WHO (South East Asia), nine Bio-Safety Level III laboratories and four regional national institutes for virology.

The scheme will also provide funds to set up 15 emergency operation centres and two mobile hospitals, operationalise 17 new public health units and strengthen existing units at the 32 airports, 11 seaports and seven land crossings. On nutrition, Sitharaman said that to strengthen “content, delivery, outreach, and outcome”, it has been decided to merge the supplementary nutrition programme and Poshan Abhiyan to launch “Mission Poshan 2.0”. “We shall adopt an intensified strategy to improve nutritional outcomes across 112 aspirational districts,” she said.

Sitharaman said that WHO has “repeatedly” stressed the importance of clean water, sanitation and clean environment “as a prerequisite to achieving universal health”. “The Jal Jeevan Mission (Urban), will be launched. It aims at universal water supply in all 4,378 urban local bodies with 2.86 crore household tap connections, as

well as liquid waste management in 500 AMRUT cities. It will be implemented over five years, with an outlay of Rs. 2,87,000 crore," she said.

Source: Kaunain Sheriff M, Indian Express, 02.02.2021



DCG(I) calls for suggestions from industry to reduce compliance burden

Pharma Associations are likely to submit their recommendations by early next month

The Drug Controller General of India (DCGI) has asked industry associations to submit their representations highlighting aspects or issues in the Drug and Cosmetics Rule 1945 that can be made redundant to reduce the compliance burden on the industry.

In a recently held webinar, 'Reducing Regulatory Compliance Burden', the DCGI interacted with industry representatives from IDMA, BDMA, FOPE, OPPI, CIPI, HDMA – Laghu Udyog and asked them to highlight regulatory issues faced by the industry.

Some of the associations have already submitted their representation, whereas many of them are likely to submit it by early next month. The IDMA representative requested that instead of making Schedule M mandatory it should be in the form of guidelines. The IPA representative expressed that the implementation of Schedule M should be done at the earliest.

IDMA suggested making separate rules for excipients and disinfectants and also pointed out that there is a need to properly define APIs and NSQs to avoid misinterpretation.

The association also highlighted issues pertaining to shelf-life of formulations. It said that in the current scenario, shelf-life of formulations is not allowed to go beyond the shelf-life of APIs. It also stressed that bulk drugs which are exported and returned for reasons of non-compliance of physical parameters like moisture, particle size and bulk density should be permitted to be sold in the domestic market. It is not allowed currently. Similarly, HDMA and IPA requested for QR codes on APIs. BDMA will be preparing a detailed report to submit to the regulatory authority on joint inspection for WHO certification which is taking a long time.

During the session, the association representatives also suggested creating Centre-State Committees wherein industry experts can also join. And these

Committees can help in updating the guidelines as is done in the WHO.

Dr Rajesh Gupta, All India Head, Laghu Udyog Bharati Pharma Wing and President of Himachal Drug Manufacturers Association, said, "To ensure ease of doing business modules, we need to amend various sections of D&C Act 1940, which was discussed by all associations like IDMA, FOPE, BDMA, HDMA, CIPI. During the presentation, we demanded that instead of suspension and licences cancellation on prima-facia, there should be a consideration for an improvement period and show cause notice for compliance to genuine and valid license manufacturing holders."

"We have also requested that Section 33 P guidelines should become a Rule and law should protect genuine manufacturers and license holders from spurious allegations," said Gupta. He said that due to misuse of Section 17(c) and (D), many genuine and valid license holders are being prosecuted.

Sudarshan Jain, Secretary-General, Indian Pharmaceutical Alliance, commented, "We are in the process of preparing a representation requested by the DCGI. In the next few days, we will be able to submit our recommendations to the authority."

Dr Viranchi Shah, National Vice President, IDMA, informed, "This is an excellent and apt initiative of the DCGI, Dr Somani. Removing the redundant provisions under the D&C Act and rules will greatly enable the updation of the law to the needs of the current times. The current law is over 75 years old, formed in an era when India imported most of our pharma needs.

Today, the scenario has changed, we are global producers, and therefore the change in Act and Rules is due, in order to fit the current and future needs of the society. This step will also help reduce the burden of compliance and help improve the efficiency of the operations of this industry. This is a path-breaking initiative with a long term vision and IDMA heartily welcomes it."

Source: Usha Sharma, Express Pharma, 29.01.2021



MoEF amendment brings APIs and intermediates under single category

The Ministry of Environment, Forest and Climate Change (MoEF) has issued a letter with an amendment that clubs APIs and intermediates as a single category instead of individual products. The move has been appreciated

by industry stakeholders as it will provide them with the flexibility to change the raw material mix/or product mix within the sanctioned pollution load.

The Ministry has taken the decision based on the several presentations made by the industry representatives requesting for issuance of Prior Environmental Clearance under the provisions of EIA notification 2006.

According to issued communication by the MoEF, the matter has been examined in the Ministry and henceforth all the Expert Appraisal Committees of Environment Ministry/SEAc (State Expert Appraisal Committee) should appraise the proposal for prior Environmental Clearance under the provisions of EIA notification 2006 and subsequent amendments under the Environmental Impact Assessment (EIA) notification 2006 for APIs and intermediates as a single category instead of individual products.

Accordingly, the EAC/SEAC should recommend the permissible pollution load i.e. quantity and quality including the composition of emissions, discharge and solid waste generation from such activity for inclusion in the prior Environmental Clearance.

Mahesh Doshi, National President, IDMA, expressed, “It is a long pending demand from the IDMA. On behalf of the Indian pharma industry, we acknowledge the initiated efforts taken by the DoP Secretary, S Aparna. After understanding the industry’s concerns she ably managed to lead a high delegation from the Ministry of Environment, Foreign and Climate Change and managed to deliberate in favour of the industry. Certainly, this step will help the industry to further flourish the Indian pharma industry’s image in the competitive global pharma market.”

B R Sikri, VP, BDMA and Chairman, FOPE, commented, “It is a welcome step. The industry has been pursuing this issue with GoI for several years and it is a very positive step on behalf of the Environment Ministry because it will increase production since within the load sanctioned we will be able to switch over to other product ranges. I wish it would have been done long back but there is a saying “*Der aye durust aye,*” i.e. better late than never. It will have far-reaching, positive consequences for the nation provided State Pollution Control Boards do not find fault in implementing this great change in the system. *Atma Nirbhar Bharat* is now achievable since the Government’s way of working has changed and it has started listening to the industry.”

Source: Usha Sharma, Express Pharma, 30.01.2021



Covid blessing? Finally, biotech gets booster shot

After years of being ignored by successive FMs, the Covid-19 pandemic finally forced the government to take note of the biotech sector that has been leading the fight against the dreaded Coronavirus.



FM prescribed several direct and indirect booster doses this year, including Rs. 35,000 crore allocation for Covid-19 vaccination, national rollout of pneumococcal vaccine and investments in public research and innovation infrastructure. Pointing out that this is the first time the FM has spoken about preventive and curative health and wellbeing, Bharat Biotech CMD Dr Krishna Ella said the announcements were significant and far-reaching. “FM’s commitment providing more funds to contain the pandemic spread and provide an effective for the vaccination scheme will lead to accomplishing a Covid-19 free Bharat,” Ella said.

KEY TAKEAWAYS	
<p>₹35,000Cr for Covid-19 vaccination</p> <p>► National rollout of Pneumococcal vaccine</p>	<p>I am disappointed at the lack of specific initiatives to boost R&D, which is a very important aspect of <i>Atmanirbhar Bharat</i></p> <p>— Ram Kaundinya DIRECTOR GENERAL, FEDERATION OF SEED INDUSTRY OF INDIA (FSII)</p>
<p>₹50,000Cr allocation for National Research Foundation</p> <p>9 Bio-Safety Level III laboratories</p> <p>4 regional National Institutes of Virology</p>	<p>Increased allocation for healthcare along with steps to set up health and wellness centres will make quality healthcare more affordable — K Anand Kumar MD, INDIAN IMMUNOLOGICALS LIMITED</p>

Serum Institute of India CEO Adar Poonawalla said the emphasis on healthcare spending and immunisation will help India recover rapidly from the pandemic and also encourage more innovation and expansion. Speaking of healthcare infrastructure and vaccines, Poonawalla said: “Investments in these areas have prevented hospitalizations

and resulted in a healthier and more productive workforce, leading to an efficient economy.”

Biocom CMD & Association of Biotech Led Enterprises (ABLE) Chairperson Dr Kiran Mazumdar Shaw said while there were several moves to strengthen the public research and innovation ecosystem, the big missing piece was the lack of encouragement to private sector R&D. Stating that India has been recognised as being at the epicentre of Covid-19 management, she said: “It’s disappointing the government feels we don’t need R&D incentives and should be left to fend for ourselves, but they ought to look at it more seriously.” “Covid-19 has opened their eyes.

The government has moved positively and I am very glad they are trying to strengthen the biotech manufacturing base, but what about R&D, which is the legs on which the sector stands? It’s a move forward but the step is too small,” said Shantha Biotechnics founder K I Varaprasad Reddy.

Source: The Times of India, 02.02.2021



Union Budget 2021-22: Vaccine-Focus a shot in the arm

Indian Union Budget 2021-22: Against the backdrop of the Covid-19 pandemic, Finance Minister Nirmala Sitharaman announced on 1 February that the Centre was providing Rs. 35,000 crore for vaccination against the disease. The Budget documents mention a Rs. 33,572 crore ‘provision of financial assistance to meet expenditure on Covid-19 vaccination’ in FY22. While the Serum Institute of India had said earlier this year that it will make 10 crore doses of Covishield, one of the two vaccines approved in India, available to the Centre at Rs. 200 per dose, at Rs. 500 for a two-dose-vaccine regime, the provision should cover doses for 67 crore people.

The government estimates a 30-crore target population (comprising health and frontline workers, people above the age of 50 and people below 50 with co-morbidities) for its priority inoculation drive, while, as per the Socio-Economic and Caste Census 2011 data, there were 13.4 crore households in India whose highest-earning member had a monthly income of below Rs. 5,000.

The budgeted spend for health and family welfare, though, is nearly 11% lower than the revised estimates for the current fiscal, at Rs. 71,268 crore versus FY21 revised estimate (RE) of Rs 78,866 crore — a chunk of FY21RE spend, over the FY21 budget estimate (BE) of Rs. 65,011 crore, could be attributed to emergency response to the Covid-19 pandemic. “The continuing modest allocation towards the healthcare sector would make it challenging for the government to meet its target of public sector healthcare investment of 2.5% of the GDP by 2025,” said Kapil Banga, Assistant Vice President, ICRA.

Sitharaman also announced the launch of a new centrally-sponsored scheme, the PM Atma Nirbhar Swasth Bharat Yojana, with an outlay of Rs. 64,180 crore over six years. The scheme aims to bolster primary, secondary and tertiary healthcare in the country and envisages setting up of public health laboratories in all districts and critical care hospital blocks in 602 of these.

With pandemic/epidemic readiness a big policy concern, the scheme will also focus on setting up of 15 health emergency operation centres. Apart from creation of new public health units and strengthening of existing ones at 50 points of entry to India, nine biosafety level (BSL) III labs — India mandates BSL II/III for all SARS-CoV-2 manipulations, with virus isolation, cell culture, and neutralisation assay reserved for BSL III labs only — and four National Institutes of Virology will also be set up.

The announcement has received a mixed response from health-sector experts. “A total allocation of Rs. 64,180 crore over a period of six years may thinly spread the resources to many announcements under this programme. However, a beginning has been made in this direction,” said Sarit Rout, a health economist with the Public Health Foundation of India. Ali Mehdi, who leads the Health Policy Initiative, however, believes instead of a new central scheme, the money should have gone to the states. “The Centre should accept that health is a state responsibility and try to strengthen state systems,” Mehdi says.

Source: Sarthak Ray, Financial Express, 02.02.2021



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Webinar on “Accelerating and De-Risking Your Product Development” on the 11th of February, 2021 at 4.00 pm

Aptar Pharma and Indian Drug Manufacturers Association (IDMA) is organizing a Webinar on “Accelerating and De-Risking Your Product Development” on the 11th of February, 2021 at 4.00 pm.

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Please note that after receipt of your registration form, the attendee link will be shared with you.

Looking forward to your support and participation in making this webinar a grand success.

Thanks & regards,

Daara B Patel

Secretary – General

IDMA

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