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IDMA BULLETIN

VOL. NO. 52 | ISSUE NO. 31 (PAGES: 32) | 15 TO 21 AUGUST 2021 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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Date: 26th August, 2021
Time: 3:00 PM - 4:00 PM

(Details on Page: 4)

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IDMA & APTAR Pharma Webinar

on "Intranasal Immunization: Promises and Challenges"

Date: 2nd September, 2021
Time: 4.30 PM - 6 PM

(Details on Page: 5)

ASSOCHAM, IDMA and BDMAI Webinar

on Future of Healthcare Logistics and Supply Chain

Date: 28th August, 2021
Time: 3.00PM - 4.30PM

(Details on Page: 26)

IDMA - GSB and Nutrify Today Webinar

on
"The Switch 2-RX to OTC"

Date: 27th August, 2021
Time: 4.00 PM - 5.15 PM

(Details on Page: 27)

HIGHLIGHTS

★ **IDMA Representation for Inclusion of Pharmaceutical Sector for Remission of Duties and Taxes on Exported Products (RoDTEP) Scheme & DGFT Notification No.19/2015-2020 dt. 17.8.2021** *(Page No. 10)*

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Vol. No. 52 **Issue No. 31** **15 to 21 August 2021**

IDMA WEBINARS:

IDMA - SAP Webinar on Global Bharat = Digital Transformation 4

IDMA - APTAR PHARMA Webinar on Intranasal Immunizatiion: Promises and Challenges 5

ASSOCHAM, IDMA and BDMAI Webinar on Future of Healthcare Logistics and Supply Chain 26

IDMA -GSB and Nutrify Today Webinar on "The Switch 2-RX to OTC" 27

IDMA ACTIVITIES:

Innovations in vaccine development: What next?: by Dr Ananth Pannala 8

IDMA Representation for Inclusion of Pharmaceutical Sector for Remission of Duties and Taxes on Exported Products (RoDTEP) Scheme & DGFT Notification No.19/2015-2020 dt. 17.8.2021 10

PARLIAMENT NEWS:

In Lok Sabha & In Rajya Sabha 12

GOVERNMENT COMMUNICATIONS:

Submission Date Extended to 25th October 2021 wrt Evaluation of Certain PRE 1988 permitted Fixed Dose Combinations (FDCs) de novo for manufacture for sale in the Country without due approval from Central Licensing Authority - reg. 19

NATIONAL NEWS:

Limited trade pact with US deferred: Working with US on market access issues, says Piyush Goyal 20

RoDTEP: A work in progress 21

Exporters want steel, pharma under RoDTEP 22

Roche warns of shortage of Covid-19 drug tocilizumab 23

Shapoorji Mistry and Dadachanji-led Kaisha Group to enter pharma space 24

A packaging directive for tinplate, tin-free steel is slowing down supplies at your grocery store 24

USP Live Webinar on Best Practices in QMS Investigations 29

Advertisements ..... 2, 7, 25, 30, 31 & 32

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REGISTER NOW - IDMA & APTAR PHARMA WEBINAR on "Intranasal Immunization: Promises and Challenges" for September 2, 4.30 pm to 6 pm

Aptar Pharma and Indian Drug Manufacturers Association (IDMA) is organizing a Webinar on "Intranasal Immunization: Promises and Challenges" on 2nd September 2021, 4.30pm to 6 pm.

Please find the registration link to the webinar on "Intranasal Immunization: Promises and Challenges" for September 2, 4.30pm to 6 pm below:

https://teams.microsoft.com/registration/PkrXX3rVDkGNfALE3wYiNA,VjPgRYWeX0GWg7qPokPKGw,vhU8TNwV5kqyzLgXOBFrTg,2jpNZ4u6HEi5FmFxwyYq7A, StN7ioiQ2EmOgoFOGEoeZA, n7i4sv37r0iiFaCew7_LAA?mode=read&tenantId= 5fd74a3e-d57a-410e-8d7c-02c4df062234

The International Speakers for this webinar are

1. **Dr. Julie Suman,** President Next Breath, An Aptar Pharma company
2. **Nektaria Karavas,** Business Development Director, Aptar Pharma

The abstract of the webinar is given below :

Exploring intranasal vaccination for needle-free immunization

Today, there are three marketed nasal vaccines available for human use but many more are in development for both human and veterinary use. Nasal vaccination provides an alternative to the more conventional Injectable drug delivery system. Mucosal immunity can develop via interaction with immune modulators present in the nasal cavity, where the nasal associated lymphoid tissue (NALT) region plays a dominant role.

In this webinar, we will provide an overview of intranasal vaccine formulations for liquid and powder administration. We will then discuss the pros and cons of nasal vaccines, assess intranasal device platforms, logistical considerations that need to be taken into account, as well as present our thoughts on the opportunities that intranasal vaccination can offer.

The webinar shall be of interest to the following people:

- Heads Research Development
- Business Development
- Product Development
- Pharmaceutical Development
- Microbiologists
- Packaging Engineers
- Drug Delivery Scientists
- Formulation Development
- Formulation Scientists
- Process Development
- Quality Control
- R & D
- Research Scientist
- Product Managers
- Innovation Managers
- Virolgists
- Immunologists

Kindly note that there are no registration fees for this webinar but prior registration is compulsory.

Members are requested to participate in this webinar in large numbers and avail benefits from the same.

Thanks & regards,

Daara B Patel *Secretary – General*	**Prachi Singhai** *Manager-Marketing & Communication,* *India & S E Asia*
Indian Drug Manufacturers' Association 102, A Wing, Poonam Chamber, A Wing, 1st Floor, Dr.A.B.Road, Worli, Mumbai-400018. Maharashtra. India. Tel No. 022 24974308 / 24944624 Cell: +91 9821868758 E-mail : actadm@idmaindia.com / accounts@idmaindia.com Website: www.idma-assn.org	**Aptar Pharma India Private Limited** part of Aptargroup, Inc., Crystal Lake, Illinois, USA, and having Registered Office at R - 854 , TTC Industrial Estate Thane Belapur Road, MIDC RABALE, Navi Mumbai, 400701 Mumbai, India. Tel. + 91 22 61951900 / Cell : +91 9892026098 Email : prachi.singhai@aptar.com Website: www.aptar.com

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Innovations in vaccine development: What next?

Dr Ananth Pannala, *MPharm, PhD, FRSC, SFHEA*

Dear Reader,

COVID-19 pandemic has affected the whole world in a way that is unprecedented. The origin of the SARS CoV-2 and the true scale of number of cases and deaths in every country is debatable. Nevertheless, it is clear that the spread of the virus is continuing worldwide with a devastating effect on the global economy. The control of the pandemic was essentially by implementing strict measures such as social distancing, use of personal protective equipment, personal hygiene and sanitation. There were numerous occasions since the beginning of the pandemic when governments across the world had rejoiced that their measures to control the spread of the infections had worked. However, non-compliance of safety measures and new strains of the virus led to the rise of the next wave of infections.

SARS-CoV-2 gene sequence was published in the beginning of the year 2020 and since then researchers, both academic and industrial, have worked hard in the development of a range of vaccines. The list of new vaccines include viral vector vaccines (AstraZeneca/Oxford/Serum Institute India; Jannsen; CanSino; Gamaleya), mRNA based vaccines (Pfizer/BioNTech; Moderna; CureVac; Inovio Pharmaceuticals) and inactivated vaccines (Bharat Biotech; Sinovac; Sinopharm), to name a few. Most of these vaccines were approved for human use by the regulatory bodies. There are a number of other vaccines, including attenuated vaccines and protein vaccines that are currently in various stages of clinical trials around the world.

India is the largest vaccine supplier with Serum Institute India being the single largest vaccine manufacturer in the world. In January 2021, India was the largest producer and supplier of COVID-19 vaccines to the world. Millions of doses have been produced and supplied free to countries in need as a goodwill gesture too. Yet, India mostly depends on other countries, especially USA and EU, for the supply of consumables for vaccine production.

Dr Pannala is a Principal Lecturer in Pharmaceutics in the School of Pharmacy and Biomolecular Sciences, University of Brighton, UK. His research interest and expertise includes development and evaluation of new technologies based on nanotechnology and microtechnology for delivering therapeutically active molecules for targeted drug delivery.

Dr Pannala completed his BPharm and MPharm from College of Pharmaceutical Sciences, Manipal and his PhD from King's College London. He is a Fellow of the Royal Society of Chemistry and a Senior Fellow of Higher Education Academy. Dr Pannala has nearly 30 years of research experience in both academia and pharmaceutical industry.

Dr Pannala has more 30 publications in peer-reviewed international journals, which have been cited more than 25,000 times. He is the Lead for the Biomaterials and Drug Delivery Research and Enterprise group at University of Brighton. He has so far guided 7 PhD students as a principal supervisor and more than 75 Masters Students in their research projects. He has been successful, as a co-applicant, in procuring research income from various funding bodies. Dr Pannala is a reviewer of grant applications for RCUK, British Council, Horizon 2020 and others. He regularly reviews journal articles for international research journals in the field of Pharmaceutics, Pharmacology and Biomedical Sciences.

According to a report by the world trade organisation, a typical vaccine production may use thousands of different materials that are sourced from suppliers around the world. Some of these essential materials for producing a simple

vaccine would include cell culture media, a bioreactor bag, filters for clarification/purification/sterilisation and micro-carrier beads for protein growth to name a few. The manufacturer prepares and submits to the regulatory body a master document containing details of the raw materials, suppliers, the production process, as well as details of clinical trials for their approval before the vaccine can be manufactured for general supply and use.

Political decisions made by the former government of USA introduced various restrictions on the supply of vaccine consumables. These decisions were possibly made to ensure that the local demands were met before any of the resources can be exported. This led to a serious shortage in India of raw materials, packaging materials, critical consumables such as culture media and various equipment due to these embargoes. These restrictions have hit the production of vaccines for majority of the suppliers around the world. In such a situation, can the vaccine manufacturers approach suppliers in other countries such as in China or Russia? Unfortunately, this is not quite so simple. It would be difficult to make any changes to the raw materials or suppliers for producing an approved vaccine and it would require a thorough validation as well as applying for regulatory clearance, again. This would lead to severe delays in the production and immunisation of the general population, with an obvious increase to the costs involved.

How would a change of supplier affect vaccine production? Any change in raw material has the potential for the quality of the product being affected. The main issue is with maintaining quality and safety. Although US is not the sole supplier of these consumables with other countries like China and Russia having some capacity, it does play a predominant role in vaccine manufacture. There were reports of some batches of Johnson and Johnson and AstraZeneca vaccines manufactured by a US based company rejected by the FDA for failing manufacturing quality. A key principle that is followed by pharmaceutical/biopharmaceutical manufacturers around the world is, "do no harm".

As mentioned previously, some of the essential consumables in vaccine production such as cell culture media, bioreactor bags, filters and micro-carrier beads are predominantly manufactured and exported by biotechnology industries based in the USA. For example, cell culture media is produced by HyClone Laboratories Inc. and Merck Millipore (both based in USA), Lonza Group AG (Switzerland), CellGenix Gmbh (Germany) and HiMedia Laboratories (India). The cell culture media market share is valued at $4.65b USD in 2020 and is projected to increase to $8.24b USD by 2028, a compound annual growth rate (CAGR) of 7.38%. Similarly, the expected CAGR by 2027 for other consumables such as single use bioreactor systems is 15.5% ($6.39b USD), for micro carrier beads to be 5.52% ($1.9b USD) and for micro filters is expected to be 7.7% ($8.48b USD).

On a positive note, the new technologies that were developed to tackle SARS-CoV-2 pandemic have relied on the quality and procurement of consumables from suppliers around the world. These vaccines were developed, tested and implemented in less than a year. These are extraordinary medical and scientific breakthroughs. The pandemic is ongoing and it is vital that the current immunisation drive goes through unhindered. There is a fair prospect that these developments will help in controlling this and any future pandemic. The ultimate goal is to produce the vaccines in an environment that is independent of unexpected supply chain interruptions.

Therefore, there is a unique opportunity for Indian Pharmaceutical, Biotechnological and Engineering firms to look at the production of not only the finished products such as vaccines but also to manufacture the essential raw materials. This would not only increase the self-reliance of Indian biotechnology industry but will also help in controlling the price of the vaccines produced. However, the major challenge for this approach is satisfying the quality and regulatory requirements of the raw materials to meet the stringent specifications for vaccine manufacture.

Courtesy: Indian Drugs, Editorial, 58 (06), June 2021

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IDMA Representation for Inclusion of Pharmaceutical Sector for Remission of Duties and Taxes on Exported Products (RoDTEP) Scheme & DGFT Notification No.19/2015-2020 dt. 17.8.2021

IDMA has submitted the following representation on 19th August 2021 to Shri. B.V.R. Subrahmanyam, IAS, Commerce Secretary, Ministry of Commerce & Industry, New Delhi with the copies to Mr. Tarun Bajaj, IAS, Secretary, Department of Revenue, Ministry of Finance; Ms. S. Aparna, IAS, Secretary to the Government of India, Department of Pharmaceuticals, and Mr. Amit Yadav, IAS, Director General of Foreign Trade, Ministry of Commerce & Industry on the above subject :

Greetings from Indian Drug Manufacturers' Association.

IDMA has successfully completed 59 glorious years of its existence, providing support to its members for supplying affordable quality medicines, not only to the people of India, but also to people all over the world. **The IDMA Membership consists of over 1000 plus wholly-owned Indian large, medium and small companies manufacturing Formulations & APIs.** IDMA represents the interests of SSI, MSME and large Indian Companies in both APIs and Formulations in domestic and export markets. At present, we have 8 State Boards located in Tamil Nadu, Kerala & Puducherry, Gujarat, West Bengal, Haryana, Himachal Pradesh & Uttarakhand, Madhya Pradesh, Telangana & Karnataka.

We are with the government in their efforts to boost India's merchandise exports to US$ 400 Bn for the year 2021-22. The Pharmaceutical exports had reached 24.41 Bn in the year 2020-21. The target for the year 2021-22 has been set for USD 29 Bn. The Industry has been able to achieve substantial growth in exports, thanks to the support and initiatives by the Government at various levels. However, with the recent withdrawal of MEIS scheme and the exclusion of the pharmaceutical sector from the RoDTEP has been a dampener for the Industry. This will also have a negative impact on the pharmaceutical exports.

In this context, we would be grateful for your considering our below mentioned recommendations:-

1. The earlier MEIS scheme was offered by the Government as partial compensation for the inefficiencies faced and indirect taxes borne by the Indian Industry which were not compensated through set-offs and exemptions. MEIS Scheme was not really an incentive but helped the industry, especially the smaller MSME exporters to be competitive and promote their exports by becoming competitive in the global market.
2. Since the MEIS Scheme has been construed or interpreted as an incentive by WTO, the same has been discontinued and the Government has brought in a logical and fair scheme called **RoDTEP (Remission of Duties and Taxes on Exported Products)**. The essence of this scheme is to identify and realistically estimate the hidden and embedded duties and taxes which constitute a significant portion of the total costs and gets built-in and carried forward into the exported products. (The embedded and hidden costs are the Excise Duty and Sales tax on fuel, electricity, etc. which impact transportation costs and energy costs). Thus along with the product, we are also exporting our Taxes as well. This increases our product cost thereby making our Indian products non-competitive vis-a-vis our competitors such as exporters from China, Bangladesh, Pakistan, etc. This factor is crucial in the extremely competitive global market.
3. As agreed by all concerned, the basic principle behind bringing in RoDTEP Scheme, which is compliant with WTO norms, is to eliminate the embedded & hidden costs from our cost structure through direct compensation or rebate. This Scheme will thus attempt to remove the inadequacies in our system and also help to make our products competitive in the World, by avoiding the export of taxes and duties.

4. The Indian Industry is also facing several other disadvantages such as Port inefficiencies, higher rates of interest compared to global financial markets, delay in IGST Refunds, inadequate infrastructure which lengthens our working capital cycle thereby increasing our financial cost, etc. In addition, the Pharmaceutical industry is carrying an additional burden on account of the Inverted Duty Structure locking its fund with GST Portal. These handicaps also deserve compensation through rebates. These factors are so far not addressed.

5. It is an acknowledged fact that all sectors are bearing the brunt of hidden and embedded duties and taxes in their business operations. The degree of impact may vary, depending upon their cost structure, energy intensiveness, level of transportation, and dependence on a multitude of factors. However there is no denying that all industries face such taxes and duties and hence all deserve to be compensated through the RoDTEP scheme. This has been the basic objective of the RoDTEP scheme which is expected to be fulfilled across all industries, impartially and fairly. The rates of compensation will of course vary. Each industry was accordingly given a chance to represent/submit the impact of such costs in their businesses and RoDTEP rates were to be finalized by the RoDTEP Committee appointed by the Government.

6. Many IDMA members have accordingly submitted their comprehensive cost data to the RoDTEP Committee along with their assumptions and calculations while estimating the RoDTEP rate they deserve for their different products. The RoDTEP rates have been estimated from 2.5% to 5.5% for different products, in API as well as Formulations categories.

7. It has been therefore disappointing to see that our Industry has been completely overlooked while assigning the RoDTEP rates in the announcement made by the Ministry of Commerce on 17th August 2021. **This denial is not only unfair to our industry but is also discriminatory.** While the impact of hidden taxes and duties is considered and allowed for most of the industry sectors, we wonder why the same has not been extended to our pharmaceutical industry! **The fact that our industry and its producers are bearing the hidden and embedded costs cannot be denied - it is surprising that the Government has not allowed its fair compensation as promised in the RoDTEP Scheme.**

Sir, this anomaly needs to be rectified on priority as otherwise, our exporters will become non-competitive in the global arena. The impact will be most severe on the SSI and MSME Units that survive on wafer-thin margins in the exports market. For them, this will imply significant loss, and they may not be able to survive in business.

Sir, this will be a tremendous loss not only to the exporters but also to our country which takes pride in being a Pharmacy to the World.

The target set by the industry and the government to increase the pharmaceutical exports in the near future will only remain a dream if the required support is not provided to the industry

Thanking you and with regards,

Yours sincerely,
For Indian Drug Manufacturers' Association,

Mahesh H Doshi
National President

● ● ●

In Lok Sabha & In Rajya Sabha

In Rajya Sabha

Usage of Difference Vaccines in India

Rajya Sabha Unstarred Question No. 1704

Dr. Narendra Jadhav:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) the details of the COVID-19 Vaccines which are allowed for use in India along with a chronological account of approval granting process for these vaccines.

(b) the per cent of India's rural population that has got vaccination doses, the details thereof, State-wise:

(c) the details of COVID-19 vaccine supplies received by Government and their dispatch to different States for inoculation;

(d) whether Government monitors the inoculation numbers for each kind of vaccine in use; and

(e) if so, the details on number of doses used, vaccine-wise, including centre of vaccination-Government or private, month-wise and State-Wise?

Answered on 03rd August 2021

A. (a) to (e): Three vaccines, namely Covishield manufactured by M/s Serum Institute of India, Covaxin manufactured by M/s Bharat Biotech International Limited and Sputnik V that have been granted permission for restricted use in emergency situation by the National Regulator i.e. Drugs Controller General of India [DCG(I)] are being currently used under the Covid-19 vaccination programme in India. In addition, Moderna vaccine has also been granted permission for Emergency Use Listing (EUL).

Covishield and Covaxin were granted permission for Emergency Use Listing (EUL) in January 2021, Sputnik V in April 2021 and vaccine produced by Moderna in June 2021.

Between 1st April 2021 to 29th July 2021, approximately 57% of the total COVID-19 vaccine doses administered were administered in Rural COVID-19 Vaccination Centres (CVCs) while 40% doses were administered in urban CVCs and remaining 3% doses were administered in CVCs that are not specifically classified as urban or rural in the CoWIN portal.

Details of COVID-19 vaccine supplied free of cost to all State/UTs as on 29th July 2021 is at Annexure-1.

The number of doses administered by different State/UT, vaccine-wise as on 29th July 2021 is at Annexure-2.

*(**Note:** Annexures not reproduced, interested members may contact IDMA Secretariat for details)*

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Sale of Medicines and Pharmaceuticals on E-Platforms

Rajya Sabha Unstarred Question No.1712

Shri Vivek K. Tankha:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) the details of the steps being undertaken by the Ministry to regulate the sale of medicines and pharmaceuticals on e-platforms; and

(b) the details of the steps being undertaken to curb the problems, such as sale of counterfeit drugs, verification of drugs, online sale of psychotropic substances, improper use of medicine, etc?

Answered on 03rd August 2021

A. (a) & (b): In order to regulate the online sale of medicines comprehensively, the Government published draft rules for inviting comments from public/stakeholders for amendment to the Drugs and Cosmetics Rules, 1945 for incorporating provisions relating to regulation of sale and distribution of drugs through e-pharmacy.

The draft rules contain provisions for registration of e-pharmacy, periodic inspection of e-pharmacy, procedure for distribution or sale of drugs through

e-pharmacy, prohibition of advertisement of drugs through epharmacy, complaint redressal mechanism, monitoring of e-pharmacy, etc.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Contradictory Views on Vaccine Dosage Gap

Rajya Sabha Unstarred Question No. 1719

Shri Naranbhai J. Rathwa:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a): whether it is a fact that there is contradictory views on two vaccine dosage intervals and NITI Aayog is examining the time gap between the two doses;

(b): if so, the details in this regard;

(c): the dose gap prescribed at present by Government and what is the time interval if a person gets COVID-19 virus after first dose of vaccine; and

(d): whether some public health experts from AIIMS have suggested that there is no need to inoculate those who have documented COVID-19 infection after first dose and, if so, the details thereof?

Answered on 03rd August 2021

A. (a) to (d): The Covid Working Group of National Technical Advisory Group on Immunization (NTAGI) recommended extension of the gap between the first & second doses of Covishield vaccine to 12-16 weeks based on available scientific evidence particularly from the United Kingdom as well as WHO global guidance. This recommendation has been considered & also recommended by the National Expert Group on Vaccine Administration for Covid-19 (NEGVAC).

The Ministry of Health & Family Welfare has accepted this recommendation for extension of the gap between the first and second doses of Covishield vaccine to 12-16 weeks.

In addition Government of India has accepted NEGVAC recommendations and directed all States/ UTs that individuals who have received the 1st dose and got Covid-19 infection before completion of the dosing schedule, their 2nd dose should be deferred by 3 months from the date of clinical recovery from Covid-19 illness.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Remdesivir as A Generic Drug

Rajya Sabha Unstarred Question No. 1720

Shri K.R. Suresh Reddy:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether Government has taken any steps to consider Remdesivir as generic drug; and

(b) if so, the details thereof?

Answered on 03rd August 2021

A. (a) & (b): Generic medicines are generally those which contain same amount of same active ingredient(s) in same dosage form and are intended to be administered by the same route of administration as that of branded medicine.

Considering the emergency COVID situation and to ensure adequate availability, based on the data/ documents submitted by the applicant company and recommendations of the Subject Expert Committee, Central Drugs Standard Control Organisation has granted permission to manufacture and market Remdesivir injectable formulations for restricted emergency use in the country.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Domestic Production of Covid Vaccines

Rajya Sabha Unstarred Question No. 1738

Dr. Amee Yajnik:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether Government intends to invoke the Patents Act, 1970 to increase the domestic production of COVID-19 vaccines;

(b) if so, the details thereof including the anticipated timeline for such invocation and implementation of the same and, if not, the reasons therefor; and

(c) the reasons why compulsory licensing has not yet been invoked to increase the domestic manufacturing of COVID-19 vaccines and other medical resources?

Answered on 03rd August 2021

A. (a) to (c): Since no patent has been granted for any COVID-19 vaccine in India. Hence, does not arise.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Science budget for COVID-19 research

Rajya Sabha Unstarred Question No. 1748

Shri Surendra Singh Nagar:

Q. Will the Minister of Science and Technology be pleased to state:

(a) whether Government proposes to allocate science budget for COVID-19 related research; and

(b) if so, the details thereof and, if not, the reasons therefor?

Answered on 03rd August 2021

A. (a) Yes Sir. Government of India allocated science budget for COVID-19 related research.

(b) DBT and its Public Sector Undertaking, Biotechnology Industry Research Assistance Council (BIRAC), have allocated an amount of appx. Rs 1300 Cr. for COVID-19 Research and Product Development. Under the COVID-19 Research Consortium as a part of the comprehensive efforts to facilitate development of indigenous research solutions to tackle COVID-19, 107 projects were supported in thematic areas of COVID-19 vaccines (17), diagnostics (45), therapeutics (22) and biomedical interventions (23). To advance biomedical research DBT has supported five COVID-19 biorepositories. Further, the Indian SARS-CoV-2 Genomic Consortium (INSACOG), a Consortium of 28 regional sequencing labs, was launched, to ascertain the status of new variants of SARS-CoV-2. “Mission COVID Suraksha – The Indian COVID-19 vaccine development Mission” is being implemented at a total cost of Rs. 900 Cr. The Mission is supporting the development of COVID-19 vaccine candidates (05), facilities for animal challenge studies (03), facilities for immunogenicity assays (03), clinical trial sites (19). Additionally, facility enhancement of Bharat Biotech and 3 Public Sector Undertakings to support augmented production of Covaxin, is also being supported under the Mission.

Department of Science and Technology (DST) earmarked an amount of approximately Rs 200 Cr. for COVID-19 related research for implementation through its different programmes, Autonomous Institutions and statutory bodies like Science and Engineering Research Board and Technology Development Board.Council of Scientific and Industrial Research (CSIR) has allocated Rs.10444.39 lakhs from its Government budgetary support and internal resources for implementing projects related to COVID-19 related research.Department of Biotechnology (DBT), supported COVID-19 related research activities under the umbrella schemes of "Biotechnology Research and Development" and “Industrial and Entrepreneurship Development”.

Minister of State (I/C) of The Ministry of Science and Technology& Earth Sciences (Dr. Jitendra Singh)

Availability of Medicines at Affordable Prices

Rajya Sabha Unstarred Question No. 272

Dr. V. Sivadasan:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether Government is aware of the fact that there are some diseases which require medicines that cost very huge amount of money, like the Zolgensma medicine for the Spinal Muscular Atrophy which costs around rupees 16 crores for one dose; and

(b) whether Government intends to provide these medicines at affordable prices for the ordinary people, if so, the details thereof?

Answered on 03rd August 2021

A. (a): Yes, the Government is aware of the fact that there are some diseases which require medicine that cost very huge amount of money, like the Zolgensma medicine for the Spinal Muscular Atrophy which costs around Rupees 16 crores for one dose;

(b): The issue of the pricing of drugs does not pertain to Ministry of Health and Family Welfare (MoHFW). However, National Policy for Rare Diseases, 2021 has been issued by MoHFW on 30.03.2021. Certain provisions have been made therein to address the need of financial assistance to the patients suffering

from rare diseases. The Policy can be accessed at website-https://main.mohfw.gov.in/documents/policy.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Delay in Approval of Permits to Domestic Companies for Vaccine Production

Rajya Sabha Unstarred Question No.276

Shri T.G. Venkatesh:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether Government has been giving permits to the domestic companies to produce COVID-19 vaccines in the country;

(b) if so, the details thereof;

(c) the number of companies that have been given approvals and the estimated quantum of production of vaccines by these companies;

(d) whether it is a fact that there is a delay in giving the approvals to the vaccine production companies in spite of increasing death toll in the country; and

(e) the steps being taken by Government to accelerate the vaccine production in the country?

Answered on 20th July 2021

A. (a) to (c): The Central Drugs Standards Control Organization (CDSCO) has granted permission for production/manufacture of COVID-19 vaccines for restricted use in emergency situation to the following three companies:

1. M/s Serum Institute of India Pvt., Ltd., Pune for ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) on 03.01.2021. The estimated production quantity is around 130 Million doses/month.
2. M/s Bharat Biotech International Limited, Hyderabad for Whole Virion Inactivated Corona Virus Vaccine on 03.01.2021. The estimated production quantity is around 17.5 Million doses/month.
3. M/s Ra (biologicals) Panacea Biotec Ltd., New Delhi Gam-COVID-Vac Combined vectorvaccine (SPUTNIK-V) on 02.07.2021. The estimated production quantity is around 5 Million doses/month.

(d) to (e): There is no delay in giving such approvals. In fact, CDSCO has taken the following measures for fast tracking of approvals of COVID-19 Vaccines:

(a) A system is in place for fast track processing of application for clinical trial & approval for COVID-19 Vaccines by CDSCO.

(b) As per CDSCO's order dated 15.04.2021, the COVID Vaccines already approved by CDSCO for restricted use in emergency situation in India, and proposed to be fill finished at a site within the country different from the manufacturing site by receiving bulk of the approved vaccine, will be approved by CDSCO based on inspection & CDL release. Additionally, if such a vaccine is manufactured in India from basic drug substance stage to the fill-finish stage, it will also be given manufacturing licensee, based on inspection, for stock piling & CDL release.

(c) Further, order was issued on 01.06.2021 on regulatory pathways for approval for restricted use in emergency situation of COVID-19 Vaccines in India which are already approved for emergency use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL) providing for exemptions from conduct of post approval parallel local bridging trials and each batch testing of the vaccine by the CDL, Kasauli subject to condition that it is approved by the National Control Laboratory of the country of origin, and released by CDL, Kasauli based on such certificate and summary lot protocol, to further expedite the approvals of imported vaccines.

(d) Subsequently, one complete application for manufacturing of Gam-COVID-Vac Combined vector vaccine (SPUTNIK-V) using Ready to fill bulk was received on 29.06.2021 from M/s Ra (biologicals) Panacea Biotec Ltd., New Delhi & on the basis of above order CDSCO has granted manufacturing permission for restricted use in emergency situation on 02.07.2021, and manufacturing license was issued on 05.07.2021.

(e) Further, for augmentation of production capacity, CDSCO has granted permission to

M/s Indian Immunological Limited, Hyderabad for manufacturing of Whole Virion Inactivated Corona Virus (COVAXIN) Bulk Vaccine on 26.03.2021 for examination, test and analysis purpose.

Further, Department of Biotechnology under the Ministry of Science & Technology has launched 'Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission', as part of the third stimulus package, Atmanirbhar Bharat 3.0. The Mission is being implemented by Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking (PSU) of Department of Biotechnology.

Under the mission, facility augmentation of Bharat Biotech and 3 Public Sector Enterprises (PSEs) including Haffkine Biopharmaceutical Corporation Ltd, Mumbai; Indian Immunologicals Limited (IIL), Hyderabad and Bharat Immunologicals Biologicals Limited (BIBCOL), Bulandshahr; for augmented production of Covaxinare supported.

Further, Technology transfer of Covaxin production to Gujarat COVID Vaccine Consortium (GCVC), including Hester Biosciences and OmniBRx Biotechnologies Pvt Ltd, led by Gujarat Biotechnology Research Centre (GBRC), Department of Science and Technology, Govt. of Gujarat, are facilitated under Mission COVID Suraksha.

Further, in order to strengthen the vaccine development efforts, clinical trial lot manufacturing of various vaccine candidates is supported.

Additionally, 30 Crore doses of the protein subunit vaccine candidate of Biological E, which is currently in phase III clinical trials, have been pre-ordered by Government of India.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Measures Taken to Meet Vaccine Demand

Rajya Sabha Unstarred Question No.278

Shri Sanjay Raut:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether it is a fact that Serum Institute of India and Bharat Bio-tech are unable to meet vaccine demands at affordable price in the country, if so, details thereof;

(b) the details of the steps taken by Government to produce more vaccines in the country to meet the need;

(c) whether Government is considering to give licenses to many eligible private Indian pharma companies to produce more vaccines in the country to curtail demand-supply gap;

(d) if so, the details thereof; and

(e) if not, the reasons therefor?

Answered on 20th July 2021

A. (a): Adequate quantity of COVID-19 vaccine are expected to be available from January 2021 to December 2021 to achieve desired vaccination coverage amongst eligible population of India.

(b): The Department of Biotechnology (DBT), Ministry of Science & Technology, is supporting the implementation of 'Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission'. Under the Mission, facility augmentation for production of Covaxin is being supported whereby Bharat Biotech and 3 Public Sector Enterprises (PSEs) including Haffkine Biopharmaceutical Corporation Ltd, Mumbai; Indian Immunologicals Limited (IIL), Hyderabad; Bharat Immunologicals Biologicals Limited (BIBCOL), Bulandshahr; are being supported. Additionally, technology transfer of Covaxin production to Consortium of partners including Hester Biosciences and OmniBRx Biotechnologies Pvt. Ltd., led by, Gujarat Biotechnology Research Centre (GBRC), Department of Science and Technology, Govt. of Gujarat, is being facilitated by the Department of Biotechnology. These efforts are expected to enhance the production of Covaxin in the coming months.

Government of India has also provided 100% advance to domestic vaccine manufacturers in respect of procurement order placed with them. These funds can be used by such manufacturers for their capacity augmentation.

Government of India has also provided financial assistance to one of the vaccine manufacturers for 'At-risk manufacturing' of COVID-19 vaccine.

Regulatory norms have also been streamlined for approval of vaccines in India that have received

Emergency Use License (EUL) by FDA of United States, MHRA of United Kingdom, PMDA of Japan or WHO-EUL.

(c) to (e): Stock piling manufacturing license for COVID-19 vaccines have been given to M/s Hetero (Sputnik V), M/s Cadilla (ZyCoV-D) & M/s Biological E (Corbevax), in addition to the existing COVID-19 vaccine manufacturers in the country.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

In Lok Sabha

Global level market for MSMEs

Lok Sabha Unstarred Question No. 1613

Shri Sanjay Bhatia:

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state:

(a) the details of the steps taken by the Government for helping small traders to become self reliant and establish themselves in global market;

(b) whether a reputed panel of experts is proposed to be formed which will consider how to reach out to customers across the world; and

(c) whether steps have been taken by the Government for MSMEs to expand their business at global level and to serve international customers and if so, the details thereof?

Answered on 29th July 2021

A. (a) : Ministry of Micro, Small and Medium Enterprises (MSME) through its MSME-Development Institutes (DI) situated in all States, facilitates MSMEs to export from Domestic Tariff Area (DTA) and Special Economic Zone (SEZ). For this purpose, 52 Export Facilitation Cells (EFC) have been established to provide hand-holding support to MSMEs as well as creating linkages with Export Promotion Councils, Commodity Boards, etc. Further, Government has recently included retail and wholesale trades under the MSME category making them eligible for Priority Sector Lending (PSL).

(b) & (c): To support MSMEs reach out to customers across the world, Ministry is implementing International Cooperation Scheme (ICS) facilitating participation of the MSMEs in International Exhibitions, Trade Fairs, Buyer-seller meets etc. Further, various other schemes are being implemented by the Ministry to help MSMEs expand their business in the global market by providing them assistance for technology upgradation, skill development, quality certification etc. Besides, Directorate General of Foreign Trade (DGFT) is implementing schemes like Niryat Bandhu Scheme (NBS) for mentoring new and potential entrepreneurs about the intricacies of foreign trade and Interest Equalization Scheme (IES) to provide cheaper source of rupee credit for pre-shipment and postshipment activities, wherein all tariff lines are covered for MSMEs with 5% subvention rates.

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

Emergency Credit Line Guarantee Scheme

Lok Sabha Unstarred Question No. 1650

Shri Sunil Kumar Singh:

Shri Balak Nath:

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state:

(a) the details of Emergency Credit Line Guarantee Scheme run by the Government;

(b) the number of beneficiaries in different categories of Micro, Small and Medium Enterprises (MSMEs) under this scheme, State-wise;

(c) whether the eligible and Covid affected MSMEs have been given incentives under the above scheme and if so, the details thereof;

(d) whether there is any proposal to provide exemption from capital gains tax to the beneficiaries of the above scheme in view of the impact of Covid; and

(e) if so, the details thereof?

Answered on 29th July 2021

A. (a) to (c): Emergency Credit Line Guarantee Scheme (ECLGS) was announced as part of the Atma Nirbhar Bharat Package in 2020 with the objective to help businesses including MSMEs to meet their operational liabilities and resume businesses in view of the distress caused by the COVID-19 crisis, by providing Member Lending Institutions 100 percent guarantee against any losses suffered by them due to

non-repayment of the ECLGS funding by borrowers. The interest rate under the scheme was capped at 9.25 percent for Banks and Financial Institutions and 14 percent for Non-Banking Financial Institutions. The overall ceiling initially announced for ECLGS was Rs 3 lakh crore which was subsequently enhanced to Rs 4.5 lakh crore.

The eligibility criteria for availing credit under ECLGS are:

- For ECLGS 1.0, MSME units, Business Enterprises, Mudra Borrower and individual loans for business purpose having loan outstanding upto Rs.50 crore and days past due upto 60 days as on 29.02.2020.
- For ECLGS 2.0, Borrower belonging to 26 stressed sectors identified by Kamath Committee & Healthcare sector having loan outstanding above Rs.50 crore and upto Rs.500 crore and days past due upto 60 days as on 29.02.2020.
- For ECLGS 3.0 Borrower belonging to Hospitality, Travel & Tourism, Leisure & Sporting and Civil Aviation sector having days past due upto 60 days as on 29.02.2020.
- For ECLGS 4.0 Existing Hospitals/Nursing Homes/Clinics/Medical Colleges/units engaged in manufacturing of liquid oxygen, oxygen cylinders etc. having credit facility with a lending institution with days past due upto 90 days as on March 31, 2021.

The number of guarantees issued under this scheme, category-wise and statewise are at Annexure I and II respectively.

(d) & (e): As informed by Ministry of Finance, Department of Revenue, no such proposal is under consideration.

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

ECLGS

Lok Sabha Unstarred Question No. 1662

Shrimati Shardaben Anilbhai Patel:

Shri Dulal Chand Goswami:

Shri Mitesh Rameshbhai Patel (Bakabhai):

Q. Will the Minister of **MICRO, SMALL AND MEDIUM ENTERPRISES** be pleased to state:

(a) the number of Micro, Small and Medium Enterprises (MSMEs) registered with the Government;

(b) the number of the said enterprises benefitted under Covid-19 scheme of the Government;

(c) the number and percentage of the said enterprises which have applied for availing benefits under the Emergency Credit Line Guarantee Scheme (ECLGS) introduced by the Government; and

(d) the number and percentage of the said enterprises which have availed the benefits under ECLGS?

Answered on 29th July 2021

A. (a): As per Udyog Aadhaar Portal, number of MSMEs registered (since September 2015 to 30.06.2020) in All India was 102,32,468.

On 1st July, 2020, after adoption of new definition of MSMEs, a new registration portal 'Udyam Registration' has been launched by M/o MSME and so far 36,70,538 classified MSMEs are registered on the portal in All India (from 01.07.2020 to 15.07.2021).

(b) to (d): The Emergency Credit Line Guarantee Scheme (ECLGS) was announced as a part of the Aatma Nirbhar Bharat Package 2020 with the objective to help MSMEs/small businesses to meet their operational liabilities and resume businesses in the view of the distress caused by the COVID-19 crises, by providing MLIs 100 per cent guarantee against any losses suffered by the due to non-repayment of the ECLGS funding by borrowers. The overall cap of admissible guarantee of ECLGS has further been raised from Rs. 3 lakh crore to Rs. 4.5 lakh crore on 28.06.2021.

As part of the Aatma Nirbhar Bharat Abhiyaan, under the Emergency Credit Line Guarantee Scheme (ECLGS), around 1.09 crore MSME borrowers have been provided with guarantee support amounting to Rs. 1.65 lakh crore as on 02.07.2021.

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

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Submission Date Extended to 25th October 2021 wrt Evaluation of Certain PRE 1988 permitted Fixed Dose Combinations (FDCs) de novo for manufacture for sale in the Country without due approval from Central Licensing Authority - reg.

ATTENTION MEMBERS

IDMA has received an email communication on 19th August 2021 from Dr. V G Somani, DCG(I) in regards to the Public Notice dated 19th August 2021 (as reproduced below) on the subject mentioned above **wherein the date for submission of the information has been extended from 25th August 2021 to 25th October 2021.**

This is continuation to this Directorate Notice of even number dated 26th July 2021 on the subject cited above whereby all the concerned stakeholders were requested to submit the information in the prescribed format by **25th August 2021** till 5.00 p.m.

We are thankful to our DCG(I) Dr. V G Somani for this kind gesture.

We therefore once again request all our members to submit their information in the prescribed format along with relevant supporting documents in hard copy as well as soft copy (i.e. in C.D. Form) to the CDSCO (FDC Division) Office, New Delhi latest by **25th October 2021 till 5.00 p.m.**

Thanks & regards,

Daara B Patel
Secretary - General

Evaluation of certain pre 1988 permitted Fixed Dose Combinations (FDCs) de novo for manufacture for sale in the country without due approval from Central Licensing Authority - reg.

File No. 4-01/2013-DC (Misc. 13 PSC Part II), dated 19th August 2021

This is in continuation to this Directorate notice of even number dated 26.07.2021 on the subject cited above whereby all the concerned stakeholders were requested to submit the information in the prescribed format by 25.08.2021 till 5:00 PM.

In this regard, various representations were received requesting for further extending the timeline for submission of the information. The issue was considered by this office and it has been decided that concerned stakeholders may be permitted to submit the information in the prescribed format by 25.10.2021 till 5:00 PM.

In view of above, all the concerned stakeholders may note that date for submission of information in the prescribed format along with relevant supporting documents in hard copy as well as soft copy (i.e. in C.D. Form) is extended upto 25.10.2021 till 5:00 PM.

Sanjeev Kumar,
Deputy Drugs Controller (India),
Central Drugs Standard Control Organization,
Directorate General of Health Services,
New Delhi.

Limited trade pact with US deferred: Working with US on market access issues, says Piyush Goyal

Goyal was apprising exporters of the opportunities on the FTA front that they can reasonably expect over the short-to-medium term and manage their expectations accordingly and boost exports.

The US is India's largest export market, having made up for outbound shipment of almost $52 billion in FY21. (Representative image)

The US has hinted that it no longer wants a "limited" trade deal with India that was negotiated for months under the Trump administration and was to cover products with annual bilateral trade of about $13 billion.

Addressing top representatives of over a dozen export promotion councils and others at a meeting in Mumbai on Thursday, Commerce and Industry Minister Piyush Goyal said: "The US, as of now, has kind of indicated that they are not looking for a new trade agreement. But we look at working with them on market access issues on both sides. That will also be a big opportunity for our export sector."

The talks on market access issues will likely cover non-tariff barriers, mutual recognition agreements and quality standards of imported products.

The US is India's largest export market, having made up for outbound shipment of almost $52 billion in FY21.

However, Australia has shown interest in hammering out an early-harvest deal with India soon, which will possibly be followed by similar pacts with the UK and the UAE, the minister said, as he elaborated on the government's efforts to expedite talks with key economies to forge fair and balanced trade ties. Broader free trade agreements (FTAs) involving a vast number of tariff lines can be taken up with these economies once the early-harvest deals are clinched.

Addressing concerns of exporters over the Remission of Duties and Taxes on Exported Products (RoDTEP) scheme, the minister said certain sectors (steel, pharma and chemicals) had to be kept out of its ambit this fiscal due to funds constraint. However, going forward, if there is any issue, the government could have a relook at it.

Goyal said he had already urged the finance ministry to set up a panel, either under former commerce secretary GK Pillai who headed the RoDTEP panel or somebody else, to look at any issue that may arise out of the operationalisation of the RoDTEP scheme, including requests of special economic zones or export-oriented units that felt left out of the refund programme.

However, the Minister made it clear that both RoDTEP and RoSCTL (for garments and made-up exporters) are fully WTO-compatible, and are not incentive programmes (like the MEIS).

As for trade deals, Goyal exuded confidence that once a deal with the UAE is signed, the stage will be set for similar pacts with other west Asian nations. India is looking at a trade pact with Israel as well. Trade negotiations with Canada could resume after elections are over there later this year.

However, the FTA negotiations with the EU, expected to resume later in 2021 after a gap of about eight years, could be a time-consuming process, he said, as the Bloc has 27 members with different interests. Though the EU has lost some sheen after Brexit, it still remains an important market for India. The EU, including the UK, was India's largest destination (as a trade bloc) in FY20 (before the pandemic struck), with a 17% share in the country's overall exports. Importantly, the UK accounted for 16% of India's $53.7-billion exports to the EU in FY20.

Goyal was apprising exporters of the opportunities on the FTA front that they can reasonably expect over the short-to-medium term and manage their expectations accordingly and boost exports. "Our effort is to ensure focus on countries where we have significant potential, where we can compete better and where market size is significant," he said, as he asked exporters to strive hard to achieve the lofty FY22 merchandise export target of $400 billion.

The minister also told the exporters that the country has revamped its FTA strategy. These pacts are being formulated after a comprehensive interactive process with domestic industry to ensure that "FTAs are fairly and equitably crafted". "At the same time, FTAs cannot be a one-way traffic, we also need to open our markets, if we want a larger share in foreign markets. So, we need to identify areas where we can withstand competition. We can sort out FTAs fairly quickly, if the areas where we have the ability to compete internationally can be identified, as part of a collective effort," he said, according to an official statement.

The minister impressed on all export promotion councils (EPCs) to take immediate and effective steps to rise to the challenge of achieving the merchandise export target of $400 billion for FY22 from $291 billion in FY21. He has also set a lofty target of $2 trillion for both goods and services exports by FY30.

"We need to maintain the export momentum for the next 8 months, with $34 billion exports per month to achieve this target. The goal is ambitious, but possible if all including EPCs and their members work together," he said.

To help ramp up exports, the commerce ministry will have two dedicated divisions for the services sector alone, Goyal said. Currently, one joint secretary looks after the services sector, in addition to his other responsibilities at the ministry.

Source: Banikinkar Pattanayak, Financial Express, 20.08.2021

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RoDTEP: A work in progress

An exclusion that needs to be remedied is that of Manufacturing and Other Operations in a Warehouse (MOOW)

It is expected that the soon to be announced Foreign Trade Policy will emphasise this aspect.

The announcement of the Remission of Duties and Taxes on Exported Products (RoDTEP) scheme by the Centre on August 17 elicited mixed feelings from exporters. Some have expressed relief at the guidelines and rates of the scheme being notified, while many are disappointed at the rates of remission being lower than expected. Representatives of many exporting sectors believe, in order to incentivise exports, the Centre must give higher rates of remission.

The RoDTEP scheme is meant to neutralise the cost impact of duties and taxes in the supply-chain, which are not otherwise neutralised by duty drawback, tax credits, tax refund or similar existing mechanisms. The government has studiously avoided using the word 'incentive' in any of its communiques on the RoDTEP scheme. The reason is that under the WTO rules, specifically under the Subsidies and Countervailing Measures Agreement, financial benefits to exporters provided by the government in the form of incentives are prohibited for countries above a certain stage of development. That was the ground on which the earlier scheme, the Merchandise Exports of India Scheme (MEIS), was held to be violative of WTO rules by a disputes panel in 2019. In view of this, the Centre had announced the replacement of the MEIS scheme with RoDTEP wherein the exporters are compensated only to the extent of uncompensated duty and tax cost incurred in production of export goods.

The schedule of remission rates was put together by the government after painstaking compilation of duties' and taxes' cost at various stages of production of export goods. Understandably, the exercise was time-consuming as it involved collection of data in consultation with various industry bodies, examination of the data, and computation of the remission rates based on the same. This was essential so that the scheme could survive any challenge of legitimacy at the WTO. Perhaps this is also the reason why the rates of remission are conservative as authorities decided that they should err on the side of caution. Another factor that could have governed the decision of the government is the high buoyancy visible in India's exports in the period April-July 2021. It stands to reason that if exports are doing well on their own, then sustained export growth can be better ensured by strengthening infrastructure and trade governance rather than providing financial incentives that could run afoul of WTO. It is expected that the soon to be announced Foreign Trade Policy will emphasise this aspect.

Amongst the items in the RoDTEP list are certain exclusions, with some chapters under the Harmonized System of Nomenclature (HSN) based Indian Customs Tariff completely excluded from the benefit of the scheme. These are tobacco products, mineral products, chemicals,

pharmaceuticals and fertilisers, wood pulp, fibrous cellulosic material, apparel and made up textile articles, iron, steel and articles thereof.

Another set of exclusions from benefits under the RoDTEP scheme is mentioned under the heading of 'Ineligible Supplies/Items/Categories under the scheme'. This list includes among others, exports under Advance Authorisation, Duty Free Import Authorisation, 100% Export Oriented Units, Export Processing Zones, Special Economic Zones, and products manufactured in a customs bonded warehouse. These schemes have existed for quite some time as export enablers and their exclusion from RoDTEP benefits could rob them of some popularity, considering there was no such exclusion under the earlier MEIS scheme. Further, duty drawback administered by the finance ministry, can be claimed simultaneously with RoDTEP benefits. The guidelines issued by the government however hold out some hope for most of these existing schemes, stating that the inclusion of most of the aforementioned categories and their RoDTEP rates would be decided based on the recommendations of the RoDTEP committee. One exclusion however that needs to be remedied, or at least be given beneficial consideration under RoDTEP, is the Manufacturing and Other Operations in a Warehouse (MOOW). This scheme has been highly publicised by the Centre, and has been attracting a good amount of interest amongst global manufacturing companies. It will continue to be attractive if RoDTEP benefits are not denied to those operating under MOOW.

As the government tweaks the scheme with inputs from various industry bodies, it is expected that, along with the soon-to-be-announced Foreign Trade Policy, it will add to the current momentum of exports from India.

The author is Partner (trade and customs), KPMG in India, Views are personal

Source: Manasvi Srivastava, Financial Express, 20.08.2021

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Exporters want steel, pharma under RoDTEP

Disappointed with the exclusion of iron and steel, chemicals and pharma from the ambit of the new input duty remission scheme for exports and lower rates fixed for many sectors, exporters have asked the government to take a relook and make suitable additions and increases.

The rates under the Remission of Duties and Taxes on Exported Products (RoDTEP), the Centre's new scheme to refund all input taxes and levies paid by exporters with an outlay of ₹12,450 crore, were announced on August 17 and will be applicable from January 1, 2021.

Profits may take a hit

In a petition to Commerce & Industry Minister Piyush Goyal, exporters' body FIEO pointed out that when the RoDTEP Scheme was announced on January 1, iron & steel, pharmaceuticals and chemicals were not in the excluded categories. "Moreover, all the exporters of the product groups have made shipment under the RoDTEP and also have the notional RoDTEP rates in their shipping bills," the letter added. This means that the pricing of the export items has been done assuming that they would get RoDTEP benefits. Now that it is likely that these categories will not get RoDTEP benefit, their profits may take a hit.

Agreeing with the government that some of these sectors, like iron and steel, were doing very well, the letter pointed out that though many units in the sector had impressive top lines, they were struggling with their bottom-lines. FIEO said the government must revisit the issue and extend the benefit to these sectors as well.

The exporters' organisation also pointed out that several sectors had complained that the rates of reimbursements fixed for a number of sectors were lower than the data shared on the taxes and levies actually paid.

"We have urged those exporters to share the data submitted to the committee so that the issue may be re-looked into. We agree that the committee has only worked on the data submitted by the exporter/export organisations but there may have been limitations due to the prevailing pandemic condition. Therefore, if the industry is now providing comprehensive and updated data, the RoDTEP Committee may be requested to re-visit the matter," the letter stated.

Exporters from sectors such as electronics and electrical products, engineering goods, and several agricultural items have expressed dissatisfaction with the RoDTEP rates, fixed between 0.5 per and 4.3 per cent, of value of the exported products.

Rates in MEIS

The Merchandise Export from India Scheme (MEIS), which was replaced by RoDTEP, offered higher remission rates in general for most sectors. However, since the rates

were not directly linked to the input taxes paid, it was ruled by the WTO as incompatible with multilateral trade norms and had to go.

Exporters argue that there is scope even within the RoDTEP, which had been painstakingly linked in a transparent manner with input taxes and levies paid by exporters, for rates to go up in many sectors as the actual rates announced were lower than what the taxes paid added up to.

Source : Business Line, 20.8.2021

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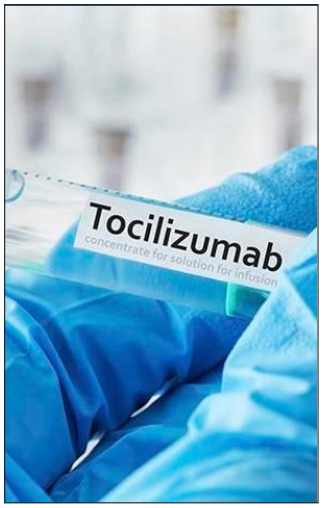
Roche warns of shortage of Covid-19 drug tocilizumab

WHO calls for tech transfer to enable more firms to produce it



After Covid-19 vaccines, Roche's tocilizumab is seeing an unprecedented demand and pressure on its global supplies.

And this has lead to agencies like Unitaid and World Health Organization to call for a technology transfer to facilitate more companies to make the product and shore-up supplies. Roche sells tocilizumab in India through Cipla, a deal formalised in 2018. Tocilizumab (brand name Actemra/RoActemra), is an IL6 inhibitor recommended by the WHO in June, to treat severe Covid-19 cases. It plays a key role in decreasing mortality and reducing the need for invasive mechanical ventilation among severely ill patients, when delivered alongside oxygen and corticosteroids.

But days ago, Roche cautioned of a global shortage of these drugs in the weeks and months ahead, "due to the unprecedented surge in worldwide demand, with US demand spiking to well-beyond 400 per cent of pre-Covid levels over the last two weeks alone". This, Roche said was "due to global manufacturing capacity limits, raw material supply constraints, the complex, labour-intensive process of manufacturing biologics, and the dynamically evolving nature of the pandemic".

Reacting to Roche's statement, the two UN agencies urged Roche "to facilitate technology transfer and knowledge and data sharing to broaden access to this important treatment". In fact, the WHO has called for an Expression of Interest to expand the number of quality-assured manufacturers of the drug and thus increase global supplies.

Not asserting patents

On whether Roche was exploring production alliances in India or elsewhere, the multinational told *Business Line:* "In the case of Actemra, we have taken the decision to not assert any patent rights against the use of Actemra to treat Covid-19 in LMICs (low- and middle-income countries) during the current pandemic." This decision was taken "to ensure that companies who are ready and able to produce biosimilar versions of Actemra could do so without delay caused by licensing negotiations for a voluntary license and without any legal uncertainty in relation to our (Roche and Chugai) patent rights", the company said.

During 2021, Roche supplied Actemra/RoActemra at levels that have increased by more than 100 per cent compared to the pre-pandemic period. And, In India, "since the start of the pandemic, we have made available approximately 2,000 per cent above the normal supply of Actemra", it added.

Call to lower price

In July, Médecins Sans Frontières/Doctors Without Borders (MSF) had called on Swiss pharmaceutical company Roche, the world's sole producer of the drug, to lower the price of the drug to make it affordable and accessible. MSF urged the company to "share the know-how, master cell lines and technology needed to produce this drug with other manufacturers across the world to ensure supply and improved access".

Roche said that even ahead of data on Actemra/RoActemra in Covid-19 becoming available in 2020, it had scaled up manufacturing and "contracted with all available large-scale manufacturers around the world to transfer our technologies – a very complex process, which is still ongoing – and maximising production." Its largest manufacturing facility is dedicated exclusively to producing treatments for patients with Covid-19, it added.

Source : The Hindu Business Line, 19.08.2021

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Shapoorji Mistry and Dadachanji-led Kaisha Group to enter pharma space

Plans to launch brands in antacids, analgesics, blood thinners, bump up hiring

Shapoorji Pallonji Mistry and Kairus Dadachanjii-led Kaisha Group, which recently exited a joint venture with German speciality glass company Schott, is now looking to launch its own pharma products in about six months.

Kaisha Group has several companies under its fold such as Kaisha Lifesciences, Sovereign Pharma, Kaisha Packaging, which cover the entire value chain from drug manufacturing to packaging. The Dadachanjis and Mistry now plan to tap the frontend of the pharma value chain by launching their own brands.

For starters, Kaisha Lifesciences has already developed some 8-9 products, most of which are already registered in India. Rishad Dadachanji, managing director of Kaisha Lifesciences, told Business Standard that these products are antacids, analgesics and blood thinners. "We have a 25-member R&D team at Kaisha, and we are also adding more people. During the past few years, we have invested around Rs 50 crore or so in product development," he added.

The firm is now recruiting a sales force and putting up a front-end team. "We are targeting to launch some products in the market in around six months' time," Dadachanji said. The group plans to start from the Mumbai market and slowly spread to other geographies.

The reason it exited the Schott joint venture was to focus on its pharmaceutical business.

Kaisha's products will be manufactured by group firm, Sovereign Pharma which is a contract manufacturer of injectables, ampoules etc. It makes complex products like the antiviral remdesivir, which is used to treat Covid-19 patients. Sovereign currently manufactures on contract basis for multinationals like Pfizer, Novartis, Mylan apart from Indian pharma firms.

Dadachanji says the group plans to add more production lines to Sovereign Pharma's plant at Daman.

The Dadachanjis also have another unit, Kairesh Innotech, which does not have investments from Mistry. Kairesh Innotech develops drug delivery systems. Dadachanji says that he would use these innovations in his products to create an edge over the other brands available in the market.

Source: Sohini Das, Business Standard, 20.08.2021

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A packaging directive for tinplate, tin-free steel is slowing down supplies at your grocery store

Manufacturers of food, beverages, paints, room fresheners and pharmaceuticals that use tin cans and peel-off packaging are facing shortages, forcing them to delay or pare production.

The packaging shortage is hitting chocolate, juice and paint companies that are looking to ramp up production in anticipation of higher demand during the upcoming festive season.

This follows a Bureau of India Standards (BIS) order effective last month. It mandates use of BIS-certified tinplate and tin-free steel for cans, easy-open ends and peel-off ends for packaging. The certification requirement has created a shortage of raw material. The industry had been importing 90% of these materials since local production isn't adequate.

"There is a lag effect in implementing the BIS certification by importers because of Covid-related supply constraints in recent months, and this is causing disruptions," said RS Sodhi, managing director of Gujarat Cooperative Milk Marketing Federation Ltd, maker of Amul chocolates and ice-cream. India's largest dairy brand sells some of its cheese, flavoured milk and infant foods in tin-based cans and containers.

The government had mandated BIS certification in July last year and given the industry until January 2021 to comply, extending this by six months. Industry executives say international suppliers have been unable to get BIS certification because of Covid-related disruptions.

Production Hampered, Or Even Stalled

Demand for tinplate and tin-free steel from the domestic industry is about 700,000 tonnes annually. Only two domestic companies manufacture the material.

"This is a problem waiting to accentuate further. Supply chain disruptions are brewing and will be further accelerated, especially for those with limited raw material bandwidth," said Yogesh Bellani, chief of Field Fresh

Foods, which makes Del Monte juices and condiments. Most Del Monte juices are packaged in cans.

"Production is being hampered, or even stalled in some cases, with acute shortage for such tin-based packs for various categories, including juices, cheeses, paints and even some medicines that use tin peel-off," said Sanjay Bhatia, president of the Metal Container Manufacturers Association (MCMA), which represents manufacturers of such packaging.

The BIS requirement is aimed at encouraging greater domestic production and reducing imports.

Further Extension Denied

"While we are supportive of the government's inclination to rely more on Indian manufacturers and minimise imports, some more time would be beneficial for the industry to comply with the updated certifications," Sodhi said. The industry had asked that the steel and steel products quality control order be pushed back until March next year, but the government rejected this.

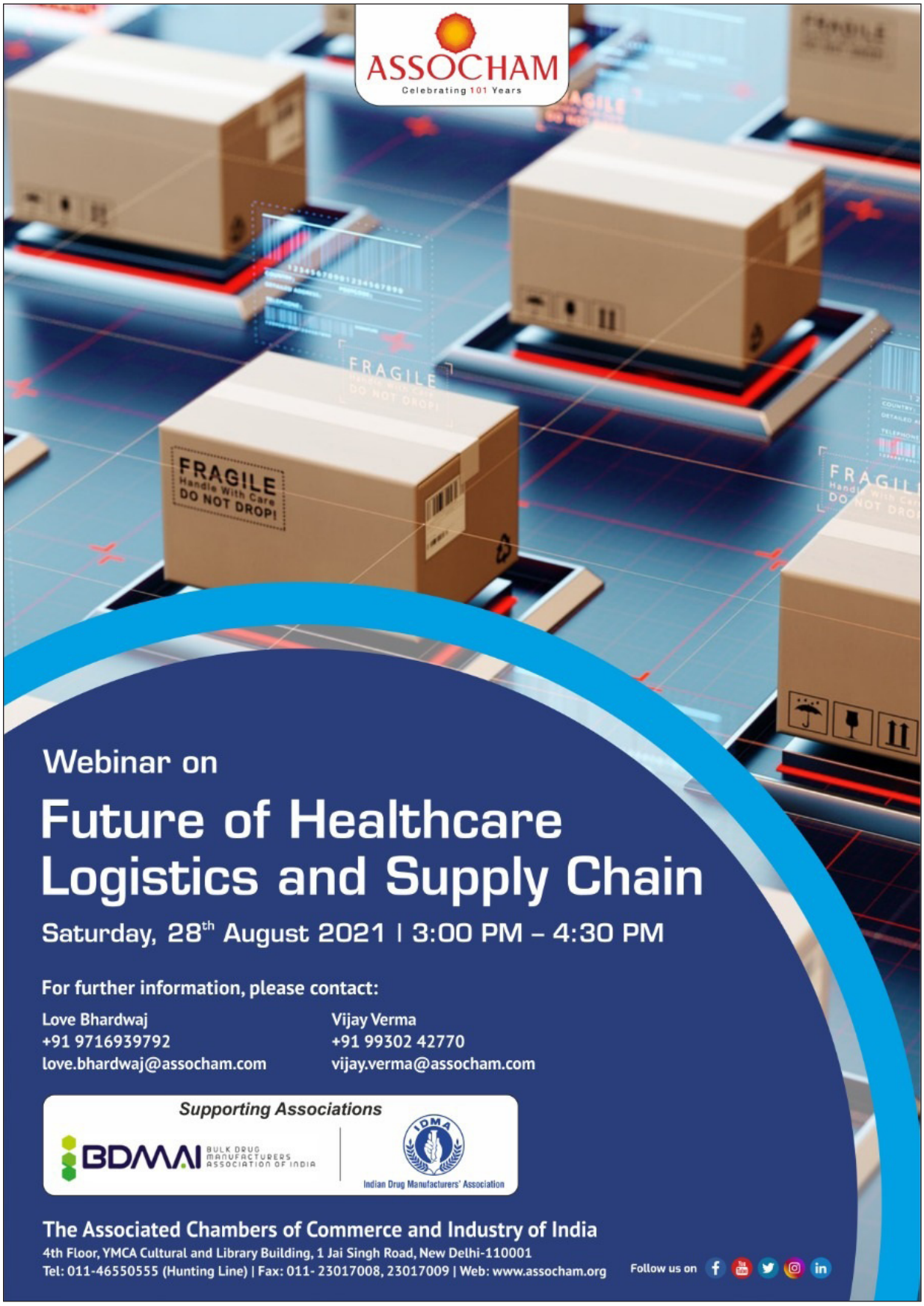
"This disruption has come at a time (when) we had targets to increase manufacturing of boxes and containers of chocolates, which are expected to be in high demand, especially in the upcoming festive months," said a senior executive at a large chocolate maker.

Industry executives said obtaining BIS certification involves complex procedures and international suppliers will not be able to get quickly approved.

Tinplate steel, or a sheet of steel coated with tin, is used for packaging products across sectors including foods, beverages, room fresheners, cans used for insecticides and so on, all of which are end-users for open-end and peel-off packaging.

"The MCMA recommends that the BIS notification be reviewed as it will impact the overall metal packaging industry, which employs over a lakh people," Bhatia added.

Source : Economic Times, 20.08.2021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Agenda

Welcome Address & Opening Remarks by – Shri Milan R. Patel, Chairman, IDMA GSB	04:00 PM to 04:05 PM
About Program & Speakers – Amit Srivastava, Chief Catalysts, Nutrify Today	04:05 PM to 04:10 PM
Workshops **MODERATOR** **Dr. Vikram A. Munshi,** *Founder, WhiteSpace Consulting & Capability Building* **PANELISTS** **1.Vikas Bansi** – *V. P. & Head (India Branded Pharmaceuticals) Jubilant Pharmova Ltd.* **2.Dhaval Katkar** - *Sr. Executive , Glenmark Pharma* **3.Brijesh Kapil** – *Experienced Global Consumer Healthcare Professional* **4.Shantaprasad Nagarmath** – *Commercial Director, Abbott*	04:10 PM to 05:00 PM
Q & A – Session would be handled by the Moderator	05:00 PM to 05:10 PM
Vote of Thanks – Shri Sumit J. Agrawal , Hon. Secretary, IDMA GSB	05:10 PM to 05:15 PM

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Course fee	:	Complimentary

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Dr. Raghunandan HV . PhD (Kuvempu University)
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He is a Pharmacist with over 25+ years of progressive experience in Pharmaceutical Quality Assurance, Quality Control, Regulatory affairs, Manufacturing of formulations/API's/Biological, Contract Manufacturing and Pharmaceutical Technical Consultation,(Reg. affairs, Product Development and Quality), Research and Pharmaceutical Education. He is an experienced Quality Auditor and has good Knowledge and know-how of Quality audits at site functional level and corporate Quality Management level.

Has also experienced in academics in the leadership role as Deputy Director and Professor at JSS Academy of Higher Education and Research. Connected Pharmaceutical Industries with Institute for student exchange and faculty Interactions. Having around 17 years of Pharmaceutical Industry work experience in the area of essential medication manufacture, and quality, regulatory. He also has work exposure to FMCG products, medical devices.

Kindly reach out to us at prathyusha.borra@usp.org / call at 9121031821 for any difficulty in registration or to get more information about the course.

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