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# IDMA BULLETIN

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## Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

## HIGHLIGHTS

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# IDMA BULLETIN

Vol. No. 52 Issue No. 27 15 to 21 July 2021

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# Vaccine Challenges

***Dr Nagaraj N Rao**, Associate Editor, Indian Drugs*

*Dear Reader,*

*According to several estimates, India currently accounts for about 20% share in the global supply of generic medicines and 62% share of the global demand for vaccines by volume. Vaccines accounted for USD 33 billion or 2% of the global pharmaceutical market in 2019 by value. This share is likely to grow by 64% and increase to USD 54 billion by 2027, as per recent developments and current market research studies. This presents a great opportunity to the Indian pharmaceutical and diagnostics/medical equipment industries and research institutes in general and to the Indian vaccine manufacturers in particular – provided the challenges can be overcome and the serious problems facing the Indian generic manufacturers are bypassed.*

*In 2019, before the onset of the COVID-19 pandemic, about 5.5 billion doses of vaccines were administered globally (excluding vaccines administered by the military or for travel and tourism), mainly for polio, diphtheria, tetanus and measles. Taking global volume into account, the three largest Indian vaccine manufacturers (Serum Institute of India, Bharat Biotech and Haffkine Institute) accounted for 44% by volume, while GSK and Sanofi accounted together for 20%. However, in value terms, nearly 90% of the global market was accounted for by four vaccine manufacturers (GSK, Merck, Pfizer and Sanofi) and they served mostly the high- income countries. The scenario will change significantly in the coming years. It is important to note that the price of vaccines is usually tiered by procurement mechanisms with pooled procurement mechanisms being associated with lower prices.*

*Global R&D efforts to develop vaccines to fight the COVID-19 pandemic are unprecedented. Currently, 102 vaccines are in clinical development and 185 are in pre-clinical development. Of the different platforms on which the vaccines are being developed, the protein subunit platform presently accounts for 31%, while the inactivated virus, RNA and viral vector (non-replicating) platforms account for 16% each. The intramuscular route of administration is being studied in three-fourths of the vaccines being developed, with*

**Dr. Nagaraj Narayan Rao** *obtained Bachelor's degrees in Science (Chemistry) and in the Technology of Pharmaceuticals and Fine Chemicals from the University of Mumbai. After working with Colgate-Palmolive (India) for two years as a laboratory chemist, he obtained his doctorate in science with magna cum laude from the University of Tuebingen, Germany, under the guidance of Prof. Dr. H. J. Roth. He carried out post-doctoral research at the Institute of Biotechnology of the Research Center Juelich, Germany. He was a member of the Editorial Board for the first official German-language version of the European Pharmacopoeia. He was a visiting scientist at Juelich and a visiting faculty at the Institute of Chemical Technology Mumbai from 1993 to 2007 in the field of bioprocess technology. He has authored several original research articles, a patent, review articles and book chapters in the fields of pharmaceuticals, biotechnology, brewery and surface coatings. He was Chief Editor of the "Transactions of the MFAI" for a few years. He contributes a monthly 'Report from India' to a leading German technical journal since fourteen years and is a distinguished alumnus of the Research Center Juelich.*

*Dr. Rao is co-founder of the RRR group of small and medium enterprises, manufacturing organic fine chemicals, formulations for surface coating technologies and fertilizers, process sensors and process units for life sciences, brewery and chemical process industries, as well as representing select overseas companies for cell culture media, bulk drugs and used chemical equipment and plants.*

*intra-nasal, sub-cutaneous and intra-dermal routes accounting for 7, 5 and 4%, respectively.*

*Likewise, the efforts being put in and by India are unprecedented. On the one hand, some vaccine manufacturers have been quick to adapt technologies developed abroad, such as from the UK or the USA. On the other hand, some manufacturers have been able to scale-up technologies developed by Indian research laboratories (such as NIV and IICT), foreign laboratories and even in-house labs to produce vaccines on a large scale. There is pragmatism in the air - public sector vaccine manufacturers, such as Indian Immunologicals and Haffkine Institute are getting technology transferred for manufacturing India's first whole-virion inactivated viral vaccine. While the former is "a stone's throw away" from Bharat Biotech, the latter is availing the expertise of experts from IIT Bombay and ICT Mumbai for speedy and successful transfer of technology. Even transferring technology within the same company to different locations has its challenges. Besides, the challenges faced by the Indian companies receiving vaccine technology from the same source are not identical. Large batches of vaccines have had to be rejected in the recent past in the US due to quality issues – another reminder of the complexities of vaccine manufacturing. It is worthwhile to mention that the Indian government, in an unusual step, has encouraged Indian manufacturers by placing firm orders and making advance payments. The CDSCO has adopted a practical approach in dealing with COVID-19 vaccine applications, including those for restricted emergency use and foreign-approved vaccines. Regulatory authorities in most countries have become flexible with regard to combating the current pandemic. Some state governments in India are focussing on creating vaccine-manufacturing clusters.*

*One of the challenges faced by the Indian vaccine manufacturers is the crucial shortage of equipment, for example, small- and large-scale bioreactors and fermenters, with long waiting times for equipment ordered abroad. Indian equipment manufacturers should seize this opportunity, even if they have to buy technology or collaborate with leading global players. Another problem relates to the availability of critical, consistent-quality raw materials and consumables, and Indian manufacturers have a huge opportunity here too. Of course, each country would like to meet its own requirements first. The newer vaccines being produced to combat COVID-19 need specialised skills in genetics and mammalian cell culture – the latter being a field familiar to the Indian biopharmaceutical manufacturers. National research laboratories such as CCMB in Hyderabad, CIIMS in Nagpur and IISc in Bengaluru are intensifying their efforts in all aspects connected to strengthening the fight against COVID-19.*

*Methods for testing vaccine effectiveness are still being developed, which is not surprising, considering the fact that the newer vaccines are themselves largely emerging products from platforms which now have the opportunity to be tested on larger populations across different countries. Due to the lack of randomisation of persons to vaccination in real-world and real-time settings, observational studies may be biased, which can lead to a consequent deviation from the actual effectiveness of the vaccine. Mention may be made here of the bias of misclassification of the outcome due to imperfect lab test performance in diagnosing COVID-19 infection. Let us - the scientific, electronic, print and social media fraternity included here - leave the cautious interpretation of results of systematic studies to the experts.*

*At the time of writing, India had administered more than 230 million doses of vaccines (needless to say, made in India) and also exported 67 million doses to over 95 countries. All said and done, still, each one of us has probably lost at least someone dear due to COVID-19.*

*Indian Drugs looks forward to receiving research articles related to vaccine development, manufacturing, formulation, testing, quality assurance, diagnostics and more.*

*Happy reading!*

*Courtesy: Indian Drugs, Editorial, 58 (05), May 2021*

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NDPS MATTERS

# The issuance of export permits for Narcotic and Psychotropic substances has been digitalised - reg.

**Notification G.S.R. 490(E), 16th July, 2021**

In exercise of the powers conferred by section 9, read with section 76 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby makes the following rules further to amend the Narcotic Drugs and Psychotropic Substances Rules, 1985, namely: —

1. **Short title and Commencement:**
   (1) These rules may be called the Narcotic Drugs and Psychotropic Substances (Second Amendment) Rules, 2021
   (2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Narcotic Drugs and Psychotropic Substances Rules, 1985, in rule 58, sub-rule (2), for clause (b), the following clause shall be substituted, namely: -

   "(b) the import certificate in original or in electronically generated format, issued by the Government of the importing country certifying the official approval of the concerned Government;

   Provided that where the import certificate in electronically generated format issued by the Government of importing country, the export authorisation shall be issued, after verification of such electronic format through bar code or through official website or through email of the Government of importing country;

   Provided further that in case the substance is not controlled in the importing country, the exporter shall submit a certificate or letter, in lieu of such import certificate, confirming, no objection to the import or that the substance is not controlled in importing country."

**F.No.N/11012/3/2017-NC-II**

*Dinesh Bouddh, Director, Ministry of Finance, Department of Revenue, New Delhi.*

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GOVERNMENT NOTIFICATION

# Time extension for B2 category product - reg.

**Notification S.O. 2859(E), 16th July, 2021**

Whereas, the Central Government, in exercise of its powers by sub-section (1) and clause (v) of sub-section (2) of section 3 of the Environment (Protection) Act, 1986 has published the Environment Impact Assessment Notification, 2006 vide number S.O. 1533(E), dated the 14th September, 2006, (hereinafter referred to as the said notification) making the requirement of prior environmental clearance from the concerned regulatory authority mandatory for all new projects or activities listed in the Schedule to the said notification, their expansion and modernisation and/or change in product mix, as the case may be, before any construction work or preparation of land by the project management except for securing the land;

And Whereas, in view of the CoVID-19 pandemic and the requirement to expedite drug manufacturing the 'said notification' was amended vide notification no. S.O. 1223(E), dated 27th March, 2020 wherein it was notified that all proposals for projects or activities in respect of Active Pharmaceutical Ingredients (API), received up to 30th September, 2020, shall be appraised as Category 'B2' projects. Subsequently, the above mentioned period was extended by six months from 30th September, 2020 to 30th March, 2021 vide notification no. S.O. 3636(E) dated 15th October, 2020;

And Whereas, in view of the outbreak of the second wave of COVID-19 pandemic, the Central Government has received requests for further extension of the time period beyond 30th March, 2021 as there is a continued requirement to expedite drug manufacturing;

And Whereas, the Central Government deems it necessary to provide another window in view of the second wave of COVID-19 pandemic and continued requirement of expeditious drug manufacturing;

Now, Therefore, in exercise of powers conferred by sub-section (1) and clause (v) of sub-section (2) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government, hereby makes following further amendments in the said notification, namely:-

In the said notification, in the Schedule, against item 5(f), in column (5), for the third paragraph the following paragraph shall be substituted, namely:-

*"All proposals for projects or activities in respect of Active Pharmaceutical Ingredients (API), received from 16th July, 2021 to 31st December, 2021, shall be appraised, as Category 'B2' projects, provided that any subsequent amendment or expansion or change in product mix, after the 31st December, 2021, shall be considered as per the provisions in force at that time."*

**F.No. 22-25/2020-IA.III**

*Dr Sujit Kumar Bajpayee, Joint Secretary, Ministry of Environment, Forest and Climate Change,*

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# Central Government grants ONE TIME EXEMPTION from revision of Ceiling Price under Para 18(1) of the DPCO - reg.

**ATTENTION MEMBERS**

The Ministry of Chemicals and Fertilizers, Dept. of Pharmaceuticals has issued a Notification (F. No. 31011/05/2018-Pricing) dated 19th July 2021. Copy of the said Notification is reproduced below for your ready reference).

Thr Notification states that the Central Government hereby grants ONE TIME EXEMPTION from revision of Ceiling Price under Para 18(1) of the Drugs (Prices Control) Order, 2013 and to keep in abeyance the Revision of Ceiling Prices after completion of 5 years till NLEM 2021 is released by the Ministry of Health and Family Welfare.

This is for your kind information, please.

Thanks and regards,

Daara B Patel
Secretary - General

**Notification S.O.(E), F.No.31011/05/2018-Pricing, dated 19th July, 2021**

In exercise of the powers conferred by section 3 of the Essential Commodities Act, 1955 (10 of 1955), the Central Government hereby grants the one time exemption from revision of ceiling price under pars 18(i) of the Drugs (Prices Control) Order, 2013 and to keep in abeyance the revision of ceiling prices after completion of 5 years term till NLEM 2021 is released by the Ministry of Health & Family Welfare.

*Rajneesh Tingal, Joint Secretary, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, New Delhi.*

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# Explanation by Mr B G Barve, Chairman, Excise & Taxation Committee, IDMA

Wherever any appeal is required to filed before Joint/ Additional Commissioner (Appeals), Commissioner (Appeals), Appellate Authority for Advance Ruling, Tribunal and various courts against any quasi-judicial order or where a proceeding for revision or rectification of any order is required to be undertaken, the timeline for the same would stand extended as per the Hon'ble Supreme Court's order.

In other words, the extension of timelines granted by Hon'ble Supreme Court vide its Order dated 27.04.2021 is applicable in respect of any appeal which is required to be filed before Joint/ Additional Commissioner (Appeals), Commissioner (Appeals), Appellate Authority for Advance Ruling, Tribunal and various courts against any quasi-judicial order or where proceeding for revision or rectification of any order is required to be undertaken and is not applicable to any other proceedings under GST Laws.

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## Clarification regarding extension of limitation under GST Law in terms of Hon'ble Supreme Court's Order dated 27.04.2021 - reg.

**Circular No. 157/13/2021-GST, dated 20th July, 2021**

*To,*
*The Principal Chief Commissioners/ Chief Commissioners/ Principal Commissioners/Commissioners of Central Tax (All)*
*The Principal Director Generals/ Director Generals (All)*

The Government has issued notifications under Section 168A of the CGST Act, 2017, wherein the time limit for completion of various actions, by any authority or by any person, under the CGST Act, which falls during the specified period, has been extended up to a specific date, subject to some exceptions as specified in the said notifications. In this context, various representations have been received seeking clarification regarding the cognizance for extension of limitation in terms of Hon'ble Supreme Court Order dated 27.04.2021 in Miscellaneous Application No. 665/2021 in SMW(C) No. 3/2020 under the GST law. The issues have been examined and to ensure uniformity in the implementation of the provisions of law across the field formations, the Board, in exercise of its powers conferred by section 168 (1) of the Central Goods and Services Tax Act, 2017 (hereinafter referred to as "CGST Act"), hereby clarifies the issues detailed hereunder:

2.1 The extract of the Hon'ble Supreme order dated 27th April 2021 is reproduced below for reference:

"*We, therefore, restore the order dated 23rd March, 2020 and in continuation of the order dated 8th March, 2021 direct that the period(s) of limitation, as prescribed under any general or special laws in respect of all judicial or quasi-judicial proceedings, whether condonable or not, shall stand extended till further orders. It is further clarified that the period from 14th March, 2021 till further orders shall also stand excluded in computing the periods prescribed under Sections 23 (4) and 29A of the Arbitration and Conciliation Act, 1996, Section 12A of the Commercial Courts Act, 2015 and provisos (b) and (c) of Section 138 of the Negotiable Instruments Act, 1881 and any other laws, which prescribe period(s) of limitation for instituting proceedings, outer limits (within which the court or tribunal can condone delay) and termination of proceedings.*

*We have passed this order in exercise of our powers under Article 142 read with Article 141 of the Constitution of India. Hence it shall be a binding order within the meaning of Article 141 on all Courts/ Tribunals and Authorities.*"

2.2 The matter of extension of period of limitation under Section 168A of the CGST Act, 2017 was deliberated in the 43rd Meeting of GST Council. Council, while providing various relaxations in the compliances for taxpayers, also recommended that wherever the timelines for actions have been extended by the Hon'ble Supreme Court, the same would apply.

3. Accordingly, legal opinion was solicited regarding applicability of the order of the Hon'ble Supreme Court to the limitations of time lines under GST Law. The matter has been examined on the basis of the legal opinion received in the matter. The following is observed as per the legal opinion:-

(i) The extension granted by Hon'ble Supreme Court order applies only to quasi-judicial and judicial matters relating to petitions/ applications/ suits/ appeals/ all other proceedings. All other proceedings should be understood in the nature of the earlier used expressions but can be quasi-judicial proceedings. Hon'ble Supreme Court has stepped into to grant extensions only with reference to judicial and quasi-judicial proceedings in the nature of appeals/ suits/ petitions etc. and has not extended it to every action or proceeding under the CGST Act.

(ii) For the purpose of counting the period(s) of limitation for filing of appeals before any appellate authority under the GST Law, the limitation stands extended till further orders as ordered by the Hon'ble Supreme Court in Suo Motu Writ Petition (Civil) 3 of 2020 vide order dated 27th April 2021. Thus, as on date, the Orders of the Hon'ble Supreme Court apply to appeals, reviews, revisions etc., and not to original adjudication.

(iii) Various Orders and extensions passed by the Hon'ble Supreme Court would apply only to acts and actions which are in nature of judicial, including quasi-judicial exercise of power and discretion. Even under this category, Hon'ble Supreme Court Order, applies only to a lis which needs to be pursued within a time frame fixed by the respective statutes.

(iv) Wherever proceedings are pending, judicial or quasi-judicial which requires to be heard and disposed off, cannot come to a standstill by virtue of these extension orders. Those cases need to be adjudicated or disposed off either physically or through the virtual mode based on the prevailing policies and practices besides instructions if any.

(v) The following actions such as scrutiny of returns, issuance of summons, search, enquiry or investigations and even consequential arrest in accordance with GST law would not be covered by the judgment of the Hon'ble Supreme Court.

(vi) As regards issuance of show cause notice, granting time for replies and passing orders, the present Orders of the Hon'ble Supreme Court may not cover them even though they are quasi-judicial proceedings as the same has only been made applicable to matters relating to petitions/ applications/suits, etc.

4. On the basis of the legal opinion, it is hereby clarified that various actions/compliances under GST can be broadly categorised as follows: -

**(a) Proceedings that need to be initiated or compliances that need to be done by the taxpayers:-**

These actions would continue to be governed only by the statutory mechanism and time limit provided/ extensions granted under the statute itself. Various Orders of the Hon'ble Supreme Court would not apply to the said proceedings/ compliances on part of the taxpayers.

**(b) Quasi-Judicial proceedings by tax authorities:-**

The tax authorities can continue to hear and dispose off proceedings where they are performing the functions as quasi-judicial authority. This may interalia include disposal of application for refund, application for revocation of cancellation of registration, adjudication proceedings of demand notices, etc.

Similarly, appeals which are filed and are pending, can continue to be heard and disposed off and the same will be governed by those extensions of time granted by the statutes or notifications, if any.

**(c) Appeals by taxpayers/ tax authorities against any quasi- judicial order:-**

Wherever any appeal is required to filed before Joint/ Additional Commissioner (Appeals), Commissioner (Appeals), Appellate Authority for Advance Ruling, Tribunal and various courts against any quasi-judicial order or where a proceeding for revision or rectification of any order is required to be undertaken, the time line for the same would stand extended as per the Hon'ble Supreme Court's order.

5. In other words, the extension of timelines granted by Hon'ble Supreme Court vide its Order dated 27.04.2021 is applicable in respect of any appeal which is required to be filed before Joint/ Additional Commissioner (Appeals), Commissioner (Appeals), Appellate Authority for Advance Ruling, Tribunal and various courts against any quasi-judicial order or where proceeding for revision or rectification of any order is required to be undertaken, and is not applicable to any other proceedings under GST Laws.

6. It is requested that suitable trade notices may be issued to publicize the contents of this Circular.

7. Difficulty, if any, in implementation of this Circular may please be brought to the notice of the Board.

**File No: CBIC-20006/10/2021**

*Sanjay Mangal, Pr. Commissioner (GST), Central Board of Indirect Taxes and Customs, GST Policy Wing, Ministry of Finance, Department of Revenue, New Delhi.*

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# In Lok Sabha & In Rajya Sabha

## In Lok Sabha

## COVID-19 Impact on Companies

### Lok Sabha Un-Starred Question No. 25

### Shri Tapir Gao:

### Shri Lallu Singh:

**Q.** Will the Minister of **CORPORATE AFFAIRS** be pleased to state:

(a) whether the second wave of corona has adversely impacted the economic conditions of the companies in the country;

(b) if so, the details thereof;

(c) whether the Government has taken any steps to improve the condition of the affected companies; and

(d) if so, the details thereof?

### Answered on 19th July 2021

**A.** (a) to (d): The number of new companies incorporated in the Country under the provisions of the Companies Act, 2013 from April 2021 to June, 2021 is 36,191 as compared to 18,968 number of new companies in the corresponding period of last year which is an increase of 17,223 number of new Companies. The following steps have been taken by the MCA during the COVID-19 Pandemic:-

(i) The Companies Fresh Start Scheme (CFSS), 2020 during the period 1.4.2020 to 31.12.2020 (launched to make a fresh start for companies to be a fully compliant company by allowing them to file belated documents in MCA 21 registry without any additional fees from 1st April to 31st December, 2020). The said scheme has also given immunity from prosecutions and proceedings for imposition of penalty which might arise on account of such delayed filing of documents. As per records, 473131 number of Indian Companies and 1065 number of Foreign Companies have been benefited by availing the CFSS, 2020 scheme for filing their pending documents.

(ii) The MCA introduced an LLP Settlement Scheme, 2020 to provide one- time relaxation in additional fees to the defaulting Limited Liability Partnerships.

(iii) Keeping in view the second COVID wave and considering the difficulties arisen due to resurgence of COVID-19 pandemic, the Ministry has granted relaxation on levy of additional fees for companies / LLPs in filing certain forms.

(iv) Considering the difficulties arisen due to resurgence of COVID-19 pandemic, the Ministry vide General Circular no. 7/2021 dated 03.05.2021 has granted relaxation of timelines and condoned the delay in filing forms that are related to creation / modification of charges (CHG-1 Form and CHG- 9 Form) by a company or charge holder and where the date of creation / modification of charge is (i) before 1.4.2021, but the time line for filing such form had not expired under section 77 of the Act as on 1.4.2021; or (ii) falls on any date between 1.4.2021 to 31.5.2021 (both dates inclusive).

(v) The companies have been allowed to hold Extraordinary General Meetings (EGMs) through Video Conferencing (VC) or other audio-visual means (OAVM) complemented with e-Voting facility/simplified voting through registered emails till 30th June, 2021.

(vi) The companies have been allowed to conduct their Annual General Meetings (AGMs) by Video Conferencing (VC) or other audio-visual means (OAVM) whose AGMs were due to be held in the year 2020 or become due in the year 2021 to conduct their AGMs on or before 31.12.2021.

(vii) The Companies (Indian Accounting Standards) Rules, 2015 have been amended vide notification dated 18.06.2021, inter-alia, to extend the benefits of COVID-19 related rent concession, that were introduced last year, from 30th June, 2021 to 30th June, 2022.

(viii) The mandatory requirement of holding meetings of the Board of the companies within the intervals provided in section 173 of the Companies Act, 2013 (CA-13) (120 days) were extended by a period of 60 days till next two quarters i.e., till 30th September, 2020. Considering the second COVID wave, the Ministry further extended the aforesaid relaxation for the year 2021-22 and accordingly the time gap between two consecutive meetings of the Board may extend to 180 days during the Quarter – April to June 2021 and Quarter – July to September, 2021, instead of 120 days as required in the Companies Act, 2013.

(ix) The Ministry enhanced the period to thirteen months from 1st December, 2019 within which existing Independent directors may apply online for inclusion of their names in the databank for Independent Directors vide amendments in the Companies (Appointment & Qualification of Directors) Rules, 2014 from time to time. Further, the Companies (Creation and Maintenance of databank of Independent Directors) Rules, 2019 have been amended vide notification dated 18.06.2021 to provide that in case an individual has delayed in applying to the Institute for inclusion of his name in the data bank of Independent Directors or in case of delay in renewal thereof, the Institute shall allow such inclusion or renewal, as the case may be, after charging a further fees of one thousand rupees on account of such delay.

(x) Non-compliance of minimum residency in India for a period of at least 182 days by at least one director of every company, under Section 149 of the CA-13 shall not be treated as a non-compliance for the financial year 2019- 20 and 2020-21.

(xi) Requirement for investing 15% of amount of debentures maturing in a particular year in specified instruments has been done away with for Listed companies & NBFCs when such debentures are issued on a private placement basis.

(xii) Time allowed to Auditors and Audit Firms for filing NFRA-2 form with the NFRA has been extended till a total period of 270 days in view of the difficulties faced during COVID-19 related disruption.

(xiii) Last date of submission of Cost Audit Report by the Cost Auditor to the management of the company has been extended till 31st December 2020 and additional fee has been relaxed for filing of CRA-4 (form for filing of cost audit report) for financial year 2019-2020.

**Minister of State (Independent Charge) of the Ministry of Statistics and Programme Implementation; Minister of State (Independent Charge) of the Ministry of Planning; and Minister of State for Corporate Affairs Rao Inderjit Singh**

## Dealing in Crypto Currency

### Lok Sabha Un-Starred Question No. 53

**Shri Lavu Sri Krishna Devarayalu:**

**Shrimati Chinta Anuradha:**

**Shri P.V. Midhun Reddy:**

**Shri Pocha Brahmananda Reddy:**

**Shri Sridhar Kotagiri:**

**Q.** Will the Minister of **CORPORATE AFFAIRS** be pleased to state:

(a) whether the Government has made it mandatory for Indian companies to disclose their dealings in crypto-currency or digital currency;

(b) if so, the details thereof, and

(c) the details of the number of companies that have disclosed their dealing in crypto-currency with MCA as on date?

### Answered on 19th July 2021

**A.** (a)&(b): Ministry of Corporate Affairs has amended Schedule III to the Companies Act, 2013 effective from 1st April, 2021 vide Notification dated 24.03.2020 which mandates various disclosures by the companies in their Financial Statements including the following disclosures with regard to virtual currency/ Crypto currency transactions undertaken by them during the financial year:-

i. Profit or loss on transactions involving Crypto Currency or Virtual Currency;

ii. Amount of Currency held as at the reporting date;

iii. Deposits or advances from any person for the purpose of trading or investing in Crypto Currency/ Virtual Currency.

(c): The filings of Financial Statements for the Financial Year 2021-22 are not yet due.

**Minister of State (Independent Charge) of the Ministry of Statistics and Programme Implementation; Minister of State (Independent Charge) of the Ministry of Planning; and Minister of State for Corporate Affairs Rao Inderjit Singh**

## "Financial Assistance for Developing Covid Vaccine"

### Lok Sabha Unstarred Question No-127 (For Answer on-19.07.2021)

### Shri Anto Antony

**Q. Will the Minister of FINANCE be pleased to state:**

(a) whether the Government has provided financial assistance to any firm for developing Covid-19 vaccination;

(b) if so, the details thereof including the amount so far disbursed to such firms;

(c) whether the Government has any statistics regarding the amount earmarked for Covid- 19 vaccination purpose;

(d) if so, the details thereof;

(e) whether the Government has decided to provide free vaccination for all; and

(f) if so, the details thereof and the estimated cost of vaccination for all?

### Answered on 19th July 2021

**A.** (a) and (b) Yes Sir, the Department of Biotechnology (DBT), Ministry of Science & Technology, through its Public Sector Undertaking, the Biotechnology Industry Research Assistance Council (BIRAC), has provided financial support to public research institutes and industry for COVID-19 Vaccine Development. Financial support was provided to nearly 09 private industries for the development of vaccines for COVID-19, whereby an amount of Rs.489 Cr., has been allocated and an amount of Rs. 148 Cr. has been disbursed.

(c) and (d) In the Union Budget 2021-22, an Outlay of Rs 35,000 crore has been made towards COVID-19 vaccination.

(e) and (f) Yes, all citizens are entitled to free vaccination. In financial year 2021-22, a provision of Rs.35,000 Cr has been made for Covid-19 vaccination. Apart from this, if required, the Government has also committed to provide additional funds for this as announced in para number 38 of the Budget Speech of Hon'ble FM for the financial year 2021-22.

**Minister of State In Ministry of Finance (Shri Pankaj Chaudhary)**

## Tax Exemption on Covid-19 Treatment

### Lok Sabha unstarred Question No. 196

### Shri C.N. Annadurai:

### Shri Dhanush M. Kumar:

### Shri Gajanan Kirtikar:

### Shri Gautham Sigamani Pon:

**Q.** Will the Minister of **FINANCE** be pleased to state:

(a) whether the Government has decided to provide income tax exemption to the amount received by a taxpayer for medical treatment from an employer or from any person for treatment of Covid-19 during the financial year 2019-20 and subsequent years;

(b) if so, the details thereof along with the aims and objective behind this move;

(c) whether the Government has also decided that ex-gratia received by family members of individuals who died due to Covid-19 will be exempt from income tax and if so, the details thereof and if there is any ceiling on the amount received;

(d) whether the Government has also extended some key tax compliance deadlines due to impact of Covid-19 pandemic and if so, the details thereof; and

(e) the success achieved by the Government after implementing Vivad se Viswas scheme?

### Answered on 19th July 2021

**A.** (a) Yes Sir.

(b) Income-tax exemption shall be provided to the amount received by a taxpayer for medical treatment from an employer or from any person for treatment of COVID-19 during financial year 2019-20 and subsequent years. The aim of this exemption is to provide relief to taxpayers who suffered on account of COVID-19 and had to incur sum for medical treatment of COVID-19 after taking help from employer or any person. It is the stated policy of the Government to discourage cash transactions and move towards less cash economy. Hence, there is no proposal to increase the limit of cash transactions permissible under various provisions of the Income- tax Act, 1961.

(c) Yes Sir, in order to provide relief to the family members of taxpayers who have lost their lives due to Covid-19, the Government has decided that income-tax exemption shall be provided to ex-gratia payment received by family members of a person from the employer of such person or from other person on the death of the person on account of Covid-19 during FY 2019-20 and subsequent years.

The exemption shall be allowed without any limit for the amount received from the employer and the exemption shall be limited to Rs. 10 lakh in aggregate for the amount received from any other persons.

(d) Yes Sir, the Government has extended various key tax compliance deadlines due to impact of COVID-19 pandemic. The detail of these extended timelines is provided in the Annexure.

(e) The government has resolved significant number of pending direct tax disputes amicably with the taxpayers under Vivad se Vishwas Scheme, 2020. This was the primary objective of the Scheme as provided in the short title therein 'An Act to provide for resolution of tax and for matters connected therewith or incidental thereto'. The total number of pending tax disputes as on the eligibility date was 5,10,491. **Total 1,32,353 declarations have been received under the scheme, entailing disputed tax amounting to Rs 99,765 crore. These declarations relate to 1,46,701 pending disputes (including cross appeals).** Thus, the declarations received under the Scheme cover around 28.73% of pending tax disputes.

**The Minister of State In Ministry of Finance**
**(Shri Pankaj Chaudhary)**

***Annexure***

**1. Extension of various key tax compliance under Direct Taxes:**

The Taxation and Other Laws (Relaxation and Amendment of Certain Provisions) Act, 2020 (hereinafter referred to as "TOLA") was enacted to ease the compliance requirement of taxpayers under the specified Acts mentioned in the TOLA. Further, vide various notifications, the time period of compliance was further extended. Time limit has also been extended through various circulars. The combined effect of TOLA and the said notifications/ circulars are as under:

(i) Various time limits for compliances and statutory actions under the taxation laws, other related legislations and the rules or notifications prescribed/ issued under these Acts were extended;

(ii) Due date for filing of ITR for Financial Year 2019-20 (relevant to Assessment Year 2020-21) was extended to 10th January, 2021 for non-auditable cases and non-company cases. For auditable cases, company cases and cases having international transactions, the due date was extended to 15th February, 2021. Due date for furnishing of tax audit report was also extended from 30th September, 2020 to 15th January, 2021.

(iii) The time for filing income-tax returns for Financial Year 2018-19 (relevant to Assessment Year 2019-20) was extended to 30th November, 2020;

(iv) Date of assessments getting barred on 30th September, has been extended to 30th Sept 2021.

(v) Extension of date for filing declaration under the Direct Tax Vivad se Vishwas Act, 2020 [enacted for resolution of pending disputes related to the Act] was extended to 31 March 2021. Further, the due date of payment without any additional amount has been extended to 30th August 2021.

(vi) The date for payment of self-assessment tax in case of taxpayers whose self-assessment tax liability is up to Rs. 1 Lakh was extended to 10th January,2021 (for non-auditable cases and non-company cases) and to 15th February, 2021 (for cases where tax audit is mandatory and company/international transaction cases).

(vii) The date for making various investment/ payment for claiming deduction under Chapter VIA-B of the Income-tax Act (hereinafter referred to as "the Act") was extended to 31st July, 2020.

(viii) The date for making investment/construction/purchase/deduction in respect of capital gains under section 54 to 54GB of the Act for period between 20th March 2020 and 29th September was extended to 30th September, 2020.

(ix) The date for commencement of operation for the SEZ units for claiming deduction under section 10AA of the Act was extended to 30th September, 2020 for the units which have received necessary approval by 31st March, 2020.

(x) The time limit for furnishing of TDS/TCS statements and issuance of TDS/TCS certificates in relation to FY 2019-20 was extended to 31st July, 2020 and 15th August, 2020 respectively.

(xi) The date for passing of order or issuance of notice by the authorities and various compliances under various direct taxes and Benami Law was extended to 31st March, 2021.

(xii) The date for linking of Aadhaar with PAN has been extended to 30th September, 2021.

(xiii) Implementation of new procedure for approval/ registration/ notification of certain entities u/s 10(23C), 12AA, 35 and 80G of the Act was deferred from 01.06.2020 to 01.04.2021 and the last date of filing application has been extended to 31st August 2021.

(xiv) Applicability of clause 30C and clause 44 in respect to reporting of GAAR compliance and GST in Form 3CD of the Income-tax Rules, 1962 (hereinafter referred to as "the Rules") has been extended till 31.03.2022.

(xv) The time limit for filing appeal before the Commissioner (Appeals) under Chapter XX of the Act which was required to be filed by 01.04.2021 or thereafter was extended to 31.05.2021 or within the time provided under the relevant section, whichever is later.

(xvi) The time limit for filing objection to Dispute Resolution Panel (DRP) under Section 144C of the Act, for which the last date of filing under that section was 1" April 2021 or thereafter, was extended to 31st May 2021 or within the time provided under that section, whichever is later.

(xvii) The time limit for furnishing Income-tax return in response to notice under section 148 of the Act, for which the last date under the said notice is 01.04.2021 or thereafter, was extended to 31st May 2021 or within the time allowed under that notice, whichever is later.

(xviii) The due date for furnishing belated/ revised returns for AY 2020-21 which was required to be furnished by 31.03.2021 under sub-section (4)/sub-section (5) of section 139 of the Act, was extended to 31.05.2021.

(xix) The time limit for payment of TDS under section 194-IA (consideration for immovable property), section 194-IB (rental income) and section 194M (payment to contractors) of the Act and filing of challan-cum-statement for such tax deducted, which were required to be paid and furnished by 30.04.2021 under rule 30 of the Income-tax Rules, 1962 (the Rules) , was extended to 31st May 2021.

(xx) The time limit for furnishing statement in form No. 61, containing particulars of declarations received in form No.60 (person not having PAN who enters into a transaction requiring quoting of PAN), which was required to be furnished by 30.04.2021 was extended to 31.05.2021.

(xxi) The time limit for furnishing of Statement of Financial Transactions (SFT) for the FY 2020-21, which was required to be furnished by 31.05 2021 under rule 114E of the Rules and various notifications issued thereunder, was extended to 30.06.2021.

(xxii) The time limit for furnishing the Statement of Reportable Account for the calendar year 2020, which was required to be furnished by 31.05.2021 under rule 114G of the Rules, was extended to 30.06.2021.

(xxiii) The TDS/TCS Book Adjustment Statement in form No 24G for the month of May 2021, which was required to be furnished by 15.06.20221 under rule 30 and rule 37CA of the Rules, was extended to 30.06.2021.

(xxiv) The time limit for sending the statement of TDS from contributions paid by the trustees of an approved superannuation fund for the FY 2020-21, which was required to be sent by 31.05.2021 under rule 33 of the Rules, was extended to 30.06.2021.

(xxv) The due date of furnishing the ITRs for the Financial Year 2020-21 (relevant to the Assessment Year 2021-22) which were required to be furnished under sub-section (1) of section 139 of the Act by:

- 31.07.2021 has been extended to 30.09.2021
- 31.10.2021 has been extended to 30.11.2021
- 30.11.2021 has been extended to 31.12.2021

Consequential relief also provided in payment of self-assessment tax by the extended date, if the amount payable is one lakh rupees or less.

(xxvi) The due date for furnishing belated/ revised returns for the Financial Year 2020-21 (relevant to the Assessment Year 2021-22) which were required to be furnished by 31.12.2021 under sub-section (4)/sub-section (5) of section 139 of the Act, has been extended to 31.03.2022.

(xxvii) The due date of furnishing of Report of Audit under any provision of the Act for the Financial Year 2020-21, and which was required to be done by 30.09.2021 has been extended to 31.10.2021.

(xxviii) The due date of furnishing Report from an Accountant by persons entering into international transaction or specified domestic transaction under section 92E of the Act for the Financial Year 2020-21, which was required to be done by 31.10. 2021, has been extended to 30.11. 2021.

(xxix) The time period for filing objections to DRP and Assessing Officer under section 144C of the Act, the last date for which was 01.06.2021 or thereafter, has been extended to 31.08.2021 or the date provided under the said section whichever is later.

(xxx) The time limit for furnishing the TDS Statement for the last quarter of the Financial Year 2020-21, which was required to be furnished by 31.05.2021 under rule 31A of the Rules, was extended to 15.07.2021

(xxxi) The time limit for furnishing the TDS certificate in form No.16 to the employee under rule 31 of the Rules which is required to be done by 15.06.2021, has been extended to 31.07.2021.

(xxxii) The time limit for furnishing the statement of income paid or credited by an investment fund to its unit holder, in form No. 64D for the FY 2020-21, which was required to be furnished by 15.06.2021 under Rule 12CB of the Rules, was extended to 15.07.2021.

(xxxiii) The time limit for furnishing the statement of income paid or credited by an investment fund to its unit holder in form No. 64C for the Financial Year 2020-21, which was required to be furnished by 30.06.2021 under rule 12CB of the Rules, has been extended to 31.07.2021.

(xxxiv) The date for compliances to be made by the taxpayers for investment, deposit, payment, acquisition, purchase, construction etc , for the purpose of claiming exemption on capital gains under section 54 to 54GB of the Act, for which the last date is between 01.04.2021 to 29.09.2021 (both days inclusive), has been extended to 30.09.2021.

(xxxv) The time limit of furnishing the Quarterly Statement in form No. 15CC by authorized dealer in respect of remittances made for the quarter ending on 30.06.2021, which was required to be furnished by 15.07.2021 under rule 37 BB of the Rules, has been extended to 31st July, 2021.

(xxxvi) The time limit for furnishing the Equalization Levy Statement in form No. 1 for the Financial Year 2020- 21, which was required to be filed on or before 30.06.2021, has been extended to 31.07.2021.

(xxxvii) The time limit for furnishing the annual statement under sub-section (5) of section 9A of the Act by the eligible investment fund in form No. 3CEK for the Financial Year 2020-21, which was required to be filed by 29.06.2021, has been extended to 31.07.2021.

(xxxviii) The time limit for uploading of the declarations for non-deduction of TDS received from recipients in form No. 15G/15H during the quarter ending 30.06.2021, which was required to be uploaded by 15.07.2021 has been extended to 31.08.2021.

(xxxix) The time limit for exercising of option to withdraw pending application filed before the erstwhile Income Tax Settlement Commission under sub-section (1) of section 245M of the

Act in form No. 34BB, which was required to be exercised by 27.06.2021 has been extended to 31.07.2021.

(xl) Time Limit for passing penalty order has been extended to 30.09.2021.

(xli) Time limit for issuance of notice under section 148 of the Act which was required to be issued by 31.03.2021 was extended to 30.06.2021.

(xlii) Time limit for passing of orders by assessing officer consequent to receipt of directions from DRP which were required to be passed by 31.03.2021 was extended to 30.06.2021.

(xliii) Time Limit for processing Equalisation Levy returns has been extended to 30.09.2021.

(xliv) Time limit for passing or orders and issuance of notice by the Adjudicating Authority under the Prohibition of Benami Property Transaction Act, 1988 which was required to be passed/issued by 30.06.2021 has been extended to 30.09.2021.

(xlv) Circular was issued to the effect that in case if a person has submitted valid Forms 15G and 15H to the banks or other institutions for FY 2019-20, then these form 15G and 15H will be valid up to June 30, 2020, for FY 2020-21 also.

**2. Extension of various key tax compliance under indirect taxes:**

**(I) Following measures have been taken in view of COVID-19 pandemic in the year 2020: -**

(i) In regard to composition scheme, -

a) Due date for furnishing FORM GSTR-4 for FY 2019-20 was extended till 31.10.2020.);

b) Due date for payment of tax in FORM CMP-08 for last quarter of FY 2019-20 was extended till 07.07.2020;

c) Composition scheme for FY 2020-21 could be opted till 30.06.2020.

(ii) 10% cap on availment of Input Tax Credit in FORM GSTR-3B in terms of the provision of Rule 36(4) of CGST Rules, 2017 to be made applicable on cumulative basis for period of February to August, 2020 instead of on monthly basis.

(iii) Conditional waiver of late fees for delayed furnishing of FORM GSTR-3B for the taxpayers if return furnished till the specified dates for the tax periods Feb 2020 to April 2020 for taxpayers with turnover of more than 5 crores (Feb 2020 to July 2020- for taxpayers with turnover up to 5 crores).

(iv) Further, the amount of late fee payable has been capped at Rs. 500/- for each return for the tax period from February, 2020 to July, 2020, if such returns are furnished by 30th September, 2020. The late fee is NIL if the tax liability is zero.

(v) Measures related to Interest on delayed payment of tax:

(a) For taxpayers with turnover above Rs. 5 crores in the preceding FY, for FORM GSTR-3B for the months from February, 2020 to April, 2020, there would be no interest for first fifteen days after the due date and thereafter at 9% p.a. till 24.06.2020.

(b) For taxpayers with turnover of up to Rs. 5 crores in the preceding FY, for FORM GSTR-3B for the months from February, 2020 to July, 2020, there would be no interest till specified dates and thereafter at 9% p.a. till 30.09.2020.

(vi) Late fees for FORM GSTR-1 were waived for tax periods March 2020 to June 2020 and Quarter Jan to Mar 2020 and Apr to Jun 2020, if such statement is furnished by specified dates.

(vii) Extension of due date for FORM GSTR-3B :

(a) For month of May, 2020 to specified date for all taxpayers.

(b) For month of August, 2020 for taxpayers having turnover of up to Rs. 5 crores.

(viii) An enabling section 168A was inserted in the CGST Act, 2017 to empower the government to extend the due date in case of force-majeure event. Notifications have been issued using the said power, to extend the due date for compliance for almost all the provisions of Act. For almost all the provisions of Act, any time limit for completion or compliance of any action, by any authority or by any person, under the CGST Act, which falls during the period from the 20.03.2020 to the 30.08.2020, was extended up to the 31.08.2020.

(ix) Validity of e-way bills was extended till 30.04.2020 for those expiring between period 20.03.2020 to 15.04.2020. Further, validity of e-way bills was extended till 30.06.2020 for those expiring on or after 20.03.2020 and generated on or before 24.03.2020. Provision for blocking of e-way bill for non-filing of two or more GSTR-3B was suspended from 20.03.2020 to 15.10.2020.

(x) Time limit for completion or compliance of any action in respect of goods being sent or taken out of India on approval for sale or return for which such compliance falls during the period from the 20.03.2020 to the 30.10.2020 was extended till 31.10.2020.

(xi) Time limit for completion or compliance of any action in respect of Section 171 (NAPA provisions) for which such compliance falls during the period from the 20.03.2020 to the 30.03.2021 was extended till 31.03.2021.

(xii) The facility of verifying returns (FORM GSTR-3B) through Electronic Verification Code**,** instead of Digital Signature Certificate, was provided during the period 21.04.2020 to 30.09.2020 in respect of the companies registered under Companies Act, 2013. Similarly, they could file the statement of outward supplies (FORM GSTR-1) during the period from the 27.05.2020 to 30.09.2020 verified through electronic verification code (EVC).

**(II) Following measures have been taken in view of the outbreak of the second wave of COVID-19 pandemic in the year 2021: -**

(i) Concessional rates of interest in lieu of the normal rate of interest of 18% per annum for delayed tax payments have been prescribed as follows:

a. For registered persons having aggregate turnover above Rs. 5 Crore: A lower rate of interest of 9 per cent for the first 15 days from the due date of payment of tax and 18 per cent thereafter, for the tax payable for tax periods March 2021, April 2021 and May 2021 payable in April 2021, May 2021 and June 2021 respectively, has been notified.

b. For registered persons having aggregate turnover upto Rs. 5 Crore (for both normal taxpayers and those under QRMP scheme)**:**

i. Nil rate of interest for the first 15 days from the due date of payment of tax, 9 per cent for the next 45 days, and 18 per cent thereafter, for the tax payable for the period March 2021 has been notified.

ii. Nil rate of interest for the first 15 days from the due date of payment of tax, 9 per cent for the next 30 days, and 18 per cent thereafter, for the tax payable for the period April 2021 has been notified.

iii. Nil rate of interest for the first 15 days from the due date of payment of tax, 9 per cent for the next 15 days, and 18 per cent thereafter, for the tax payable for the period May 2021 has been notified.

c. For registered persons who have opted to pay tax under the Composition scheme: NIL rate of interest for first 15 days from the due date of payment of tax and 9 per cent for the next 45 days thereafter has been notified for the tax payable for the quarter ending 31st March, 2021.

(ii) Waiver of late fee for specified period after due date for the returns has been provided as follows:

a. For registered persons having aggregate turnover above Rs. 5 Crore:

Late fee waived for 15 days in respect of returns in FORM GSTR-3B furnished beyond the due date for tax periods March, 2021, April, 2021 and May 2021, due in the April 2021, May 2021 and June 2021 respectively;

b. For registered persons having aggregate turnover upto Rs. 5 Crore:

**i.** Late fee waived for 60 days in respect of the returns in FORM GSTR-3B furnished beyond the due date for tax periods March, 2021 (for taxpayers filing monthly returns) due in April 2021.

**ii.** Late fee waived for 45 days in respect of the returns in FORM GSTR-3B furnished beyond the due date for tax period April, 2021 (for taxpayers filing monthly returns) due in May 2021.

**iii.** Late fee waived for 30 days in respect of the returns in FORM GSTR-3B furnished beyond the due date for tax period May, 2021 (for taxpayers filing monthly returns) due in June, 2021.

c. For registered persons filing FORM GSTR-3B on quarterly basis, Late fee waived for 60 days beyond the due date for period Jan-March, 2021.

(iii) Extension of due date of filing GSTR-1, IFF, GSTR-4 and ITC-04:

a. Due date of filing FORM GSTR-1 and IFF for the month of April 2021 and May 2021 has been extended by 15 days.

b. Due date of filing FORM GSTR-4 for FY 2020-21 has been extended from 30th April, 2021 to 31st July, 2021 .

c. Due date of furnishing FORM ITC-04 for Jan-March, 2021 quarter has been extended from 25th April, 2021 to 30th June, 2021.

(iv) 5% cap on availment of Input Tax Credit in FORM GSTR-3B in terms of the provision of Rule 36(4) of CGST Rules, 2017 to be made applicable on cumulative basis for period of April, May and June, 2021 in the return for tax period June, 2021 or the quarter ending in June, 2021.

(v) The filing of GSTR-3B and GSTR-1/ IFF by companies using electronic verification code has been enabled for the period from the 27.04.2021 to 31.08.2021.

(vi) Extension in statutory time limits under section 168A of the CGST Act: Time limit for completion of various actions, by any authority or by any person, under the GST Act, which falls during the period from 15th April, 2021 to 29th June, 2021, has been extended up to 30th June, 2021, subject to some exceptions as specified in the notification.

## In Rajya Sabha

## Disposal of COVID-19 biomedical waste

### Rajya Sabha Unstarred Question No. 27

### Smt. Vandana Chavan:

**Q.** Will the Hon'ble Minister of **ENVIRONMENT, FOREST AND CLIMATE CHANGE** be pleased to state:

(a) steps Government is taking to promote segregation at source and separate waste collection of COVID-19 and non COVID-19 waste, and ensure efficiency of incinerators in case this waste is not segregated;

(b) details of monitoring mechanisms at incineration plants to check water and air based pollution caused by increased biomedical waste;

(c) details of waste generation to incineration capacity, and States that adopted hazardous waste treatment, storage, and facilities for disposal of biomedical waste, State/UT- wise; and

(d) details of steps Government has taken to create awareness and citizen engagement on disposal of COVID-19 biomedical waste and reduce plastic-pollution due to same?

### Answered on 19th July 2021

**A.** (a) The Ministry of Environment, Forest and Climate Change (MoEFCC) had notified the Biomedical Waste Management Rules, 2016 (BMWM Rules, 2016) under Environment (Protection) Act, 1986, which stipulates source segregation of the Bio-Medical waste (BMW) into four categories as prescribed under Schedule -I of said Rules. The respective State Pollution Control Boards (SPCBs)/ Pollution Control Committees (PCCs) implement BMWM Rules, 2016 provisions through issuance of authorisation to Healthcare Facilities (HCFs) and Common Biomedical Waste Treatment Facility (CBWTF) operators. The Central Pollution Control Board (CPCB) has prepared following guidelines on segregation, treatment and disposal of BMW:

- Management of Healthcare Waste in Healthcare Facilities as per Biomedical Waste Management Rules, 2016;
- Guidelines for Common Biomedical Waste Treatment Facilities; and
- Handling, Treatment and Disposal of Waste Generated during Treatment/Diagnosis/ Quarantine of COVID-19 Patients

(b) The BMWM Rules, 2016 provisions stipulate the treatment options in respect of source- segregated categories under Schedule-I. Similarly, the Schedule-II mandates the standards prescribed for incinerator stack emission, treated effluent, autoclave/microwave/hydroclave and chemical disinfection. SPCBs/ PCCs monitor HCFs and CBWTFs for compliance of prescribed standards of emissions, liquid effluents and waste. The CPCB also randomly verify the compliance status of HCFs and CBWTFs and take action on non-compliances as per Rule provisions.

(c) The CPCB has reported that there are 202 operational CBWTFs in the country for treatment and disposal of BMW. To treat additional COVID-19 BMW during pandemic, Tamil Nadu and Maharashtra had utilized hazardous waste incinerators for disposal of yellow colour coded (incinerable) COVID19 waste,in line with CPCB Guidelines. The State-wise total BMW generation (COVID as well as non-COVID waste) and HCF/ CBWTF incineration capacity isprovided below:

| State/ Union Territory | BMW Generation (Tonnes/ day) | CBWTF/ HCF Incineration capacity (Tonnes/day) |
|---|---|---|
| Andaman and Nicobar | 0.71 | - |
| Andhra Pradesh | 22.38 | 33 |
| Arunachal Pradesh | 0.49 | - |
| Assam | 9.65 | 4 |
| Bihar | 35.65 | 26.4 |
| Chandigarh | 5.6 | 4.8 |
| Chhattisgarh | 8.07 | 15 |
| Dadar and Nagar Haveli | 0.34 | - |
| Delhi | 38.91 | 37 |
| Goa | 1.81 | - |
| Gujarat | 49.07 | 83 |
| Haryana | 22.46 | 39.6 |
| Himachal Pradesh | 4.45 | 5.28 |
| Jammu and Kashmir | 9.07 | 9.84 |
| Jharkhand | 6.25 | 12.2 |
| Karnataka | 85.43 | 90.5 |
| Kerala | 59.21 | 33 |
| Lakshadweep | 0.11 | - |
| Madhya Pradesh | 24.03 | 38.4 |
| Maharashtra | 83.36 | 74 |
| Manipur | 1.14 | 2.4 |
| Meghalaya | 1.53 | 0.8 |
| Mizoram | 0.97 | - |
| Nagaland | 0.99 | - |
| Odisha | 22.16 | 12.36 |
| Puducherry | 6.98 | 5 |
| Punjab | 19.36 | 11.7 |
| Rajasthan | 24.2 | 32.2 |
| Sikkim | 0.59 | - |
| Tamil Nadu | 70.54 | 57 |
| Telengana | 23.31 | 47.4 |
| Tripura | 1.42 | - |
| Uttarakhand | 5.53 | 3.2 |
| Uttar Pradesh | 62.33 | 74.64 |
| West Bengal | 49.52 | 69.6 |
| **TOTAL** | **757.6** | **822** |

(d) The CPCB Guidelines on 'Handling, Treatment and Disposal of Waste Generated during Treatment/ Diagnosis/ Quarantine of COVID-19 Patients' stipulates specific steps for stakeholders to handle COVID-19 waste as mentioned below:

- Personal Protective Equipment's (PPEs) like masks and gloves used in general household and commercial places, offices, etc. needs to be kept separately in paper bag for minimum 72 hours prior to disposal with general waste, after cutting/ shredding;
- Discarded PPEs at commercial establishments, shopping malls, institutions, offices, etc. need to be stored in separate bin for 3 days, and thereafter disposed of as dry general solid waste after cutting/ shredding;
- PPE waste generated at crematoriums / graveyards need to be treated as BMW and disposed of accordingly, either through HCF staff or Urban Local Body
- These guidelines were issued in very beginning of COVID Pandemic in March, 2020 and the same were revised four times looking at the situation requirement;

Further, information regarding BMW and COVID-19 waste management like Technical guidelines/ Do's and Don't(s)/ Posters/ Videos etc. has been placed in the public domain for information and awareness of general public.

**Minister of State In The Ministry of Environment, Forest and Climate Change (Shri Ashwini Kumar Choubey)**

## Encouragement to MSMEs

### Rajya Sabha Unstarred Question No. 95

### Smt. Chhaya Verma:

### Shri Vishambhar Prasad Nishad:

### Ch. Sukhram Singh Yadav:

**Q.** Will the Minister of **Micro, Small and Medium Enterprises** be pleased to state:

(a) the details of economic package given by Government to restart Micro, Small and Medium Enterprises (MSMEs) and outcome thereof;

(b) whether the amount fixed by Government to revive the MSMEs sector is too less due to which there would be uncertainty in the said sector for a long time; and

(c) whether any study has been conducted to fix the amount of finance needed for the recovery of MSMEs sector and the details of resources that will have to be made available for the same?

### Answered on 19th July 2021

**A.** (a)& (b): The Ministry of MSME implements various schemes and programmes for growth and development of MSME Sector in the country. These schemes and programmes include Prime Minister's Employment Generation programme (PMEGP), Scheme of Fund for Regeneration of Traditional Industries (SFURTI), A Scheme for Promoting Innovation, Rural Industry & Entrepreneurship (ASPIRE), Interest Subvention Scheme for Incremental Credit to MSMEs, Credit Guarantee Scheme for Micro and Small Enterprises, Micro and Small Enterprises Cluster Development Programme (MSE-CDP), Credit Linked Capital Subsidy and Technology Upgradation Scheme (CLCS-TUS).

Post Covid-19, Government has taken a number of initiatives under Aatma Nirbhar Bharat Abhiyan to support the MSME Sector in the country especially in Covid-19 pandemic. Some of them are:

i) Rs 20,000 crore Subordinate Debt for MSMEs.

ii) Rs. 3 lakh crores Collateral free Automatic Loans for business, including MSMEs.

iii) Rs. 50,000 crore equity infusion through MSME Fund of Funds.

iv) New revised criteria for classification of MSMEs.

v) New Registration of MSMEs through 'Udyam Registration' for Ease of Doing Business.

vi) No global tenders for procurement up to Rs. 200 crores, this will help MSME.

An online Portal "Champions" has been launched on 01.06.2020 by Hon'ble Prime Minister. This covers many aspects of e-governance including grievance redressal and handholding of MSMEs. Through the portal, total 35,361 grievances have been redressed upto 12.07.2021.

(c): Studies have been conducted by National Small Industries Corporation (NSIC) and Khadi and Village Industries Commission (KVIC) to assess the impact of COVID-19 Pandemic on MSMEs including units set up under Prime Minister's Employment Generation Programme (PMEGP).

A. The main findings of the online study conducted by NSIC to understand the operational capabilities and difficulties faced by the beneficiaries of NSIC schemes amid Covid-19 pandemic are as follows:

i. 91% MSMEs were found to be functional.

ii. Five most critical problems faced by MSMEs were identified as Liquidity (55% units), Fresh Orders (17% units), Labour (9% units), Logistics (12% units) and availability of Raw Material (8% units.)

B. The findings of the study conducted by KVIC are as under:

i. 88% of the beneficiaries of PMEGP scheme reported that they were negatively affected due to Covid-19 while the remaining 12% stated that they were benefitted during Covid-19 Pandemic.

ii. Among the 88% who were affected, 57% stated that their units were shut down for some time during this period, while 30% reported drop in production and revenue.

iii. Among the 12% who had benefitted, 65% stated that their business increased as they had units in retail and health sector and around 25% stated that their units benefitted as they were dealing with essential commodities or services.

iv. On the question of regular payment of salaries to the employees, around 46.60% respondents stated that they had paid the salaries in full, 42.54% reported to have partially paid and 10.86% reported to have not paid salary for some time during this period.

v. Majority of the beneficiaries expressed the need for additional financial support, relaxation of waiver of interest and marketing support for their products.

**Minister of Micro, Small and Medium Enterprises (Shri Narayan Rane)**

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## Challenges in MSMEs sector

### Rajya Sabha Unstarred Question No.103

### Shri Binoy Viswam:

**Q.** Will the Minister of **Micro, Small and Medium Enterprises** be pleased to state:

(a) whether Government has taken cognizance of the fact that definition of Micro, Small and Medium Enterprises (MSMEs) has been a constraint for many SMEs to access institutional support;

(b) mechanism Government uses to differentiate MSMEs from other corporate entities, in light of no separate registration of MSMEs under Companies Act;

(c) whether Government is considering an increase in the size and extension of the period of availability of Emergency Credit line mandated for providing collateral free loans to MSMEs; and

(d) challenges identified by Government relating to the MSMEs sector and the manner it proposesto resolve these challenges?

### Answered on 19th July 2021

**A.** (a) & (b): The present criteria of classification of Micro, Small and Medium Enterprises (MSMEs) is based on the composite criteria of their investment and turnover, which is transparent, progressive and easy to implement. This criteria was notified vide notification no. S.O. 2119(E) dated 26.06.2020. Accordingly, MSMEs can register themselves on Udyam Portal. Institutional support is as per the guidelines/directions of the institution providing the support.

(c): The Cabinet, in its meeting dated 30.06.2021, has approved additional funding of Rs 1.50 lakh crore under Emergency Credit Line Guarantee Scheme (ECLGS), thereby enhancing the total funding under ECLGS to Rs 4.5 lakh crore. Presently, the validity of ECLGS is upto 30.09.2021.

(d): On the basis of Consultations held with various stakeholders / Industry Associations of the country, certain specific challenges such as need for easy finance, more liquidity, moratorium on loans, etc. have been identified. To resolve these challenges, recently the Government has taken a number of initiatives under Aatma Nirbhar Bharat Abhiyan to support the MSME sector in the country, especially in Covid-19 pandemic. Some of them are:

i. Rs. 20,000 crore Subordinate Debt for MSMEs.

ii. Rs.3 lakh crores Collateral free Automatic Loans for business, including MSMEs.

iii. Rs. 50,000 crore equity infusion through MSME Fund of Funds.

iv. New Revised criteria of classification of MSMEs.

v. New Registration of MSMEs through 'Udyam Registration' for Ease of Doing Business.

vi. No global tenders for procurement up to Rs. 200 crores.

An Online Portal "Champions" has been launched on 01.06.2020 by Hon'ble Prime Minister. This covers many aspects of e-governance including redressal of grievances and handholding of MSMEs. Through the portal, a total 35,562 grievances have been redressed upto 15.07.2021.

RBI has also announced several measures to Reduce Financial Stress of MSMEs.

**Minister of Micro, Small and Medium Enterprises (Shri Narayan Rane)**

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## Phasing Out Single Use Plastic

### Rajya Sabha Unstarred Question No. 46 .

### Shri M. Shanmugam:

**Q.** Will the Minister of **ENVIRONMENT, FOREST AND CLIMATE CHANGE** be pleased to state:

(a) the policy of Government is phasing out single use plastics in the country;

(b) the quantum of plastic being used annually in the last three years; and

(c) the details of efforts made to reduce use of plastic in the coming years?

### Answered on 19th July 2021

**A.** (a) A multi-pronged strategy has been adopted to phase out identified single-use plastic items in the country, which comprises of (i) awareness generation and behavioural change, (ii) regulatory regime for phasing out of identified single use plastic items, having low utility and high littering potential, (iii) engagement with stakeholders, and (iv) strengthening of institutional mechanism for collection, segregation, recycling and environmentally sustainable end of life disposal of plastic waste, as envisaged in Plastic Waste Management Rules, 2016.

Already, the Plastic Waste Management Rules, 2016, prohibits manufacture, import, stocking, distribution, sale and use of carry bags and plastic sheets less than fifty microns in thickness in the country. There is complete ban on sachets using plastic material used for storing, packing or selling gutkha, tobacco and pan masala.The Ministry of Environment, Forest and Climate Change had also issued a draft notification in the Gazette of India vide GSR No. 169 (E) on 11th March 2021 for amending Plastic Waste Management Rules, 2016, inter alia prohibiting the use of identified single use plastic items by 2022, for public consultation.

(b) The annual plastic waste generated in the last three years is given below.

| Sr. No. | Year | Plastic Waste Generation (TPA) |
|---|---|---|
| 1. | 2019-2020 | 34,69,780 |
| 2. | 2018-2019 | 33,60,043 |
| 3. | 2017-2018 | 23,83,469 |

(c) The following efforts have been made to reduce the use of identified single use plastic items:

(i) The States/UTs have been requested to constitute a Special Task Force under Chairpersonship of Chief Secretary/Administrator for elimination of single use plastics and effective implementation of Plastic Waste Management Rules, 2016. Already, 13 States/UTs have constituted the Special Task Force till date. A National Level Taskforce has also been constituted by the Ministry for taking coordinated efforts to eliminate identified single use plastic items and effective implementation of Plastic Waste Management Rules, 2016

(ii) The State /UT Governments and concerned Central Ministries/Departments have also been requested for the development of a comprehensive action plan for elimination of single use plastics and effective implementation of Plastic Waste Management Rules, 2016, and its implementation in a time bound manner.

(iii) Directions under Section 5 of Environment (Protection) Act,have been issued to all States/ UTs for setting up for institutional mechanism for strengthening enforcement of PWM Rules. Guidelines for assessment of Environmental Compensation for violation of PWM Rules 2016 have also been issued. The Ministry has also issued "Standard Guidelines for Single-Use Plastic" on 21st January 2019 to all States/UTs and Ministries.

(iv) The Government has been taking measures for awareness generation towards elimination of single use plastics and effective implementation of Plastic Waste Management Rules, 2016.A two month long Awareness Campaign of Single Use Plastic 2021 has been organized. The Ministry has also organized pan India essay writing competition on the theme for spreading awareness amongst school students in the country. To encourage innovation in development of alternatives to identified single use plastic items and digital solutions to plastic waste management, the India Plastic Challenge – Hackathon 2021, has been organized for students of Higher Educational Institutions and start-ups recognized under Start up India Initiative.

**Minister of State In the Ministry of Environment, Forest and Climate Change**
**(Shri Ashwini Kumar Choubey)**

## Ocugen seeks approval for Covaxin in Canada

***The move follows the release by Bharat Biotech of Phase 3 clinical trial results, which demonstrated efficacy and safety in nearly 25,800 adults, it said***

Ocugen, Bharat Biotech's partner for US and Canada for COVID-19 vaccine Covaxin has initiated a rolling submission to Health Canada for the jab, the US company said in a regulatory filing.

The move follows the release by Bharat Biotech of Phase 3 clinical trial results, which demonstrated efficacy and safety in nearly 25,800 adults, it said.

Often referred to as a rolling review, this allows Health Canada to start its review right away, as information continues to come in, to accelerate the overall review process.

Ocugen initiated the rolling submission through its affiliate, Vaccigen.

Health Canada will make a decision upon review of the evidence submitted that supports its safety, efficacy and quality.

The rolling submission process was recommended and accepted under the Minister of Health's Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19 and transitioned to a new drug, Ocugen said.

"We thank Health Canada for their upcoming review of Covaxin and look forward to working with them so that we can offer the possibility of another safe and effective option to be used in their fight against COVID-19 and its Delta variant," Dr Shankar Musunuri, Chairman of the Board, CEO and Co-Founder of Ocugen said.

Covaxin was developed in collaboration with the Indian Council of Medical Research (ICMR) National Institute of Virology (NIV).

*Source: PTI, 16.07.2021*

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## India to get 7.5mn shots from Moderna

India will receive 7.5 million doses of US pharma major Moderna's Covid-19 vaccine as part of the Covid-19 Vaccines Global Access (COVAX) programme, the World Health Organization's regional director for South-East Asia Dr Poonam Khetrapal Singh told news agency ANI on Monday. On June 30, India approved the import of Moderna's mRNA technology based Covid-19 vaccine, paving way for the entry of the first international Covid-19 vaccine into the Indian market. HT reported in its July 1 edition that about 7 million doses of the Moderna vaccine will be made available for India. On behalf of Moderna, India's Cipla Ltd applied to Drugs Controller General of India for approval to import the vaccine. However, Cipla will not be able to retail the vaccine since its has only been given emergency use authorisation, said an official in the Central Drugs Standard Control Organisation.

*Source: Hindustan Times, 20.07.2021*

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## RBI must sacrifice inflation aim to aid growth, says ex-Governor C Rangarajan

*While the RBI targets to keep retail inflation at the 4% midpoint of its 2%-6% target band, gains in price-growth have exceeded its upper tolerance limit in the past two months.*

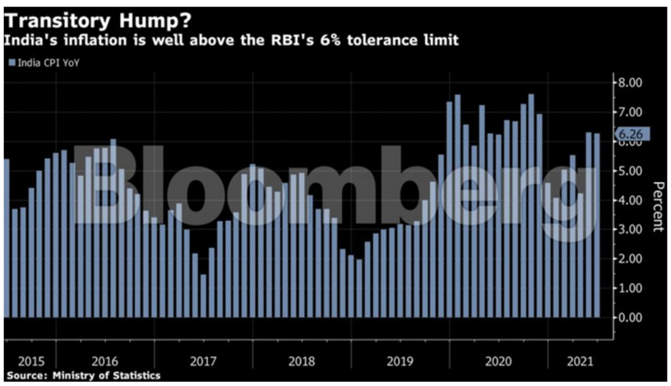
**The federal government's large borrowing plan and the Reserve Bank of India's willingness to support it are bound to fan inflation, Chakravarthy Rangarajan, who headed the RBI during 1992-97, said in an interview. What the central bank should be worried about is how high the inflation goes up, he said.**

India's monetary policy makers need to support economic growth even at the cost of their inflation-fighting credentials, as tackling the pandemic situation requires extraordinary measures, a former central bank governor said.

The federal government's large borrowing plan and the Reserve Bank of India's willingness to support it are bound to fan inflation, Chakravarthy Rangarajan, who headed the RBI during 1992-97, said in an interview. What the central bank should be worried about is how high the inflation goes up, he said.

While the RBI targets to keep retail inflation at the 4% midpoint of its 2%-6% target band, gains in price-growth have exceeded its upper tolerance limit in the past two months. Governor Shaktikanta Das judged the event as ‘transitory’ and one caused by supply-side issues, while the Monetary Policy Committee he heads kept borrowing costs unchanged at a record low last month to support growth.

Rangarajan wants the rate-setters, who are due to review policy early next month, to go one step further and say that they will support growth even if the inflationary trend is more than just a hump.




The MPC “should be willing to say that growth is important in the current situation,” said Rangarajan, who sees consumer prices ending up well above the RBI’s 5.1% outlook for this fiscal year. “And therefore we should be willing to accept a little more inflation.”

The government, which originally penciled in a near-record borrowing of 12.1 trillion rupees ($162 billion) this year to spur spending in the economy, has separately announced raising an additional 1.58 trillion rupees debt to compensate states for a shortfall in a nationwide consumption tax collection.

“People who talk about the need for expanded government expenditure have to accept the fact that this will result in price increase,” Rangarajan said.

**Here are excerpts from the interview:**

### Fiscal Deficit

- India will miss its fiscal deficit target of 6.8% of gross domestic product by at least 1 percentage point, with overall government borrowing, according to his estimates, rising to 16.3 trillion rupees
- Such borrowing plan cannot happen through normal sources and thus RBI’s support is essential to see it through

**Growth Prospects**

- India can achieve 9% growth rate in the absence of a third wave of the pandemic, he said. That’s slower than the 9.5% pace forecast by the RBI
- India’s potential growth has been falling from much before the pandemic. The most important component for India’s growth is investment as a part of GDP and that figure is going down from past several years
- “Best way to stimulate growth in the short- and mid-term is really by raising the investment,” Rangarajan said. “The government should do whatever it can to raise capital expendiuture”

**Forex Reserves**

- RBI will continue to build up some more reserves if flows keeps coming in
- However, there’s the possibility that flow of funds will weaken once interest rates are reversed in advanced economies and already there are signs that interest rates will be reversed in those economies

*Source: Jaiveer Shekhawat, Economic Times, 20.07.2021*

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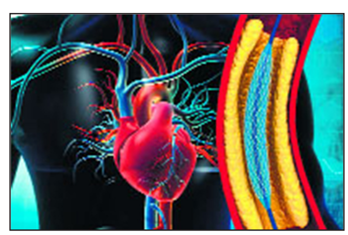
## Japanese firm, Director booked for overpriced medical devices



A Japanese company dealing in cardiac catheters and other medical devices, its director and sales head in India have been booked for cheating, forgery and criminal conspiracy for increasing prices of its products in violation of the National Pharmaceutical Pricing Authority (NPPA).

### Stock value Rs4.14 cr more than allowed

- Cardiac catheters and neurovascular guidewires are non-scheduled drugs, prices of which are fixed by manufacturers
- Under the NPPA provisions, the increase in the MRP of non-scheduled drugs during the preceding 12 months must not be more than 10%

- The Japanese company, however, hiked the prices of cardiac catheters by 19% and that of neurovascular guidewires by 12%

**Cardiac catheters**

A catheter is a very small, flexible, hollow tube which is inserted into a blood vessel. The doctor threads it through the blood vessel into the heart. Once the catheter is in place, several tests may be done.

**Neurovascular guidewires**

These are the metallic and non-metallic structures which guide the catheter through the blood vessels for the placement in the cardiology and radiology angiographic procedures.

The FIR under Sections 420, 467, 468, 471 and 120-B of the IPC, and Sections 7 and 13 of the Prevention of Corruption Act was registered in the GurugramSadar police station on Friday on the orders of the district courts.

Sharad Mehrotra, president of the Gurugram Chemists and Druggists Association, had filed a criminal complaint in the district courts when the police did not register an FIR after he had submitted a complaint and documents obtained under the RTI Act, pointing towards violation by the company.

Amandeep Chauhan, Drug Control Officer, Gurugram, had inspected several premises, including that of the Japanese company, on March 26, and found that the company had raised prices of cardiac catheters and neurovascular guidewires beyond the level permitted by the NPPA.

These are non-scheduled drugs, prices of which are fixed by the manufacturers. But under the NPPA provisions, the increase in the MRP during the preceding 12 months must not be more than 10 per cent.

The company, however, had hiked the prices of cardiac catheters by 19 per cent and that of neurovascular guidewires by 12 per cent.

On June 1, when a team from the Food and Drug Administration (FDA) led by Assistant Drug Controller ManmohanTaneja conducted another inspection, it was found that the value of the stock was Rs 4.14 crore more than the prescribed limit.

Subsequently, the FDA team visited some renowned hospitals in Gurugram and it was found that the price charged by the Japanese company was even higher than the wrongfully enhanced MRP.

The company failed to give a satisfactory reply to the notice served on it.

When the authorities failed to take action against the company, Mehrotra lodged a police complaint, claiming it must have cheated many people of several crores of rupees as it had in operation for long.

The police, however, did not take action.

Armed with documents obtained under the RTI, Act, Mehrotra moved a criminal complaint in the court of Additional District and Sessions Judge. Within 24 hours, the Judge ordered registration of an FIR under Section 156 (3) of the CrPC.

*Source: Sushil Manav, Tribune News Service, 17.07.2021*

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## Amid Covid battle, drug companies get green breather from government

Amid continued threat of Covid-19 pandemic and possibility of its third wave, the Centre has exempted drug manufacturers from stringent environmental clearance processes till December 31.

Under the exemption, notified by the environment ministry on Friday, all such proposals will be appraised for speedy green clearances by putting activities relating to ‘Active Pharmaceutical Ingredients’ (API) under ‘B2’ category projects.

Since projects under ‘B2’ category do not require environment impact assessment (EIA) and public hearings, drug manufacturers can get speedy green clearance. The flexibility is believed will help domestic drug manufacturers self-reliant in the manufacture of APIs which are used as raw materials for producing medicines.

All proposals for projects or activities in respect of Active Pharmaceutical Ingredients (API), received from 16th July, 2021 to 31st December, 2021, shall be appraised as Category ‘B2’ projects,” said the ministry’s notification under the Environment (Protection) Act, 1986.

It, at the same time, clarified that all such projects/ activities after December 31 would be considered as per the provisions in force at that time. The ministry in its notification justified the liberal approach in granting green clearance due to the existing Covid-19 threat. It said, “The central government deems it necessary to provide another window (of exemption) in view of the second wave of Covid-19 pandemic and continued requirement of expeditious drug manufacturing."

It noted the ministry had received requests for further extension of the time period beyond the earlier one which expired on March 30 as "there is a continued requirement to expedite drug manufacturing" in view of the outbreak of the second wave of the pandemic.

Rules notified under the 1986 Act classify projects into three categories – category 'A' which needs to be appraised by the ministry, category 'B' where states need to give clearance and category 'B2' which exempts projects from EIA and public hearing.

Though the ministry had earlier issued notification twice while granting the exemption to drug manufacturers, there was no such specific order beyond March 30.

*Source: Times of India, 19.07.2021*

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## 17 European nations have given nod to Covishield: Serum Institute of India

PUNE: The owner and CEO of Covishield-maker Serum Institute of India (SII), Adar Poonawalla, dismissed on Saturday the need for a "marketing authorisation application" to the European Union (EU), saying "16 of the 27 member countries" and Switzerland (not part of the EU) have currently approved the vaccine based on the WHO's pre-qualification or emergency use listing (EUL).

France on Saturday became the latest EU member country to approve Covishield for travel. Poonawalla told TOI the EU countries that had approved Covishield included "Germany, and the Netherlands,". "Slowly, every EU nation is accepting Covishield. But Italy and a few others have not approved it yet. We did not make any application to those who have approved it. Europe, the US, and everyone else have to acknowledge that this vaccine (Covishield) is of good quality because WHO has approved it," he said. The 16 EU countries are Austria, France, Belgium, Bulgaria, Finland, Germany, Greece, Hungary, Iceland, Ireland, Latvia, Malta, the Netherlands, Slovenia, Spain and Sweden, he said.

*Source: Times of India, 18.07.2021*

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## Centre Building 30-day Buffer Stock of Life-saving Covid Drugs as India Braces for Imminent 3rd Wave

With the country bracing for an imminent third wave of Covid-19, the Centre has geared up to build a 30-day buffer stock or inventory of essential Covid-19 medicines like Remdesivir and Favipiravir.

Apart from the life-saving drugs, the government is also restocking common drugs and supplements like paracetamol, antibiotics, and vitamins, the Business Standard reported.

"The Centre is planning to procure 5 million vials of remdesivir ahead of the third wave. What's better is that this time, the government is paying us in advance," the Business Standard quoted a source.

A leading scientist at the Indian Council of Medical Research (ICMR) on Saturday predicted that the third wave of COVID-19 would arrive in India around the end of August, with about 1 lakh cases each day.

Professor Samiran Panda, speaking about the severity of the third wave, said that if the virus does not further mutate, the scenario will be similar to the first wave, according to a report by India Today. However, if it does mutate, things might get a lot worse.

Professor Panda is the director of the ICMR's epidemiology and communicable diseases division.

While the third wave may not be as devastating as the second wave in India, Panda believes that a low vaccination rate and loosening of restrictions may result in an increase in cases. The Imperial College London and the ICMR collaborated on mathematical modelling to arrive at this conclusion.

*Source : News18, 19.07.2021*

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## Angrezi snobs should shut up. It's our chatpata lingo that unites us

Dear Mansukhbhai, Please don't take tension or have any chinta about your English. Remember, neither are you a match referee at Wimbledon, nor Shashi Tharoor. Apnadesh, apneyvichar, apnibhasha. We don't need to write or speak English like the Brits, who chew up half their words, suffer from a condition called a 'stiff upper lip' and swallow too much. Even in England, they have hazar accents — is Cockney understood by anybody? We are proud of our Indian accent (yes, including the award-winning restaurant by the same name) and we should be showing off our many, colourful versions of English instead of feeling embarrassed. Just see the variations — Hinglish (Hindi), Bonglish (Bengali), Minglish (Marathi ), Tamlish (Tamil), Telglish (Telugu), Gujlish (Gujarati), Punjlish (Punjabi) — arrey baba, we have enriched English, not mangled it.

Mansukh L Mandaviya is India's newly-minted Minister of Health and Family Welfare and Chemicals and Fertilisers. Both portfolios are crucial and of special importance during these difficult times. Yet he was mercilessly trolled on the day he took his oath and was sworn in as a member of Narendra Modi's recently rejigged Cabinet, replacing that 'end game' walla — Dr Harsh Vardhan, who was rightly or wrongly accused of speaking out of turn and declaring the pandemic over just as the second wave of the deadly virus came and crushed us. The good doctor making his exit was described as an 'otorhinolaryngologist' (huh? Cannot pronounce the word and have zero idea what it means). I'm happy to settle for the humble vet. It is commendable that the 49-year-old who was born into a farmer's family in Hanol (Palitanataluka), studied veterinary science, completed his Master's degree in political science, and is where he is today. Who cares if he tweets like a Gujjubhai! It's the content that counts. Only P Chidambaram has a problem with that. Proficiency in our former ruler's language is hardly the only qualification to judge someone's merit. If anything, it displays a slavish attraction to the language of our former masters.


**Elite bias: Those mocking Mansukhbhai Mandaviya should know that English doesn't equal intellect**

Trolling those who do not speak English with a pretentious public school accent reveals the pathetic colonial mindset of trollers. The artificial 'snob meter' kicks in when prominent folks mess up a language that is borrowed and not their matrubhasha. Mocking them for mixing up spellings or pronunciation is kinda mean and immature. A fruity accent does not make the person posh! In today's far more egalitarian world, the only thing that counts is authenticity. It is far better to be yourself — as Mansukhbhai has instinctively figured. Check his response when asked what he had to say to trolls who made fun of him ("I do not have anything to say," he said with a smile).

Going forward, many more public figures in India will be facing similar problems. They will be called 'vernacs' or 'vernies' by those who were privileged enough to get an education in what are mistakenly described as 'convent' schools where English is the medium of education. Mansukhbhai, like the Prime Minister, is a product of a Gujarati medium school. He should be proud of it and wear it like a badge of honour.

I'd go a step further and suggest he should speak in his mother tongue at press conferences, and let the scribes figure. What are interpreters for? And tickers on televised interviews? We have no problems when President Emmanuel Macron sticks to French and loftily refuses to speak English. Why create problems for Mansukhbhai and others who are not comfortable using an alien language?

An entire political saga gets written whenever we discuss sensitive language issues in our country. Language is emotive and fluid. How an individual uses it, can make or break his or her career. Indians speak in many tongues (pun intended). It is our hybrid, chatpata lingo that unites us. That, and our chatpata snacks. Both are jhakaas! 'Ganwaar' is good! It's time to convert that putdown into a compliment. English does not equal intellect.

There are any number of glib talkers in parliament, who do just that — talk! We want our Mansukhbhai to walk the talk. Because, I'm pretty sure, as a Gujarati with farming roots he knows the one word everybody in the cutthroat world of politics understands perfectly — paisa. When paisa talks, the duniya listens. And the Gujju accent gets instantly understood. So guys, stop that thakela convo. Mansukhbhai… kaivaandonathi.

*Source: Shobhaa De , TOI, 17.07.2021*

## Health minister Mansukh Mandaviya debunks allegations of vaccine shortage

***Mandaviya debunked allegations of vaccine shortage and said 114.6 million doses were available in June and the supply has been enhanced to 135 million in the month of July.***

Following a series of statements on vaccine shortage by Congress MP Rahul Gandhi, health minister Mansukh Mandaviya took to Twitter to dispel supply fears and said state governments were informed about vaccines a fortnight in advance.

Mandaviya debunked allegations of vaccine shortage and said 114.6 million doses were available in June and the supply has been enhanced to 135 million in the month of July. "Based on the discussion with manufacturers, the health Ministry had informed all states/UTs on June 19 regarding number of doses of the vaccine to be made available in July. Subsequently, on June 27 and July 13, the states were also informed in advance about the availability of vaccines every day for the first and second fortnight of July. This was done so that states are aware of the time and quantity of doses and thereby plan the vaccination drive in a better and effective manner," Mandaviya said in a series of tweets.

He said despite giving advance information to states on the vaccine availability, "if mismanagement and long queues of vaccination beneficiaries are being seen, it is clearly evident what the real issue is and who is responsible for this state of affairs".

The statement comes after repeated tweets by Congress MP Rahul Gandhi alleging a shortage. Mandaviya said: "Persons who are making statements in the media, that are creating misinformation and panic in the people, need to introspect whether they have distanced themselves so much from governance processes and the related information being given to them, that they are not even aware of the correct advance information been provided regarding availability of vaccines."

*Source : ET Bureau, 15.07.2021*

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## Costs of raw material for drugs rise by 139%

***A steep rise in the cost of raw materials for essential drugs, called active pharmaceutical ingredients (API) in pharma circles, by 139% in certain cases since the pre-pandemic level, is pinching the industry hard.***

A steep rise in the cost of raw materials for essential drugs, called Active Pharmaceutical Ingredients (API) in pharma circles, by 139% in certain cases since the pre-pandemic level, is pinching the industry hard. The overall increase, averaging nearly 50% in the wake of high-priced imports and supply disruptions from China, have raised doubts on the availability of drugs and could lead to shortages, particularly of those that are key in Covid therapy.

API prices of certain drugs like fever and pain relief drug paracetamol and life-saving antibiotic Meropenem (also used for Covid), and anti-diabetic metformin, have more than doubled to as high as 139%, 127% and 124% respectively, putting the spotlight back on India's near total-dependence on the Dragon. Nearly 70% of the country's APIs are imported from China, while the dependence is as high as 90% for certain life-saving antibiotics like cephalosporins, azithromycin and penicillin. Since these medicines are under price control, companies are forced to absorb the higher cost, raising questions about their viability. In this scenario, over time, certain medicines could disappear from retail shelves with companies switching to high-value products where margins are protected. In the wake of limited availability, patients may have to bear the brunt and be forced to shift to newer, steeply priced alternatives, industry experts say.

*Source: Rupali Mukherjee, TNN, 20.07.2021*

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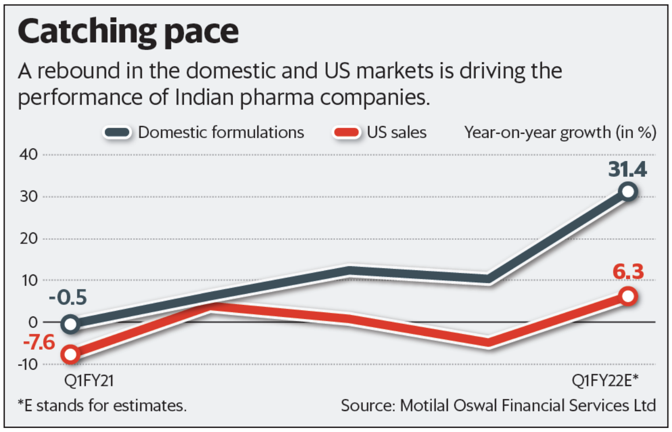
## Pharma sector's earnings to be fired by dual engines during Q1

***The Indian pharma market (IPM) had grown 37% y-o-y and 15% sequentially in Q1***

*The sharp uptick in domestic formulation sales and improved prospects in US generics is expected to drive 12% year-on-year (y-o-y) growth in aggregate sales in Q1FY22 (Photo: Pradeep Gaur/Mint)*

Pharma firms are expected to report a strong performance in the June quarter. Not only are domestic formulation sales likely to be high, driven by contribution from covid treatment drugs, even US sales growth is expected to be helped by the low base of last year.

The sharp uptick in domestic formulation sales and improved prospects in US generics is expected to drive 12% year-on-year (y-o-y) growth in aggregate sales in Q1FY22, according to analysts at Motilal Oswal Financial Services Ltd (MOFSL). The Indian pharma market (IPM) had grown 37% y-o-y and 15% sequentially in Q1. The growth was driven by sales of covid treatment drugs and other drugs. The recovery in acute therapies like gastro, anti-infectives, antibiotics and chronic therapies are expected to help these firms post strong growth.




MOFSL expects a y-o-y growth of 60% each in domestic formulations sales for Glenmark Pharmaceuticals Ltd, Cipla Ltd and Cadila Healthcare Ltd. The addition of the Wockhardt portfolio and better traction in chronic therapies is expected to drive 50% y-o-y growth for Dr Reddy's in Q1, as per MOFSL. Analysts at Centrum Stock Broking Ltd also believe Cipla and Dr Reddy's to post the highest growth in the domestic market. They expect other large firms to deliver growth above 25%. Investor interest on multinational companies remains high, thanks to their domestic focus and strong branded portfolio. Centrum expects Abbott India Ltd and Pfizer Ltd to post strong double-digit growth. While Q1 may see extraordinary growth led by covid drugs, the domestic pharma market is seeing a growth rebound as well. The IPM growth on a trailing 12-month basis remained strong at 11.7%. Notably, forward prospects are looking decent as the September quarter is a seasonally strong one, with acute segment sales catching pace.

Centrum said distributor channel checks indicate that demand continues to be high and with the ebbing of the second wave, the industry is preparing for the anti-infective season. "The India formulations business offers multi-decade double-digit growth as higher per capita income, awareness and health insurance penetration will increase pharmaceutical consumption," analysts at Emkay Global Financial Services said.

As the domestic formulations market remains important, US sales growth remains key for driving the performances of many Indian pharma firms. Improved prescription flow in the US is providing traction to specialty and respiratory products sales and is positive for many Indian pharma firms. Analysts at MOFSL expect the y-o-y growth trajectory in US sales to reverse its downtrend and deliver 6% y-o-y growth in June quarter. Lupin and Sun Pharma are expected to record 27%/24% y-o-y growth in US sales for the quarter. Since 1 April, the Nifty Pharma index has risen almost 18%, beating the 6.4% return in the Nifty 50 index.

*Source: Ujjval Jauhari, HT Mint, 21.07.2021*

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## Zydus vaccine under close review, approval likely to get delayed

***Zydus had applied for emergency use authorisation (EUA) for its vaccine on July 1, but it is yet to be taken up by the subject expert committee that advises the drug regulator on applications seeking approval for vaccines, new drugs and clinical trials.***

The drug regulatory authority is closely examining data on ZydusCadila's Covid-19 vaccine, focusing primarily on its effectiveness and immunogenicity.

The immunogenicity levels of Cadila's vaccine need a closer study and this, in turn, may delay the approval process, people in the know told ET.

Zydus had applied for emergency use authorisation (EUA) for its vaccine on July 1, but it is yet to be taken up by the subject expert committee that advises the drug regulator on applications seeking approval for vaccines, new drugs and clinical trials.

The regulatory authority is closely reviewing the data. There are some concerns regarding the immunogenicity data which is not up to the mark, "a person in the know said. Zydus did not respond to ET's request for comment.

Zydus developed the vaccine, ZyCov-D, with the support of the central government's department of biotechnology and the Indian Council of Medical Research. It has shown 66.6% efficacy in an interim study on more than 28,000 volunteers, including nearly 1000 in the age group of 12-18 years.

The regulatory is currently doing a rolling review of the immunogenicity, or the immune response of the body, of the vaccine by looking at how it is performing in real time as data emerges from trials.

"Once the regulatory body is satisfied, the application will be taken up by the subject expert committee,"said the person.

When it gets the approval , it will become the fifth vaccine to get EUA in India, after Serum Institute of India's Covishield, Bharat Biotech's Covaxin, Russian vaccine Sputnik V and the vaccine of US firm Moderna.

ZyCov-D will also be the world's first DNA Vaccine. Zydus Managing Drector Sharvil Patel had earlier said it would lauch the vaccine in 45 to 60 days after regulatory approval.

The vaccine has a needle free application system whereby a spring powered applicator deliveries the shot. The company is expected to produce 10million doses by mid August and 50million by December.

It plans to join hands with third party manufacturers to increase production once it gets approval from the drug regulator. While the company has yet to disclose the price of vaccine, it is expected to be within the range of the currently available vaccines.

*Source :Teena Thacker, Economic Times, 17.7.2021*

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