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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

Attention Member

Postponement of our IDMA 60th Year Celebrations scheduled for 7th & 8th January 2022 due to the current Covid-19 and the Omicron variant situation
New dates will be announced shortly

(Page No. 6)

HIGHLIGHTS

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IDMA BULLETIN

Vol. No. 52 **Issue No. 48** **22 to 30 December 2021**

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NATIONAL NEWS:

ASYMMETRIC ORGANOCATALYSIS!

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

Dear Reader,

Two basic reactions that were taught to us in the organic chemistry courses were the aldol condensation reaction and the Diels-Alder reaction. In aldol condensation, discovered by the French chemist Charles Wurtz in 1872, an enolate ion reacts with a carbonyl compound in the presence of an acid/base catalyst to form a β-hydroxy aldehyde or a β-hydroxy ketone, usually followed by dehydration to give a conjugated enone. If the enolate ion and the carbonyl group are present in the same molecule, then the aldol reaction is intramolecular. It is an extremely useful carbon-carbon bond-forming reaction. The Diels-Alder reaction, discovered in 1928 by the German chemist Otto Diels and his student Kurt Alder, is the reaction between a conjugated diene and an alkene, a so-called dienophile, to form an unsaturated six-membered ring. It is called a cycloaddition reaction, since the reaction involves the formation of a cyclic product via a cyclic transition state. Uncatalysed Diels–Alder reactions usually require extended reaction times at elevated pressures and temperatures with the formation of by-products, hence various catalysts are employed. The Diels-Alder reaction also has great industrial relevance and the discoverers were crowned with the 1950 Nobel Prize in Chemistry. The aldol condensation reaction and the Diels-Alder reaction typically require catalysts, basically Brønsted acids, Brønsted bases, Lewis acids or Lewis bases. This triggered the minds of Dr. David MacMillan and Dr. Benjamin List for different reasons at different locations in USA around not so different times, more than twenty years ago, culminating in their being jointly awarded the Nobel Prize in Chemistry for this year.

David MacMillan was born in Bellshill, Scotland and is proud of his working class upbringing in New Stevenston. Extremely grateful for having excellent teachers at school and later at Glasgow University ("trust the institutions", he says), he followed his sibling, like many of us, to join a physics degree course after school. After one year of attending early morning physics lectures in bitterly cold and wet halls, he switched over to chemistry, where the lectures began two hours later in warm and dry halls. MacMillan obtained his doctorate from the University of California, Irvine and undertook postdoctoral research at Harvard University. Spending eight hours sitting in front of a hood wearing gloves and filling vials with highly air- and moisture-sensitive transition metal catalysts was frustrating and appeared very unnatural. He believed that if catalysis occurs in nature under simple conditions, there must be a way to catalyse reactions using simple, small organic molecules "that all have in their stockrooms". He moved to the University of California, Berkeley in 1998 to fulfil this dream independently. The challenge was to design a molecule which could store and transfer electrons, in much the same way a metal centre accepts and donates charge during a traditional catalytic cycle.

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

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

He experimented with imidazolidinone to this end in Diels-Alder reactions. He subsequently moved to Caltech in 2000 and to Princeton University in 2006. The term "organocatalysis" was first coined in his 2000 JACS seminal publication "New Strategies for Organic Catalysis: The First Highly Enantioselective Organocatalytic Diels-Alder Reaction". His group pioneered cascade catalysis and the use of ordinary light for photoredox catalysis during the days when only UV light was considered to have sufficient energy to be effective.

Benjamin List was born in Frankfurt and went to school there. He was already fascinated by chemistry by the age of 11, although he had not yet been introduced to it. He studied chemistry at the Free University of Berlin, before obtaining his doctorate in 1997 from the Johann-Wolfgang-Goethe University in Frankfurt. He moved to Scripps Research Institute in La Jolla, USA for post-doctoral studies. He returned to Germany in 2003, beginning research at the Max-Planck-Institute für Kohlenforschung in Mülheim and has remained there ever since. List was aware of the largely unnoticed Hajos-Parrish-Eder-Sauer-Wiechert reaction of more than two decades earlier, in which the simple, naturally occurring amino acid proline had indeed catalysed an intramolecular aldol reaction. List began exploring this chemistry in great depth.

MacMillan reminds us that new concepts are not expensive - the raw materials for the first Diels-Alder reaction cost less than 10 cents – though the follow-up may be expensive. Finding new reactivity principles is, of course, not easy. He firmly believes that creativity can be learnt and it is very important to learn to formulate questions. At Princeton, the research happens with the speed of "Tuesday to Friday", that is, experimented in the lab on a Tuesday, the results shared with an industrial partner the same day and the latter confirming and using it by Friday for synthesis. He regrets that a lot of fashion is happening in science.

List views catalysts as one molecule away from magic. He rationalised and structured all that was happening in asymmetric organocatalysis until then in the two Thieme Science of Synthesis volumes of 2013, along with Keiji Maruoka – one for Lewis acids and bases and the other for Brønsted acids and bases. These standard works catalysed further systematic research in organocatalysis: a field where basically electrons or protons are either donated or removed to convert raw materials to products. The Mülheim MPI is a renowned Centre for Catalysis, with great scientists such as Franz Fischer (of Fischer-Tropsch coal hydrogenation fame), Karl Ziegler (of Ziegler-Natta organometallic mixed catalysts for polymerisation fame) and Guenther Wilke (of transition-metal catalysis and polyamide-12 fame) at the helm of affairs for 31, 26 and 24 years, respectively.

List lists the complex alkaloid strychnine, blood-thinner warfarin, anti-depressant paroxetine and the anti-influenza drug oseltamivir as examples where asymmetric organocatalysis has helped dramatically. Strychnine, for example, can now be produced in only 12 steps and the production process is 7000 times more efficient than the classical synthesis method. In perfumery, MacMillan notes that the Swiss fragrance company Firmenich uses organocatalysts in its production of a compound known as the 'bloom constituent'. Experiencing a pleasant burst of fragrance during showering, washing clothes by hand or taking wet fabric out of a washing machine are critical in-use judgement moments for determining a brand or product's value and the 'bloom constituent' has been a tremendous success, especially in the USA. The Princeton Catalysis Initiative, in which all departments talk to each other, is highly productive. One concept introduced is called as "speed dating for scientists", where the hot results of research from the lab are presented in 5-minute presentations, usually in one slide. More informal collusions with each other on the Princeton campus is strongly encouraged. Princeton boasts of 10 Nobel Laureates in chemistry.

The early days of research in the field of asymmetric organocatalysis were tough and competitive between the two groups, with some overlaps. Since then, the field and the mutual respect and admiration have only grown. The Nobel committee staff messaged, for example, List to get the phone number of MacMillan to break the news. Both the Nobel Laureates believe that they are "only scratching on the surface" and there is a lot more to be discovered and understood.

Gone are the days when asymmetric or chiral compounds, whether for use in medicine, perfumery or agriculture, could only be obtained by (enzymatic, whole-cell) biotransformations or by using transition-metal based catalysts. The organocatalysts being discovered around the world as a result of the pioneering work of List and MacMillan are expanding the realms of asymmetric organic synthesis in a manner never imagined or possible before.

Indian Drugs looks forward to receiving papers on organic synthesis using organocatalysis.

Happy reading!

Courtesy: Indian Drugs, Editorial, 58 (10), October 2021

Postponement of IDMA 60th Annual Day

Dear Member,

This refers to our IDMA 60th Year Celebrations which were scheduled to be held on **Friday 7th & Saturday 8th January 2022 at Hotel Sahara Star, Mumbai.**

We have been receiving several calls from our members and exhibitors with regards to the current Covid-19 and the Omicron variant situation and the uncertainty & anxiety it has created. Due to the rapid spreading of the Covid-19 and its variant Omicron throughout the city of Mumbai, our members have been requesting to postpone the gala celebrations.

As a responsible Pharmaceutical Association and keeping in mind the interest, health and safety of our members, the Organizing Committee in an emergency meeting held this evening i.e. Thursday, 30th December 2021 decided to postpone the IDMA 60th Year Deliberations and Celebrations till further notice.

Please be rest assured that the Annual Day Deliberations and Celebrations would be organized with great gusto and enthusiasm at a later date during 2022. We will ensure that members would receive the information at least 30 days prior to the new date.

Also, kindly be rest assured that the registration fees as well as the hotel booking charges paid by you will continue to remain valid till the new date which will be announced.

The inconvenience caused to our members and well-wishers specially the outstation members is sincerely regretted.

We sincerely thank all our members for their support, co-operation and understanding during these tough and trying times.

Wishing you, your family and all at your esteemed organization a safe, healthy, fruitful and a covid-19 variant free year 2022.

Thanking you,

Yours sincerely,
For Indian Drug Manufacturers' Association,

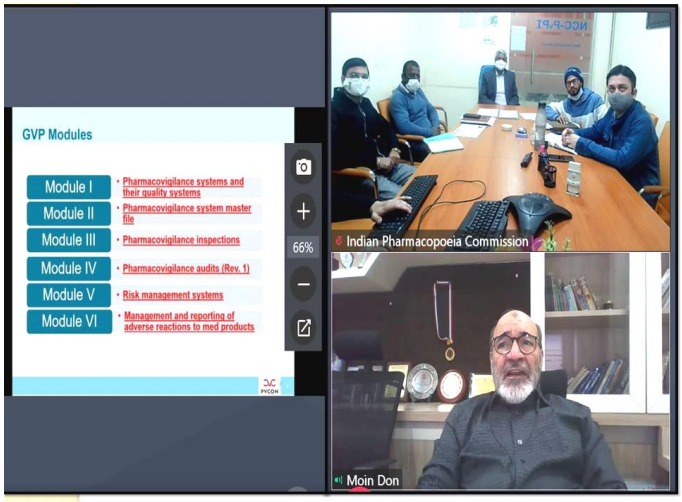
Bharat Shah
Chairman, Organizing Committee, IDMA
60th Year Celebrations

Mahesh H Doshi
National President

Daara B Patel
Secretary - General

PRESS RELEASE

Webinar organized by the National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI) on "Basics of Good Pharmacovigilance Practices with reference to Module VI"



The National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI) located at Indian Pharmacopoeia Commission Ghaziabad, successfully organized a Webinar on "Basics of Good Pharmacovigilance Practices with reference to Module VI" for Pharmacovigilance Associate under PvPI on 29th December 2021 by **Mr. Moin Don** (CEO, PVCON Consulting Services).

The webinar started with welcome address by Dr. Jai Prakash, Officer-in-Charge, PvPI. He extended his warm greetings and best wishes to all the participants on behalf of NCC-PvPI, IPC.

A total of 103 participants (Pharmacovigilance Associates) from ADR Monitoring Centre across the country attended this webinar. Dr. R.S Ray, Mr. Akash Deep Rawat, Mr. Girjesh Vishwakarma, Mr. Omkar Mishra from NCC PvPI supported during the webinar.

Note: Please visit IPC website (www.ipc.gov.in) for regular updates.

● ● ●

Extension of Last Date for Submitting applications for Scrip based FTP Schemes

Notification No. 48/2015-2020-DGFT, dated 31st December 2021

In exercise of the powers conferred by Section 5 of the Foreign Trade (Development and Regulation) Act, 1992 read with Para 1.02 of the Foreign Trade Policy, 2015-20, the Central Government hereby amends the para 3.13A of the FTP 2015-20 (as notified vide Notification no. 26 dated 16th September, 2021) with immediate effect. The para 3.13A shall now read as below:

3.13A: Last Date of Submitting Applications for Scrip based Schemes

(a) In supersession of the existing laid down provisions in the Hand Book of Procedures, 2015-20 with regard to last date for submitting online applications for scrip based claims, the last date for submitting online applications stands revised to **31st January 2022** for the following schemes i.e.

i. for MEIS (for exports made in the period (s) 01.07.2018 to 31.03.2019, 01.04.2019 to 31.03.2020 and 01.04.2020 to 31.12.2020),

ii. for SEIS (for service exports rendered for FY 18-19 and FY 2019-20),

iii. for 2 % additional ad hoc incentive (under para 3.25 of the FTP — for exports made in the period 01.01.2020 to 31.03.2020 only)

iv. for ROSCTL (for exports made from 07.03.2019 to 31.12.2020) and

v. for ROSL (for exports made upto 06.03.2019 for which claims have not yet been disbursed under scrip mechanism).

After **31.01.2022**, no further applications would be allowed to be submitted and they would become time-barred. Late cut provisions shall also not be available for submitting claims at a later date.

(b) In supersession of the laid down provisions on applicable late cut as in para 9.02 of the HBP, the new late cut for applications submitted upto **31.01.2022** as indicated above shall be:

Sr. No.	Scheme	Period of Exports (Let Export Date in the period) / Services rendered in the period	Late Cut (as % age of Entitlement under the Scheme)
1	MEIS	FY 2018-19 (01.07.2018 to 31.03.2019)	10%
2	MEIS	FY 2019-20 and FY 2020-21 (upto 31.12.2020)	Nil
3	SEIS	FY 2018-19	5 %
4	SEIS	FY 2019-20	Nil
5	ROSCTL	07.03.2019 to 31.12.2020	Nil
6	ROSL	Upto 06.03.2019	Nil

Effect of this Notification: The last date of submitting applications under MEIS, SEIS, ROSCTL, ROSL and 2% additional ad hoc incentive (under para 3.25 of FTP) which was earlier notified to be 31.12.2021 has been extended till **31.01.2022.**

File no. 01/61/180/288/AM20/ PC-3 (Part 1)

Amit Yadav,
Director General of Foreign Trade and Additional Secretary,
Ministry of Commerce & Industry,
Department of Commerce,
Udyog Bhawan,
New Delhi

In Lok Sabha & In Rajya Sabha

In Rajya Sabha

Investment by foreign companies

Rajya Sabha Unstarred Question No. 684

Dr. Kirodi Lal Meena:

Q. Will the Minister of Commerce and Industry be pleased to state:

(a) whether any reformative efforts have been taken by Government to attract investment by foreign companies and setting up trading units in India;

(b) if so, the efforts made towards this and the sectors in which said efforts have been made;

(c) whether Government is currently taking steps or proposes to take steps in this direction; and

(d) if so, the details of possible measures for attracting foreign investment in the country?

Answered on 3rd December 2021

A. (a) & (b): Government has put in place a liberal and transparent policy for Foreign Direct Investment (FDI), wherein most of the sectors are open to FDI under the automatic route. FDI Policy in India has been liberalized and simplified in the past few years, especially in the trading sector. 100% FDI is permitted in Single Brand Product Retail Trading (SBRT) and 51% FDI is permitted in Multi Brand Retail Trading (MBRT). Further, 100% FDI is allowed in Food Product Retail Trading to give impetus to food processing industry. Local Sourcing Conditions in SBRT have been eased with a view to provide greater flexibility and ease of operations to SBRT entities.

(c) & (d): The Government reviews the FDI policy on an ongoing basis and makes changes from time to time, to ensure that India remains an attractive & investor friendly destination. The intent is to remove policy bottlenecks that may be hindering investment inflows into the country. Changes are made in the policy after having intensive consultations with stakeholders including apex industry chambers, Associations, representatives of industries/groups and other organizations taking into consideration their views/comments.

The Minister of State in the Ministry of Commerce & Industry (Shri Som Parkash)

In Lok Sabha

Regional Trade Agreements

Lok Sabha Unstarred Question No. 1703

Shri Sushil Kumar Singh:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) the exact number of Regional Trade Agreements (RTAs) category-wise, that India currently has with countries/regions;

(b) the names of Free Trade Agreements (FTAs) India currently has;

(c) whether there are instances of re-routing goods through the countries with which India has RTAs by certain countries;

(d) if so, the ways in which ministry is dealing with this issue; and

(e) the exact monetary value of trade carried out through RTAs in the last five years, year-wise?

Answered on 8th December 2021

A. (a) & (b): India currently has 11 Free Trade Agreements (FTAs)/Regional Trade Agreements (RTAs) with other countries/regions. In addition, it has 6 limited coverage Preferential Trade Agreements (PTAs). The details are as under:

(i) Free Trade Agreements (FTAs)

Sr. No.	Name of the Agreement
1	India-Sri Lanka Free Trade Agreement (FTA)
2	Agreement on South Asian Free Trade Area (SAFTA)
3	India-Nepal Treaty of Trade
4	India-Bhutan Agreement on Trade, Commerce and Transit

5	India-Thailand FTA - Early Harvest Scheme (EHS)
6	India-Singapore Comprehensive Economic Cooperation Agreement (CECA)
7	India-ASEANFTA
8	India-South Korea Comprehensive Economic Partnership Agreement (CEPA)
9	India-Japan CEPA
10	India-Malaysia CECA
11	India-Mauritius Comprehensive Economic Cooperation and Partnership Agreement (CECPA)

(ii) Preferential Trade Agreements (PTAs)

Sr. No.	Name of the Agreement
1	Asia Pacific Trade Agreement (APTA)
2	Global System of Trade Preferences (GSTP)
3	SAARC Preferential Trading Agreement (SAPTA)
4	India-Afghanistan PTA
5	India – MERCOSUR PTA
6	India – Chile PTA

(c) & (d): A few instances of re-routing of goods through the countries with which India has FTAs/ RTAs have come to notice. To address this issue, Government has issued Customs (Administration of Rules of Origin under Trade Agreements) Rules, 2020 (CAROTAR, 2020) with effect from September 21, 2020 to supplement the procedures prescribed under different FTAs. These rules also cast responsibility on the importers to conduct due diligence for ensuring that the goods meet the prescribed rules of origin. The newly introduced provisions act as deterrent against misuse of trade agreements. In addition, an FTA monitoring committee has been constituted with representation from government departments, trade and industry bodies to identify issues relating to misuse of FTA provisions and recommend action.

(e): The value of India's trade with FTA/RTA partner countries in the last five years is as below:

(Figures in US $ Million)

Export/ Import	2016-17	2017-18	2018-19	2019-20	2020-21
India's exports	59152.29	67576.95	73550.13	63515.49	63105.49
India's imports	65789.08	77692.17	93287.57	87327.72	74538.07

(Source: DGCIS)

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

Talks with UAE

Lok Sabha Unstarred Question No. 1709

Shri Asaduddin Owaisi:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) whether the Minister of Commerce was on a visit to UAE recently;

(b) if so, the outcome of the meeting;

(c) whether any roadmap was chalked out for robust investment;

(d) if so, the details thereof; and

(e) the other issues discussed, which are bottlenecks in the trade between the two countries?

Answered on 8th December 2021

A. (a) to (e) : Yes. The Commerce and Industry Minister visited UAE from 1st - 3rd October, 2021. During the visit, the Minister inaugurated Indian Pavilion at World Expo 2020, Dubai on 1st October 2021 and co-chaired with His Highness Sheikh Hamed bin Zayed Al Nahyan, Member of the Executive Council of the Emirate of Abu Dhabi in the 9th Meeting of the India-UAE High Level Joint Task Force on Investments on 2nd October, 2021. During the visit, a comprehensive dialogue was held between the two countries encompassing the entire gamut of bilateral commerce and economic relations with detailed discussions on new opportunities for trade and investment. Both the sides agreed to continue coordination and cooperation at the highest official levels for the early resolution of all the outstanding issues and exploring ways to facilitate investment in areas of mutual interest with potential for economic growth. The details of issues discussed and

outcomes of the meeting have been stated in Joint Press Release after the conclusion of the meeting. Joint Press Release is enclosed at **Annexure**.

Annexure

MINISTRY OF COMMERCE & INDUSTRY

9th Meeting of the India-UAE High Level Joint TaskForce on Investments

His Highness Sheikh Hamed bin Zayed A1 Nahyan, Member of the Executive Council of the Emirate of Abu Dhabi, and Shri Piyush Goyal, Minister of Commerce & Industry, Consumer Affairs, Food & Public Distribution, and Textiles, Government of India, co-chaired the ninth meeting of the UAE-India High Level Joint Task Force on Investments ('the Joint Task Force') today in Dubai. Senior officials representing relevant government authorities and various investment entities from both countries took part in the meeting.

The Joint Task Force was established in 2013 as a key foru m for promoting economic ties between the UAE and India, which were further strengthened by the signing of the Comprehensive Strategic Partnership Agreement between the two countries in January 2017 by Indian Prime Minister Shri Narendra Modi and His Highness Sheikh Mohamed bin Zayed A1 Nahyan, Crown Prince of Abu Dhabi and Deputy Supreme Commander of the UAE Armed Forces.

At this ninth meeting of the Joint Task Force, the two sides noted the impact of the COVID -19 pandemic on global trade and investment and reiterated the importance of continuing to strengthen the deep economic ties between the two countries. Both sides recognised the collaboration between India and UAE during this difficult period and appreciated the leadership provided by the two countries in their regions to confront the pandemic.

The meeting reviewed the positive outcomes achieved through the work of the Joint Task Force to date, and the two sides agreed to continue exploring ways to facilitate investment in areas of mutual interest with the potential for economic growth.

The progress of ongoing discussions for the India -UAE Comprehensive Economic Partnership Agreement, which will be a significant and wide-reaching step in promoting trade and investment between the two countries, was reviewed during the meeting. In this regard, both sides appreciated the efforts made to expedite discussions towards a well-balanced agreement that will considerably deepen bilateral economic ties and benefit the economies of both countries.

Participants also considered ongoing efforts to amend the UAE and India's longstanding Bilateral Investment Treaty and noted the importance of concluding the negotiation process as soon as possible.

At the meeting, discussions were also held on exploring mutually beneficial methods and incentives to facilitate further investment from UAE sovereign investment entities in key priority sectors in India. The positive steps made by the Indian government in this context were noted and both sides agreed to continue to focus on ways of providing tax incentives to certain UAE sovereign investment entities.

The importance of active involvement from the UAE Special Desk within Invest India, the National Investment Promotion Agency of India, in expediting the resolution of both legacy issues and current difficulties experienced by UAE companies and banks in India was discussed. The Indian side also highlighted some long-standing issues faced by Indian investors in the UAE. Both sides agreed to continue coordination and cooperation at the highest official levels for the early resolution of these issues.

Given the importance of air transport in facilitating bilateral ties and people -to-people connections, both sides agreed that their respective civil aviation authorities should continue to work together on a priority basis, for their mutual benefit, to ensure the speedy normalisation of air transport operations between the two countries.

Commenting on the ninth meeting of the Joint Task Force, His Highness Sheikh Hamed bin Zayed A1 Nahyan, Co- Chair of the Joint Task Force and Member of the Executive Council of the Emirate of Abu Dhabi, said:

"India and the UAE share a broad and deep strategic partnership, and this has helped bilateral economic ties continue to strengthen despite the challenges of the COVID-19 pandemic. The Joint Task Force offers an important platform for dialogue between our two countries, raising new opportunities for trade and investment, and removing bottlenecks to further cooperation. Looking ahead, India and the UAE share ambitious goals to expand trade and investment activities between our countries, and the

Joint Task Force will continue to play an important role in achieving these objectives."

Shri Piyush Goyal, Co-Chair of the Joint Task Force and Minister of Commerce & Industry, Consumer Affairs, Food & Public Distribution, and Textiles, Government of India, said:

"India and UAE have longstanding ties which have become stronger in the recent times and our continued engagement even during the pandemic reflects the priority this partnership holds for both our nations. Our leadership accords a special place to our relationship with the UAE and our bilateral forums like the Joint Task Force provide effective mechanisms to build on our long-standing friendship. Given the strong growth prospects of the Indian economy, we look forward to increased investment from the UAE in diverse sectors of India. We are sure that the world will continue to witness greater achievements in the India -UAE partnership in the future."

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

Single Window System

Lok Sabha Unstarred Question No. 1713.

Shri Margani Bharat:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state:

(a) the details of single window rolled out by the Ministry for investors;

(b) whether the proposed window helps end-to-end support to investors and industry and if so, the details thereof; and

(c) the details of the Know Your Approval Service proposed under the National Single Window System?

Answered on 8th December 2021

A. (a) & (b): While presenting Budget 2020-21, Hon'ble Finance Minister announced plans to set up an Investment Clearance Cell (ICC) that will provide "end to end" facilitation and support to investors, including pre-investment advisory, provide information related to land banks and facilitate clearances at Centre and State level. The cell was proposed to operate through an online digital portal.

Subsequently, as per the mandate, DPIIT along with Invest India initiated the process of developing the portal as a National Single Window System (NSWS). Envisioned as a one-stop for taking all the regulatory approvals and services in the country, NSWS [www.nsws.gov.in] was soft-launched on 22nd September, 2021 by Hon'ble Commerce & Industry Minister.

This national portal integrates the existing clearance systems of various Ministries/ Departments of Government of India and State Governments without disruption to their existing IT portals.

Currently, approvals of 19 Ministries/ Departments and 10 States Single Window Systems have been on-boarded on the NSWS Portal. List of the onboarded Ministries/ Departments and States may be seen at **Annexure**.

(c) **:** The Know Your Approvals (KYA) Module is an information wizard which guides investors to identify an indicative list of requisite pre-operations approvals/ licenses applicable. This is facilitated by answering a series of questions which gets populated basis the information provided by the investor in the previous question. Post submission of the KYA questionnaire, the investors are able to view an indicative list of licenses pertaining to the Central/ State Governments that are applicable to them. The investors are also guided on these questions and their applicability/ purpose by an Information Toolbox. This is to enhance the ease of user experience and eliminate information asymmetry on this module.

The KYA service is live on NSWS with 544 approvals across concerned 32 Central Ministries/ Departments and 2715 approvals across 14 States. Total 3259 approvals are listed.

ANNEXURE

Annexure Referred to in reply to parts (a) & (b) of the Lok Sabha Unstarred Question No. 1713 for answer on 08.12.2021.

Ministries/ Departments integrated with NSWS:

1. M/o Corporate Affairs
2. M/o Environment, Forest & Climate Change
3. M/o Labour & Employment
4. D/o Food & Public Distribution
5. D/o Consumer Affairs

6. M/o Health & Family Welfare (FSSAI & CDSCO)
7. D/o Promotion of Industry and Internal Trade
8. D/o Commerce
9. D/o Telecommunications
10. M/o Information & Broadcasting
11. M/o Power
12. M/o Railways
13. D/o Biotechnology
14. D/o Revenue
15. M/o Civil Aviation
16. M/o Agriculture & Farmers Welfare
17. D/o Fisheries
18. M/o Textiles
19. M/o Petroleum and Natural Gas

States integrated with NSWS:

1. Goa
2. Gujarat
3. Himachal Pradesh
4. Odisha
5. Uttar Pradesh
6. Uttarakhand
7. Punjab
8. Karnataka
9. Andhra Pradesh
10. Telangana

The Minister of State in the Ministry of Commerce & Industry (Shri Som Parkash)

Development of Nano Science Technology

Lok Sabha Unstarred Question No.1719

Shri Gnanathiraviam S.:

Q. Will the Minister of **SCIENCE AND TECHNOLOGY** be pleased to state:

(a) whether the Government is aware of the local mission of research and development of Nano Science and Technology;

(b) if so, the details thereof and the steps taken for development in the field;

(c) whether the Government proposes to allocate more funds to encourage effective research work in this field; and

(d) if so, the details thereof ?

Answered on 8th December 2021

A. (a) Yes Sir. The Government of India (GOI), through Department of Science and Technology (DST), launched Nano Science and Technology Initiative (NSTI) in October 2002 to promote research and development in advanced area of Nano S&T. The initiative that was launched, was in line with similar initiatives launched by the developed countries across the world like USA, South Korea, Germany etc. Japan, a leader in Nano R&D, had an early launch almost at the starting of early 1990s.

(b) DST was assigned the nodal Ministry/ Department for the promotion of R&D in Nano Area. As a follow-up of this initiative, the GOI launched the Nano Mission-Phase I (2007-12) as an "Umbrella Capacity Building Program", anchored by DST, with an allocation of Rs. 1000 crores for 5 years. During this period DST supported Nano Science Units in several Institutes/ Universities/ National Labs like Indian Institute of Science-Bengaluru, Indian Institute of Technology - Mumbai, Kanpur, Varanasi and Chennai, Tata Institute of Fundamental Research (TIFR), Mumbai. At the end of Phase-I, in 2011, 4 Computational Materials Science units for exploring new Advanced Nano Materials and its applications were also set up at JNCASR-Bengaluru, Indian Institute of Science-Bengaluru, SN Bose National Centre for Basic Sciences and SP Pune University, Pune. The DST had spend Rs 568.83 crore in this Nano Mission Phase-I.

During the same period, the other scientific Ministries/ Departments/ Agencies recognising the advantage of Nano Size materials R&D also started promoting Nano R&D in their own specific domain. As a result, of these combined R&D efforts by all S&T Departments/ Ministries & other S&T funding agencies, India's position in Nano S&T research publications, that was at twelve position globally in 2002, improved to sixth global position in 2010. It may be noted that since 2005-12, India has been ranked globally as the third fastest growing nation with a Cumulative Aggregated Growth Rate (CAGR) of 29% in scientific publications in Nano Science and Technology. This growth

resulted in India reaching the third global position in 2013-14, which it has retained till now, in terms of research publications in the field of Nano Science & Technology. The Nano Mission was brought under Research and Development Programme in 2017-18 with more focus on developing Nano Technology. In 2019, we supported an Industry-Institute Joint project on development of inner anti-rust coating in pipes used for Chemical and Petro-chemical industries.

Subsequent to launch of Nano Mission Phase – I by DST, D/o Electronics and IT (DeitY) initiated a programme to establish Nanotechnology Initiatives Division to provide competitive support to carry out R&D through Grant-in- Aid (GIA) with a focus on developing Nanoelectronics based technologies and its commercialization. Other respective S&T Ministries/ Departments/ S&T Funding Agencies like D/o Biotechnology, CSIR, ICAR, ICMR, DoS, DAE and DRDO also started supporting R&D in Nano Science and Technology field in their respective domain though their EMR support Schemes. Representatives of all these funding agencies are involved in all meetings of DST.

In 2005, MeitY through one time funding of Rs 100 crore established two state of the art Centre of Excellence in Nano Electronics Research (CENs) at IIT-Mumbai and IISc-Bengaluru respectively to carry out R&D in Nanoelectronics area. R&D carried out at these Centres have resulted in many nanoelectronics based technologies/ sensors. Recently, MeitY and DST had funded a major project titled NNetRA (Nanoelectronics Networking for Research and Application) at IISc and IITs at Mumbai, Chennai, Kharagpur and New Delhi at a total cost of 299 crore, with financial support distributed of 1:1:1 between DST, MeitY and the Institute. The objective of this project is to upgrade projects technologies from TRL 3-5 to TRL - 8-9 (Industry ready technologies for transfer). With two level monitoring done every 6 months followed by a Project Steering Committee every year, the Institutes have been able to upgrade TRL levels of 17 technologies to make them industry ready. These technologies are in five specific areas namely Agriculture, HealthCare, Environment, Devices and Security and Safety.

The Indian Council for Agricultural Research (ICAR) had also initiated R&D in various fields of agriculture and allied areas employing Nanotechnology from 2OO4 onwards. The important areas which they are exploring include:

- Developing Polymeric Nano Materials for Packaging and Efficient Delivery of Nutraceuticals;
- Nano-based detection of organophosphate pesticides using metal- organic framework conjugates;
- Effective delivery of nutrients, insecticides and fungicides through nano-particulates for better yield of ground nut and Chilli;
- Development of nano-particle (NP) based RNA delivery system for imparting resistance to viruses;
- Effects of metal oxide nanoparticles on soil bacterial communities; and
- Improvement in cotton Fabric quality by plasma Nano Technology and using Novel Nano coating for imparting antibacterial and UV protection properties in cotton and other textiles.

The key areas of Nanotechnology related research in Animal and Dairy Sciences include;

- Development of thermostable peste des petits ruminants (PPR) vaccine;
- Using spontaneously assembling of bio-degradable mesoporous silica nano-scaffolds;
- Characterization and studies on residual effect of iron oxide nano particles on frozen bovine spermatozoa;
- Development of stem cell laden nanomaterial scaffold for nerve, bone and cartilage tissue regeneration in animals;
- Development & Evaluation of a nano-carrier based novel Foot-and- Mouth disease virus vaccine for non-parental delivery;
- Nanoparticles as delivery vehicles for fortification of milk and milk products etc.

Recently, the IFFCO's Nano Biotechnology R&D Centre at Kalol, Gujrat has developed liquid Nano Urea that may be a good substitute for solid Urea, since plants can absorb upto 80 percent of Nano Urea which is in the form of a stable particle as against solid Urea which is absorbed as ion that is unstable.

DST, for manpower training, also has Domestic Post-Doctoral Fellowship programme, where candidates who have completed/ submitted their Doctoral Thesis can apply. Also, to generate specialized manpower in the Nano Electronics Area, MeitY has been supporting

a programme called Indian Nanoelectronics User Programme (INUP) since 2008 with DST PIs also emanating from this training at CENs. In September, 2021, MeitY has approved new training programme namely INUP-i2i (Indian Nanoelectronics User Programme-Idea to Innovation) at IIT-Mumbai, IIT-Chennai, IIT-New Delhi and IIT-Kharagpur and IISc to provide the facility at these CENs to maximum researchers in the country, thus expanding the user base and also support/mentor Start-ups/Industry and R&D projects in the nano field.

On the International Collaboration front, Nano Mission now NPNST has already collaborations with DESY, Germany for use of State-of-Art Synchortron namely PETRA-III by Indian Users. In fact, India has contributed for building a India specific Beam Line at PETRA-III against which, DESY has allowed 758 days of Beamline time on the remaining 22 beam lines which has been successfully utilised by Indian Scientists. As a result of this, the DESY has signed an MoU with JNCASR on behalf of DST for further cooperation on similar lines for next 5 years. Till February, 2020, the number of Scientists and students who visited PETRA is 53 with 41 Joint papers published in Journals of repute.

Similarly, we have arrangement with KEK Photon factory under the Japan Agreement for utilising the photon beam lines by Indian Scientists. We have funded an instrumentation attachment with a specific Beam line that is used extensively & dedicatedly by Indian Scietists with Scientists from other countries joining on a competitive basis. We are about to complete the Phase-II of KEK Photon factory and the Joint Steering Committee has given a go ahead to prepare the proposal jointly for Phase-III, which will be processed shortly. Till December, 2020, 243 Scientists and their students have used the facility with 143 Joint Publications in leading Journals.

The third International Collaboration is with Rutherford Appleton Laboratory in Oxfordshire, UK where ISIS Neutron and Muon Source, available in RAL Lab is used by the Indian Scientific Community since 2015. It is a world-leading Centre for Research in the Physical and Life Sciences and the UK Science and Technology Facilities Council (STFC) owns it. ISIS Neutron and Muon Source produces beams of neutrons and muons that allow scientists to study materials at the atomic level using a suite of instruments, often described as 'super-microscopes'. Till March, 2021, 104 Scientists and their PhD students have visited RAL facility and have 20 Joint Publications in leading journals. The STFC is keen to collaborate further for 5 years more and are currently engaged with their Indian Counterparts in developing a Detailed Project Report for submitting the same soon to DST for further processing.

Apart from these three International Collaborations, we also support Indian Scientists for using other beam-line facilities in France, South Korea etc, where they are allotted beam-time on a competitive basis by the facility managers.

(c) & (d) DST, DBT, MeitY, ICAR & ICMR have been continuously providing/ allocating funds to Nano S&T which are limited due to allocation to each body. In fact the output per Re spent is perhaps higher than many of the developed countries. The allocation of core grants to Autonomous Institutes of DST working in the area of Nano S&T has also increased over the last 3 years as is evident from the table below:

Allocation of grants to AIs during the last 2 years (Rs in Lakh)

S. NO	INSTITUTE	2019-2020	2020-2021	% increase
1.	INDIAN ASSOCIATION FOR THE CULTIVATION OF SCIENCE (IACS), KOLKATA	11684.72	12763.00	9
2.	CENTRE FOR NANO AND SOFT MATTER SCIENCES, BENGALURU	1358.46	1374.00	2
3.	INSTITUTE OF NANO SCIENCE AND TECHNOLOGY (INST), MOHALI	2709.00	3189.00	17
4.	INTERNATIONAL ADVANCED RESEARCH CENTRE FOR POWDER METALLURGY AND NEW MATERIALS (ARCI), HYDERABAD	5201.13	6116.00	17

5.	JAWAHARLAL NEHRU CENTRE FOR ADVANCED SCIENTIFIC RESEARCH, BENGALURU	10928.16	10267.00	--
6.	S.N. BOSE NATIONAL CENTRE FOR BASIC SCIENCES (SNB), KOLKATA	3438.64	4469.00	29
		35320.11	38178.00	8

The conversion of Nano Mission into a regular scheme has been recommended by the Third Party Evaluation Committee that evaluated all Schemes of DST, since work in this inter-disciplinary area is/ has opened up several avenues right from Novel Nano Materials with variable parameters for use in Automobiles/ Aircrafts etc. for lighter weight to Nano Electronic based devices, Nano Pharmaceuticals for Health Care to Nano – Agro Food with high nutritional value and Nano based security devices.

Further, it is becoming difficult to undertake such Applied and Translational R&D in Nano S&T area, for technology development for societal benefit. Therefore, the need for providing sustained and more support in this sector would surely make the area attractive for R&D and sustainable in the long-run. This needs to be executed through a coordinated way with close dialogue with the other User Ministry/ Department/ S&T funding body in a meaningful way. This may open means for suitable funding to Nano S&T, if done in a proper coordinated way, to avoid duplicities/ redundancies in funding.

Minister of State (Independent Charge) of the Ministry of Science and Technology and Earth Sciences (Dr. Jitendra Singh)

Export Turnover

Lok Sabha Unstarred Question No. 1819

Shri Velusamy P.:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) the total merchant export turnover during the last three years and the current year;

(b) whether the Government is having any data on default payment on exports;

(c) if so, the accumulated amount outstanding with the various financial institutions till date;

(d) the total amount settled by the ECGC (Export Credit Guarantee Corporation) till date to various default payments to banks;

(e) whether the Government is having any proposal to infuse capital to support ECGC; and

(f) if so, the details thereof?

Answered on 8th December 2021

A: (a) India's merchandise export during last three years and current year are as follows:

Years	Value of Merchandise export (US$ Billion)
2018-19	330.08
2019-20	313.36
2020-21	291.81
2020-21 (Apr-Nov)	174.46
2021-22 (Apr-Nov)*	263.42

*Sourc: DGCI&S. * Provisional*

(b) & (c): The accumulated amount of payments on export of goods and services outstanding with the various financial institutions as on 2nd December 2021 as provided by Reserve Bank of India (RBI) is as follows:

(Value in Rs Crore)

Outstanding export invoice amount for lessthan 9 months	Outstanding export invoice amount for morethan 9 months	Outstanding export invoice amount for morethan 15 months
14,91,747	13,54,134	9,90,342

Source: RBI

(d)**:** The total amount settled by Export Credit Guarantee Corporation (ECGC) on various default payments to banks under Export Credit Insurance Cover for Banks (ECIB) from 2016-17 to 2020-21 and April-September 2021-22 are as follows:

Years	Claim settled (₹ in Crore)
2016-17	655.50
2017-18	1131.47
2018-19	813.39
2019-20	261.64
2020-21	761.87
2021-22 (Apr-Sept)	79.52

(e) & (f): Government has approved proposal for capital infusion of Rs. 4,400 crore to ECGC Ltd. for the period 2021-22 to 2025-26 to support additional exports of Rs. 5.28 lakh crore over a five year period.

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

Export of Medical Equipment

Lok Sabha Unstarred Question No. 1789

Dr. Vishnu Prasad M.K.:

Q. Will the Minister of **COMMERCE & INDUSTRY** be pleased to state:

(a) whether it is a fact that an increase in the export of medical equipments and medicines from the country has been registered during COVID period; and

(b) if so, the increase in exports as compared to that during pre-COVID period and the amount of foreign exchange earned through these exports by the country?

Answered on 8th December 2021

A. (a) & (b): Yes, Sir. Exports of medical equipment and pharmaceuticals registered a growth of 10% and 18.19% respectively, during Covid period (i.e. 2020-21) vis-à-vis the previous year (2019-20), as per details given below:

India's Medical Equipment and Pharmaceuticals Exports (in US$ million)

Category	2019-20	2020-21	Growth
Medical Equipment (Consumer Durables, Electronics equipment, Implants, IVD Reagents, Surgical Instruments)	2292.87	2532.16	10%
Pharmaceuticals (Ayush & Herbals, Bulk Drugs & Drug Intermediates, Drug Formulations & Biologicals, Surgicals)	20703.46	24469.23	18.19%

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

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FSSAI MATTERS

Extension of period for modification/migration of License by existing FSSAI Licensed Manufacturers - reg.

File No.: 15(31)2020/FoSCoS/RCD/FSSAIpt9, dated 27th December 2021

To,

1. *All Food Businesses Operators, Associations, Food Safety Mitra and Other Stakeholders*
2. *Commissioner of Food Safety of all States/ UTs*
3. *Directors of all Regional Offices, FSSAI*
4. *CITO - to upload on FSSAI's website.*

Reference to following FSSAI Orders:

i) FSSAI Order of even number dated 16th June, 2021 regarding mandatory modification of license by existing FSSAI Licensed Manufacturers as per the new methodology for Standardised Product Selection in FoSCoS till 31st December, 2021 (Copy enclosed).

(ii) FSSAI Order of even number dated 16th September, 2021 regarding mandatory migration of State License into Central License by Manufacturers of products covered under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 (Copy enclosed).

2. With the approval of the Competent Authority, it has been decided to extend the last date for mandatory modification/migration of license as per the above said orders from **31st December 2021 to 31st March, 2022, beyond which FBOs who do not get their license modified/migrated, shall not be able to apply for renewal of license.**

Enclosure: *As stated above*

Yours Sincerely,

Inoshi Sharma, Executive Director (Cs), Food Safety and Standards Authority of India, (A Statutory Authority established under the Food Safety & Standards Act, Regulatory Compliance Division, FDA Bhawan, Kotla Road, New Delhi

File No. 15(31)2020/FoSCoS/RCD/FSSAI
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety & Standards Act, 2006)
(Regulatory Compliance Division)
FDA Bhawan, Kotla Road, New Delhi-110002

Dated, the 16th June, 2021

ORDER

Subject: Extension of period for modification of License by Existing FSSAI Licensed Manufacturers without modification fee– reg.

Reference FSSAI order dated 29th October, 2020 regarding modification of license by existing FSSAI Licensed Manufacturers without modification fee till 30th June 2020 (Copy enclosed).

2. With the approval of the competent authority, it has been decided to extend the period for modification of license by existing FSSAI licensed Manufacturers **without any modification fee till 31st October, 2021.**

3. Further, it has been decided that such FSSAI Licensed Manufacturers who do not modify license by 31st October 2021, shall be permitted to apply for modification of their FSSAI license **with fee up to 31st December, 2021.** Thereafter, no modification of License would be permitted **wef 1st January, 2022.**

4. FSSAI Licensed Manufacturers shall not be permitted to apply for renewal of their license wef 1st January, 2022 in case of non-compliance with this order.

5. This issues with the approval of the competent authority.

Yours sincerely,

(Inoshi Sharma)
Executive Director (CS)
Email: ed-office@fssai.gov.in

To,

1. All Food Businesses Operators, Associations, Food Safety Mitra and other stakeholders
2. Commissioner of Food Safety of All States/ UTs
3. Directors of all Regional Offices, FSSAI
4. CITO- to upload on FSSAI's website

Copy for information to -

1. PPS to Chairperson, FSSAI- For information
2. PS to CEO, FSSAI - For information
3. Head (RCD)

No. 15(31)2020/FoSCoS/RCD/FSSAI

Food Safety and Standards Authority of India

(A Statutory Authority established under the Food Safety and Standards Act, 2006)

(Regulatory Compliance Division)

FDA Bhawan, Kotla Road, New Delhi - 110002

Dated, the 29th October 2020

Order

Subject: Extension of period for Modification of License by Existing FSSAI Licensed Manufacturers without modification fee - reg.

Reference FSSAI order of even number dated 28th May 2020 regarding modification of license by existing FSSAI Licensed Manufacturers without modification fee till 31st December 2020 (copy enclosed).

2. Consequent to the approval of Food Authority in its 31st meeting held on 20th October, 2020, it is informed that the period for modification of license by existing FSSAI Licensed Manufacturers, without any modification fee is extended till 30th June 2021.

3. This issues with the approval of Comptent Authority in exercise of the powers vested under Sections 18(2)(d) and 16(5) of Food Safety and Standards Act, 2006.

Enclosure: As stated

(Parveen Jargar)
Joint Director (RCD)
Tel No: 011-23237433

To -

1. All Food Business Operators, Associations, Food Safety Mitra and other Stakeholders
2. Commissioner of Food Safety of concerned States/UTs
3. Directors of all Regional Offices, FSSAI
4. Head (IT) – for uploading on website

Copy for information to -

1. All Divisional Heads of FSSAI
2. PPS to Chairperson, FSSAI
3. PS to CEO, FSSAI

No. 15(31)2020/FoSCoS/RCD/FSSAI
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety and Standards Act, 2006)
(Regulatory Compliance Division)
FDA Bhawan, Kotla Road, New Delhi - 110002

Dated, the 28th May, 2020

ORDER

Subject: Modification of License by Existing FSSAI Licensed Manufacturers upon launch of FoSCoS- reg.

The Food Authority in its meeting held on 6th November 2019 had approved the proposal regarding mapping of Standardized Food Products with Food Category System for the purpose of licensing and registration of manufacturers. Consultation paper on the proposal was prepared, circulated and uploaded on FSSAI website on 17.12.2019 for comments and suggestions. The comments received have been thoroughly examined and wherever needed, Standards Division, FSSAI has been consulted to finalize the mapping of Standardized Food Products with Food Category System. The documents on finalized mapping and the methodology for clubbing of various products under one group are available on www.foscos.fssai.gov.in.

2. The key features of the selection based approach for Standardised Products while applying for FSSAI License (only for Manufacturers/Processors) are as below:

a) At present, while applying for license in FSSAI's online system i.e. Food Licensing and Registration System (FLRS – https://foodlicensing.fssai.gov.in), the manufacturer applicant types the name of food product he intends to manufacture in the text box provided. It replaces the text box approach with selection options for standardised food products, with the launch of Food Safety Compliance System (FoSCoS – https://foscos.fssai.gov.in).

b) The change is only for manufacturer (including re-packer, re-labeller) of food products. Manufacturer will have to select a standardized product only out of list provided on the licensing platform. The standardised product shall have its classification as per food category system indicated for convenience. In case, not falling under standardized product, FBO will have to apply under Proprietary Food, Non specified Food or Supplements/Nutraceuticals as the case may be. In these cases, text box approach will continue. Licensing for all KoBs other than manufacturer, such as catering (food services), transporter, wholesaler, storage, e-Commerce etc will continue to be on the basis of broad food product categories.

c) Category 99 is a residual category for licensing purpose for products such as additives/processing aids/enzymes etc. It is proposed to continue the text box approach for category 99 as while some Food Additives & other substances have standards, there are many for which standards are under development. At an appropriate time in future, this category may also be considered to be moved to Standardised list approach.

d) A new Category 100 is being created only for the purpose of licensing, wherein standardised products do not have Food Category System mapped, will be listed.

e) Under the Food category *15.0 -Ready to eat Savouries* and *16.0 - Prepared Food,* there are no standardized food products; hence a manufacturer (say of ready to eat packets) needs to take central licence under Proprietary Food Category.

f) Many manufacturers who have licences in wrong food category or have license for non-standardized products as standardized food products in previous system, will be required to get their license modified.

g) In case of existing FBOs holding valid licenses for manufacturing of food products, they shall be required to modify their existing license upon migrating to new system i.e. FoSCoS (https://foscos.fssai.gov.in) by selecting the products from available list of standardised products. A window for modification of license, without any modification fee has been provided to such licensed manufacturers for period upto 31st December 2020). Further, before such product migration to standardised products list, if their renewals of licenses get due, then renewal window for only one year will be provided once instead of 1-5 years as specified in FSS (Licensing and Registration of Food Businesses) Regulations, 2011.

3. This issues with the approval of Competent Authority in exercise of the powers vested under sections 18(2)(d) and 16(5) of Food Safety and Standards Act, 2006.

Encl: <u>As stated</u>

(Dr Shobhit Jain)
Executive Director (Compliance Strategy)
Email: ed-office@fssai.gov.in

To

1. All Food Business Operators involved in Manufacturing/Processing of Food Products
2. Commissioner of Food Safety of all States/UTs and all Central Licensing Authorities
3. CITO, FSSAI: For uploading on FSSAI website.

Copy for information to -

1. Head (RCD)
2. PPS to Chairperson, FSSAI
3. PS to CEO, FSSAI

File No. 15(31)2020/FoSCoS/RCD/FSSAI
Food Safety and Standards Authority of India
(A Statutory body under Ministry of Health and Family Welfare)
(Regulatory Compliance Division)
FDA Bhavan, Kotla Road, New Delhi-110 002
Food Safety Compliance System (https://foscos.fssai.gov.in)

Dated, the 14 September, ~~2020~~ 2021

Order

Subject: Food businesses manufacturing products covered under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 to be covered under the purview of Central Licensing Authorities-reg.

At Present, the food businesses operators (FBOs) manufacturing products covered under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 hereinafter referred to as **'Nutraceutical Regulations'** are being licensed by the State as well as the Central Licensing Authorities under the General manufacturing i.e. FBOs having production capacity of 2MT per day are eligible for State License while FBOs having production capacity of more than 2MT per day are eligible for Central License.

2. Now Considering the complexity and sensitivity of the products covered under the Nutraceutical regulations and of the products covered under it, it has been decided with the approval of the Food Authority to license food businesses manufacturing products covered under the said regulations through Central Licensing Authorities only, irrespective of turnover of the FBOs. Henceforth, the Central License option shall be available for manufacturers of food products covered under Nutraceutical regulations.

3. Accordingly, all existing State Licensed FBOs having license for the food products under Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 shall migrate to Central License with a modification fee of Rs. One Thousand [Rs. 1000] only and the payment of the differential amount between State License fee and Central License fee for remaining number of complete years of validity of their existing licenses by **31st December 2021**. Further, State Licensed FBOs manufacturing products under Nutraceutical Regulations shall not be able to apply for renewal of their license after 31st December 2021.

4. All existing applications for new/modification licenses [under processing] with State Licensing Authorities shall stand rejected and fee paid shall be refunded to the concerned FBOs in such cases. Such FBOs shall be required to resubmit the application with full fee to the concerned Central Licensing Authorities.

5. It is further informed that FSSAI has already enabled food businesses to migrate/modify their licenses from State License to Central License without change in existing license number w.e.f 1st June 2021, thereby facilitating food businesses to save overhead costs and undue hassle which otherwise, might have occurred due to change in existing license number and subsequently loss of pre-printed packaging material, if any.

6. This issues with the approval of the Competent Authority.

Yours sincerely,

(Inoshi Sharma)
Executive Director (CS)
Email: ed-office@fssai.gov.in

To -

1. All Food Business Operators, Associations, Food Safety Mitra and other Stakeholders
2. Commissioner of Food Safety of concerned States/UTs
3. Directors of all Regional Offices, FSSAI
4. Head (IT) – for uploading on website

Copy for information to -

1. All Divisional Heads of FSSAI
2. PPS to Chairperson, FSSAI
3. PS to CEO, FSSAI

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GOVERNMENT COMMUNICATION

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 27th Decembr 2021

This is with reference to this office Notice of even no. dated 21.12.2021 on the subject cited above. In this regard, various representations have been received from Stakeholders with the request to postpone the expert committee meeting scheduled to be held on 29.12.2021 & 30.12.2021 as most of the companies will not be available for the meeting on account of year end holidays.

In view of above, the said meeting has been postponed and schedule for the next meeting will be communicated shortly.

This is for information of all the concerned.

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

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Covid-19: Centre calls meeting with States on children vax/booster on Tuesday

Covid-19 variant Omicron cases in India rise to 487

The Centre has convened a meeting with States on Tuesday to decide on the framework for vaccinating children and administering the booster dose for the eligible population.

Prime Minister Narendra Modi had on Saturday announced a vaccination programme for those in 15-18-year age group from January 3 along with 'precautionary doses' for healthcare and frontline workers from January 10. In addition, those above 60 with co-morbidities will also have the option of getting a booster shot on doctor's advice. So far, Zydus Cadila and Bharat Biotech have got the drug regulator's approval for using their vaccines on children. However, it is not yet clear if Zydus Cadila's ZyCov D will be administered on the 15-18 set.

"All the States have a meeting with the Centre on December 28 via video conferencing to discuss the framework for implementing the children vaccination programme and booster dose for healthcare/frontline workers," a State Health Ministry source told *Business Line.*

According to Uttarakhand Health Ministry sources, there are up to 12 lakh children in the 15-18 age group and the State has stocks of around 5 lakh Covaxin shots. Likewise, in Rajasthan there are about 51 lakh in the 15–18-age group and the State has nearly 4 lakh of Covaxin doses.

"As Covaxin is an injectable vaccine and the workers are already trained to administer it, no further training is needed. However, on the CoWIN platform, there is a need to open a window for the 15-18-year set," a Health Ministry source said.

According to Bharat Biotech sources, manufacturing has been scaled up in phases across the company's facilities in Hyderabad in Telangana, Malur in Karnataka and Ankleshwar in Gujarat and Pune in Maharashtra.

"The company is able to expand Covaxin manufacturing capacity in a short timeline, mainly due to the availability of its specially designed Bio-Safety Level-3 production campuses to manufacture inactivated viral vaccines," the Bharat Biotech source added. "We are on target to reaching our goal of ~1.0 billion doses of annualised capacity and at present the company is producing 60-70 million shots per month," the source stated.

According to the Health Ministry, currently, States have more than 17.90 crore of vaccine doses with them. However, it is not yet clear how many of them are Covaxin shots.

On the decision to vaccinate children, India's top virologist T. Jacob John, a retired Professor and Head of the Departments of Clinical Virology and Microbiology at CMC Vellore, told *Business Line* that it is welcome step, as also the booster dose plan for frontline and healthcare workers. But "it's too little and too slow" to face the Omicron onslaught that is around the corner.

"Omicron was knocking at our door from late November, and our best bet was to build a wall of high immunity against it even as we figured out whether that wall was strong enough or not," John said. "Now, building a wall is a bit too late and too little because what about people below 15 and those below 60 who won't get a booster," he added. According to him, the booster dose should be expanded to a wider population and children below 15 should also be inoculated.

Omicron cases up

Omicron cases in India stood at 487 on Sunday. For the first time, in Indore, 8 fresh cases were added, per agency reports. Andhra Pradesh added 2 and Karnataka 7.

Overall, India reported 6,987 new cases with 162 deaths in the last 24 hours till 8:00 am on Sunday, per Health Ministry data. Meanwhile, the Delhi government has imposed night curfew from Monday.

Source: The Hindu, Business Line, 27.12.2021

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Covaxin gets nod for use in kids above 12

India's drug regulator granted an emergency use authorisation (EUA) to Bharat Biotech's Covid-19 vaccine Covaxin for children aged 12-18 years on Saturday, people in the know told ET.

In October 2021, the Subject Expert Committee of the Central Drugs Standard Control Organisation (CDSCO),

which evaluates vaccine applications, had recommended granting an approval for Covaxin for children aged between 2 and 18 years. However, the regulator has decided to restrict the approval to only teens, instead of the younger age group.

Bharat Biotech said Covaxin is formulated uniquely such that the same dosage can be administered to adults and children.

"We have documented excellent safety and immunogenicity data readouts in Children," it said in a statement, adding that the vaccine has established a proven record for safety and efficacy in adults for the original variant and subsequent variants. "We look forward for Covaxin to provide similar levels of protection for adults and children alike," the company said.

Bharat Biotech said Covaxin is formulated uniquely such that the same dosage can be administered to adults and children

Covaxin is now the second vaccine to have got an EUA for the age group 12-18 in India. Zydus Cadila's ZyCov-D received its nod in August, but it is not yet being administered to either adults or children.

Calls to vaccinate children have gained momentum, as concerns about the increased transmissibility and rapid spread of the Omicron have grown. The Covid-19 working group, which advises the government on vaccines, will meet in January to decide on a policy for vaccinating children.

Hyderabad-based company had submitted "interim data" from its vaccine trial in children aged 2 to 18 years to the drug regulator, becoming the country's first company to have tested its Covid jab on kids of this age group. The EUA, however, is subjected to certain conditions. "The company should continue the study as per the approved clinical trial protocol," one of the person in the know said.

Source: Teena Thacker, ET Bureau, 26.12.2021

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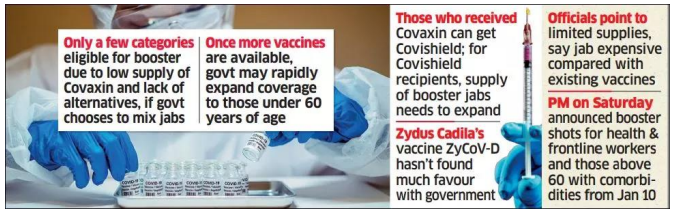
Government may go for mixing vaccines for booster doses; move based on a soon-to-be-released study

The government may stipulate that booster doses - which are to be administered from January 10 to healthcare workers and those over 60 with comorbidities - should be a vaccine different from the one administered for the first two doses. Thus, people who received Covishield could be eligible for a shot of Covaxin and vice-versa.

"One could give an additional dose of the same vaccine but the results aren't as good as when the jabs are mixed," a senior government official told ET, explaining the reason for the government possibly recommending mixing of jabs.

The official added that Serum Institute's Covovax (the Indian brand name for Novavax) was also a leading contender to become a booster dose for those who have been administered Covishield, in case the government stipulates mixing of shots.

"Covovax is likely to get an emergency use authorisation (EUA) in India soon with the Subject Expert Committee set to review its application for EUA on Monday. Once that happens we could very rapidly expand the age groups that could receive the booster shot," the official said, adding that an upcoming vaccine from Biological E was another jab the government was hoping to approve. "Currently, the biotechnology company is facing some manufacturing bottlenecks," the officer added.



The Covid-19 working group will meet this week to review the data on the existing vaccines and take the final call. "The decision to administer booster doses to a few categories was due to the relatively low supply of Covaxin and lack of any other alternative to it if the government chooses to mix the jabs," the senior government official told ET, adding that once more jabs were available, the

government would rapidly expand the coverage to those below 60.

The likely move to mix vaccines while giving booster doses is based on a government study the results of which will be published soon, the officer told ET. Also, the officer added, a separate field trial of a small size showed significant increase in antibodies when Covishield and Covaxin were administered as mixed shots. What we have learnt is that the issue is no longer about safety or efficacy when you mix the vaccines, it is whether mixing the jabs gives you a higher boost," the official said, explaining what the details of the study would focus on.

According to the health ministry's data, almost 580 million people have received both jabs of the Covid vaccine while 830 million have so far received a single jab. Out of this, close to 90% of Indian adults have received Covishield so far.

Source: ET, 27.12.2021

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Children above 15 to get Bharat Biotech's Covaxin only, for now

The Centre is of the opinion that booster shots are population- and frequency-specific interventions

As India's adolescents queue up for their Covid shots on January 3, they have only one option available right now — Bharat Biotech-made Covaxin. Cadila Healthcare-developed deoxyribonucleic acid (DNA) vaccine ZyCoV-D — approved by the drug regulator for use in children aged 12 and above — will not be used right away to vaccinate youngsters aged 15 and above, claimed sources.

Government sources indicated the National Technical Advisory Group on Immunisation in India has not recommended the use of ZyCoV-D for the time being for children below 18. "Even after the Drugs Controller General of India (DCGI) approved the DNA vaccine for use in children aged 12 and above, it has been decided that the vaccine will only be used for those aged 18 and above. This leaves us with only one vaccine for use in adolescents aged 15 and above — Covaxin," said a source, adding the government is going by scientific evidence and advice alone.

On Saturday, the DCGI approved the use of Covaxin for children aged 12 and above. On October 12, the subject expert committee advising the DCGI had approved Covaxin for use in children as young as 2 years and beyond. The DCGI, however, took its time to come up with a final consent for Covaxin, and has approved its use for 12 years and above.

Prime Minister Narendra Modi in his address to the nation on Christmas Day said 'precaution dose' will be given to the elderly (60 years and above) with comorbidities upon furnishing a doctor's certificate.

India had listed around 20 major comorbid conditions when vaccinations began in the earlier months of 2021.

The comorbid conditions included cardiovascular diseases, diabetes, kidney ailments, cirrhosis, cancer, sickle cell anaemia, organ transplants, prolonged use of steroids or other immunosuppressant drugs.

The same set of comorbidities will be considered when evaluating if someone is eligible for an additional shot or a third shot. "Someone may have diabetes, but at what level the disease qualifies as a comorbid condition is something a doctor will decide upon and certify accordingly," said a government source.

While registering on CoWIN, one needs to either upload the certificate of comorbidity signed by a registered doctor, or carry a printed version of it to the vaccination centre. Children will, however, have a simple process of registration — anyone eligible (15 years and above) will register for getting their shots.

FOR THE LITTLE WARRIORS

- NTAGI has not recommended ZyCoV-D for use under 18
- DCGI has approved ZyCoV-D, Covaxin for 12 years and above
- Govt will use Covaxin for now to vaccinate children
- Gap between second shot and additional dose for 60+ will be 7-9 months.

Moreover, the gap between the third dose and the last received dose (second dose) will be seven to nine months. The government will soon issue guidelines addressing these issues.

"Before January 10, guidelines will be issued on gaps between doses, which vaccine can be taken as a precaution dose, etc. These will be based on scientific advisory," said a government source.

Once someone is vaccinated, antibodies are generated against the pathogen, which decline after a period of time,

but T-cells (or memory cells) remain active. No major studies are there which track the T-cell response over a long period of time for the Covid vaccines available.

"However, in India five or six major studies have tracked antibodies generated by Covaxin and Covishield. These studies have found that unlike messenger ribonucleic acid (mRNA) vaccines like Pfizer and Moderna, the rise and decline of antibodies generated by Covishield and Covaxin are not sharp enough," said a government source in the know.

He added that antibodies generated by Covishield and Covaxin show a gradual rise and a gradual weakening. "The gap or distance between the initiation of the increase and the decline is anywhere between seven and nine months and T-cells remain active even after that. Ideally, an additional dose or precaution shot should be given after seven to nine months after the second vaccine dose. However, in the case of Pfizer and Moderna (or mRNA vaccines), this gap is three to four months," added the source.

The Centre is of the opinion that booster shots are population- and frequency-specific interventions. "When we say we are giving 'boosters' to 60 years and above, it implies that the door is open to other age groups. When we say it is a precaution dose or additional dose, that door is not open," clarified a source.

Decisions on allowing 'precaution shots' or additional shots for other age groups will be taken eventually if the need arises.

Source: Sohini Das, Business Standard, 26.12.2021

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US nod for Covid-19 drug molnupiravir raises hope for Indian approval

Oral medication targets ribonucleic acid polymerase, a part of the virus that has not changed much after mutations in the Omicron variant.

The USFDA's approval on Thursday for Merck and Ridgeback Biotherapeutics' antiviral drug to treat Covid-19 paves the way for India to do the same soon.

Molnupiravir, an affordable oral drug, targets the ribonucleic acid polymerase, a part of the virus that has not changed much after mutations in the Omicron variant.

The subject expert committee (SEC) that is advising the Drugs Controller General of India (DCGI) had sought more data from a consortium of drugmakers--Dr Reddy's Laboratories (DRL), Torrent Pharmaceuticals, Emcure Pharmaceuticals, Sun Pharmaceutical Industries (Sun Pharma), and Cipla.

"In its last meeting, the SEC had requested more data from all companies. On behalf of the consortium, we have submitted the data. We now await the next SEC meeting," a spokesperson for DRL told 'Business Standard'.

These five drugmakers had come together in June to jointly sponsor, supervise, and monitor the clinical trial in India. Between March and April this year, the five companies had individually entered into a non-exclusive voluntary licensing agreement with Merck Sharp Dohme (MSD) to manufacture and supply molnupiravir to India and over 100 low- and middle-income countries.

This apart, drugmakers like Hetero Labs have also done trials independently on molnupiravir in India.

The US Food and Drug Administration (USFDA) had issued an emergency use authorization (EUA) for molnupiravir for the treatment of mild-to-moderate coronavirus disease in adults who are at high risk for progression to severe COVID-19, including hospitalisation or death.

The USFDA said molnupiravir should be initiated as soon as possible after Covid-19 is diagnosed and within five days of symptom onset. The drug is not authorised for use in people younger than 18.

Source: Business Standard, 25.12.2021

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Omicron Can Evade Protection Offered By Covid Vaccines, Antibody Therapies: Study

The study, published in the journal Nature on Thursday (December 23), also highlights the need for new vaccines and treatments that anticipate how the SARS-CoV-2 virus may soon evolve

Washington: Omicron can evade the immune protection conferred by COVID-19 vaccines and natural infection, according to a peer-reviewed study which also suggests that the new variant of coronavirus is completely resistant to antibody therapies in use today. The study, published in the journal Nature on Thursday (December 23), also highlights the need for new vaccines and treatments that anticipate how the SARS-CoV-2 virus may soon evolve.

The researchers from Columbia University in the US and the University of Hong Kong noted that a striking

feature of Omicron is the alarming number of changes in the variant's spike protein that could pose a threat to the effectiveness of current vaccines and therapeutic antibodies.

The study tested the ability of antibodies generated by vaccination to neutralise Omicron in laboratory tests that pitted antibodies against live viruses and against pseudoviruses constructed in the lab to mimic the variant.

The researchers found that the antibodies from people double-vaccinated with Moderna, Pfizer, AstraZeneca, and Johnson & Johnson COVID-19 vaccines were significantly less effective at neutralising Omicron compared to the original virus.

Antibodies from previously infected individuals were even less likely to neutralise Omicron, they said.

People who received a booster shot of either Pfizer or Moderna vaccines are likely to be better protected, although even their antibodies exhibited diminished neutralising activity against Omicron, the study shows.

"The new results suggest that previously infected individuals and fully vaccinated individuals are at risk for infection with the Omicron variant," said David Ho, a professor at Columbia University Vagelos College of Physicians and Surgeons.

Even a third booster shot may not adequately protect against Omicron infection, but of course it is advisable to get one, as you will still benefit from some immunity, Mr Ho added.

The researchers noted that the findings are consistent with other neutralisation studies, as well as early epidemiological data from South Africa and the UK, which show efficacy of two doses of the vaccines against symptomatic disease is significantly reduced against Omicron.

The study also suggests that all of the monoclonal antibody therapies currently in use and most in development are much less effective against Omicron.

Monoclonal antibodies are laboratory-made proteins that mimic the immune system's ability to fight off harmful pathogens such as viruses.

In neutralisation studies with monoclonal antibodies, only one — Brii198 approved in China — maintained notable activity against Omicron, according to the researchers.

A minor form of Omicron is completely resistant to all antibodies in clinical use today, they said.

The study authors note that Omicron is now the most complete "escapee" from neutralisation that scientists have seen.

They also identified four new mutations in the spike protein of Omicron that help the virus evade antibodies, a finding that could inform the design of new approaches to combat the variant. The SARS-CoV-2 virus uses the spike protein to enter and infect the human cells.

The researchers suggest that new vaccines and treatments need to be developed that can better anticipate how the virus is evolving.

It is not too far-fetched to think that SARS-CoV-2 is now only a mutation or two away from being completely resistant to current antibodies, either the monoclonal antibodies used as therapies or the antibodies generated by vaccination or infection with previous variants, Mr Ho added.

Source: Business Standard, 25.12.2021

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World economy to top $100 trillion in 2022 for first time: report

LONDON: The world's economic output will exceed $100 trillion for the first time next year and it will take China a little longer than previously thought to overtake the United States as the No.1 economy, a report showed.

British consultancy Cebr predicted China will become the world's top economy in dollar terms in 2030, two years later than forecast in last year's World Economic League Table report. India looks set to overtake France next year

and then Britain in 2023 to regain its place as the world's sixth biggest economy, Cebr said.

"The important issue for the 2020s is how the world economies cope with inflation, which has now reached 6.8% in the U.S.," said Cebr deputy chairman Douglas McWilliams.

"We hope that a relatively modest adjustment to the tiller will bring the non-transitory elements under control. If not, then the world will need to brace itself for a recession in 2023 or 2024."

The report showed Germany was on track to overtake Japan in terms of economic output in 2033. Russia could become a Top 10 economy by 2036 and Indonesia looks on track for ninth place in 2034.

Source: International The News, 28.12.2021

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E-commerce, pharma to revive demand for packaging paper: Crisil

High realisations and stable raw material prices will help in improving the operating profitability of packaging paper players

A strong revival in consumer spending amid waning impact of the Covid-19 pandemic will help the paper packaging industry bounce back with revenue growth of 15 per cent this fiscal, ratings agency Crisil said.

The industry had reported a decline of 8 per cent in the previous fiscal.

Besides, the agency said that capacity utilisation and operating leverage will also improve and, together with continued high realisations and almost stable raw material prices will help in improving the operating profitability of packaging paper players this fiscal.

Consequently, with capacity utilisation improving, players are also likely to commence capital expenditure for enhancing capacity by 10 per cent over fiscals 2023 and 2024. "A stronger-than-anticipated growth in e-commerce sales due to increasing safety and hygiene consciousness, healthy double-digit growth in domestic pharmaceutical sales, and revival in consumer durable sales are driving demand for packaging paper," said Anuj Sethi, Senior Director, Crisil Ratings.

"Consequently, capacity utilisation of paper packaging players is seen rising to over 80 per cent this fiscal from 65-70 per cent in the last. Increased sales volume and 6-7 per cent higher realisations mean revenue growth will be healthy this fiscal."

Furthermore, the report cited that a gradual recovery in apparel sales, too, will support revenue growth.

Notably, Crisil expects operating profitability of packaging paper players to reach the pre-pandemic level of over 17 per cent this fiscal, compared with 15.5 per cent last fiscal, backed by better operating leverage and higher realisations.

"Also, the costs of key inputs such as waste paper, which saw a sharp rise last fiscal, have now stabilised, which will help improve operating profitability," the agency said.

The nationwide lockdown to contain the pandemic had hit sales of apparel and consumer durables during last fiscal.

Apart from the lockdown, lower growth in domestic pharmaceutical sales had impacted revenue of paper-packaging companies, which had seen healthy compound annual growth of 7-8 per cent in the preceding five fiscals.

"A moderate third wave, if it occurs, is unlikely to materially impact recovery for the packaging paper segment. However, movement in prices of key raw materials, such as imported wastepaper, will bear watching," Crisil said.

As things stand, the domestic paper industry is dominated by the paper packaging segment, accounting for 50-55 per cent of the sector's capacity, followed by writing and printing paper, newsprint and specialty paper and other segments.

The paper packaging segment comprises paperboard and kraft paper used in packing pharmaceutical, e-commerce goods, consumer durables, fast-moving consumer goods and ready-made garments.

Source: Parul, SME Futures, 28.12.2021

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Covid-19 vaccine stock-taking: Does India have enough to expand the drive?

India will begin to give a third shot to a section of its elderly population from January 10, besides opening up vaccination for children aged 15 and above. But do we have enough vaccine stockpiles in the country to support a seamless drive?

A back of the envelope calculation shows that India has roughly over 680 million doses of Covid-19 vaccines consisting primarily of Covishield doses. This includes the 179 million unused doses available with states as of December 26, and a stockpile of 500 million doses lying at Serum Institute of India's (SII) Pune plant.

Vaccination for children aged 15 and above is allowed from January 3. There are some 120 million children aged 12-18, and in all around 400 million under 18. It can be estimated that the demand for adolescent vaccination (15-18 years) would be less than 70-80 million. For the "precaution shot" for the elderly, people above 60 with comorbidities are eligible. India's elderly population is 138 million, according to the National Statistical Office's "Elderly in India 2021" report.

Even if we consider 50 per cent of this population to have serious comorbidities making them eligible for a third Covid-19 shot, the number roughly comes to 70 million.

Together, children and the elderly would create an additional demand of 140 million doses or so. Of this, children would only be administered Covaxin (and not ZyCoV-D), while the elderly could be given either Covishield, Covaxin, Sputnik V or ZyCoV-D. Government sources indicated to Business Standard that the gap between the second dose and the additional dose for the elderly is likely to be nine months, at least. Therefore, the demand would grow gradually as more people become eligible. Vaccinations for the elderly began in March this year.

We do not know the stock lying with Bharat Biotech and Dr Reddy's Laboratories (DRL) for Covaxin and Sputnik V, respectively. However, a senior Bharat Biotech official said: "We will start our batches to make about 80 million doses a month soon. The supplies would come to the market around March-April. It takes 90 days or so to make Covaxin, and then there are quality checks at the plant, followed by certification by government laboratories, after which the vaccines are released into the market."

Zydus Cadila's yet to be launched DNA plasmid vaccine ZyCoV-D is expected to add to the vaccine supply.

Zydus Cadila MD Sharvil Patel told Business Standard that its partner Shilpa Medicare will start commercial production from January, and the company would be able to supply 10 million monthly doses from February-March.

Meanwhile, SII is in a wait-and-watch mode before it steps on the gas to produce a large number of Covishield doses. The company has cut down production by half in the wake of muted demand for its vaccine.

It has a stock of 500 million doses, of which 50 per cent are in bulk form, which can be converted into finished formulation in about a month's time or so. The company has a capacity to store 600-700 million doses at its site, and is making only 120-125 million doses a month now, down from 250 million a month earlier.

SII said it cannot comment on plans to ramp up production till there is information from the government. The Centre is expected to release guidelines for children and elderly vaccinations in the coming weeks. A crucial factor in determining demand is whether the government will opt for a mix-and-match vaccine approach for the additional shots for the elderly.

Experts say mixing vaccine shots may give better results to boost immunity. However, last week AstraZeneca said a booster shot of the AstraZeneca-Oxford Covid-19 vaccine Vaxzevria significantly boosts antibody levels against the Omicron variant. More vaccines, too, are expected to hit the market soon: Covovax (SII), Corbevax (Biological E), and intranasal vaccine BBV154 (Bharat Biotech).

Biological E has the capacity to make one billion doses of Corbevax annually, but the vaccine is not yet approved. Bharat Biotech aims to make 80 million doses a month or 1 billion annual doses of BBV154, which is in clinical trials now. And SII has submitted Covovax data to the drug regulator; approval is awaited. SII can make 50 million monthly doses of the vaccine at Pune.

Source: Sohini Das, Business Standard, 27.12.2021

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Bharat Biotech eyes 1 billion doses of nasal Covid-19 vaccine in 2022

Covaxin maker Bharat Biotech is targeting to make one billion doses annually of its intranasal vaccine in 2022 that is under clinical trials now.

The Hyderabad-based vaccine maker is also looking for global partners to manufacture and distribute the vaccine overseas.

BBV154, the intranasal vaccine, can be administered as a nasal spray or a drop. It cannot be taken at home though, but needs to be administered in a clinical setting.

The adenovirus vector-based vaccine helps trigger generation of IgA antibodies that line the nasal mucosa.

Bharat Biotech claims that the vaccine helps reduce transmission of the Sars-CoV-2 virus as it attacks the virus at the first points of entry — the nose and the upper respiratory tract. "We are scaling up manufacturing of the intranasal vaccine now. The target is a billion annual doses for the nasal vaccine. The sites, which make Covaxin now (Bengaluru, Hyderabad, Pune), will also have facilities to make the nasal vaccine," a senior company executive told Business Standard.

"We are looking for global partners both for manufacturing and distribution," the company added.

It is a live adenovirus vector platform that is similar to the Oxford-Astra Zeneca or Johnson & Johnson vaccines. "We have done a lot of work to stabilise the spike protein. The antibodies in the nose are IgA, which are also present in the upper respiratory tract," the executive added.

Meanwhile, Bharat Biotech has sought permission to start phase 3 clinical trials of the vaccine. The company is testing the vaccine as a booster shot for someone who has had Covid infection or received two shots of any other vaccine.

The phase 3 trial size will be lesser than the Covaxin trial (25,800 participants).

"We are not considering an efficacy trial right now, because many people are either sero-positive or vaccinated. So mostly, we are testing the safety, immunogenicity and specifically as a booster dose (after any vaccine). The trial protocol would be designed accordingly," the company executive said.

It has conducted phase 2 trials on 650 volunteers. Recruitment for the phase 2 trials was completed by September. The first phase had 175 participants.

The company had conducted three-legged phase 2 clinical trials for its intranasal vaccine. The vaccine was tested in three combinations — two nasal shots, first a Covaxin shot followed by the nasal vaccine, or Covaxin following a nasal shot.

The idea was to see which combination induces better and long-lasting immune response. Therefore, the intranasal vaccine could be used as a combination with the intramuscular Covaxin shot. Bharat Biotech will first establish the intranasal vaccine for adults and then consider children's trials.

Experts have said the intranasal vaccine is a good idea. Commenting on the nasal vaccine, Jacob John, former head of Centre for Advanced Research in Virology at the Indian Council of Medical Research said to have a nasal vaccine is a "fantastic idea" for two reasons — firstly, it can potentially create sterile immunity. Secondly, it is easy to administer, and thus, scalable.

Source: Business Standard, 27.12.2021

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Exports rise 36% to $23.8 bn in first 3 weeks of December

India exported items worth $23.8 billion during the first three weeks of December, up 36.2 per cent year-on-year.

This came amid robust external demands for goods, according to preliminary data collated by the commerce and industry ministry.

The growth was 27.7 per cent as compared to the same period of 2020. In terms of value, goods worth $18.65 billion were exported two years ago.

Export of other items, excluding petroleum oil and lubricants, increased more than 28 per cent (December 1-21) over the same period of 2021 as well as 2020 and 2019. According to data, the value of export grew by over a fourth to $7.36 billion during the third week of December as compared to the same time period of 2021. It was up 15.4 per cent during the same time period in 2020.

There has been a sustained increase in exports since the beginning of the year due to recovery in key global markets and robust demand. The pace of growth in exports was slower in November. Exports growth fell to 26.49 per cent in November from 43.05 per cent in the previous month. In terms of absolute value, it fell to $29.8 billion, the lowest in nine months.

India aims to achieve a target of $400 billion in the current fiscal year, and has met nearly two-thirds of its annual export target during April- November.

Source: Shreya Nandi, Business Standard, 28.12.2021

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Pharma firms to be in better health in 2022

The year 2021 has not been particularly smooth for Indian pharmaceutical companies. Higher competitive intensity in the US posed challenges. This affected growth in the base business of some drugmakers. But, with covid-induced disruptions easing, overall US sales improved.

The acute segment drove growth in the domestic market this year. Data from India Ratings and Research Pvt. Ltd shows that the acute segment has seen robust performance since March (average growth at 29% year-on-year). This data also showed that after the normalization of the high growth months of April (51.5% growth) and May (47.8%), the average IPM (Indian Pharma Market) growth from June to November has been healthy (11.6%). The growth spike over April-May was aided by sales of covid treatment and associated products. Plus, the base was favourable due to the lockdown last year.

As we move into 2022, while the acute segment sales may remain firm, the base would be high, and that's a challenge. Further, sales growth in the chronic segment is expected to pick up pace. Broadly, analysts expect 2022 to be better, with growth momentum continuing in India. Additionally, large product approvals and launches are likely to support growth in US sales, too. "In India, chronic drugs should see a recovery in growth after a sluggish 2021 led by pickup in patient visits to doctors and a more benign base. There is also an opportunity for above-average price hikes in NLEM (national list of essential medicine) drugs in April 2022," said Prashant Nair, an analyst at Ambit Capital Pvt. Ltd.

This should benefit companies with high domestic market exposure, including Cipla Ltd, Dr Reddy's Laboratories Ltd, Glenmark Pharmaceuticals Ltd and Cadila Healthcare Ltd, among others. Additionally, the US market is key for many Indian manufacturers. Even as sales in the US market have gathered pace, competitive intensity and the resu-ltant pricing pressures are problems. To overcome pricing pressures, companies need large product launches in the US, many of which are pending approval. This would be a key monitorable in the coming year. Companies such as Lupin, Cipla and Dr Reddy's are expected to see the approval and launch of generics of respiratory products including Spiriva, Advair, and multiple myeloma drug Revlimid, which can potentially alter their growth trajectory meaningfully. But progress may be a tad slow. "The next round of key US product launches for Indian generic companies is expected only in H2CY22; that could improve sales going forward in the next two-three quarters," said Naveen Kulkarni, chief investment officer, Axis Securities.

Meanwhile, note that the US drug regulator has resumed plant inspections after travel restrictions were eased. This means many companies whose facilities have remained under the US drug regulator's scanner for long may get respite. For instance, Lupin's Goa facility, which was under import alert since 2017, has finally got clearance. On the flip side, more inspections at manufacturing facilities of other pharma companies would increase the risk of fresh regulatory issues erupting. In general, active pharma ingredients and contract manufacturers remain in good health, helped by the anticipated fall in raw material prices. Manufacturers may also benefit as global customers move away from China. Year-to-date, the Nifty Pharma index rose by 6%, underperforming the Nifty 50 index, which increased by 22% during the same period. "Healthcare sector valuations relative to the broader market are not demanding. With the recovery in growth, it should attract greater interest from investors," Nair said.

Source: The News Caravan Staff with inputs from mint – Markets, 28.12.2021

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PUBLICATIONS DIVISION

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