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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

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NATIONAL NEWS

The 25 year Circle and the CL to VL Transition©

by

Dr. Gopakumar G. Nair

Editor, IDMA Bulletin & Indian Drugs

(gopanair@gnaipr.net**)**

There is a colloquial proverb "The doctor prescribed what the patient loved to consume". Since independence, India has been, struggling for a "bridge" which we have succeeded in achieving and crossing. It did not come easy, but we have achieved it by collective united intensive bargaining. Ever since WTO and TRIPs, the pharma industry have been appealing for liberal licencing as in copyrights, trademarks, designs etc. including "FRAND" licencing, it took 25 years of concerted action to extend Voluntary Licencing to patents also. The relevance of this 25 year pattern emerges as follows :

Introduction

In the late sixties, when Shri G.P. Nair and Dr. Abraham Patani and others appeared before the Parliamentary Select Committee consisting of eminent parliamentarians like Shri Atal Bihari Vajpayee, Shri C. Achuta Menon and the committee headed by Smt. Dr. Susheela Nayyar, Shri Achuta Menon asked one question which came like a "bolt from the blue". The IDMA team was least expecting it and had not come prepared to answer that. Shri Achuta Menon asked "Mr. Nair, you say that Indian R&D is too nascent and are not competent to undertake research leave alone drug discovery research. You want that product patent be abolished for pharmaceuticals, chemicals, and foods. How do you expect that you will become equipped to undertake your own manufacturing with technology generation and domestic research? Mr. Nair, assuming that we agree and recommend to grant your request for abolition of product patent regime, how soon will you be able to become self-reliant in pharmaceutical research so that we can review the re-introduction of product patents for pharmaceuticals?" Taken by surprise Mr. Nair looked at Dr. Patani and had a whisper of a conversation between them, before Mr. Nair replied "25 years, we hope to be self-reliant to come up with our own product and process patents for drugs in 25 years, Sir". The committee said "so be it". The Parliamentary Committee recommended for abolition of product patents for pharmaceuticals, (drugs), chemicals and foods. With personal intervention of the then dynamic Indian Prime Minister, Smt. Indira Gandhi, the Patents Act, 1970 was born. However, the Act did not come into force till 20th April 1972. The MNC lobbies in Delhi was strong enough to ensure that the Act remains in "limbo", by delaying the drafting and tabling of the related "Patent Rules" indefinitely. IDMA, having realised the "tricks of the trade", requested Shri Bhai Mohan Singh, the then CMD of fast-emerging Ranbaxy Laboratories to take over the President-ship of IDMA. This turned the tables in our favour. The Patent Rules, 1972 was tabled on the house of the Parliament in March, 1972 and became effective in April, 1972. Consequently, the Patents Act, 1972 became legally effective from 20th April 1972.

This created big ripples in the Indian Pharma space. A large number of MNC pharma companies walked out of India, closing down their operations. It was the landmark case of Farbewerke Hoechst vs. Unichem and others involving infringement if Tolbutamide product patent which Unichem lost (J. Vimadal's judgement makes interesting reading) which triggered the anti-product patent climate in India. Prior to this case, the Indian Patents and Designs Act, 1911 had come under fire from the Bakshi Tekchand Committee Report of 1949. The Committee (Tekchand) observed as follows.

"The Committee also observed that the Patents Act should contain clear indication to ensure that food and medicine and surgical and curative devices are made available to the public at the cheapest price commensurate with giving reasonable compensation to the patentee". Thereafter, while the Hoechst vs. Unichem case was in progress, in 1957, the Justice Rajagopala Ayyangar Committee was entrusted by the government to examine the question of revising the Indian Patents Act. While the Rajagopala Ayyangar Committee hearings and reports were in progress, the adverse judgement against Unichem (Tolbutamide infringement & injunction) triggered and expedited cause for abolishing product patents in

pharma. Three times between 1958 and 1970 the Patents Amendment Bill was tabled in Parliament and had lapsed without consideration of the Parliament. The then strong MNC lobby succeeded till the IDMA was born in early 1960s (1962 to be specific) and took upon the Patents amendment for product patent abolition as the major mission. Eventually, as described earlier IDMA and a few leading Indian companies such as CIPLA (Dr. K.A. Hamied), Unichem (Padmabhushan Amrut Modi) and later Ranbaxy and others took the lead in successfully achieving the product patent abolition in 1970/72.

India's pharma industry growth phases can be divided into three phases:-

1. India's pharma self-reliance era
2. Post WTO & TRIPs emergence era
3. Current CL to VL era

India's pharma self-reliance era

India set upon itself to establish its own pharma branded generic formulations since 1972. It was not sheer coincidence that the IDPL (Indian Drugs & Pharmaceuticals Ltd.) was set up in India in collaboration with Russia (USSR). Consequent to IDPL establishing manufacturing facilities in multiple locations in India (HQ-Hyderabad) not only that many Bulk drugs (APIs) started becoming available indigenously, but many technically qualified chemists, pharmacists and pharma technology experts and chemical engineering specialists started emerging in the Indian Pharmaceutical Industry horizon. Around this time many technically and managerially qualified and experienced employees of MNCs and public laboratories like IDPL, HAL and others started setting up their own manufacturing facilities.

Post 1970/72, the Government of India has also been extremely pro-active in supporting the fledgling Indian Pharma Industry. It was very common those days for Members of Parliament and even Ministers of State visiting pharma locations for discussing ways and means to boost Indian pharmaceutical industry. It was in 1974 that the Hathi Committee was formed by the Government of India with Shri Jaysukhlal Hathi as the Chairman. The 15 member Hathi Committee and the sub-committees met intensively, often at private locations, clubs such as India International Centre and Wellington Club or similar, often in Industry Association offices. The widely acclaimed Hathi Committee Report was released in 1975. The Hathi Committee's contribution was to motivate, prioritize and support the achievement of self-sufficiency in medicines and the abundant availability of essential drugs at affordable and reasonable prices. Hathi Committee Report recommendations and the Indian pharma manufacturing entrepreneurship coupled with API technology infusion by IDPL opened up the golden era of Indian pharmaceutical industry. HAL (Hindustan Antibiotics Ltd) established in 1954 contributed immensely to indigenous penicillin production till excessive governmental corruption in later years killed it virtually. IDPL established in 1954 with Russian Technology, also suffered the same fate due to excessive governmental interference. IDPL's and HAL's contribution in the early years of Indian pharma industry's growth has been remarkable. It may not be out of place to recall IDPL as the "mother liquor" of all Indian Pharmaceutical Industry as most of Indian technologies and leading pharma industry leaders like Dr. Anji Reddy emerged from this *"Amrit manthan"* of IDPL.

The New Drugs Policy, 1978 made the biggest impact on Indian pharma industry. The provisions of this policy clearly indicated that the Government of India has not only been hand-holding India but has also been pushing and prodding for faster growth and up-gradation. The 1978 pharma policy required the larger Indian companies to spend at least 4% of their turnover for R&D.

Another initiative from the government in their 'carrot and stick' policy was to introduce the "Ratio Parameters" to encourage indigenous bulk drug production. Indian organised sector companies were required to produce a minimum bulk drug production in the ratio of 1:10 of formulations. MNC companies were required to have a ratio of 1:5 bulk drugs to formulations ratio. On the carrot front, formulations based on domestically produced bulk drugs were given price control concessions, though only for a short period. The introduction of ratio parameters saw a major interest to tie-up with smaller dedicated bulk drug manufacturers. Even though, the MNCs discontinued the bulk drug production once the ratio parameter policy was withdrawn the larger Indian companies continued to make bulk drugs and even intermediates till China, in a concerted and calculated strategy, started dumping bulk drugs into India at highly uneconomical and too-low-to compete prices, thereby dealing a death-blow to Indian bulk drug (API) manufacturing industry to some extent. Taking full advantage of the "carrot" policy, Indian indigenous pharma companies set up extensive marketing divisions and grew by leaps and bounds through branded generic marketing. The 1987 New Drug Policy gave extensive boost to Indian

Pharma Industry which largely benefited Indian companies 8 to 9 out of 10 top pharma companies in India were fully Indian owned companies.

Post WTO & TRIPs emergence era

The alarming growth of pharma industry in India (also in a couple of other developing countries) alerted the developed countries and the MNCs from there. Consequently, with an intention to stem this unstinted growth and to change the rules of the game with a new regime, negotiations were started under the Uruguay Round in 1983 to ament the GATT, suitably as desired. After many rounds of negotiations and the Dunkel Draft Treaty (DDT, it was humorously called), consensus was arrived at by 1994. Consequently WTO was born (GATT transformed with many other treaties, conventions and agreements) along with the TRIPs (Trade Related aspects of Intellectual Properties) Agreement. Industrial Properties under Paris Convention and the Copyrights (which was emerging from pure "Artists" rights to expanded software and related techno commercial writings) to be coined "Intellectual Property" rights. There were extended intensive negotiations both pre-TRIPs and post-TRIPs on the implementation (in stages as allowed in TRIPs). On 1.1.1995 both WTO and TRIPs came into force in India and other countries.

To comply with TRIPs provisions, India amended the Patents Act, 1970 in three phases. The first amendment failed in Indian Parliament in 1995. Consequent to which USA & Europe dragged India to the DSB (Dispute Settlement Board) of WTO, who ruled against India. Consequently, the first amendment was passed in 1998 followed by the second amendment in 2003. The final amendment proposed through a Bill dated 24th December 2004 and Draft Rules dated 26.04.2004 met with stiff opposition in Parliament. On 25th January 2005, the then Minister of Commerce, Mr. Murasoli Maran made a proposal on the floor of the Parliament. If there is an all-party consensus to pass the Patent Amendment Bill before Parliament rises, all amendments moved will be accepted as such. The opposition moved few amendments including the "pre-grant" as well as "post-grant" oppositions (earlier only post-acceptance opposition was available) and the Bill was passed. Product patent regime abolished 25 years back in 1970, returned to India through TRIPs of 1995 and the 3rd amendment of 2005. It is interesting to note that the 25 years "breathing time" negotiated by IDMA for abolition of product patents, came to be a reality through the TRIPs & WTO.

The initial apprehensions of Indian Associations and NGOs (National Working Group headed by Mr. B.K. Keayla and Dr. Vedaraman (earlier Controller General of Patents) were fully taken care by eminent Indian negotiators like Shri A.V. Ganesan, so much so we had acquired abundant flexibilities through TRIPs negotiations. These flexibilities were built into the TRIPs compliant and repeatedly amended (Indian) Patents Act, 1970.

Consequently, contrary to the strategic expectations of developed countries, Indian Pharma Industry, which was largely restricted to India with some exports to developing countries and marginal exports to developed countries, post-WTO and TRIPs made breakthrough entries into the developed markets of USA, Europe and others. Unlike the gradual growth of the 1970s to 1990s, Indian Pharma Industry grew by leaps and bounds post-WTO & TRIPs.

Throughout Indian Pharma's growing years, the appeal for grant of Voluntary Licenses by Innovator Companies to larger Indian companies fell on deaf ears. The provisions for Compulsory Licence were inbuilt even in the Paris Convention adopted in 1883. Consequently almost all Patents Acts or Codes of all countries had the provision of Compulsory Licence in their Acts. USA has a government use provision under 28 USC 1498. India had the provision for Compulsory Licence even in the 1911 Act which government fortified in the 1970 Act and continued to exist in the amended Patents Act, 1970. This was considered as TRIPs compliant as TRIPs itself provides for third party use. Even though the provision of Compulsory Licence existed, it was never invoked seriously. In 2012, the then Controller General of Patents, Shri P.H. Kurian, after protracted but reasonably swift proceedings and hearings, granted India's first (and only) Compulsory Licence (CL). This was contested all the way upto the Supreme Court. Justice Aftab Alam of the Supreme Court confirmed the validity of the grant of CL to NATCO for Nexavar. Having tasted success in CL, more and more companies were keen to apply for CL. By this time two major developments emerged.

Current CL to VL era

Of late, India is having friendly trade negotiations on bilateral basis with USA & Europe (successfully with Japan) and hence, India decided in principle not to entertain any CL applications or not to grant CLs. In the meantime, Indian domestic giants had emerged as Indian Multi Nationals. Sun Pharma (commenced in 1983) had become the largest Indian Company after

merger of Ranbaxy. Dr. Reddy's born out of the passion of Dr. Anji Reddy, had grown equally big and global under new generation. CIPLA, born in 1935 who under Dr.K.A. Hamied and Dr.Yusuf Hamied were relay racing for the Indian Nationalism and self-reliance, were also globalizing and professionalising post 2015. Post the negotiated split of Cadila, the Zydus (Cadila Healthcare) emerged strongly and has now became a true innovator company of global repute. Biocon (Dr.Kiran Mazumdar) has emerged as a truly global biologics company. Alkem, Mankind, Torrent, Glenmark, Emcure, Strides, the list of emerging giants goes on. The global innovator companies were left with no option than to grant Voluntary Licences. This strategy was led by Gilead and others who had many Indian patent infringement litigations. Roche, BMS, Eli Lilly, Merck and others too had experienced protracted Indian patent litigations. Having qualified suitors in the post 2010 era, the innovator companies have opted for the Voluntary Licencing option with the blessings of the Government of India.

What the Indian Pharma Industry originally was seeking from innovator companies was Voluntary Licencing. The Patent Act provides that the request for Voluntary Licence should be made prior to applying for Compulsory Licence. Now that Voluntary Licences are being granted (only criterion being qualified with QA/QC, GMP and in-house innovative research) on almost every new drug, the need for seeking Compulsory Licence appears redundant in changing times. The Government of India is also encouraging the Voluntary Licencing of Patents (we were arguing for last 20 to 30 years for VLs, as such licencing practices are in vague for years for Copyrights, trademarks, brand names etc.). Technically qualified Indian Pharma Companies following global regulatory and IP practices are now receiving VLs without having to go for CLs. CIPLA is the best example. No more patent litigations and disputes appears to be the current CIPLA's strategy. CIPLA is receiving VLs liberally under the new regime along with the likes of Dr. Reddys, Cadila Healthcare (Zydus), Hetero, Jubilant and the top Indian pharma giants. We were clamouring for CLs so that we may get VLs. We are now getting VLs for the asking (provided we qualify). VLs appear to be a preferred flavour to CL without compromising on quality. This is what the Government of India is also saying.

We are back to the colloquial saying "The doctor prescribed what the patient love to consume". We wanted VLs to start with, we are getting VLs as illustrated below in recent days.

Drug	Licensor	Licensee
Remdesivir	Gilead Sciences	Cipla Ltd., Dr. Reddy's Laboratories Ltd.; Eva Pharma; Ferozsons Laboratories; Hetero Labs Ltd.; Jubilant Lifesciences; Mylan; Syngene, a Biocon company; and Zydus Cadila Healthcare Ltd.
Tocilizumab	Roche	Cipla
Molnupiravir	Merck	Cipla, Dr Reddy's Laboratories, Emcure Pharmaceuticals, Hetero Labs and Sun Pharmaceutical Industries
Baricitinib	Eli Lilly and Company	Cipla, Lupin, Sun Pharmaceutical Industries, Dr Reddy's, MSN Laboratories, Torrent Pharmaceuticals, Natco Pharma Limited and BDR Pharmaceuticals
Sputnik V vaccine	Russian Direct Investment Fund (RDIF)	Dr. Reddy's Laboratories, Gland Pharma, Stelis Biopharma, Virchow Biotech and Panacea Biotec, Hetero
Covishield	AstraZeneca/University of Oxford	Serum Institute of India

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Clarification regarding submission of PSUR for New Drugs beyond 4 years of approval: IDMA representation to DCG(I)

The Association has submitted the following representation on 20th May 2021 to Dr. V. G. Somani, Drugs Controller General of India, Central Drugs Standard Control Organization, New Delhi on the above subject

Greetings from Indian Drug manufacturers' Association.

We would like to bring to your kind notice a request made by the concerned officers reviewing the PSURs to submit the PSURs for the New Drugs even after the period of 4 years from the date of approval.

The New Drugs Clinical Trial Rules 2019 in Para (C)(iii) of the Fifth Schedule clearly states the requirement of filing PSURs for the first 2 years every 6 months and thereafter annually for the next 2 years. The requirement continues to state that the CLA may advise filing of the PSURs for an extended period beyond 4 years in certain cases if it is considered necessary in the interest of public health.

Some of our members have informed us that such a request for an extended period is being made routinely for all categories of products. We therefore request you to kindly issue a clarification that the requirement of the extended period will apply only in the cases notified by your good office.

Incidentally, we had made a representation to your office dated 19th October 2020 on the non-applicability of filing of PSURs as per NDCT Rules for the Prof. Kokate Committee approved FDCs. We also had made a request to adopt the initially approved pathway for such approvals that required for filing of PSURs as per Schedule Y, by comprehensively providing the background of the regularisation of FDCs approved through this route of individual NOCs issued to the manufacturers. We are enclosing a copy of this representation for your ready reference.

In view of the new issue being raised and considering the earlier request which has not been reviewed, the manufacturers are put to a lot of inconvenience of filing a lot of information that may not be beneficial from the patient's standpoint.

We sincerely request you to consider the concerns raised by the industry and issue a suitable clarification and not insist on filing PSURs for an extended period beyond 4 years in routine cases.

We take this opportunity to thank you for finding time to discuss with the industry various regulatory issues for reducing the regulatory compliance burden. The issue of PSUR raised by us in this and our letter of 19th October 2020, if resolved will help the industry ensure better compliance with this requirement and will reduce the additional burden our members are facing during the present challenging pandemic.

We request you to allot us time for a short video call with you to explain the matter in detail and seek your guidance to resolve this long-standing issue.

Looking forward to a favourable response from you.

Warm regards,

Mahesh H Doshi
National President

Encl: IDMA Representation dated 19th October 2020 (as reproduced below)

Pathway for Regularization of Kokate Committee approved FDCs including 471 FDCs of Vitamins, Minerals and Micro-nutrients

Greetings from Indian Drug Manufacturers' Association.

We thank you for notifying the list of 471 FDCs relating to Vitamins, Minerals and Micro-nutrients approved by Prof Kokate Committee. We also appreciate that since 2018, you have notified the list of rational SLA Approved drugs covering 1681 FDCs and 450 FDCs.

We have noted from your above-mentioned letter that for grant of product licenses to subsequent applicants for these 471 FDCs by the SLAs, the applicants are required to comply with the PSUR requirements as per the new NDCT Rules 2019.

Several member companies from the MSME sector will be adversely impacted both operationally and financially by this decision that applies the current regulation retrospectively for the existing marketed products, by considering them as 'New Drugs' as defined in the NDCT Rules.

We would like to bring to your kind notice, a brief background of the pathway followed so far for dealing with a typical situation of one of its kind, where all the SLA approved FDCs could be reviewed for their safety and efficacy successfully thereby approving only rational FDCs and withdrawing permission to FDCs found to be not rational.

This exercise could be completed due to the pathway followed for issuing NOCs to the applicants under 18 month Policy and the pathway communicated through various circulars issued by the DCGI office for the subsequent applicants of the FDCs approved by Kokate Committee that is briefly described below:

a) The Circular dated 16th March 2017 described the pathway and provided instructions, among others, for payment of as Rs. 15,000/- as the fees and for filing the PSUR, in accordance with the provisions of Schedule Y.

b) The Circular dated 5th June 2017 that followed further clarified the details of the documents to be submitted by the subsequent applicants holding the SLA approved licenses for the approved FDCs and by those who were new manufacturers.

c) The Circular dated 12th December 2018 from the DCG(I) issued after the list of Kokate Committee approved 1681 FDCs was published, specified the fees to be paid as Rs.15,000/- and PSUR to be filed in accordance with Schedule Y, consistent with the previous Circular, while allowing the direct application to the SLA and approval of such FDCs without the submission of the NOC from the DCG(I) office.

The requirements for PSUR filing was also specified similarly in the NOCs issued by the DCG(I) office to individual companies who had submitted the safety and efficacy data for these FDCs.

It is pertinent to note that the drugs reviewed under 18 months policy were already marketed for several years and were not considered as 'New Drugs'. This is evident from the fact that NOCs and not Form 46 were issued to the companies for these products after the FDCs were declared as rational by the Committee.

This pathway was advised (and was modified to facilitate approvals through various Circulars mentioned above) based on the active engagement and consultation with all the stakeholders, as a practical and acceptable solution for dealing with a unique regulatory situation. Following this pathway, the licenses to the applicants were issued by the SLAs for the applications received for the products cleared so far (1681 + 500) and the companies started filing the PSUR as per Schedule Y as specified in the above mentioned DCG(I) Circulars and also as specified in the NOC letters issued by the DCGI office.

In the meantime, it is observed that the PSUR reviewers at the DCG(I) office have started to write to the manufacturers of such earlier approved FDCs to submit, midway, the PSUR data in accordance with the provisions of the new NDCT Rules 2019.

We have now observed that the recent letter dated 3rd August 2020 has also included this requirement as a condition for regularization of these FDCs that sets aside the PSUR requirement as per Schedule Y specified in the Circulars, dated 16th March 2017 and 12th December 2018 and introduces the requirement of PSUR in accordance with the NDCT Rules.

It is important to note that all the FDCs cleared by the 18 months policy of submission of safety and efficacy data were the existing products and were dealt with this agreed pathway for ensuring that safety and efficacy of the products are established before they are approved for further marketing. This pathway allowed all the manufacturers - the existing, the subsequent applicants and the new manufacturers to follow a uniform procedure considering the special circumstances of approval of such FDCs.

It is therefore difficult to understand as to why this pathway is modified for the fees to be paid and the PSURs to be filed in accordance with the new NDCT Rules by considering them as 'New Drugs'. This requirement is not consistent with the NOCs issued to the manufacturers.

This insistence to follow the stringent PSUR requirements as per new NDCT Rules for the products existing in the market for several years will not serve any useful purpose in terms of benefit to patients. Besides, a compilation of such huge data for these molecules is time-consuming and very expensive, particularly for the MSME sector since they will have to outsource this service from the expert consultants.

Besides this requirement has created a typical situation where the companies have already filed the PSUR for the last 2 years as per Schedule Y are now required to comply with the new NDCT Rules.

You will appreciate that the procedure of review of SLA approved FDCs, that was started in the year 2013, has taken several years to conclude and the products are approved at different intervals of time. In the meantime, new NDCT Rule 2019 has been notified. However, in our opinion, approval of the FDCs after 2019 cannot be the reason for making applicable new rules because fundamentally these products cannot be considered as 'New Drugs' and secondly, some of the manufacturers will have to pay fees and file detailed PSURs for the same set of the products as per new rules.

In view of this, we request you to make a uniform policy applicable to all manufacturers - for those who were issued NOCs for these FDCs under the 18-month policy and for all the subsequent applicants for all the FDCs cleared under this route regardless of the date approval.

We, therefore, request you to issue a clarification that the pathway prescribed in the DCG(I) Circular dated 12th December 2018 shall be followed for all the FDCs cleared in this route and as specified in the Circular:

1. A fees of Rs.15,000/- shall be charged, and
2. PSURs shall be filed in accordance with Schedule Y (that is also specified in the individual NOCs)

We also request you to withdraw any notices issued for filing PSURs as per new NDCT Rules that will help many small and medium sized companies to comply with the requirements followed by all the previous applicant, uniformly.

Yours sincerely,

Mahesh Doshi
National President

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Request for initiation of Remote Inspections for WHO GMP Renewal : IDMA representation to DCG(I)

The Association has submitted the following representation on 20th May 2021 to Dr. V. G. Somani, Drugs Controller General of India, Central Drugs Standard Control Organization, New Delhi on the above subject:

Greetings from Indian Drug Manufacturers' Association

As we are aware, the COVID 19 pandemic has created unprecedented disruption in manufacture and supply of regular medicines and more particularly the new drugs required for treatment of COVID.

Your office, under your leadership has done a phenomenal job by introducing several measures for ensuring supply of much-needed APIs and drug products, such as fast track approval of new drugs for compassionate use, approval for import of COVID drugs and globally approved vaccines etc.

India has also helped the global community in supply of many COVID-related and other essential medicines required for treating comorbidities particularly in COVID patients. In view of this, ensuring timely export of these medicines from India is very important.

In order to ensure this, the manufacturers have to possess the updated WHO GMP Certification. Many of our member companies have represented that in view of discontinuation of the on-site inspections, the renewal of WHO GMP certificates is held up affecting the export of medicines.

As you are aware, the global regulatory community has adopted successfully the tool of remote inspections

for inspection of facilities by adopting a risk-based approach. For example, MHRA has completed 750 remote inspections.Many other drug-manufacturing regulatory agencies worldwide routinely conduct virtual inspections, and have done so since COVID-19 began to shut down travel of inspectors.

Even the industry has developed best practices for auditors or regulatory inspectors to conduct virtual inspections of drug-manufacturing facilities and the virtual inspections are conducted remotely through audio or video streaming techniques, or both. Advanced technology is available and is easily controlled by remote auditors in such a fashion as to replicate the physical presence on-site of an inspector or even a team of inspectors.

In view of this, we humbly request you to kindly consider conducting remote audits for WHO GMP compliance to ensure uninterrupted supply of the essential medicines.

Warm regards,

Mahesh H Doshi
National President

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IDMA's proposal to Department of Pharmaceuticals (DoP) wrt Customs Duty Exemptions for Covid Drugs and their Raw Materials – reg.

The Association has submitted the following representation on 19th May 2021 to Mr. Navdeep Rinwa, IAS, Joint Secretary to the Government of India, Department of Pharmaceuticals, on the above subject:

Greetings from Indian Drug Manufacturers' Association.

At the outset, we thank you for the kind opportunity given to IDMA to partake in the meeting to discuss proposal wrt Customs Duty Exemptions for Covid Drugs and their Raw materials, held on 15th May 2021 under your chairmanship.

We would like to submit that Bulk Drug Manufacturers' Association have already submitted their recommendations vide their letter of 18th May 2021. In addition to the submission made by BDMA; we are recommending the following two intermediates for the Customs Duty exemption:

1. Erythromycin Thiocyanate HS Code : 2941.5000 is used to manufacture Azithromycin.
2. Intermediate 2 keto-L Gluconic Acid HS Code: 29183090 is used to manufacture Vitamin C.

Thanking you and with regards,

Mahesh H Doshi
National President

Request for prioritization of Pharmaceutical Industry workforce for COVID-19 Vaccination – IDMA representation to National Health Mission

The Association has submitted the following representation on 19th May 2021 to Dr. M. K. Aggarwal , DC (UIP), National Health Mission , Ministry of Health & Family welfare , Government of India on the above subject:

Greetings from Indian Drug Manufacturers' Association (IDMA).

We, at IDMA, thank you and the Government for actively supporting our Pharma Industry. Due to the

increase in the Covid-19 pandemic especially the second wave wherein many of our pharmaceutical employees at manufacturing plants, field and offices have been seriously affected. Thus leading to high absenteeism and having a huge impact on production. We are able to maintain consistent supplies so far on account of the inventories being held by us.

We sincerely request you to kindly consider prioritization of the Pharmaceutical employees for vaccination as a special case. Our member companies are ready to bear the cost of the vaccination for their employees and are in contact with the local hospitals for the same.

In this regard, we request you to kindly issue a direction / order from your Office for the same. The Representation from IDMA is enclosed for your kind perusal and information.

Thanks & regards,

Daara B Patel
Secretary General

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DGFT MATTER

Introduction of an online e-EPCG Committee module for accepting applications seeking relaxation in Policy/ Procedure in terms of para 2.58 of FTP 2015-20

Trade Notice 05/2021-22, dated 19th May, 2021

To,
All IEC Holders Members of Trade and Industry,
All Export Promotion Councils/Commodity Boards,
All RA's of DGFT.

1. The members of trade are hereby informed that this Directorate is introducing an online e EPCG Committee module on the DGFT website, a new module as a part of IT Revamp, for receiving applications for seeking relaxation in policy / procedure in terms of para 2.58 of FTP 2015-20.

2. Henceforth, the applications for seeking relaxations in terms of para 2.58 of FTP 2015-20 under the EPCG Committee would be accepted through online mode only. No manual submission of applications for the same would be allowed. The members of trade can login to the portal, fill in the requisite details in the form, upload the necessary documents and submit the application after paying requisite fee. The system will generate a file number which can be used for tracking purposes through the portal. The Directorate would issue online deficiency letters calling for any additional information required and the exporter would be able to reply to the deficiency letters online. The entire processing of the applications and communication of the decision of the committee would be in online mode only.

3. The members of trade can file applications to e-EPCG Committee module through following navigation -

https://dgft.gov.in/ → Login using registered user credentials for the IEC holder → Services → EPCG → Apply for EPCG Committee.

4. The members of trade are advised to go through the Online Help Manual and FAQ documents before filing the applications under the module. The Online Help Manual and FAQ documents would be available under https://dgft.gov.in/ > Learn > Application Help & FAQs.

5. In case any technical issue is faced, the same may be intimated to the DGFT Helpdesk by raising a CRM ticket on the portal or calling on the toll-free helpline @ 1800-111-550 or sending an email to dgftedi@gov.in.

Shobhit Gupta, Deputy Director General of Foreign Trade, Directorate General of Foreign Trade, Directorate General of Foreign Trade, Ministry of Commerce & Industry, Udyog Bhawan, New Delhi.

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Enhancement of facilities under the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017

The Finance Minister had in her Budget Speech this year announced that the Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017 (IGCR, 2017) would be amended to boost trade facilitation. Accordingly, the Central Board of Customs and Indirect Taxes(CBIC) had immediately enhanced the scope of these rules on 2nd February 2021.

The CBIC has now issued a Circular No.10/2021-Customs, dated 17th May 2021 in order to assist the trade in understanding the improvements in the IGCR, 2017 so that they may make full use of the new facilities.

The IGCR, 2017 lay down the procedures and manner in which an importer can avail the benefit of a concessional Customs duty on import of goods required for domestic production of goods or providing services. One major change that accommodates the needs of trade and industry is that the imported goods have been permitted to be sent out for 'job work'. The absence of this facility had earlier constrained the industry especially those in the MSME sector which did not have the complete manufacturing capability in-house.

Importantly, even importers who do not have any manufacturing facility can now avail the IGCR, 2017 to import goods at concessional Customs duty and get the final goods manufactured entirely on job work basis. However, some sectors such as gold, jewellery, precious stones and metals have been excluded.

Another major incentive now provided is to allow those who import capital goods at a concessional Customs duty to clear them in the domestic market on payment of duty and interest, at a depreciated value. This was not allowed earlier and manufacturers were stuck with the imported capital goods after having used them as they could not be easily re-exported.

Further, the procedure for availing the concessional Customs duty under these rules have been reviewed and rationalized. The required intimations and records can be sent by email to the jurisdictional Customs officer thereby obviating any physical interface.

The CBIC Circular also mentions that the list of Customs officers overseeing the IGCR, 2017 is available at https://www.cbic.gov.in/htdocs-cbec/home_links/enquiry-points-home.

(Circular No 10/2021- Customs dated 17th May 2021 reprodcued under Custom matter)

Source:18 May 2021, PIB Delhi

● ● ●

Shri Mansukh Mandaviya reviews requirement and supply of Amphotericin B - ensures availability Minister urges judicious use of the drug

MoS for Chemicals and Fertilizers Shri Mansukh Mandaviya today reviewed the requirement and supply position of Amphotericin-B which cures Mucormycosis. The Government has chalked out a strategy with manufacturers to ramp up domestic production as well as to import the drug from all over the world.

The Minister has observed that the supply of Amphotericin-B has been increased many folds. But currently there is a sudden demand surge. He has assure that the Government is committed to making all possible and necessary efforts to make it available to needy patients.

The Government has also outlined the system for efficient distribution and supply chain management of Amphotericin B. The shortage is expected to get resolved at the earliest. Shri Mandaviya has urged States to use this drug judiciously by strictly following the prescribed guidelines.

Source: 18 May 2021, PIB Delhi

● ● ●

Dr Harsh Vardhan chairs 26th meeting of Group of Ministers (GOM) on COVID-19

Lauds the Leadership of Prime Minister and Defence Minister for the Launch of New Drug to Fight COVID-19

17 More Labs to be added to INSACOG network to monitor variants of COVID

Remdesivir Production more than Tripled since Government Intervention

Scale-up of Amphotericin-B manufacture to treat COVID fungal Infections

Co-WIN to be made available in Hindi and Regional Languages Soon

Dr. Harsh Vardhan, Union Minister of Health & Family Welfare chaired the 26th meeting of the high-level Group of Ministers (GoM) on COVID-19 here today. He was joined by Dr S. Jaishankar, Minister of External Affairs and Shri Hardeep S. Puri, Minister of Civil Aviation, Shri Mansukh Mandaviya, Minister of State for Ports, Shipping and Waterways (I/C), & Chemical and Fertilizers, and Shri Nityanand Rai, Minister of State, Ministry of Home Affairs. Shri Ashwini Kumar Choubey, Minister of State, Health & Family Welfare joined the meet digitally.

Dr. Vinod K Paul, Member (Health), NITI Aayog was present virtually.

At the outset, Dr. Harsh Vardhan expressed his appreciation to all COVID warriors who have remained steadfast in their duty during the pandemic, which is now in its twelfth month, without showing any signs of deprivationan fatigue.Speaking on their contribution to the country's achievements today, he said, "India's COVID 19 New Cases have dropped to less than 3 lakhs for the first time after 26 days. Also, a net decline of 1,01,461 cases have been recorded in the active caseload in the last 24 hours."

Dr. Harsh Vardhan lauded the efforts of defence scientists and the leadership of Defence Minister Shri Rajnath Singh and Prime Minister Shri Narendra Modi for launching India's first indigenous drug 2-deoxy-D-glucose or 2-DG (developed by DRDO in collaboration with INMAS and Hyderabad based Dr. Reddys laboratories). The research efforts for the drug started in April 2020 and completed recently when DCGI gave it emergency use approval (EUA). The Minister informed the members that the drug has the potential to become a game changer in our response against COVID pandemic as it reduces the dependence of patients on oxygen administration and has the potential of getting absorbeddifferentially and in a selected manner. In the COVID infected cells, it inhibits virus synthesis and energy production for the process.

He noted that the Centre continues to help States under a 'whole of government' approach to tide over the Pandemic. 422.79 lakh N95 masks, 176.91 lakh PPE kits, 52.64 lakh Remdesivir injections and 45,066 ventilators were distributed among States/UTs.

Dr. Harsh Vardhan informed his colleagues that 17 new labs are going to be added to the INSACOG network to increase the number of samples screened and allow for more spatial analysis. The Network is presently served by 10 labs located at different corners of the country.

Dr. Sujeet K Singh, Director (NCDC) presented a detailed report on the mutations of SARS-CoV-2 and Variants of Concern (VoCs) being reported in India. He showed figures related to the state-wise prevalence of VoCs like the B.1.1.7 and B.1.617 across India. B.1.1.7 lineage (UK variant) was found predominant in samples collected in Punjab and Chandigarh between February and March, 2021.

Dr. Balaram Bhargava, Secretary (Health Research) & DG ICMR presented on the innovative changes in testing policy that would widen its scope of application and help in mass screening for COVID, particularly in peri-urban and rural settings where health infrastructure is relatively weak. Deployment of mobile RT-PCR testing vans and amplification of RAT tests was presented as the way forward. While the present capacity is around 25 lakhs (RTPCR-13 lakh and RAT- 12 lakh), this is projected to exponentially increase to 45 lakhs (RTPCR-18 lakh and RAT- 27 lakh) under the new testing regimen.

DG, ICMR also informed regarding the Home Isolation guidelines which has been converted into Hindi and other regional languages for wider reach. Warning signs for hospitalization, admission to ICU and for potential administration of Remdesivir and Tocilizumab were also highlighted.

Ms. S. Aparna, Secretary (Pharma) informed that a dedicated cell has been created to coordinate production and allocation of drugs in demand to treat COVID-19. Manufacturers have been advised to increase production drugs. The three-pronged strategy undertaken was apprised to the Ministers:

- Identification of new suppliers and addressing operative issues faced by suppliers exploring all the possible ways to meet the demand.
- Rational distribution of drugs to states/UT to avoid hoarding in drug producing states, constant monitoring of the supply chain and quick resolution of issues between states and suppliers.
- Enforcement against hoarding and black-marketing was also initiated through DCGI SDCs.

Stress was laid on the procurement and allocation of Remdesivir, Tocilizumab and Amphotericin-B. She notified that demand for Favipiravir too increased although the drug is not recommended in COVID medical guidelines. She suggested IEC campaigns for judicious use of these drugs. She also highlighted that Remdesivir Production has more than tripled in the country with government intervention from around 39 lakh to 118 lakh vials per month. Demand for Amphotericin-B which is used for treatment of Mucor mycosis has also increased. Five suppliers have been identified and efforts are being made for optimal allocation of the drug. States were given 1 lakh vials from 1st to 14th May 2021 while avenues for import are being actively explored.

Secretary (Pharma) further emphasized that States must make equitable distribution among govt and private hospitals and keep hospital and general public informed on availability and shop details, help prevent unnecessary stockpiling and ensure timely payments to the manufactures.

The Union Health Secretary apprised the meeting that the CoWIN platform is being made available in Hindi and 14 regional languages by next week.

Shri Amitabh Kant, CEO, NITI Aayog, Shri Rajesh Bhushan, Secretary (Health), Shri Pradeep Singh Kharola, Secretary (Civil Aviation), Ms. S. Aparna, Secretary (Pharma),Ms. Vandana Gurnani, Addl. Secretary and Mission Director, NHM (Health), Ms. Arti Ahuja, Addl. Secretary (MoHFW), Dr Manohar Agnani, Addl. Secretary (Health), Dr. Sunil Kumar, DGHS (MoHFW), Shri Amit Yadav, DG, Foreign Trade (DGFT), Dr. Sujeet K Singh, Director (NCDC), Shri Sanjeeva Kumar, Member Secretary, National Disaster Management Authority (NDMA)and other senior government officials participated through video conference. Representatives of the Armed Forces and ITBP were also present.

Source: 17 May 2021, PIB Delhi

Index Numbers of Wholesale Price (Base Year 2011-12) in India for the month of April, 2021

The Office of Economic Adviser, Department for Promotion of Industry and Internal Trade is releasing index numbers of Wholesale Price in India for the month of April, 2021 (Provisional) and for the month of February, 2021 (Final) in this press release. Provisional figures of Wholesale Price Index (WPI) are released on 14th of every month (or next working day) with a time lag of two weeks of the reference month and compiled with data received from institutional sources and selected manufacturing units across the country. After 10 weeks, the provisional index is finalized, released and frozen thereafter.

In April, 2021 (over April, 2020), the annual rate of inflation (YoY), based on monthly WPI, stood at 10.49% (Provisional).The annual rate of inflation in April 2021 is high primarily because of rise in prices of crude petroleum, mineral oils viz petrol, diesel etc, and manufactured products as compared to the corresponding month of the previous year. The details of All India Wholesale Price Indices and Rates of Inflation for different commodity groups forApril, 2021are at Annex I.The Annual rate of Inflation (Y-o-Y) based on WPI for different commodity groups in the last 6 monthsis atAnnex II. The WPI Index for different commodity groups in the last 6 months is at Annex III.

Table 1: Index Numbers & Annual Rate of Inflation(Y-o-Y)*

All Commodities/ Major Groups	Weight (%)	Feb-21 (F)		Mar-21 (P)		Apr-21 (P)	
		Index	Inflation	Index	Inflation	Index	Inflation
All Commodities	100	**128.1**	4.83	129.3	7.39	131.7	10.49
I Primary Articles	22.6	**147.1**	**3.01**	**146.2**	**6.40**	**151.8**	**10.16**
II Fuel & Power	13.2	**105.7**	**2.03**	**109.7**	**10.25**	**108.6**	20.94
III. Manufactured Products	64.2	**126.0**	**6.06**	**127.3**	**7.34**	**129.4**	**9.01**
Food Index	24.4	**153.4**	**3.58**	**153.4**	**5.28**	**158.9**	**7.58**

*Note: P: Provisional, F: Final, * Annual rate of WPI inflation calculated over the corresponding month of previous year.*

The monthly rate of inflation, based on month over monthmovement of WPI index, in April 2021 stood at 1.86% (Provisional) as compared to March 2021. The last six-month M-o-M rate of inflation is summarized below:

Table 2: Month Over Month (M-o-M) Rate of Inflation#

All Commodities/ Major Groups	Weight (%)	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21 (P)	Apr-21 (P)
All Commodities	100	1.21	0.24	0.88	1.26	0.94	1.86
I Primary Articles	22.6	0.66	-3.14	-2.09	1.52	-0.61	3.83
II Fuel & Power	13.2	3.63	2.87	3.92	4.97	3.78	-1.00
III. Manufactured Products	64.2	1.00	1.40	1.62	0.56	1.03	1.65
Food Index	24.4	-0.13	-3.13	-1.87	1.05	0.00	3.59

Note: P: Provisional, # Monthly rate of inflation, based on month over month (M-o-M) WPI calculated over the preceding month.

Monthly inflation in Major Groups:

Primary Articles (weight 22.62%):- The index for this major group increased by (3.83%) to 151.8 (Provisional) in April, 2021 from 146.2 (Provisional) for the month of March, 2021. Prices of Minerals (6.66%), Crude Petroleum & Natural Gas (4.80%), Food Articles (3.84%) and Non-food Articles (2.65%) increased in April, 2021 as compared to March, 2021.

Fuel &Power (weight 13.15%):- The index for this major group declined by (-1.00%) to 108.6 (Provisional) in April, 2021 from 109.7 (Provisional) for the month of March, 2021. Prices of Coal (0.32%) and Mineral Oils (0.29%) increased in April, 2021 as compared to March, 2021. Prices of Electricity (-4.96%) declined in April, 2021 as compared to March, 2021.

Manufactured Products (weight 64.23%):- The index for this major group increased by (1.65%) to 129.4 (Provisional) in April, 2021 from 127.3 (Provisional) for the month of March, 2021. Out of the 22 NIC two-digit groups for Manufactured products, 20 groups have witnessed increase in prices in April 2021 compared to March 2021. The increase in prices areprimarily contributed by the manufacture of basic metals, food products, chemical & chemical products, textiles, and rubber & plastic products. Two groups that have witnessed decrease in prices are manufacture of other manufacturing and printing and reproduction of recorded media in April, 2021 as compared to March, 2021.

WPI Food Index (weight 24.38%)- The Food Index consisting of 'Food Articles' from Primary Articles group and 'Food Product' from Manufactured Products group have increased from 153.4 in March, 2021 to 158.9 in April, 2021. The rate of inflation based on WPI Food Index increased from 5.28% in March, 2021 to 7.58% in April, 2021.

Final Index for the month of February, 2021- For the month of February, 2021 the final Wholesale Price Index and inflation rate for 'All Commodities' (Base: 2011-12=100) stood at 128.1 and 4.83% respectively.

Response Rate- The WPI for April, 2021 have been compiled at a weighted response rate of 76 percent, while the final figure for February, 2021 is based on the weighted response rate of 91 percent. The Provisional figures of WPI will undergo revision as per the final revision policy of WPI. This press release, item indices, and inflation numbers are available at home page http://eaindustry.nic.in.

Next date of press release: 14/06/2021 for the month of May, 2021.

Annex-I

All India Wholesale Price Indices and Rates of Inflation (Base Year: 2011-12=100) for April, 2021

Commodities/Major Groups/Groups/ Sub-Groups/Items	Weight	Index (Latest Month)*	Latest month over month		Cumulative Inflation (YoY)		WPI Based rate of Inflation (YoY)	
			2020-2021	2021-2022*	2020-2021	2021-2022*	Apr-20	Apr-21*
ALL COMMODITIES	100.00	131.7	-1.00	1.86	-1.57	10.49	-1.57	10.49
I. PRIMARY ARTICLES	22.62	151.8	0.29	3.83	-1.08	10.16	-1.08	10.16
A. Food Articles	15.26	162.1	2.18	3.84	3.83	4.92	3.83	4.92
Cereals	2.82	157.3	0.62	1.42	3.63	-3.32	3.63	-3.32
Paddy	1.43	161.2	2.13	-0.19	3.63	-0.92	3.63	-0.92
Wheat	1.03	155.9	-1.04	3.79	6.40	-3.29	6.40	-3.29
Pulses	0.64	175.3	4.56	2.34	14.63	10.74	14.63	10.74
Vegetables	1.87	152.2	5.82	1.53	3.14	-9.03	3.14	-9.03
Potato	0.28	161.3	7.41	12.17	62.05	-30.44	62.05	-30.44
Onion	0.16	164.1	-10.86	-31.94	72.34	-19.72	72.34	-19.72
Fruits	1.60	197.0	12.19	22.89	0.26	27.43	0.26	27.43
Milk	4.44	154.7	0.26	-0.32	5.87	2.04	5.87	2.04

Eggs, Meat & Fish	2.40	162.1	-0.41	4.78	2.31	10.88	2.31	10.88
B. Non-Food Articles	4.12	143.2	-0.72	2.65	-2.98	15.58	-2.98	15.58
Oil Seeds	1.12	195.7	0.60	5.78	1.89	29.95	1.89	29.95
C. Minerals	0.83	184.3	-1.72	6.66	-2.47	19.60	-2.47	19.60
D. Crude Petroleum & Natural Gas	2.41	89.6	-22.87	4.80	-46.17	79.56	-46.17	79.56
Crude Petroleum	1.95	88.2	-29.23	6.01	-58.76	160.18	-58.76	160.18
II. FUEL & POWER	13.15	108.6	-9.75	-1.00	-12.65	20.94	-12.65	20.94
LPG	0.64	107.1	-7.39	1.04	-1.11	20.34	-1.11	20.34
Petrol	1.60	95.1	-16.60	0.21	-23.92	42.37	-23.92	42.37
HSD	3.10	101.7	-12.14	-0.59	-20.42	33.82	-20.42	33.82
III. MANUFACTURED PRODUCTS	64.23	129.4	0.08	1.65	0.17	9.01	0.17	9.01
Mf/o Food Products	9.12	153.5	-0.15	3.16	5.33	12.62	5.33	12.62
Vegetable And Animal Oils and Fats	2.64	181.1	-0.71	6.03	10.97	43.28	10.97	43.28
Mf/o Beverages	0.91	125.5	0.32	0.16	1.87	0.40	1.87	0.40
Mf/o Tobacco Products	0.51	160.3	1.23	1.58	2.09	2.49	2.09	2.49
Mf/o Textiles	4.88	128.4	0.26	1.02	-2.01	9.74	-2.01	9.74
Mf/o Wearing Apparel	0.81	139.7	0.36	0.22	-0.07	0.58	-0.07	0.58
Mf/o Leather and Related Products	0.54	118.3	0.17	1.37	-2.40	0.51	-2.40	0.51
Mf/o Wood and of Products of Wood and Cork	0.77	138.2	-0.15	0.58	-0.75	4.22	-0.75	4.22
Mf/o Paper and Paper Products	1.11	133.5	0.17	4.13	-2.66	10.70	-2.66	10.70
Mf/o Chemicals and Chemical Products	6.47	127.0	-0.26	1.60	-3.92	10.24	-3.92	10.24
Mf/o Pharmaceuticals, Medicinal Chemical and Botanical Products	1.99	134.3	0.46	1.05	4.16	3.07	4.16	3.07
Mf/o Rubber and Plastics Products	2.30	121.4	-0.09	2.02	-2.19	13.14	-2.19	13.14
Mf/o other Non-Metallic Mineral Products	3.20	120.8	1.46	1.09	0.34	2.55	0.34	2.55
Cement, Lime and Plaster	1.64	123.9	3.03	1.14	2.25	1.06	2.25	1.06
Mf/o Basic Metals	9.65	127.6	0.94	3.24	-3.17	19.25	-3.17	19.25
Mild Steel - Semi Finished Steel	1.27	112.4	0.52	2.46	-1.73	16.72	-1.73	16.72
Mf/o Fabricated Metal Products, Except Machinery and Equipment	3.15	122.3	-0.43	1.16	-1.71	6.53	-1.71	6.53

*Note: * = Provisional, Mf/o = Manufacture of*

Annex-II

Commodities/Major Groups/ Groups/Sub-Groups/Items	Weight	Annual rate of Inflation (Y-o-Y)based on WPI for last 6 months					
		Nov-20	Dec-20	Jan-21	Feb-21	Mar-21*	Apr-21*
ALL COMMODITIES	100.00	2.29	1.95	2.51	4.83	7.39	10.49
I. PRIMARY ARTICLES	22.62	3.80	-0.60	-1.56	3.01	6.40	10.16
A. Food Articles	15.26	4.61	-0.92	-2.93	1.81	3.24	4.92
Cereals	2.82	-5.52	-6.52	-7.40	-6.58	-4.08	-3.32
Paddy	1.43	0.62	0.12	-0.18	-0.37	1.38	-0.92
Wheat	1.03	-10.09	-11.10	-11.62	-10.58	-7.80	-3.29
Pulses	0.64	13.04	9.69	7.92	10.25	13.14	10.74
Vegetables	1.87	15.27	-12.05	-21.06	-2.95	-5.19	-9.03
Potato	0.28	138.05	45.41	-23.48	-30.16	-33.40	-30.44
Onion	0.16	-7.60	-54.69	-32.55	31.28	5.15	-19.72
Fruits	1.60	-1.36	1.36	3.08	9.40	16.33	27.43
Milk	4.44	5.53	3.77	3.36	3.54	2.65	2.04
Eggs, Meat & Fish	2.40	0.20	1.34	-1.83	0.65	5.38	10.88
B. Non-Food Articles	4.12	8.66	2.99	4.24	4.02	11.78	15.58
Oil Seeds	1.12	8.29	7.52	8.85	14.05	23.58	29.95
C. Minerals	0.83	10.38	16.67	12.35	17.09	10.20	19.60
D. Crude Petroleum & Natural Gas	2.41	-21.51	-15.99	-9.44	5.29	32.15	79.56
Crude Petroleum	1.95	-19.87	-12.26	-2.61	19.54	73.70	160.18
II. FUEL & POWER	13.15	-7.01	-6.10	-3.82	2.03	10.25	20.94
LPG	0.64	-3.04	2.15	2.68	1.42	10.30	20.34
Petrol	1.60	-14.69	-12.94	-7.31	4.96	18.48	42.37
HSD	3.10	-19.44	-15.20	-10.31	3.16	18.27	33.82
III. MANUFACTURED PRODUCTS	64.23	3.23	4.49	5.47	6.06	7.34	9.01
Mf/o Food Products	9.12	5.17	5.11	4.99	7.01	9.01	12.62
Vegetable and Animal Oils and Fats	2.64	24.04	22.63	20.82	27.15	34.17	43.28
Mf/o Beverages	0.91	-0.08	-0.57	-0.24	0.56	0.56	0.40
Mf/o Tobacco Products	0.51	2.03	4.11	3.75	2.58	2.14	2.49
Mf/o Textiles	4.88	0.26	2.67	5.76	6.84	8.91	9.74
Mf/o Wearing Apparel	0.81	0.65	0.00	1.23	1.09	0.72	0.58
Mf/o Leather and Related Products	0.54	-1.09	0.17	1.02	-1.19	-0.68	0.51

Mf/o Wood and of Products of Wood and Cork	0.77	1.20	1.73	2.64	2.64	3.46	4.22
Mf/o Paper and Paper Products	1.11	0.25	2.02	3.08	4.49	6.48	10.70
Mf/o Chemicals and Chemical Products	6.47	1.46	3.01	3.96	6.30	8.23	10.24
Mf/o Pharmaceuticals, Medicinal Chemical And Botanical Products	1.99	3.53	3.21	0.69	0.84	2.47	3.07
Mf/o Rubber and Plastics Products	2.30	3.99	5.73	7.40	7.78	10.80	13.14
Mf/o other Non-Metallic Mineral Products	3.20	1.04	1.65	1.47	1.20	2.93	2.55
Cement, Lime and Plaster	1.64	0.51	1.44	0.93	0.34	2.94	1.06
Mf/o Basic Metals	9.65	7.83	11.78	15.31	13.18	16.60	19.25
Mild Steel - Semi Finished Steel	1.27	7.30	10.14	11.32	10.00	14.51	16.72
Mf/o Fabricated Metal Products, Except Machinery and Equipment	3.15	0.17	2.34	3.91	5.32	4.86	6.53

** = Provisional, Mf/o = Manufacture of*

Annexure-III

Commodities/Major Groups/ Groups/Sub-Groups/Items	**Weight**	**WPI Index for last 6 months**					
		Nov-20	**Dec-20**	**Jan-21**	**Feb-21**	**Mar-21***	**Apr-21***
ALL COMMODITIES	100.00	125.1	125.4	126.5	128.1	129.3	131.7
I. PRIMARY ARTICLES	22.62	152.8	148.0	144.9	147.1	146.2	151.8
A. Food Articles	15.26	170.1	161.1	155.8	157.5	156.1	162.1
Cereals	2.82	155.7	154.9	155.1	154.8	155.1	157.3
Paddy	1.43	163.1	162.2	162.0	161.7	161.5	161.2
Wheat	1.03	147.9	147.3	149.1	149.6	150.2	155.9
Pulses	0.64	172.5	168.6	166.3	168.9	171.3	175.3
Vegetables	1.87	281.6	213.9	170.6	167.5	149.9	152.2
Potato	0.28	491.1	364.4	200.7	147.5	143.8	161.3
Onion	0.16	442.3	330.7	316.0	362.6	241.1	164.1
Fruits	1.60	145.2	141.8	144.0	152.4	160.3	197.0
Milk	4.44	154.7	154.1	154.0	154.9	155.2	154.7
Eggs, Meat & Fish	2.40	149.0	151.2	150.3	154.7	154.7	162.1
B. Non-Food Articles	4.12	138.0	138.0	137.7	137.0	139.5	143.2
Oil Seeds	1.12	162.0	164.4	171.0	175.3	185.0	195.7

C. Minerals	0.83	157.4	172.2	172.8	184.3	172.8	184.3
D. Crude Petroleum & Natural Gas	2.41	67.5	74.1	78.7	85.6	85.5	89.6
Crude Petroleum	1.95	60.5	68.7	74.6	83.2	83.2	88.2
II. FUEL & POWER	13.15	94.2	96.9	100.7	105.7	109.7	108.6
LPG	0.64	79.7	85.4	88.2	100.1	106.0	107.1
Petrol	1.60	73.2	76.0	81.1	88.8	94.9	95.1
HSD	3.10	75.4	79.8	86.1	94.8	102.3	101.7
III. MANUFACTURED PRODUCTS	64.23	121.6	123.3	125.3	126.0	127.3	129.4
Mf/o Food Products	9.12	142.4	144.0	145.2	146.6	148.8	153.5
Vegetable and Animal Oils and Fats	2.64	148.1	155.0	159.0	164.4	170.8	181.1
Mf/o Beverages	0.91	123.6	123.0	123.8	124.6	125.3	125.5
Mf/o Tobacco Products	0.51	156.1	157.2	157.7	159.0	157.8	160.3
Mf/o Textiles	4.88	116.8	119.1	123.1	124.9	127.1	128.4
Mf/o Wearing Apparel	0.81	139.5	139.2	139.5	139.6	139.4	139.7
Mf/o Leather and Related Products	0.54	117.9	118.6	118.6	116.7	116.7	118.3
Mf/o Wood and of Products of Wood and Cork	0.77	134.7	135.3	136.3	136.2	137.4	138.2
Mf/o Paper and Paper Products	1.11	120.0	121.3	124.0	125.7	128.2	133.5
Mf/o Chemicals and Chemical Products	6.47	118.2	119.7	120.8	123.1	125.0	127.0
Mf/o Pharmaceuticals, Medicinal Chemical and Botanical Products	1.99	132.0	131.9	131.5	132.8	132.9	134.3
Mf/o Rubber and Plastics Products	2.30	112.0	114.4	116.1	116.3	119.0	121.4
Mf/o other Non-Metallic Mineral Products	3.20	116.9	117.4	117.4	117.9	119.5	120.8
Cement, Lime and Plaster	1.64	119.1	119.7	119.0	119.8	122.5	123.9
Mf/o Basic Metals	9.65	111.5	115.8	122.8	121.1	123.6	127.6
Mild Steel - Semi Finished Steel	1.27	100.0	103.2	107.2	105.6	109.7	112.4
Mf/o Fabricated Metal Products, Except Machinery and Equipment	3.15	115.9	117.9	119.7	120.7	120.9	122.3

** = Provisional, Mf/o = Manufacture of*

Source : PIB Delhi, 17 May 2021

Commerce & Industry Minister discusses measures to enhance Covid vaccine production with the USTR

Shri Piyush Goyal, Minister for Commerce & Industry, Railways, Consumer Affairs and Food & Public distribution had a virtual meeting with Ambassador Katherine Tai, US Trade Representative on 14th May 2021. The meeting focused on increasing vaccine availability in an inclusive and equitable manner to combat the Global pandemic caused by Covid-19. The proposal of India on waiver of certain TRIPS provisions to increase global vaccine production in order to take on the challenge of vaccinating the poorest of the poor and save lives was also discussed.

The Minister thanked the USTR for the US announcing its support for India's proposal. The Minister mentioned the supply chains for the vaccine manufacturers must be kept open and unbridled as the entire world is in dire need of vaccines. Both sides agreed to work towards the common resolve of increasing vaccine availability and saving lives.

Source: 14 May 2021, PIB Delhi

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OBITUARY

Shri Arun Kumar Ramteke

It is with a heavy heart and profound grief that we inform you of the sad demise of our esteemed faculty and a key member of the course development team, Shri Arun Kumar Ramteke Sir. Ramteke Sir passed away on May 07, 2021, due to COVID related complications. Shri Ramteke Sir was the Former Joint Drugs Controller at CDSCO HQ. He joined CDSA after his retirement from CDSCO in 2012 and was one of the longest serving personnel at CDSA. He was working in the capacity of Consultant, Regulatory Affairs. His advice on matters related to regulatory affairs, new drugs, medical devices, IVDs, biologicals, vaccine approvals was always of vital importance. We are deeply saddened at his demise and definitely will be missing his mentorship and expert advice on regulatory affairs and online courses. His support to the SWAYAM online courses as a permanent faculty will be missed the most. He will always be remembered as the one who started this theme program called 'Meet the regulators' with the CDSA Training Department way back in 2012. The loss is irreplaceable and his memories shall always remain with us. We stand together in support of Ramteke Sir's family in this difficult time.

- CDSA Team

Changes introduced through the Customs (Import of Goods at Concessional Rate of Duty) Amendment Rules, 2021- reg.

Circular No.10/2021-Customs, Dated 17th May, 2021

To,
All Principal Chief Commissioners/ Chief Commissioners of Customs/ Customs (Preventive),
All Principal Chief Commissioners/ Chief Commissioners of Customs & Central tax,
All Principal Commissioners/ Commissioners of Customs/ Customs (Preventive),
All Principal Commissioners/ Commissioners of Customs & Central tax,

1. Reference is drawn to the Customs (Import of Goods at Concessional Rate of Duty) Amendment Rules, 2021 notified vide Notification No. 09/2021-Customs (N.T.), dated 02.02.2021 so as to make certain amendments in existing Customs (Import of Goods at Concessional Rate of Duty) Rules, 2017 (hereinafter referred to as "IGCR Rules, 2017") that took effect from 2nd February, 2021.

2. The aforementioned Amendment Rules have been introduced in view of the demands from the trade and industry and having regard to their changing needs as per prevalent global practices. The amendments are also an effort towards creating an enabling environment for the promoting manufacturing by domestic industry to make them competitive globally and also make them self-reliant in furtherance of the goal of Atmanirbhar Bharat.

3. The major changes brought in vide the said Amendment Rules, 2021, are highlighted as below:

Job Work:

3.1 The facility of carrying out job work under the ambit of IGCR has been introduced.

3.2 The scope of the job work facility has been extended to an importer who is a manufacturer but without complete manufacturing facility. Also, 100% out- sourcing for manufacture of goods on job-work basis has been permitted for importers who do not have any manufacturing facility at all. However, sensitive sectors such as gold, articles of jewellery and other precious metals or stones have been excluded from the facility of job work.

Import and clearance of capital goods:

3.3 An option has been given to the importers to import capital goods for a specified purpose at a concessional rate of duty and after having put such capital goods to use for the said purpose, clear the same after payment of the differential duty and interest, at a depreciated value, with permission from the jurisdictional Customs Officer.

Bringing more end-use based exemptions under the ambit of IGCR Rules, 2017:

3.4 At present, there are certain end-use based exemptions in Notification No. 50/2017-Customs, dated 30.06.2017 which are being administered without the need to follow the procedure set out under the said IGCR Rules, 2017. With an intention to bring forth uniformity in the procedures for end-use based exemptions, the condition of compliance of the said IGCR Rules, 2017 is being provided for certain entries and these have already been notified by amending the said Notification.

4. Procedure to be followed by an importer

For the sake of clarity, the procedure set out in the IGCR Rules, 2017 is summarised as follows:

One time - Prior Intimation of intent to avail IGCR Benefit:

4.1 An importer who intends to import goods at a concessional rate of duty shall give a one-time prior information of such goods being imported to the Customs Officer under whose jurisdiction, his premises fall (jurisdictional Customs Officer). He shall also furnish -

(a) the name and address of the premises of the importer and his job worker, if any;

(b) the CTH, nature and description of imported goods used in the manufacture of goods at the premises of the importer or the job worker, if any;

(c) the CTH and description of goods produced or process undertaken at the manufacturing facility of the importer and/or his job worker, if any, or both

(d) nature of output service rendered utilising imported goods." *(refer rule 4).*

4.2 The importer is required to submit a one-time continuity bond, to cover all the imports undertaken under this procedure. It is clarified that an importer can store goods temporarily at any premises not owned by the importer, prior to their utilisation at the premises where manufacturing takes place, provided that the details of such premises are included in the prior information to be furnished. Also at all such times, the goods must remain under the control of the *importer [refer rule 4 and para 4.1(a) above].*

Intimation before import:

4.3 As and when the details are available, the importer shall provide information to the jurisdictional Customs Officer regarding the estimated quantity and value of goods to be imported, the exemption notification and serial number, the estimated duty forgone and the port of import with respect to a consignment. This information may be provided by email on a consolidated basis for a period not exceeding one year rather than in a transactional manner for every import *(refer rule 5).*

Clearance of goods from the port of import:

4.4 The importer shall also provide a copy of the intimation provided to the jurisdictional Customs Officer *(refer para 4.3 above)* to the port of import. It is clarified that, for this purpose it is sufficient to upload such intimation copy on e- Sanchit and link the same along with the other documents when filing the bill of entry. On this basis, the goods shall be allowed clearance at a concessional rate of duty.

Receipt of goods at premises of importer/job worker:

4.5 The receipt of the imported goods is to be intimated to the jurisdictional Customs Officer. It is clarified that, goods may also be sent directly to the premises of a job worker and in such cases, importer shall intimate by email such receipt of goods to the jurisdictional Customs Officer (of the jobworker) along with the copy provided to the jurisdictional customs officer (of the importer). *(refer rule 6).*

Goods sent for job work from importer's premises:

4.6 In cases where the goods are first received at the premises of the importer and are then to be sent for job work therefrom, the importer shall send the goods after giving an email intimation to the jurisdictional Customs Officer. Such intimation may be given periodically job worker wise, latest by 5th of each month for the goods sent for job work in the previous month. The importer shall always maintain a proper account of the goods being sent or received.

4.7 In such intimation, the following details shall be included:

(a) the name, address, GSTIN (or PAN) details of the job worker,

(b) the CTH, description and quantity of goods being sent, and

(c) nature and description of the job work to be carried on the imported goods.

4.8 The importer shall send such goods to the premises of the job worker under a challan, specifying the description and quantity of the goods. The challan number and date shall also be specified in the intimation given to the jurisdictional customs officer *(refer rule 6A).*

4.9 The jurisdictional Customs Officer (of the importer) shall forward a copy of such intimation received, to the Customs Officer under whose jurisdiction, the premises of the job worker are located. The maximum period for which the goods can remain with the job worker shall be six months from the date of issue of challan.

Receipt of goods from the job worker:

4.10 After the completion of job work, there can be three instances-

(a) the goods are received back in the premises of the importer, or,

(b) the goods are cleared directly from the premises of the job worker, or

(c) the goods are sent by the job worker to another job worker.

In the first two instances (a) and (b), the same may be updated in the account maintained by the importer and

subsequently shown in the quarterly returns *[refer rule 6(2) and rule 6(3) and paras 4.14 and 4.15 below].*

In the third instance (c), the goods may be sent to another job worker against a challan. As against the challan number with which the goods were sent to the job worker, the job worker shall also send the goods back to the importer or to another job worker, as the case may be, against a separate challan or with the same challan of the principal manufacturer itself, duly endorsed by him *[refer sub- clause (7) of rule 6A].*

Re-Export or clearance for home consumption:

4.11 An importer shall utilise the imported goods for the intended purpose or re-export the same, within a period of six months from the date of import, failing which the importer is liable to payment of duty with interest, as per the procedure laid out in the said IGCR Rules [*refer rule 7(1) and 7(2)].*

4.12 In the case the importer intends to clear the unutilised or defective goods on payment of requisite duty and interest, the import duty payable would be equal to the difference between the duty leviable on such goods but for the exemption availed and that already paid, if any, at the time of importation, along with interest at a rate as fixed by notification under section 28AA. The period for calculation of interest would start from the date of import of such goods and end with the date of actual payment *[refer rule 7(2)].*

Quarterly return and maintenance of account

4.13 The importer shall also submit a quarterly return by the tenth day of the following quarter, in the form prescribed, to the jurisdictional Customs Officer *[refer rule 6(3)]*. The following details are to be furnished in the quarterly return according to each bill of entry in the form provided in the annexure to the said IGCR Rules, 2017-

(a) Description of goods imported;

(b) Opening balance of goods at the beginning of the quarter;

(c) Details of goods imported, consumed, re-exported or cleared in the quarter including -

(i) the quantity and value of goods imported

(ii) the quantity of goods consumed for intended purpose

(iii) quantity of goods sent to job worker

(iv) quantity of goods received from job worker

(v) quantity of goods re-exported

(vi) quantity of goods cleared in domestic market

(vii) closing balance at the end of the quarter

(d) specified purpose for import of goods at concessional rate;

(e) goods manufactured or output service provided in the quarter;

(f) whether goods were used for the intended purpose.

4.14 The importer shall also maintain an account giving the following details, according to bills of entry –

(a) The quantity and value of goods imported;

(b) Quantity of goods consumed;

(c) Quantity of goods sent for job work;

(d) Nature of job work carried out;

(e) Quantity of gods received after job work;

(f) Quantity of goods re exported, if any;

(g) Quantity remaining in stock.

This account shall be produced to the jurisdictional Deputy /Assistant Commissioner of Customs as and when required by the said officer *[refer rule 6(2)].*

4.15 The job-worker shall also maintain an account giving details of:

(a) receipt of goods;

(b) manufacturing process undertaken;

(c) waste generated during the process, if any.

This account shall be produced to the jurisdictional Customs Officer, as and when required by the said officer.

5. Any importer or the job worker who contravenes the provisions of these rules shall be liable to a penalty as prescribed in the said rules *(refer rule 8A).* It is clarified that, this is in addition to any other action taken under the Customs Act, 1962 for recovery of duties.

6. The Directorate General of Systems, CBIC, is in the process of automating and facilitating online submission of compliances prescribed in the rules through the ICEGATE portal, thereby obviating the need for furnishing paper based documents to the Customs Officer. Meanwhile, in order to facilitate the trade, it is proposed to route all the intimations and other communications specified in the said IGCR Rules, 2017, as amended, vide e-mail to the Customs Officers concerned**.** The list of officers overseeing IGCR rules, 2017 along with their e-mail has been made available on **https://www.cbic.gov.in/htdocs-cbec/home_links/enquiry-points-home.**

7. Suitable Trade Notices/ Standing Orders may please be issued to guide the trade and industry. Difficulty, if any, faced in implementation, may be brought to the notice of Board immediately.

F.No.450/28/2016-Cus-IV

Ananth Rathakrishnan, Deputy Secretary (Customs), Central Board of Indirect Taxes & Customs, Ministry of Finance, Department of Revenue, New Delhi.

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The Appointments Committee of the Cabinet: Appoints Officers at Joint Secretary level - reg.

No. 33/03/2021-EO(SM-I), dated 14th May 2021

To
All Secretaries to the Government of India.

The Appointments Committee of the Cabinet has approved the following appointments of officers at Joint Secretary/Joint Secretary equivalent level with pay at Level 14 (₹.1,44,200 - 2,18,200/-) of the Pay Matrix:

(1) Appointment of **Shri D Senthil Pandiyan, IAS (UD:2002)**, as **Joint Secretary**, **Ministry of AYUSH**, from the date of assumption of the charge of the post, for a tenure of five years or until further orders, whichever is earlier, *vice* Shri Roshan Jaggi, IFoS (JK:1988);

(2) Appointment of **Ms. Nirupama Kotru, IRS(IT:1992)**, as **Joint Secretary & FA, Ministry of Coal**, from the date of assumption of the charge of the post, for an overall tenure of five years upto 15.05.2023 or until further orders, whichever is earlier *vice* Ms. Reena Sinha Puri, IRS (IT:1987);

(3) Appointment of **Shri Bhaskar Verma, ICAS (1995)**, as **Member Secretary, National Monuments Authority (NMA), Ministry of Culture**, from the date of assumption of the charge of the post, for a tenure of five years or until further orders, whichever is earlier *vice* Shri Navneet Soni, IRS(IT:1988);

(4) Appointment of **Ms. Lily Pandeya, IRPS (1998)**, as **Joint Secretary, Ministry of Culture**, from the date of assumption of the charge of the post, for a tenure of five years or until further orders, whichever is earlier, *vice* Shri Padma L Sahu, ICivAS (1991);

(5) Appointment of **Shri Mayank Tewari, IRSME (1993)**, as **Joint Secretary, Department of Defence**, from the date of assumption of the charge of the post, for a tenure of five years or until further orders, whichever is earlier *vice* Ms. Richa Misra, IDAS (1996);

(6) Appointment of **Ms. Nazli Jafri Shayin, IA&AS (1999)**, as **Addl. FA & Joint Secretary**, **Ministry of Defence (Finance)**, from the date of assumption of the charge of the post, for an overall tenure upto 29.12.2021 or until further orders, whichever is earlier, *vice* Shri Ashwini Kumar, IRS (IT:1988);

(7) Appointment of **Ms. Indira Murthy, CSS**, as **Joint Secretary, Ministry of Earth Sciences**, from the date of assumption of the charge of the post, for a tenure upto the date of her superannuation i.e. 30.04.2023 or until further orders, whichever is earlier, *vice* Shri Vipin Chandra, IRS (IT:1987);

(8) Appointment of **Ms. Manisha Sinha, IPoS (1992)**, as **Joint Secretary, Department of Economic Affairs**, from the date of assumption of the charge of the post, for a tenure of five years or until further orders, whichever is earlier, *vice* Shri Prashant Goyal, IAS (UT:1993);

(9) Appointment of **Shri Ashish Vachhani, IAS (TN:1997)**, as **Joint Secretary, Department of Economic Affairs**, from the date of assumption of the charge of the post, for a tenure of five years or until further orders, whichever is earlier, *vice* Shri Arvind Shrivastava, IAS (KN:1994);

(10) Appointment of **Ms. Sandhya Bhullar, IAS (GJ:2003)**, as **Joint Secretary, Department of Economic Affairs**, from the date of assumption of the charge of the post, for an overall tenure of five years upto 31.03.2024 or until further orders, whichever is earlier, *vice* Shri Sameer Kumar Khare, IAS (AM:1989);

(11) Appointment of **Shri Bhuvnesh Kumar, IAS (UP:1995),** as **Joint Secretary, Ministry of Electronics & Information Technology**, from the date of assumption of the charge of the post, for a tenure of five years or until further orders, whichever is earlier, *vice* Shri Sanjay Goel, IRTS (1991);

(12) Appointment of **Shri Patibandla Ashok Babu, IAS (AM:2003)**, as **Joint Secretary, Department of Health & Family Welfare**, from the date of assumption of the charge of the post, for an overall tenure of five years upto 25.08.2024 or until further orders, whichever is earlier, *vice* Shri Manohar Agnani, IAS (MP:1993);

(13) Appointment of **Shri Jeetendra Singh, IRSEE (1993)**, as **Joint Secretary, Department of Heavy Industry**, from the date of assumption of the charge of the post, for a tenure of five years or until further orders, whichever is earlier, *vice* Shri Amit Vardhan, IRTS (1989);

(14) Appointment of **Shri Sumant Singh, IAS (MN:2003)**, as **Joint Secretary, Department of Home Affairs**, from the date of assumption of the charge of the post, for an overall tenure of five years upto 03.12.2024 or until further orders, whichever is earlier, *vice* Shri Krishna Bahadur Singh, IFoS (UT:1995);

(15) Appointment of **Shri Sanjiv Shankar, IRS(IT:1993)**, as **Joint Secretary, Ministry of Information & Broadcasting**, from the date of assumption of the charge of the post, for a tenure of five years or until further orders, whichever is earlier, *vice* Ms. Neerja Sekhar, IAS (HY:1993);

(16) Appointment of **Shri Manoj Kumar, IRS(IT:1994)**, as **Joint Secretary, Department of Investment & Public Asset Management**, from the date of assumption of the charge of the post, for a tenure of five years or until further orders, whichever is earlier, *vice* Shri Nukala Venudhar Reddy, IIS (1988);

(17) Appointment of **Ms. Veena Tamta Bhatia, IOFS (1988)**, as **Addl. Central Provident Fund Commissioner (HQ), EPFO** under the **Ministry of Labour & Employment**, from the date of assumption of the charge of the post, for a tenure upto the date of her superannuation i.e. 30.11.2023 or until further orders, whichever is earlier, *vice* Ms. Rekha Yadav, IRPS (1995)

(18) Appointment of **Shri Sonmoni Borah, IAS (CG:1999)**, as **Joint Secretary, Department of Land Resources**, from the date of assumption of the charge of the post, for a tenure of five years or until further orders, whichever is earlier *vice* Shri Hukum Singh Meena, IAS (BH:1992);

(19) Appointment of **Shri Som Dutt Sharma, CSS**, as **Director, ISTM, Department of Personnel & Training**, from the date of assumption of the charge of the post, for a tenure of five years or until further orders, whichever is earlier, *vice* Ms. Sunita H Khurana, CSS;

(20) Appointment of **Shri Sanjeeb Kumar Mishra, IAS (OD:1997)**, as **Secretary-cum-Controller of Examination, National Recruitment Agency (NRA)** under the Department of Personnel & Training, from the date of assumption of the charge of the post, for a tenure of five years or until further orders, whichever is earlier against a newly crated post.

Srinivas R. Katikithala, Secretary Appointments Committee of the Cabinet, & Establishment Officer, Secretariat of the Appointments Committee of the Cabinet, Ministry of Personnel, Public Grievances and Pensions, Department of Personnel and Training, New Delhi.

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Appointment of Shri Shyam Jagannathan (IAS) as Development Commissioner (JS Level)- reg.

No.10/03/2019-EO(SM-I), dated 18th May 2021

To
Department of Commerce (Shri A. Wadhawan, Secretary)

1. Reference Department of Commerce OM No. 12022/30/2016-E-IV dated 09.04.2021.

2. The Appointments Committee of the Cabinet has approved the proposal of the Department of Commerce for appointment of Shri Shyam Jagannathan, IAS (AM:97) to the post of Development Commissioner (JS Level), Santa Cruz Exclusive Export Processing Zone (SEEPZ), Special Economic Zone, Mumbai under the Department of Commerce with pay at Level 14 (Rs.1,44,200 - 2,18,200/-) of the Pay Matrix for a tenure of five years from the date of assumption of charge of the post or until further orders, whichever is earlier, against an existing vacancy.

Srinivas R. Katikithala, Secretary Appointments Committee of the Cabinet, & Establishment Officer, Secretariat of the Appointments Committee of the Cabinet, Ministry of Personnel, Public Grievances and Pensions, Department of Personnel and Training, New Delhi.

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Extension of time limits of certain compliances to provide relief to taxpayers in view of the severe pandemic - reg.

Circular No.9 of 2021, dated 20th May

The Central Board of Direct Taxes, in exercise of its power under section 119 of the Income-tax Act, 1961 (hereinafter referred to as "the Act") provides relaxation in respect of the following compliances:

1) **The Statement of Financial Transactions (SFT)** for the Financial Year 2020-21, required to be furnished on or before 31st May 2021 under Rule 114E of the Income-tax Rules, 1962 (hereinafter referred to as "the Rules") and various notifications issued thereunder, may be furnished on or before 30th June 2021;

2) **The Statement of Reportable Account** for the calendar year 2020, required to be furnished on or before 31st May 2021 under Rule 114G of the Rules, may be furnished **on or before 30th June 2021;**

3) **The Statement of Deduction of Tax** for the last quarter of the Financial Year 2020-21, required to be furnished on or before 31st May 2021 under Rule 31A of the Rules, may be furnished **on or before 30th June 2021;**

4) **The Certificate of Tax Deducted at Source in Form No 16,** required to be furnished to the employee by 15th June 2021 under Rule 31 of the Rules, may be furnished **on or before 15th July 2021;**

5) **The TDS/TCS Book Adjustment Statement in Form No 24G for the month of May 2021,** required to be furnished on or before 15th June 2021 under Rule 30 and Rule 37CA of the Rules, may be furnished on or before 30th June 2021;

6) **The Statement of Deduction of Tax** from contributions paid by the trustees of an approved superannuation fund for the Financial Year 2020-21, required to be sent on or before 31st May 2021 under Rule 33 of the Rules, may be sent on or before 30th June 2021;

7) **The Statement of Income paid or credited** by an investment fund to its unit holder in Form No 64D for the Previous Year 2020-21, required to be furnished on or before 15th June 2021 under Rule 12CB of the Rules, may be furnished **on or before 30th June 2021;**

8) **The Statement of Income paid or credited** by an investment fund to its unit holder in Form No 64C for the Previous Year 2020-21, required to be furnished on or before 30th June 2021 under Rule 12CB of the Rules, may be furnished on or before 15th July 2021;

9) **The due date of furnishing of Return of Income for the Assessment Year 2021-22,** which is 31st July 2021 under sub-section (1) of section 139 of the Act, is extended to 30th September 2021;

10) **The due date of furnishing of Report of Audit** under any provision of the Act for the Previous Year 2020-21, which is 30th September 2021, is extended to 31st October 2021;

11) **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 Previous Year 2020-21, which is 31st October 2021, is extended to 30th November 2021;

12) **The due date of furnishing of Return of Income for the Assessment Year 2021-22**, which is 31st October 2021 under sub-section (1) of section 139 of the Act, is extended to 30th November 2021;

13) The due date of furnishing of Return of Income for the Assessment Year 2021-22, which is 30th November 2021 under sub-section (1) of section 139 of the Act, is extended to 31st December 2021;

14) The due date of furnishing of belated/revised Return of Income for the Assessment Year 2021-22, which is 31st December 2021 under sub-section (4)/sub-section (5) of section 139 of the Act, is extended to 31st January 2022.

Clarification 1: It is clarified that the extension of the dates as referred to in clauses (9), (12) and (13) above shall not apply to Explanation 1 to section 234A of the Act, in cases where the amount of tax on the total income as reduced by the amount as specified in clauses (i) to (vi) of sub-section (1) of that section exceeds one lakh rupees.

Clarification 2: For the purpose of Clarification 1, in case of an individual resident in India referred to in sub-

section (2) of section 207 of the Act, the tax paid by him under section 140A of the Act within the due date (without extension under this Circular) provided in that Act, shall be deemed to be the advance tax.

F. No.225/49/2021-ITA-II

Prajna Paramita, Director, Central Board of Direct Taxes, Ministry of Finance Department of Revenue, New Delhi.

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IPR MATTER

Vaccine IP waiver: Rules for everyone, Commerce Secy on easing Covaxin rights

The US has recently announced its support for waiving IP rights for Covid -19 vaccines, an issue raised in a proposal by India and South Africa, which also called for a waiver of IP rights on Covid-related interventions, including diagnostics and treatments.

Commerce Minister Piyush Goyal tweeted on Friday that he had discussed India and the US working together on trade-related aspects of Intellectual Property rights waiver with US Trade Representative Katherine Tai.

The government is hopeful of a quick decision on the waiver of Intellectual Property (IP) protection for Covid-19 vaccines and treatment, Commerce Secretary Anup Wadhawan said on Friday. The US has recently announced its support for waiving IP rights for Covid -19 vaccines, an issue raised in a proposal by India and South Africa, which also called for a waiver of IP rights on Covid-related interventions, including diagnostics and treatments.

"The US has recently joined the group of countries which are supporting the waiver. We are hopeful that in an early timeframe some decision will be reached in the WTO," said Wadhawan, adding a decision on a waiver of IP rights on vaccines would also apply to Bharat Biotech's Covid vaccine — Covaxin. Experts have called on India to lead by example by relaxing IP rights on Covaxin, which has been jointly developed by Bharat Biotech and the Indian Council of Medical Research.

"Those rules (on waiver of IP protection), whenever they come into place will apply to everyone," said Wadhawan on the potential waiver of IP rights for Covaxin.

Commerce Minister Piyush Goyal tweeted on Friday that he had discussed India and the US working together on trade-related aspects of Intellectual Property rights waiver with US Trade Representative Katherine Tai.

On trade

Wadhawan said that major logistical issues faced by exporters due to Covid-19 had largely been resolved and that exports were witnessing a broad-based recovery. "(There were) problems in terms of containers and problems in terms of adequate availability of shipping services but through concerted efforts we have resolved those issues, " said Wadhawan.

"The performance, so far, indicates very good prospects and we feel that we can reach $400 billion," Wadhawan said. Overall exports (merchandise and services) in April rose to $51.8 billion, up 93 per cent from April 2020, according to government data.

A rise in imports to $58.7 billion, up 122 per cent from April 2020, also pushed up India's trade deficit to $6.9 billion, compared to $380 million in the year-ago period when large parts of the country were under a strict lockdown.

The latest data for services sector released by the RBI is for March 2021. April data is estimates, which may undergo revision.

April exports at $30.6 billion

New Delhi: Merchandise exports surged a record 196 per cent year-on-year in April, driven mainly by a favourable base, as the country had witnessed a Covid-induced lockdown throughout April last year.

Exports in April stood at $30.6 billion, up almost 18 per cent from the same month in 2019.

According to the latest official data released on Friday, imports, too, grew 167 per cent to $45.7 billion in April, indicating improvement in domestic demand. Interestingly, gold imports surged to as much as $6.2 billion in April from a mere $2.8 million a year earlier.

Source : Economic Bureau, 15.05. 2021

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India-South Africa Covid patent waiver plea gets 62 backers

The 62 co-sponsors of a proposal floated by India and South Africa seeking patent waivers on Covid-related medical products have said that universal access to immunisation, treatments, testing and other products to control the pandemic should be the priority of all countries.

In the first ever joint statement issued Monday, the co-sponsors—that includes Indonesia, Kenya and Pakistan—said an amended waiver proposal is being worked on to clarify the scope of the proposed waiver and the time period during which it will apply. The statement is also the first joint official response after the US gave its support for text-based negotiations.

They also said that they will engage in the negotiations to achieve a waiver with the "necessary flexibility to ensure swift outcomes" as there is a need to mobilise global manufacturing capacity and to diversify supply options.

"Universal access to immunisation, treatments, testing and other products to control the pandemic should be our priority," the co-sponsors said in their statement to the World Trade Organization (WTO).

India and South Africa had in October last year sought a waiver in global intellectual property agreements to ensure uninterrupted flow of vaccines amid the ongoing pandemic.

The proposal calls for a waiver for all WTO members of certain provisions of copyrights, industrial designs, patents and protection of undisclosed information in the Trade Related Intellectual Property Rights (TRIPS) Agreement for prevention, containment or treatment of Covid-19.

It is being revised now to bring more countries on the negotiating table and proceed to text-based discussions.

Almost 130 countries support the proposal at present. The US has supported a waiver for vaccines only. "

The amended waiver proposal seeks to further clarify the scope of the proposed waiver while also addressing the period during which it will apply," they said in the statement. They also said that continuous mutations and emergence of new variants of Covid-19 highlight the significant uncertainties and complexities of controlling it and underscore the urgency of this proposal.

"Co-sponsors confirm that they will engage in this process with the necessary flexibility to ensure swift outcomes," they said, adding that any outcome in these negotiations must respect the wishes and common interests of the majority of the WTO members.

"We are keeping our scope as before. It is a matter of negotiation what the final scope will be—products, IP or the duration," said an official.

As per the submission, the promise of international solidarity and of global public good "sounds hollow as staggering inequity in access persists" as countries fail to work in solidarity and take action to remove intellectual property barriers.

Source : Kirtika Suneja, , ET Bureau, 18.05.2021

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Government may buy 50 million Pfizer Covid vaccine doses by Q3

NEW DELHI: The government and Pfizer are in "high-level" discussions that could see the pharma giant sell 50 million of its Covid vaccine doses in India by the third quarter of this year with the current negotiations pointing to a successful conclusion.

Top government officials are believed to have negotiated availability of these vaccines in a series of meetings with senior Pfizer executives with the main hurdle being the firm's insistence of indemnity that will shield it from legal action in India. While the nature of an agreement on this contentious issue is not yet clear, senior officials said the issue and other matters will be made clear in due course.

The vaccines will be available for purchase by government only for its Covid immunisation programme. Pfizer vaccines are fairly expensive but there is a growing demand for expanding the pool of vaccines available for the population in addition to the shots being made in India.

State governments like UP, Maharashtra and others have announced that they are floating global tenders for vaccine makers to sell their shots here. However, there are not too many free stocks available and the results of this exercise need to be seen even as officials said they will work with states to see what best can be done.

The current surge of the Covid pandemic in India has sharpened the demand for mass vaccinations.

The European Medicines Agency on Wednesday said the mRNA vaccines approved by it would be able to fight the new variant detected in Maharashtra. "EMA is monitoring the data on the Indian variant very closely. We are seeing promising evidence that mRNA vaccines will be able to neutralise this variant," it said. The EMA has authorised Pfizer, Moderna, Astra Zeneca and J&J vaccines for the continent.

While the US still doesn't allow Pfizer or Moderna vaccines being produced there to be exported as long as Americans need it, European manufacturing centres are probably going to be the source for the Pfizer vaccines that India intends to buy.

Source : Indrani Bagchi , TNN , 15.05.2021

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Govt. may notify export refund rates by May end: DGFT Yadav

Delay has affected exporters' pricing strategies

The government may finally notify the refund rates for taxes paid on exported goods by the end of this month, a senior trade official said on Friday, almost five months since the introduction of the Remission of Duties and Taxes on Exported Products (RoDTEP) scheme with the delay affecting exporters' pricing strategies.

Directorate General of Foreign Trade (DGFT) Amit Yadav told exporters the RoDTEP rates would be announced in 15 days, although Commerce Secretary Anup Wadhawan was non-committal on the exact timeframe during an interaction with reporters later in the day, only stating the rates may be notified 'very soon.'

Meanwhile, exporters reiterated their demand that the government bring to an end the suspense over the RoDTEP scheme urgently in order to help forge new contracts with foreign buyers amidst a minor recovery in global trade.

Sharad Kumar Saraf, president of the Federation of Indian Export Organisations (FIEO) said apart from notifying the rates, the government must release the necessary funds for RoDTEP's implementation as well as to pay outstanding dues on earlier incentive schemes for merchandise and services exports.

"Once these issues pertaining to the RoDTEP and the older Merchandise Exports from India Scheme (MEIS), that have been taken up by the Commerce and Industry Ministry with the Finance Ministry, are resolved, it will provide a further impetus to the export sector," said Mahesh Desai, chairman, Engineering Export Promotion Council.

Mr. Wadhawan said both goods and services exports had grown in April even after 'normalising for April 2020 (affected by the national lockdown) being slightly anomalous. While merchandise exports grew 195.7% in April over last year and 17.6% over April 2019, services exports had risen by 28.7% in April over last year, the Ministry said.

"The recovery is broad-based and substantial. It augurs very well for the year 2021-22," the Commerce Secretary said, exuding confidence about meeting the $400-billion export target set for this year, from about $290 billion in 2020-21.

On exporters' concerns about a slowdown in inter-State movement of goods and shortage of manpower due to the lockdowns in several States and the demand to classify export units as essential services, Mr. Wadhawan said their concerns were largely addressed.

"We have been able to balance public health issues very well with some minimal level of economic activity happening. If you see various States' orders like Maharashtra and Karnataka, they have allowed industries to operate, including export units, with necessary safeguards to allow economic activity, with a reduced workforce on the shop floor. So, at this stage, I don't see any major impact on our export prospects," he concluded.

Source : The Hindu, 14.5. 2021

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GST Council meet on May 28, tax waivers on medicines on agenda

The office of finance minister Nirmala Sitharaman on Saturday tweeted the date and timing of the meeting.

The Goods and Services Tax (GST) Council will meet for the first time in seven months on May 28 to discuss key issues such as compensation to states and tax waivers on various medicines, medical devices, and health services amid the second wave of the Covid-19 pandemic, two officials said on Saturday.

The office of finance minister Nirmala Sitharaman on Saturday tweeted the date and timing of the meeting. The move came after several states, including Punjab and West Bengal, raised the issue of an inordinate delay in convening the meeting, the officials aware of the developments said on condition of anonymity.

"Smt @nsitharaman will chair the 43rd GST Council meeting via video conferencing at 11 AM in New Delhi on 28th May 2021. The meeting will be attended by MOS Shri @ianuragthakur besides Finance Ministers of States & UTs and Senior officers from Union Government & States," a tweet from the finance minister's office said.

The GST Council is required to meet once in every quarter. Its meetings are convened by the finance ministry as the council is chaired by the Union finance minister. Finance ministers of states and Union Territories (UTs) are members of the council, the apex federal body on indirect tax matters.

The last time the council met was on October 5, 2020 (the 42nd meeting) to resolve the issue of compensating states for their revenue shortfall in 2020-21. That meeting was extended to next week on October 12 for finalising a centralised borrowing mechanism to meet the revenue shortfall. After that, the council did not meet.

Earlier this week, West Bengal finance minister Amit Mitra wrote to Sitharaman, asking her to convene the GST Council meeting immediately as states were expecting an alarming shortfall in GST compensation revenue because of the Covid-19 pandemic. "As per GoI [Government of India] projection, the shortfall was expected to be to the tune of 1,56,164 crores in 2021-22 without taking into consideration the impact of Covid Wave-2," Mitra said in the letter to the finance minister. HT reported on the letter on May 14.

Last week, Punjab finance minister Manpreet Singh Badal asked the Union finance minister to urgently convene a meeting of the council for a "serious mid-term correction" on tax issues. In his letter Badal said: "...failure to hold any constructive consultation with states for so long in such critical times makes me wonder whether Centre has usurped all the powers of states putting the spirit of cooperative federalism..."

Besides full compensation to states, many members want GST waivers on several critical items necessary for people at the time of the pandemic, including vaccines, key medicines and health care services. These matters could be discussed at the council meet, the officials mentioned above said.

Ranjeet Mahtani, partner at consultancy firm Dhruva Advisors, said the council needs to resolve other pressing issues such as inverted duty structure on certain products. "This has lingered as an issue for some time now," he said. According to him, there is a need to rationalise GST rates and reduce the number of tax slabs by merging the 12% and 18% slabs into one revenue-neutral rate. He said compensation is also a key issue for states.

At the time of introducing the new indirect tax regime in July 2017, the GST law assured states a 14% increase in their annual revenue for five years (up to 2022), and assured them that their revenue shortfall would be made good through the compensation cess levied on luxury goods and sin products such as liquor, cigarettes, aerated water, automobiles, coal and tobacco.

The issue of compensating states for their revenue losses due to a 68-day lockdown and because of the first wave of Covid-19 came up in the previous fiscal year, when GST revenues plunged and there was a gap of over 1.10

lakh crore in the collection of compensation cess. The matter was resolved after the Centre agreed to raise back-to-back loans on behalf of states and compensated them for their shortfall in revenue. It was decided that the loan would be repaid from the compensation cess revenue collected in the future.

Source : Rajeev Jayaswal, Hindustan Times, 16.05.2021

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Covaxin capacity scaled up to 500 million doses a year: Bharat Biotech

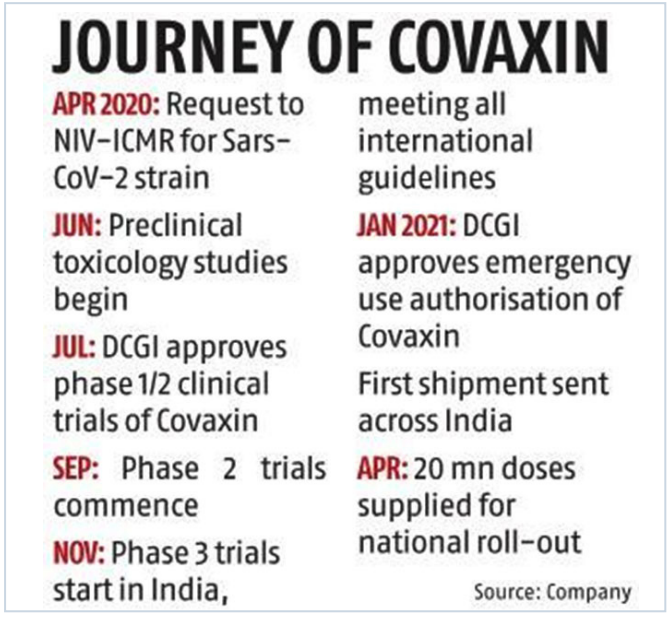
Vaccine effective against all emerging coronavirus variants, says study

Hyderabad-based vaccine maker Bharat Biotech in April expanded its Covaxin-manufacturing capacity to 500 million doses a year, the company said on Sunday.

It supplied 20 million doses to the "national roll-out" in April. In a tweet, Suchitra Ella, joint managing director of Bharat Biotech, said: "To our supporters and critics, ever since the start of the pandemic, team Bharat Biotech has been diligently developing Covaxin and scaling up manufacturing capacities to meet global and public health requirements."

In the same tweet, Ella also pointed out that Covaxin neutralises key emerging strains of the Sars-CoV-2 virus, including the double mutant B.1.617 and B.1.1.7--identified in India and the UK.

She gave a timeline capturing Covaxin's journey.



"The manufacturing scale-up has been carried out in a stepwise manner across multiple facilities at Hyderabad and Bengaluru. Inactivated vaccines, while highly safe, are extremely complex and expensive to manufacture, resulting in lower yields when compared to live virus vaccines," the company had noted in April.

A company source said: "The Bengaluru facility is getting re-purposed, and that will add another 200 million doses annually when completed. We are targeting 700 million doses a year."

The Union health ministry last week said it had procured or was in process of procuring 356 million doses of Covid vaccines including Covishield (276 million) and Covaxin (80 million). The orders have been in tranches -- for phase 2 the Central government gave orders for 20 million doses of Covaxin, of which 86 per cent has been received and the rest will come by the end of May. And for 50 million doses of Covaxin for phase 3 of Covid vaccination, the deliveries will happen between May and July.

This apart, to further increase capacities, Bharat Biotech has partnered Indian Immunologicals (IIL) to manufacture the drug substance for Covaxin. The company has said the technology transfer process is underway and IIL has the "capabilities and expertise" to manufacture the inactivated viral vaccines at commercial scale. Bharat Biotech is also exploring manufacturing partnerships in other countries.

Last month, Centre said it was providing a Rs 65-crore grant to re-purpose the Bengaluru facility.

Three public sector undertakings (PSUs) are being upgraded with the required infrastructure -- Mumbai-based Haffkine Biopharmaceutical Corporation; Indian Immunologicals, a National Dairy Development Board (NDDB) unit; and Bharat Immunologicals and Biologicals Ltd (BIBCOL), Bulandshahr, a Central PSU under the Department of Biotechnology.

Haffkine Biopharmaceutical Corporation, a PSU under the Maharashtra government, is receiving financial support of Rs 65 crore to set up a manufacturing facility that can make 20 million doses per month. Indian Immunologicals and BIBCOL will also make 10-15 million doses per month by August-September.

Meanwhile, Ahmedabad-based Hester Biosciences has said that a triparty consortium has been formed with the Gujarat government as the lead partner to explore the

prospects of manufacturing the Covid vaccine through technology from Bharat Biotech.

"Discussions are on with Bharat Biotech towards reviewing the infrastructure at Hester, the technology adaption process, and the regulatory compliances. Based on the outcome of the review, the next course of action will be determined," Hester said.

On Covaxin neutralising the key emerging variants of Sars-CoV-2, Ella said no difference in neutralisation was observed between B.1.1.7 (first isolated in the UK) and vaccine strain (D614G), which was used to develop Covaxin. She cited a study published in Clinical Infectious Diseases, a peer-reviewed medical journal.

Ella tweeted: "A modest reduction in neutralisation by a factor of 1.95 was observed against the B.1.617 variant compared to the vaccine variant (D614G). Despite this reduction, neutralising titre levels with B.1.617 remain above levels expected to be protective."

Samiran Panda, head of epidemiology and communicable division, Indian Council of Medical Research, told Business Standard: "It is not only neutralising antibody titre but also other components of our immune system that together determine how successful we would be in warding off an invading virus. I will therefore interpret this finding as good news and at the same time will emphasise the importance of using vaccines as well as face mask together as important combination intervention approach to break the chain of transmission of the virus SARS-CoV-2 as well as to mitigate the impact of the disease COVID-19."

The study quoted above said sera samples were collected from individuals infected with these emerging strains and had recovered and the results were compared with those sera samples collected from vaccine recipients.

Source: Sohini Das, Business Standard, 16.05.2021

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Govt rolls out DRDO-formed Covid drug, experts call for more research

The oral drug 2-DG (2-deoxy-D-glucose) was approved by the Drugs Controller General of India (DCGI) on May 8 as an adjunct therapy – one that supplements regular treatment – for Covid-19.

Defence minister Rajnath Singh on Monday launched an anti-Covid drug developed by the Defence Research and Development Organisation (DRDO) in collaboration with Hyderabad-based Dr Reddy's laboratories (DRL), calling it "a new ray of hope in these challenging times", although experts called for more scientific data.

The oral drug 2-DG (2-deoxy-D-glucose) was approved by the Drugs Controller General of India (DCGI) on May 8 as an adjunct therapy – one that supplements regular treatment – for Covid-19. DRDO and its partner DRL carried out a phase II trial with 40 volunteers last year and a phase III trial with 220 in 2021, according to the filings on the Clinical Trials Registry - India.

Assessments from neither have been shared yet and it was not clear from which trials the DRDO officials were determining their efficacy assessments.

"The peer-reviewed research is expected to be published soon," a senior DRDO official said, asking not to be named.

The registries also did not report in what proportion volunteers were randomised to be given 2-DG or the standard Covid care.

Defence minister Singh, who handed over the first batch of the drug to Union health minister Harsh Vardhan said the drug would reduce oxygen dependency and help patients recover sooner, citing the unreleased trial findings.

One box each of the drug sachets was also handed over to All India Institute of Medical Sciences (AIIMS) director Dr Randeep Guleria and Lieutenant General Sunil Kant of Armed Forces Medical Services (AFMS). The drug will be made available for emergency use at different hospitals across the country, the defence ministry said in a statement.

"The development and production of the drug is a shining example of public-private sector partnership to help the nation in these challenging times," the defence minister said. He added that the drug was a perfect example of India's scientific prowess and a milestone in the efforts towards self-reliance.

"In efficacy trends, the patients treated with 2-DG showed faster symptomatic cure than Standard of Care (SoC) on various endpoints. A significantly favourable trend (2.5 days difference) was seen in terms of the median time to achieving normalisation of specific vital signs parameters when compared to SoC," the defence ministry said in statement on May 8.

"It was an adaptive phase II/III trial that was conducted to determine safety and efficacy of this drug in Covid-19

patients. The drug was originally meant for treating cancer patients and then tried in Covid-19 patients with a modified dosage. The trial results were promising as it showed reduction in viral load as it impedes viral replication; length of hospitalisation also reduced; and it also reduces steroid and oxygen requirement," said Dr Akshay Budhraja, from the respiratory medicine department at Delhi's Aakash Healthcare Super Speciality Hospital, which was one of the trial locations. Dr Budhraja was one of the trial investigators.

Experts said such announcements must be accompanied with evidence. "I am not commenting on the efficacy of the drug, all I ask for is the evidence. You cannot create false hopes as you would stop patients from taking real medicines. It is not a good scientific practice to do trials and sit on the data. Trial data should ideally be published in peer-reviewed top journals so that those people who are not a part of the clinical trial can study it, question it and cross-check the legitimacy of the trial," said CM Gulhati, editor, Monthly Index of Medical Specialities (MIMS), pharmaceutical reference guide.

"I think we are really getting overactive in terms of approvals and that is not good for medical science as people who conduct clinical trials have vested interest in showing positive trial results," he said. "And everything is online these days; how much time will it take to put stuff online for people to scrutinise a claim?" he added.

The drug 2-deoxy-D-glucose has been used for decades as a possible cancer therapy as research has shown that it hampers cell growth by blocking cellular glucose supply, leading to its use as a tumor therapeutics. The hypothesis in its use in treating Covid-19 is that it could impair replication of Sars-Cov-2 by a similar mechanism of action.

The drug has still not been approved by regulators for regular cancer therapy.

Source: Hindustan Times, 18.05.2021

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Eli Lilly in pact with Natco Pharma for Baricitinib drug used to treat Covid 19

It also has licence agreements with Cipla, Lupin, Sun Pharma, Dr. Reddy's, MSN Laboratories and Torrent Pharma for the drug

American pharmaceutical company, Eli Lilly and Company ("Lilly") has issued an additional royalty-free, non-exclusive voluntary licence to Natco Pharma - a local pharmaceutical manufacturer of generic medicines to expand the availability of the drug, Baricitinib, used in the treatment of Covid 19.

Lilly received permission on May 3 for restricted emergency use by the Central Drugs Standard Control Organization (CDSCO) for Baricitinib to be used in combination with remdesivir for the treatment of suspected or laboratory confirmed COVID-19 in hospitalised adults requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

It may be recalled that early this month Natco had received an approval from CDSCO under compulsory licence based on emergency use to produce Baricitinib.

Recently, Lilly had also announced the signing of six voluntary licence agreements with Cipla, Lupin, Sun Pharmaceutical Industries, Dr. Reddy's MSN Laboratories and Torrent Pharmaceuticals, for the access of the Baricitinib drug by people in India.

Source : The Hindu Business Line, 17.05.2021

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Three more firms get the nod to produce Covaxin

Can help produce 20 million doses per month

In addition to three public sector enterprises (PSEs) that signed pacts with Bharat Biotech to produce Covaxin, three more Ahmedabad-based firms — including State-owned Gujarat Biotechnology Research Centre — will produce the Covid-19 vaccine in the country, an official statement said on Saturday.

Gujarat Biotechnology Research Centre, Hester Biosciences, and OmniBRx Biotechnologies firmed up discussions with Bharat Biotech for the Covaxin technology transfer, which would help them produce an additional 20 million doses per month. "Technology transfer agreements have been finalised with all manufacturers," the statement said.

The Department of Biotechnology (DBT), as part of a recently-announced Covid Suraksha scheme, has given a grant of ₹65 crore to Mumbai-based Haffkine Biopharmaceuticals, ₹60 crore to Indian Immunologicals Limited of National Dairy Development Board, and ₹30 crore to Bharat Immunologicals and Biologicals

Limited (BIBCOL), a DBT facility at Bulandshahr in Uttar Pradesh.

While Haffkine will help produce an additional 20 million doses per month when the facility is ready, BIBCOL can produce 10-15 million doses a month, the statement said.

Source : Business Line, 16.05.2021

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GST meet to consider relief for Covid essentials

With the growing clamour from the States for additional money to manage Covid-relief efforts, the GST Council is likely to take a decision on the matter during its 43rd meeting on May 28. The Council is also expected to consider the request for amendments in the Finance Act, compensation mechanisms for States and modifying the inverted duty structure.

The meeting comes after a long hiatus. The Council last met in October 2020.

Key issues

A senior Government official told *Business Line* that while the agenda hasn't been finalised yet, the discussions would likely focus on four-to-five key issues. "The Centre has received representations from States such as Punjab, and even from India Inc for various Covid relief measures. The meeting is expected to discuss them in detail," the official said.

Earlier this month, Punjab's Finance Minister Manpreet Singh Badal wrote to Finance Minister Nirmala Sitharaman, who also is the Chair of the Council, and sought an 'urgent discussion' on several issues. Several States have been pushing for GST exemption on items essential in the battle against Covid such as hand sanitisers, face masks, oximeters, ventilators and PPE Kits. Other demands include the lowering of interest rates under GST law and some sops for severely crippled sectors such as MSME, aviation, retail, hospitality and entertainment.

"Do we need to make an amendment to law to allow donations of goods for Covid without denying tax credits on inputs used in their manufacture or purchase. Also, is an amnesty scheme needed to condone delays in payment of taxes during Covid period," queried Badal in his letter. Similar demands came from States such as Chhattisgarh and West Bengal. India Inc is seeking GST exemption for imported relief material it was distributing for free.

GST compensation

The official further said that one of the key agenda items would be compensation. Last week, Finance Minister of West Bengal, in a letter to Sitharaman used Centre's projection to say that GST compensation shortfall is expected to be to the tune of ₹1,56,164 crore during current fiscal. According to him, this is without taking into consideration the impact of the second wave of Covid. Last year, the Centre borrowed over ₹1-lakh crore and passed it on to States as back-to-back loans with repayment guaranteed through money collected from compensation cess.

Another important item for discussion would be the amendment to GST law through Finance Act, 2017. There are a total of 15 amendments. "Normally, these amendments come into effect from January 1 with corresponding amendments in State laws. Our effort would be same," the official said. Some of these amendments include retrospective amendment on levy of GST on clubs, associations and societies, additional condition for entitlement of input tax credit (ITC), recovery without issuing show cause notice on liability declared in GSTR-1, widened scope of provisional attachment and provision related with zero-rated supply

On the subject of inverted duty structures, the official said that this anomaly has been remedied for mobile handsets. The council could look at similar corrections for items such as textiles.

Source : Business Line , 17.05.2021

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Covid-19 tests Indian pharma's limits

The touted 'pharmacy to the world' struggles to meet the needs of a country ravaged by a deadly second wave

The last several weeks have seen the collective anxiety of the country rise like never before. And the reasons are aplenty.

An acute shortage of Covid-19 drugs remdesivir and tocilizumab, for instance, saw people reaching out to strangers for just a few doses of the medicine. They were losing family members not to coronavirus, but the failure to get hospitalisation or because the hospitals that admitted them had run out of oxygen. A tragic sequence of events was witnessed in Delhi, as families, hospitals and doctors

began pleading for oxygen, including many on social media. The situation, though seemingly settled, brought home the enormity of the problem that confronts the country.

On the preventive side, too, State after State reported it had fallen woefully short of Covid-19 vaccines for its residents. The dire shortage is unbecoming for a country feted as 'pharmacy to the world', and home to the largest vaccine-maker in the world. How did it come to such a pass, especially for drugs like remdesivir and tocilizumab, which have local partners making or importing the innovator drug?

And, even more worryingly, is the industry better prepared as public health experts caution about a third wave, another surge in cases?

Pharma industry voices say the steep increase in Covid-19 cases had caught everyone unawares. Last year, too, remdesivir and oxygen had, for instance, fallen short. But companies upped their production and kept buffer stocks to deal with another steep increase in demand. Nothing, though, prepared them for what was to come, they say.

The requirement for remdesivir increased so sharply, that companies now make about three lakh vials a day — which used to be their monthly production late last year. It is a complex product that takes a month to make and has a short shelf-life, the veteran adds, optimistic that supply bottlenecks would ease later this month as capacities are expected to touch 80-90 lakh vials a month.

"Covid 2.0 is different from Covid 1.0," says Sudarshan Jain, who is with the Indian Pharmaceutical Alliance, representing large domestic drugmakers. "All factories are working to ensure continuity of medicine supplies, despite increase in cases," he says, pointing to the stress under which they work.

Lupin Managing Director Nilesh Gupta observes, "India has always been part of the solution, to make medicines for the world. To see India struggling is very, very difficult." The disease is changing and so are the medicines required to treat it, he says, adding that pharma company chiefs were interacting every day to review and make sure medicines are available. Representatives with foreign companies point to the slew of collaborations with Indian companies to make Covid medicines locally accessible.

Vaccine dependence

Industry watchers point to how Government-run facilities and "vaccine-parks" have been allowed to languish, resulting in total dependence on the private sector. Recently, the Indian Drug Manufacturers' Association sought voluntary licences for vaccines, as India does not seem to have stocks for even its initial target of 30 crore people.

IDMA's Daara Patel says that qualified local companies can help increase vaccine supplies. On why now, Patel explains that the two vaccine producers (Serum Institute and Bharat Biotech) had originally indicated that they could meet the country's demand. But with that looking unlikely now, there is an immediate need to plug the shortfall, he says.

India is still a pharmacy to the world for general drugs, says S Srinivasan of LOCOST, a non-profit organisation that makes essential medicines. But industry cannot ramp up overnight, he adds. It all boils down to an "honest" assessment of the problem, forecasting the requirement, outlining a plan, and not shying away from taking help where needed, he explains. A prescription well worth listening to, before the imminent third wave.

Tie-ups in a pillbox
Foreign drugmakers and their partners in India
Gilead Sciences (remdesivir): Dr Reddy's Laboratories (DRL), Hetero, Zydus Cadila, Syngene, Jubilant, Cipla and Mylan
Roche (tocilizumab and antibody cocktail casirivimab and imdevimab: Cipla
Merck (molnupiravir): Cipla, Hetero, Sun Pharma, Emcure and DRL
Eli Lilly (baricitinib): Cipla, Lupin, Sun Pharma
AstraZeneca-Oxford University vaccine: Serum Institute of India
Gamaleya Institute/ Russian Direct Investment Fund (Sputnik V): DRL, Hetero, Biopharma, Gland Pharma, Strides Virchow, Panacea Biotec

Source : PT Jyothi Datta, Business Line, 16.05.2021

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Biocon chief bats for highly decentralised vaccination policy

'There is a lot of confusion and mismanagement in the programme now'

In a country like India, where the demographics change from State to State, city to city, and even from one neighbourhood to another, a highly decentralised approach is needed where local governments can decide how to

vaccinate people with appropriate precautionary measures, said Biocon chairperson Kiran Mazumdar Shaw.

She was speaking as a guest speaker at a webinar organised by in GITAM Deemed to be University, here on Sunday.

She observed that there was a lot of confusion and mismanagement in the present vaccination programme in the country. She said that migration of industrial labour and elections are the main factors behind the present situation.

"We need to focus more on cab drivers, construction workers and food delivery boys for vaccination otherwise they may turn as super spreaders," she added.

'Focus on tech transfer'

While talking about Intellectual Property Rights(IPR) on vaccines, she said that instead of IPR we need to focus on technology transfer. She said that vaccine making is not simple and it involves technology that will take 8 to 9 months to establish. The country needs effective supply chain management and a token system for successful vaccination. She said that instead of child vaccination, parents must take vaccines to protect the family.

She observed that people with obesity and diabetes are more vulnerable to the present situation.

She said that all vaccines are potentially good and data analysis will prove their longevity.

GITAM Strategic Programmes Director Nidhi Razdan moderated the event.

Source : The Hindu, 17.05.2021

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Dr Reddy's to use first Sputnik batch to inoculate its own staff

Dr Reddy's Laboratories will be using the first batch of the **Sputnik** V vaccines for its staff as the company begins the **rollout** of third Covid-19 vaccine in the country. In India the company counts a staff of 10,000 employees. The company will be tying up with **Apollo Hospital** for the rollout of its vaccine for the staff.

Last week, Dr Reddy's announced that it has received the first consignment of 150,000 doses of the Sputnik V vaccine from Russia. The company said the rollout of the consignment will be subject to necessary clearances, which will be processed over soon.

"This initial quantity will be used across different channels as a pilot to line up our supply chain for the larger vaccination program rollout. Subsequent consignments will arrive in the next few weeks," said Deepak Sapra, CEO, API services, Dr Reddys in a statement.

The Russian Development Investment Fund had said that it could dispatch 50 million doses to India by end of May. DRL has indicated the supply of the vaccines will increase from Q3 2021.

Reddy's said that the imported doses of the vaccine are priced at an MRP of 948 + 5% GST per dose. The company, however, said that there is a possibility to lower price when local manufacturers begin supply. The company said that it will receive imported doses in the coming months and ultimately the supply starting from India.

RDIF and Dr Reddy's have tied up with six manufacturing partners in India.

Source : Divya Rajagopal, ET Bureau, 17.05.2021

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Cipla open to forge a partnership to distribute Covid-19 vaccines in India

The company already makes and markets antiviral drugs like remdesivir, favipiravir in India apart from importing and distributing Roche's tocilizumab (Actemra)

Cipla, which has a strong portfolio of Covid-19 drugs, says it is now open to forge a partnership to distribute Covid vaccines in India.

"We are open to having a vaccine partnership. A company that will be able to do vaccine distribution successfully in India will have significant distribution muscle – like large warehouses, cold chain capabilities, footprint throughout India. We fit the bill well. We are open to it, but as of now nothing to report," said Kedar Upadhye, global CFO of Cipla. Cipla does not want to get into vaccine manufacturing. It is augmenting its Covid-19 therapy portfolio too. Analysts felt the Covid portfolio may contribute Rs 2,000 crore in sales in FY22.

The company already makes and markets antiviral drugs like remdesivir, favipiravir in India apart from importing and distributing Roche's tocilizumab (Actemra). Covid-19 portfolio roughly accounted for 5 percent of Cipla's domestic turnover in 2020-21.

In the second wave, Cipla has added more products to its kitty – MSD's molnupiravir (oral antiviral), Eli Lilly's Baricitinib (oral drug used for inflammatory and autoimmune disorders), and Roche's antibody cocktail for Covid19.

Molnupiravir is an investigational drug which is currently being studied in a phase 3 trial for treatment of non-hospitalised patients with Covid19.Upadhye thus said that bringing Molnupiravir, an MSD drug, will take some time. "It may take a few months. Once it is approved in the US, the corresponding application will be done in India," he said.

In comparison, Eli Lilly's Baricitinib can be launched sooner. Cipla will be manufacturing the drug here too along with the bulk drug. As for Roche's antibody cocktail (Casirivimab and Imdevimab), it can be expected to be available in the next few days.

The antibody cocktail (Casirivimab and Imdevimab) is to be administered for the treatment of mild to moderate Covid patients aged 12 years and above. On March 23, Roche announced that a large phase III global trial in high-risk non-hospitalised COVID-19 patients ("outpatients") met its primary endpoint, showing that Casirivimab and imdevimab significantly reduced the risk of hospitalisation or death by 70 percent compared to placebo. Casirivimab and imdevimab also shortened the duration of symptoms by four days, Cipla has said.

Adding to this, Cipla's respiratory product budesonide, is now actively used in Covid treatment.

"Noticing strong tailwinds for the India portfolio, especially on remdesivir and antibody cocktails (once launched). Budesonide is now part of the treatment protocol. Remdesivir output almost 5-times of last peak," noted Kunal Randeria, analyst with Edelweiss Securities.

Cipla feels that Covid will continue to be an important part of its therapy portfolio over the next few years.

"Next one or two years Covid will continue to be an important part of the therapy portfolio and that is why every company is tapping into it. Acute will not do well in these times, and even some respiratory drugs may also suffer," Upadhye said. He did not wish to comment on whether Covid contribution will be more than 5 percent of the domestic turnover.

Randeria said, "FY22 is likely to be driven by domestic Covid portfolio (remdesivir, Roche's antibody cocktail and increasing budesonide use) that can contribute as much as Rs 2000 crore in sales."

Source : Sohini Das , Business Standard, 17.05.2021

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More pharma companies should be allowed to produce Covid-19 vaccines: Nitin Gadkari

Union minister Nitin Gadkari on Tuesday said that more pharma companies should be allowed to manufacture the Covid-19 vaccine in the country during the pandemic to scale up production.

While addressing a meeting via video conferencing Gadkari said, "If the demand of vaccine is more than the supply, it creates the problem. So, instead of one company, let 10 more companies be given the license to manufacture the vaccine."

"There are 2-3 laboratories in every state. They should be given the formula to produce the Covid-19 vaccines. They can give royalty," Gadkari said.

"Let them supply in the country and later if there is surplus, they may export. It can be done in 15-20 days," he added.

Currently, only two firms - Bharat Biotech and Serum Institute of India - are manufacturing Covid vaccines in the country and only three vaccines have so far been approved to be sold in India --- Covaxin, Covishield and Sputnik V.

Many states have complained about the shortage of Covid-19 vaccines. Reacting to Gadkari's comment on the shortage of the Covid-19 vaccines, national spokesperson of Congress Jaiveer Shergill said that the whole nation is demanding vaccines, BJP is supplying fake tool kits. "Mr Gadkari says to solve Vaccine demand-supply issue more manufacturing licenses should be given.

A total of 18,58,09,302 doses of Covid-19 vaccines have been administered across the country since the vaccination drive began on January 16. According to official data, 2,67,334 fresh Covid-19 cases were recorded during a 24-hour period.

"The cumulative caseload stands at 2,54,96,330, including 32,26,719 active cases, 2,19,86,363 recoveries and 2,83,248 deaths," the Union health ministry said.

Source : Times of India, 19.05.2021

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DCA puts curbs on retail sale of Mucormycosis drug

Director of Medical Education Dr K Ramesh Reddy said the fungal infection occurs only in Covid-19 patients who are diabetic, and it is a rare disease and not infectious.

HYDERABAD: Drug Control Administration (DCA) has imposed curbs on the retail sale of Amphotericin B, an injection used to treat black fungus or Mucormycosis, after the drug was in acute short supply for one week folowing a sudden spike in cases.

According to a letter sent by the Director of DCA to nearly 16 manufacturers and several other stockists and distributors of the drug, the injection can be supplied only after a government committee approves the same.

This committee will be headed by the Director of Medical Education and will decide which supplier will supply to which hospital.

"All manufacturing companies of the Liposomal Amphotericin B are hereby instructed to supply drugs directly to their stockists and to inform immediately to the DCA about quantity, name and address of stockist where drug is supplied. The stockist in turn will issue vials based on recommendation of the government committee. Not a single vial can be issued to hospitals and patients directly without recommendation," states the letter.

People with diabetes need to be cautious

Director of Medical Education Dr K Ramesh Reddy said the fungal infection occurs only in Covid-19 patients who are diabetic, and it is a rare disease and not infectious. Post Covid-19 recovery, the immunity is still low, and patients must wear masks, the Director added.

"Mucormycosis is in the air we breath and only affects those who have low immunity or diabetes. Thus, mask compliance until one gains health is crucial," he said.

Source : The New Indian Express, 19.05.2021

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Covid-19 crisis: Pharma majors step up support to affected employees

A company spokesperson said this benefit will be over and above the existing group term insurance

Pharma firms have come forward to help employees and their dependents during the pandemic. With over

Firms like Lupin and Zydus have set up helplines to assist employees and their families round-the-clock with medical assistance, counselling and doctor consultation, among others.

270,000 deaths due to Covid-19 in the country, the pharma players, who are also part of essential services, have stepped up efforts to ensure that families of employees, who succumbed to the disease, are able to have some financial support.

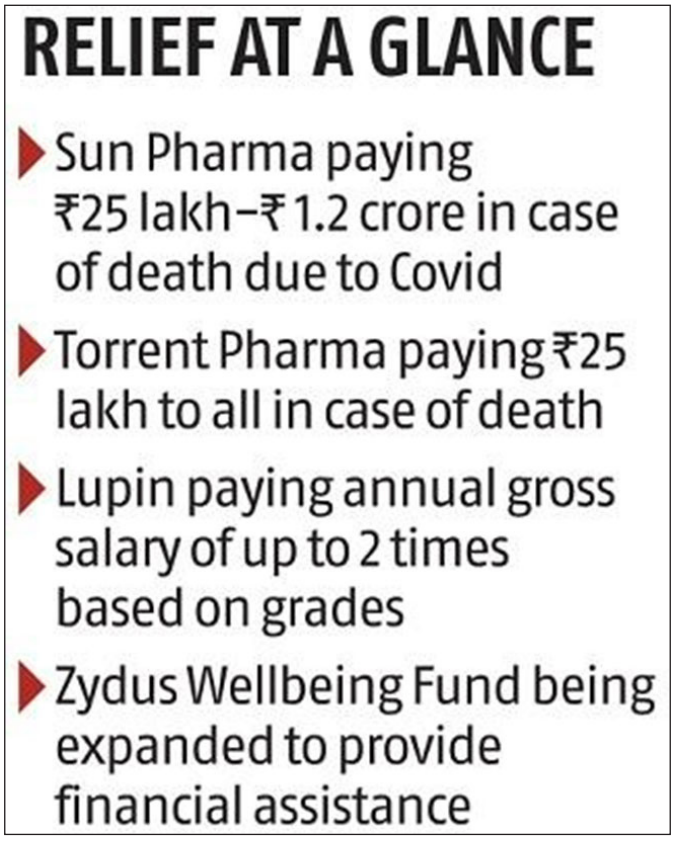
Apart from one-time payments, some of these measures include paying for children's education, arranging hospital and ICU beds, or having round-the-clock helplines to assist employees and their families.

The country's largest drug maker Sun Pharmaceuticals has announced that it will pay an amount equivalent to two years' salary (minimum of Rs 25 lakh and maximum of Rs 1.2 crore). A company spokesperson said this benefit will be over and above the existing group term insurance. "The company will also pay the education fees of children of these employees up to their graduation in India," the spokesperson added.

Ahmedabad-based Torrent Pharmaceuticals has taken a slightly different approach – it is paying out Rs 25 lakh flat to families of employees who have succumbed to Covid. "Our human resource team immediately visits the employee's family and hands over the cheque," said Jayesh Desai, executive director of the Torrent Group. Desai said having a blanket financial payment amount helps employees in the lower rungs of hierarchy more, for example, the firm's drivers. He added out of the 22,000 employees overall, 21,000 would be drawing salaries below Rs 10 lakh per annum.

Torrent has also added Rs 5 lakh Covid cover for its employees over and above the group medical insurance

policy. Together with the usual payouts, when one adds the Covid benefits, it easily works out to not less than Rs 1 crore for Torrent's employees, Desai claimed. "It is important to ensure that the family sustains and is able to pay its bills. We also give preference to recruiting family members of our deceased employees, but this is also based on merit and is a pre-Covid practice," he added.



Mumbai-headquartered Lupin is paying out an amount equivalent to two times the annual gross salary to the beneficiary of the deceased employee. The company has linked this to grades — for general manager and above, Lupin will pay the annual gross salary in case of death of the employee. It is also bearing 'isolation expenses' for the employee and their family members up to Rs 25,000 (which is reimbursable through medical insurance). Any amount over and above it will be borne by Lupin. The firm is also trying to ensure that those who are sick get access to proper healthcare facilities – it has set up a dedicated task force to secure and provide oxygen and oxygen support hospital beds to all its employees.

Another Ahmedabad-based drug major Cadila Healthcare, which is at the forefront of developing a Covid vaccine, has a Zydus Wellbeing Fund, which extends financial support in case of an employee's death. "We are in the process of widening the ambit of this (fund). We have been supporting medical expenses for the employees and their families hospitalised due to Covid. We have also set up a Covid care clinic for our employees and also offer free tele-consultation with doctors across India," a company spokesperson said.

Firms like Lupin and Zydus have set up helplines to assist employees and their families round-the-clock with medical assistance, counseling and doctor consultation, among others.

"Since last year, we have set up a central committee and a helpline, which supports employees and their families round-the-clock. Free medicine kits are being provided with immunity boosters and vitamin supplements. A team of medical advisors have been guiding employees at all locations on their treatment, if infected with Covid," the spokesperson added.

Source: Sohini Das, Business Standard, 18.05.2021

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CoWin registration for 18-44: Ratio of vaccine availability to people is 1:230, says Sharma

It's the problem of availability vis-a-vis demand; platform has no glitches, says NHA chief

The Covid-19 registration challenges faced by those in the 18-44 age group on the CoWin platform are mainly due to vaccine availability issues rather than glitches in the platform, RS Sharma, Chief Executive Officer of National Health Authority and in-charge of CoWin platform, has said.

Dismissing talks attributing the challenges in registration to glitches in the platform, Sharma said, "as of now, more than 7.5 crore people in the 18-44 age group have registered on the platform against 13.75 crore who are 45-plus.

Total doses administered to those in the 18-44 age group over the last 12-13 days are about 30 lakh (the supply figure) against the demand of 7.35 crore. So, around three lakh people in the 18-44 age group have been vaccinated per day on average. The ratio of vaccine availability to number of candidates is 1:230. It's the problem of availability of vaccine shots."

Sharma told *Business Line* that "for orderly conduct of the vaccination, we need to have data on the number of people planning to visit the centres, so that Covid appropriate behaviour can be maintained; hence the need for a digital platform."

Sharma also rejected the contention of some people that a large number of Indians will get left out of vaccination due to the digital divide being faced in the country as a result of several being technologically challenged.

"This whole talk of people getting left out is absolutely incorrect. It is important to note that if you go directly without registering yourself, you are not sure of getting a seat. It is like boarding a train without getting the reservation done," Sharma said.

Rural drive

When asked how he was ensuring that maximum people in the rural areas get inoculated, Sharma said, there are 700 million internet users in India and one family has at least one smartphone through which four registrations can be done. "If people don't have smartphones or computers, they can go to one of the 250,000 common service centres for registration. So this whole issue of digital divide raised by a certain section of urban people is unnecessary," he argued.

On the issue of coders and programmers being able to block slots, Sharma said that most people do not succeed in getting a slot due to non-availability of vaccines, so these claims are not correct. "But yes, we have opened the search capabilities which makes it easy for people if they do an algorithm search," he added.

New feature

Sharma also said CoWin platform will soon have a new feature to connect to the vaccination centre. He said CoWin has opened only two application programming interface (APIs) — one for searching for vacancies and the other for downloading the certificates. Both the APIs have helped.

Meanwhile, following the recommendations of the Covid working group on the extension of the gap between the first and second doses of Covishield vaccine to 12-16 weeks, the CoWIN digital portal has also been reconfigured to reflect this.

Source: Monika Yadav, Business Line, 17.05.2021

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Chemists union says will shut stores till staff given vax on priority

The association had not resorted to such a move so far because they wanted maintain the availability of medicines during this pandemic

More than 900,000 chemists across India have threatened to down shutters if their employees are not given covid-19 vaccines on priority similar to healthcare and front line workers such as security personnel.

"The All India Organization of Chemists and Druggists (AIOCD), a nationwide organization of 9.40 lakh chemists in India, may any time join the lockdown to protect and save the lives of its members, as they were sidelined while considering vaccination priority," the association said in a statement on Thursday. It said that the association did not opt for such a move so far as it wanted to ensure availability of medicines during the pandemic.

According to the AIOCD, its members were not included among frontline workers despite the fact that they come regularly in contact with covid-19 patients at their stores while providing medicines. Since March last year, more than 650 chemists and pharmacists have lost their lives due to covid-19, the association said.

"But now we do not want to put our members at risk and therefore we demand (that the government) vaccinate with priority all 9.4 lakh chemists and pharmacists and support staff, or we will join the regular lockdown followed by other trade members," the association said.

A similar appeal was made by the Association of Indian Medical Device Industry (AiMeD) for employees at manufacturers of covid-19-related medical equipment.

AiMeD forum coordinator Rajiv Nath on Wednesday wrote a letter to NITI Aayog member (health) V.K. Paul, who is also the chairman of the Nation Expert Group on Vaccine Administration for Covid-19 (NEGVAC), for inclusion of staff at manufacturers of covid-19 related medical supplies in the list of frontline workers and be vaccinated on priority, or, at the very least, allow such expenses to be included in corporate social responsibility activities.

Currently, only security personnel, municipal workers and revenue officials from the government are considered frontline workers. Healthcare and frontline workers as well as those over the age of 45 are considered high priority groups for covid-19 vaccinations as they are highest at risk of contracting the disease.

However, a number of professional groups such as chemists, staff of medical devices and drug manufacturing industry, transportation workers and grocery store staff are not considered frontline workers by the Centre despite their jobs requiring being in close contact with people and being considered as essential services.

Although the situation has improved under the Centre's revised policy which allows vaccination of all adults of age 18 and above, while giving priority to high-risk groups, and also allows states more liberty to make their own list of priority groups.

Source : Leroy Leo, HT Mint , 21.05.2021

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