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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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IDMA BULLETIN

Vol. No. 52 Issue No. 35 15 to 21 September 2021

IDMA ACTIVITIES:

CBDT MATTERS:

DGFT MATTERS:

FSSAI MATTERS:

PARLIAMENT NEWS:

GOVERNMENT PRESS RELEASE:

GST MATTERS:

NATIONAL NEWS:

A Report on IDMA & APTAR PHARMA - Webinar on "Intranasal Immunization: Promises and Challenges" on September 2, 2021 from 4.30 pm to 6 pm

IDMA & APTAR PHARMA organized the fourth webinar in their knowledge series titled "Intranasal Immunization: Promises and Challenges" on September 2, 2021 from 4.30 pm to 6 pm.

The webinar had a panel of elite International speakers such as

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

Mr. S R Vaidya, Chairman, MSME Committee, IDMA co-ordinated the whole webinar with excellent support from Ms. Prachi Singhai, Manager-Marketing & Communication, India & SE Asia, Aptar Pharma. There were about 50 plus participants for this webinar. Excellent & elaborate addresses by the speakers led by wonderful deliberations were the hallmark of the Webinar and indeed the success of the webinar.

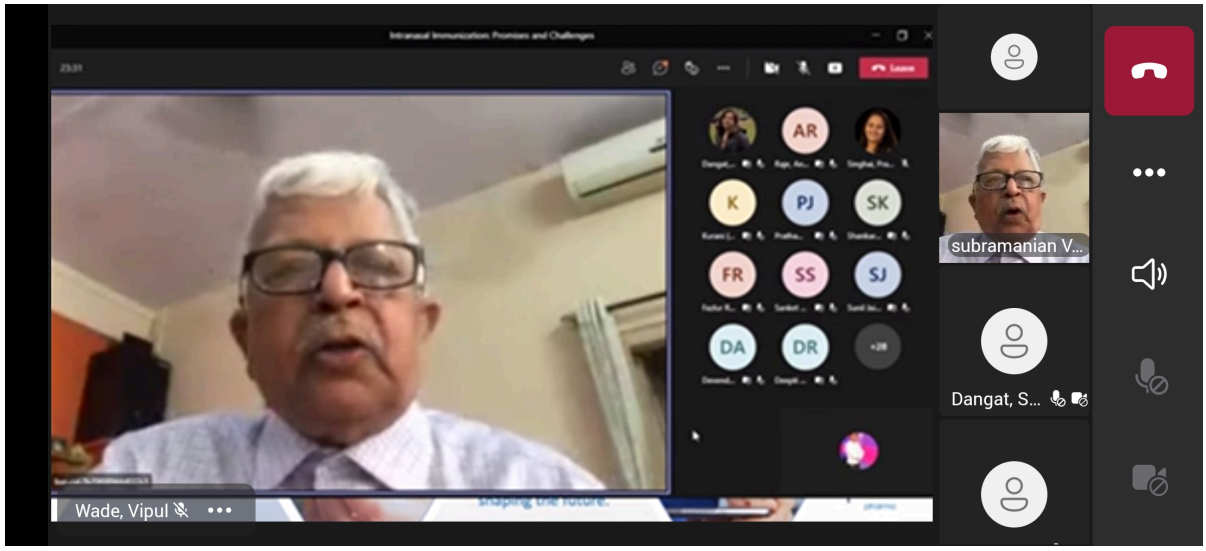
Mr. S R Vaidya initiated the proceedings with his opening remarks and welcome address. He said that it gave him great pleasure and honour to address the august gathering & on behalf of our National President, Mr. Mahesh H Doshi and Secretary – General, Mr. Daara B Patel he welcomed the speakers, Aptar Group and all the participants.

He briefed the gathering about IDMA and its initiatives specially how IDMA is organizing excellent and innovative webinars along with Aptar. He further added that during the Covid-19 Pandemic, IDMA Secretariat has played an important role in facilitating uninterrupted supply of quality medicines with excellent coordination between the Industry, Government and Regulators. IDMA through such knowledge based webinars have been updating the IDMA Members about the latest happenings in the Pharma Industry – Nationally & Globally.

The two speakers made a brilliant presentation on exploring intranasal vaccination for needle-free immunization. They were of the opinion that there are three marketed nasal vaccines available for human use but many more are in development for both human and veterinary use. Nasal vaccination provides an alternative to the more conventional Injectable drug delivery system. Mucosal immunity can develop via interaction with immune modulators present in the nasal cavity, where the nasal associated lymphoid tissue (NALT) region plays a dominant role. *(The presentation is reproduced for your kind information)*

Mr. S R Vaidya moderated the question and answer sessions very well and later summed up the proceedings saying that in this webinar, Aptar provided an overview of intranasal vaccine formulations for liquid and powder administration. They discussed the pros and cons of nasal vaccines, assess intranasal device platforms, logistical considerations that need to be taken into account, as well as present our thoughts on the opportunities that intranasal vaccination can offer.

Mr. Vaidya thanked the speakers, Aptar Pharma and the participants for their active participation, thus keeping the webinar interactive. He said he is looking forward to the next webinar in the knowledge based APTAR Webinar Series.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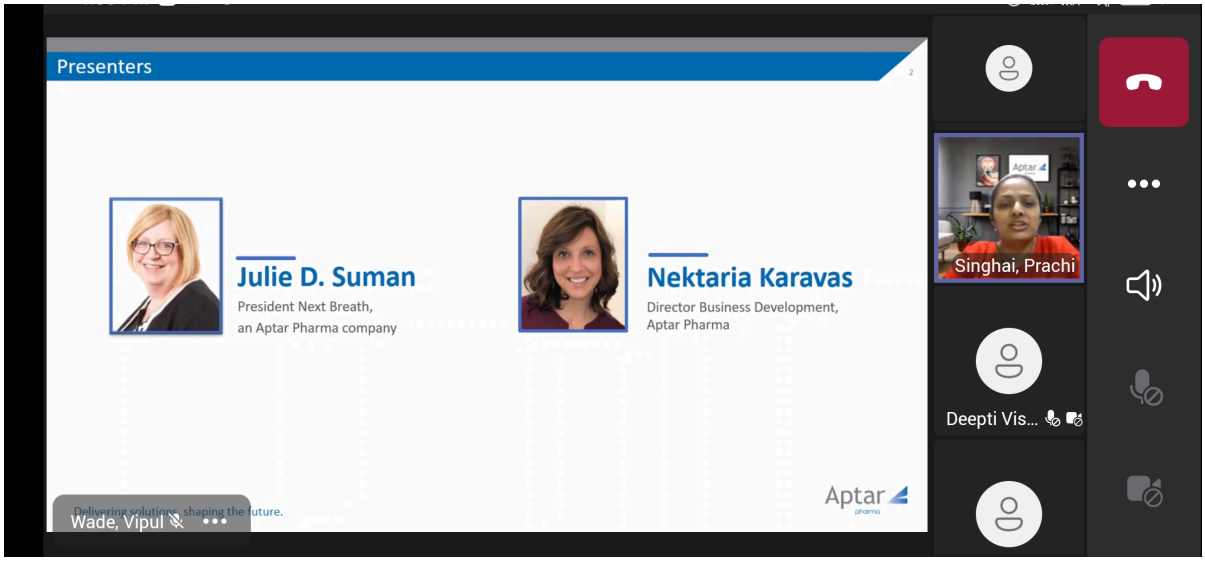
subramanian V...
Dangat, S...
Wade, Vipul


Presenters
Julie D. Suman
President Next Breath,
an Aptar Pharma company
Nektaria Karavas
Director Business Development,
Aptar Pharma
Aptar
Singhai, Prachi
Deepti Vis...
Wade, Vipul


The Aptar Pharma Advantages
Broad Therapeutic Expertise
Other Routes
Nasal
Pulmonary
Injectables
Eye Care
Dermal
Other Routes
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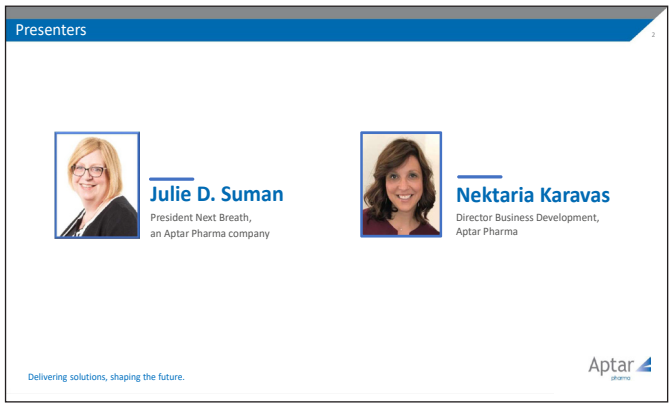
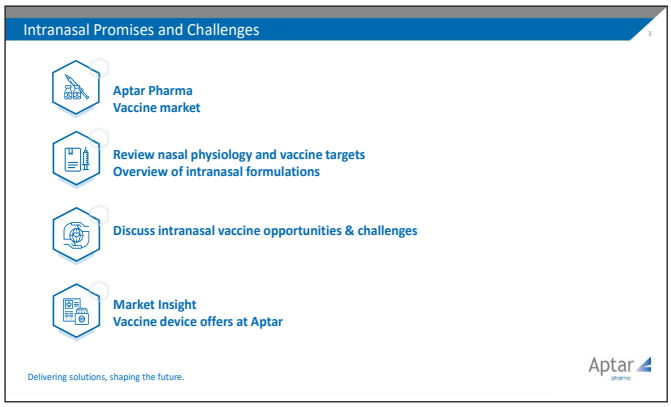
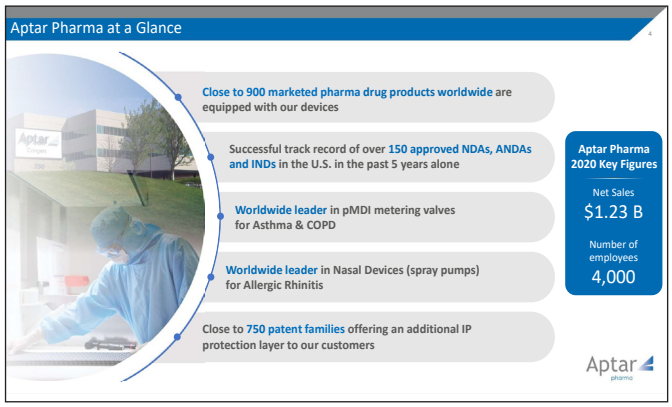
Aptar
subraman...
Dangat, S...
Wade, Vipul

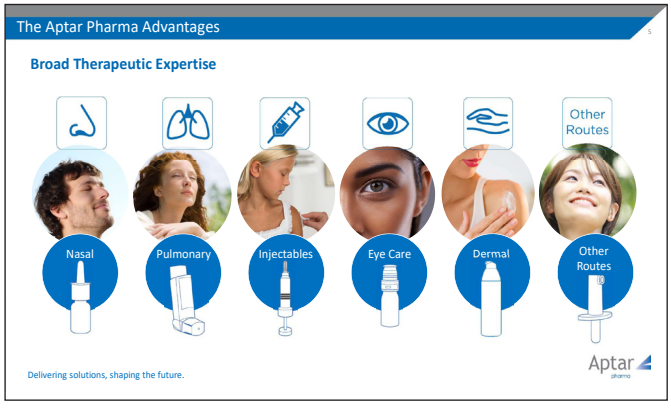
PRESENTATION

“Intranasal Immunization: Promises and Challenges”









Vaccine Market Overview

THE OVERALL VACCINE MARKET ESTIMATED $60B in 2024

Global Vaccine Market

Injectable Market	Aptar Injectable Products: RNS, Stoppers and Plungers
Nasal Drug Delivery Market	Aptar Nasal Delivery Systems
Droppers	Aptar Preservative Free Dispensing System
Capsules and Tablets	Aptar CSP and Active Packaging

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Global Vaccines in Development

3749 Vaccines

145 nasal vaccines

Less **4%** of vaccine trials are intranasal

36 covid nasal vaccines

4 Marketed intranasal vaccines for human use

Allergy	Bacterial	Hepatitis B	Parasitic Infections	SARS-CoV-2	Zika Virus
Alzheimer's	Cancer	HIV	Pertussis		
Anthrax	Ebola	Influenza	RSV	Tuberculosis	Veterinary

Prophylactic | Therapeutic

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COVID-19 Etiology

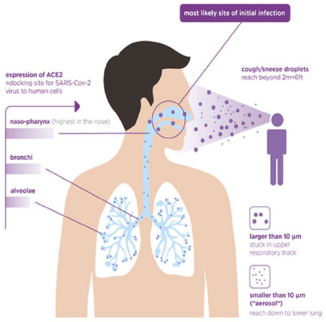

Figure adapted from S. Huang, "COVID-19 Why we should all wear masks—there is new scientific rationale." accessed March 26, 2020

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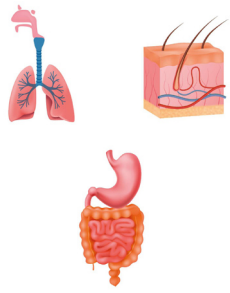
Expanding Immunization: Oral, Cutaneous and Mucosal



Intramuscular Vaccine

- Systemic immune response
- Aluminium salts widely used adjuvant
- Invasive, potential for needle sticks

Nasal Vaccine

- Systemic and local immune response
- No widely approved adjuvants
- Particulate system required to present the antigen
- Non-invasive, potential for improved compliance

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Targeting the Nose

Treatments

Allergic Rhinitis

Nasal Saline

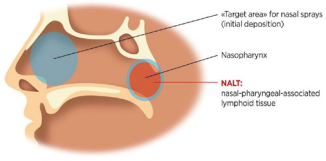
Vaccines

Lymphoid tissue

NALT

Immunocompetent cells

B cells, T cells, antigen presenting cells (APC), M cells



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Nasal Cavity Environment

Environment

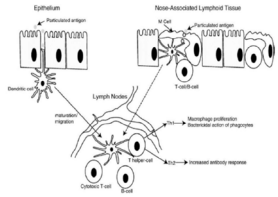
- Acidic environment
- Isotonic

Enzymatic activity

- Cytochrome p-450 enzymes present to lesser extent than GI tract
- CYP2A10 and 2A11

Mucociliary clearance

- Mucus layer is completely renewed within 15-20 min
- Cleared from nose within 15-30 min
- Age and disease state considerations



Csaba et al. Nanoparticles for nasal vaccination. Advanced drug delivery reviews. 61:140-157 (2009)

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Nasal Vaccine Development

Therapeutic

- Treatment of cancer, autoimmune and infectious diseases
- Differing immune response compared to prophylactic vaccines

Prophylactic: COVID-19

- Information extracted from WHO Novel Coronavirus Landscape, accesses February 24, 2021
- Additional platforms in preclinical phases

Nasal Vaccine Platform	Number of Doses	Clinical Phase	Developer
Viral vector (replicating)	1	2	University of Hong Kong
Live attenuated	1-2	1	Codagenix/Serum Institute of India
Protein subunit	3	1/2	Center for Genetic Engineering and Biotech
Viral vector (non-replicating)	1	1	Bharat Biotech International, Ltd.
Viral vector (non-replicating)	1	1	CyanVac LLC
	1-2	1	Oxford
Live attenuated virus	1-2	1	Meissa Vaccines, Inc.

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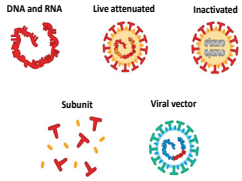
Nasal Vaccine Formulations

VACCINE PLATFORMS

Types of Vaccines



Antigen

- Particulate system required
  - Pathogen- live or attenuated
  - Nanoparticle

Adjuvant

- Potentiate antigen
- No intrinsic immunoactivity or toxicity

Excipients

- Mucoadhesive
- Stabilizing

Figure adapted from Nanoparticle-Based Vaccines Against Respiratory Viruses, *Front. Immunol.*, 24 January 2019

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Particulate Systems for Nasal Vaccination

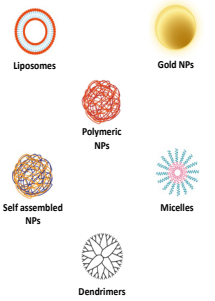
200–300 nm to be optimal for dendritic cell uptake*

- <5 µm stimulate the mucosal and systemic immune responses
- 5–10 µm stimulate only the mucosal immune system
- >5 µm can be taken up by M cells, but will remain in these cells

Particle charge

- Positive charge interact better at cell membrane
- Cationic particles may induce better immune response

Particle aggregation



*M Hellfritzsch and R Scherliess, Mucosal Vaccination via the Respiratory Tract, Pharmaceutics, 2019, 11, 375
Figure adapted from Technological Approaches for Improving Vaccination Compliance and Coverage, *Vaccines* 2020, 8, 304.

Nasal Vaccine Adjuvants

Bacterial

- Cholera toxin
- Pertussis toxin
- E. coli heat-labile toxin (LT)

Nucleic acid

- Target toll like receptors (TLR)

Cytokine

- Interleukin
- Interferon

Particles

- Virus like particles (VLP)
- Chitosan

Considerations

- Only LT has been approved in a nasal formulation → withdrawn from market
- Hypothesis neuronal uptake of LT resulting 46 cases of Bell's Palsy
- Safety → prevent CNS uptake?

Adjuvanted influenza vaccines, Hum Vaccin Immunother. 2018 Mar 4;14(3):550-564

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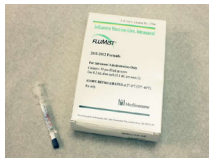
Nasal Vaccine Excipients

Goal is to avoid destabilization, aggregation, physical/chemical degradation, loss of immunogenicity

Droplets or particles administer from device should be greater than 10 µm to minimize lung deposition

Aqueous formulation considerations

- Buffer
- Amino acids
- Sugars
- Viscosity
- Osmolarity
- pH
- Delivered dose volume



FluMist

- suspension
- live virus particles
- buffered solution containing gelatin, sucrose and amino acids

Excipients

Stabilizing agent

Mucoadhesive

- Pectin
- Chitosan
- Hypromellose
- Carbomer

Vaccine	Method	Stabiliser
Influenza	Spray drying	DPPC/HES (dipalmitoyl phosphatidylcholine/hydroxythyl starch)
	Spray-freeze drying	Insulin (59)
		Arginine
		Dextran
		Lactose
		Mannitol
		Trehalose
	Freeze drying	Dextran
		HYAFF (esterified hyaluronic acid) microspheres
		Insulin
		Sorbitol
		Trehalose
	Air drying	D-xylose
Smallpox	Freeze drying	Mannitol
Measles, mumps, and rubella	Freeze drying	Sorbitol
		Sucrose
Hepatitis B	Spray-freeze drying	Insulin
		Dextran
		Trehalose

Hellfritzsch and Scherließ, Mucosal Vaccination via the Respiratory Tract. Pharmaceutics, (2019) 11 (375)

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Formulations

NASAL POWDERS

Avoid cold chain storage | Higher payload | More stable than liquid formulation

Essential powder formulation components

- Antigen (< 250nm)
- Adjuvant
- Mucoadhesive agent
- Bulking agent
- Matrix stabilizer

Powder preparation & dehydration techniques

- Freeze drying, or
- Thin film freeze drying, or
- Spray drying, or
- Vacuum drying

Final powder formulation

- Stable dispersible powder
- > 10µm particle size

G Williams, J Suman, D Marx, The Potential of Dry Powder Vaccines for Intranasal Immunization, *Current Trends in Vaccines and Vaccinology* 2021 Volume: 4.1

Nasal Powder Vaccines

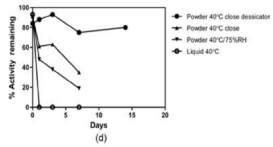
Recombinant protective antigen (rPA) delivered intranasally to rats

Novel mucosal adjuvant, a mast cell activator compound 48/80 (C48/80)

Spray freeze dried powder formulations

- Significantly elevated serum PA-specific antibody and
- Lethal toxin neutralization antibody titers that were comparable to that induced by intramuscular immunization with rPA

FORMULATION STABILITY



Stable Dry Powder Formulation for Nasal Delivery of Anthrax Vaccine, J Pharm Sci. 2012 Jan;101(1):31-47

COVID-19 Clinical and Regulatory Pathways

Emergency Use Authorization (EUA)

- FDA
- Health Canada

How Aptar Pharma can accelerate and de-risk process

- Formulation lead candidate selection
- Supply device platform
- Support pre-clinical animal studies
- In vitro modeling to support target deposition
- Stability studies
- Combination drug product support

Market Insights Nasal Vaccines

Target markets

1. Mass Vaccination, Pandemic & Specialty Vaccines
2. Early Discovery, Preclinical and Clinical Research, Commercial

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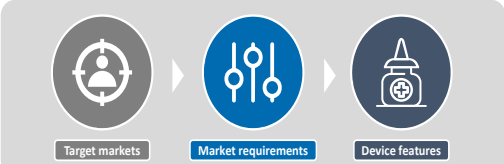
Market Insights
Nasal Vaccines



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#1 Easy to fill at CMO / Pharmaco's

#2 Cost Effective

#3 Easily Transportable (Cold Chain)

#4 Readily available for clinical trials and easily scalable for commercial

#5 End to End Service and Regulatory Support

Market requirements

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Market Insights
Nasal Vaccines

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Device features

#1 Variable dose volumes, sterile components

#2 Flexible device platform range

#3 Easily adaptable to different formulations: Liquid, Powder, Reconstituted

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Market Insights
Nasal Vaccines

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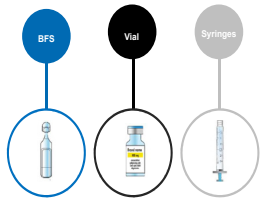
APTAR'S SOLUTION

Concepts being developed need to take into current manufacturing capabilities, needed to incorporate existing technology that could be used the vaccine space : Vials, Glass and Plastic Syringes, and technologies such as BFS.



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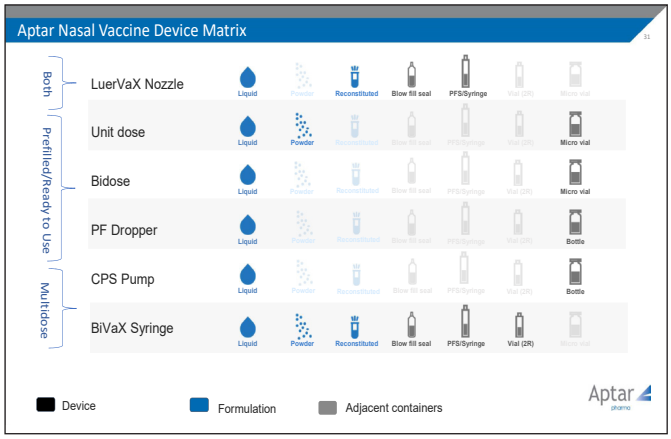
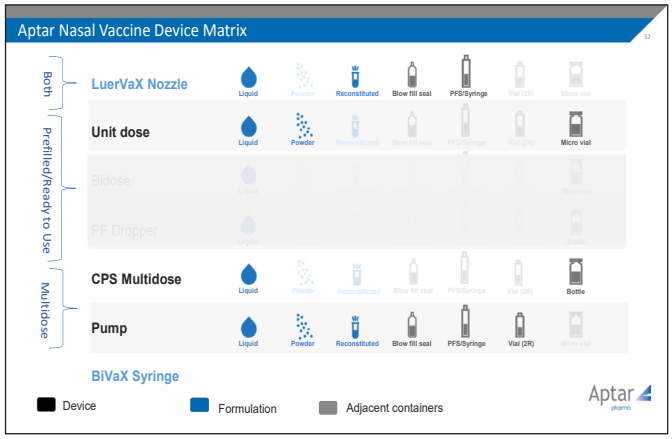

Aptar Nasal Vaccine Device Matrix
Both
Prefilled/Ready to Use
Multidose
LuerVaX Nozzle
Unit dose
Bidose
PF Dropper
CPS Pump
BiVaX Syringe
Liquid
Powder
Reconstituted
Blow fill seal
PFS/Syringe
Vial (2R)
Micro vial
Bottle
Device
Formulation
Adjacent containers
Aptar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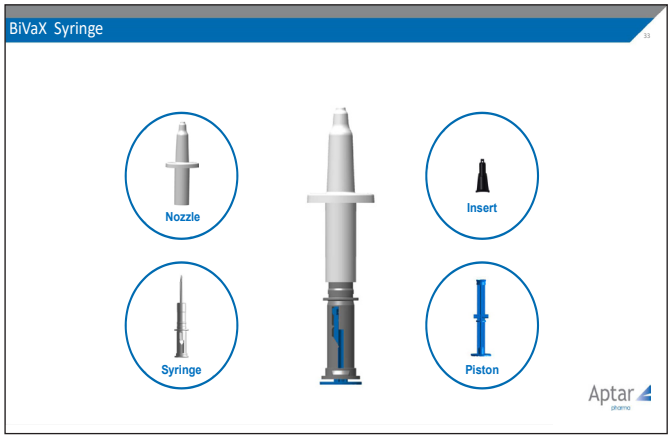
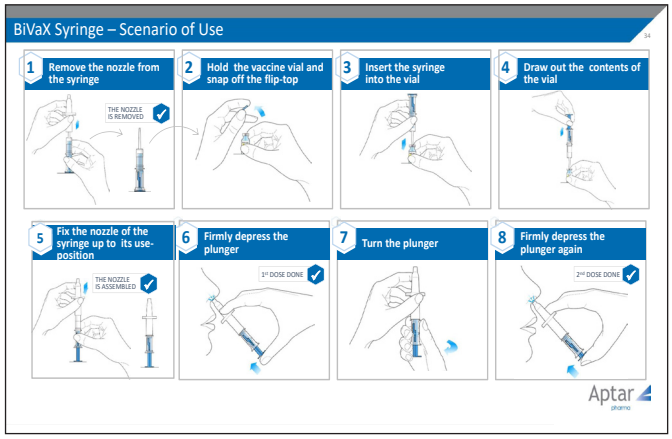
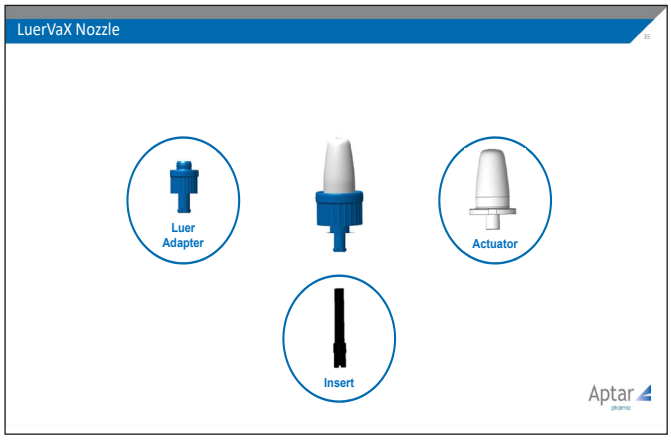
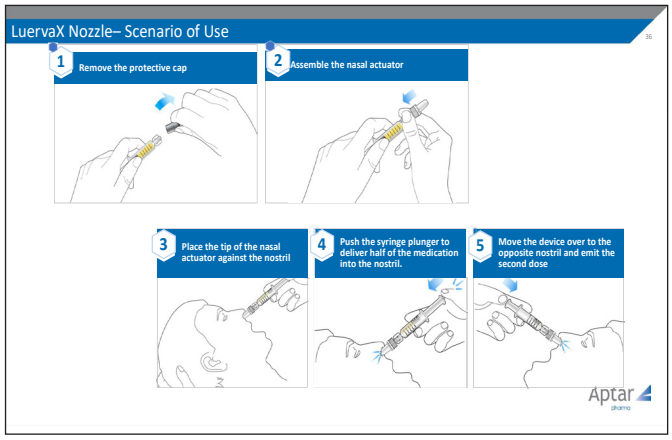

BiVaX Syringe
Nozzle
Syringe
Insert
Piston
Aptar


BiVaX Syringe – Scenario of Use
1 Remove the nozzle from the syringe
THE NOZZLE IS REMOVED
2 Hold the vaccine vial and snap off the flip-top
3 Insert the syringe into the vial
4 Draw out the contents of the vial
5 Fix the nozzle of the syringe up to its use-position
THE NOZZLE IS ASSEMBLED
6 Firmly depress the plunger
1st DOSE DONE
7 Turn the plunger
8 Firmly depress the plunger again
2nd DOSE DONE
Aptar


LuerVaX Nozzle
Luer Adapter
Actuator
Insert
Aptar


LuervaX Nozzle– Scenario of Use
1 Remove the protective cap
2 Assemble the nasal actuator
3 Place the tip of the nasal actuator against the nostril
4 Push the syringe plunger to deliver half of the medication into the nostril.
5 Move the device over to the opposite nostril and emit the second dose
Aptar

CPS Multi Dose with mass vaccination cap

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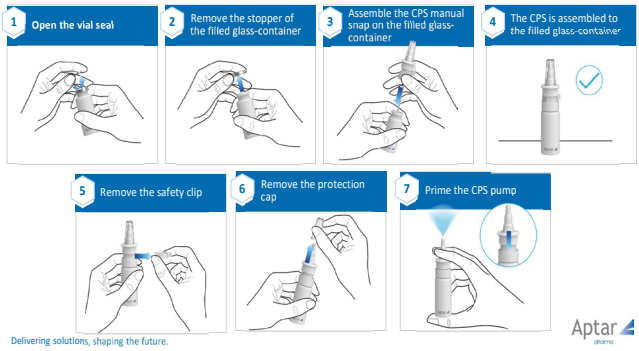
Scenario of Use



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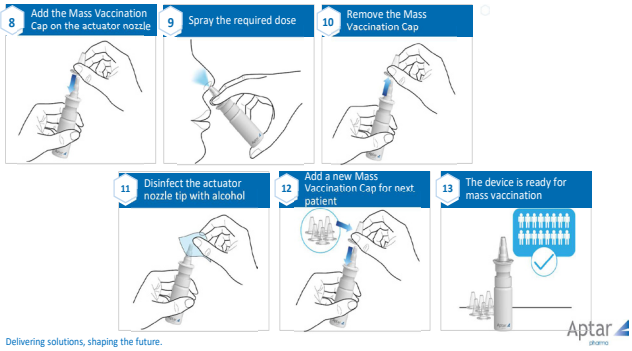
Scenario of Use



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Highlights for the CPS Platform

- Easy needle free solution & ready to use by HCP
- Existing Filling Manufacturability at CMO / Pharmaco
- Flexible dose volume from 50 to 140 mcl
- Tip seal & filter technology to protect formulation from air contamination into the container
- Reference on the market ExUSA and pending FDA approval in the US
- Can be irradiated - Sterile option according to ISO 11137
- No repriming between vaccination with mass vaccination cap

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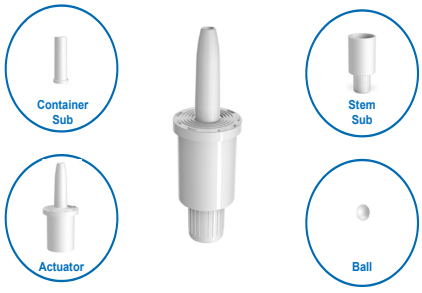
Unit Dose Powder



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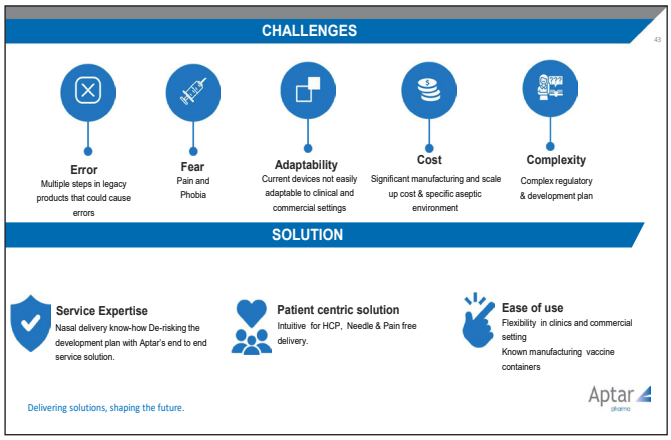
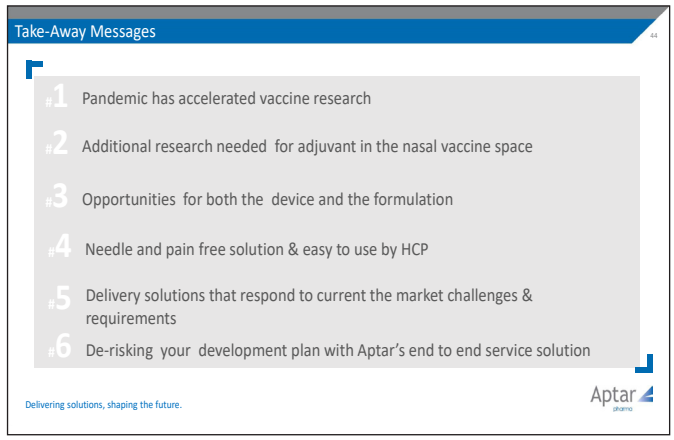
Highlights for the Nasal Powder Unit Dose Device

- Shelf life and no cold storage
- Existing Filling Manufacturability at CMO / Pharmaco
- 10 – 80 mg
- 360° Orientation easy to use by HCP
- FDA approved reference on the market

Aptar pharma





45th GST Council Meeting - Decisions taken by GST Council

Complied by Shri Prakash Rijhwani, Vice Chairman, Excise and Taxation Committee, IDMA

Highlights for Pharmaceutical Industry

- Extension of existing concessional GST rates on certain COVID-19 treatment drugs upto 31st December 2021
- GST rates on 7 other medicines recommended by Department of Pharmaceuticals reduced from 12% to 5% till 31st December 2021
- GST rate on Keytruda medicine for treatment of cancer reduced from 12% to 5%
- Life-saving drugs Zolgensma and Viltepso for Duchenne Muscular Dystrophy and Other medicines used in treatment of muscular atrophy recommended by Ministry of Health and Family Welfare and Department of Pharmaceuticals exempted from GST when imported for personal use
- GST rates on Cartons, boxes, bags, packing containers of paper etc. rationalised at 18% from 12%/ 18% - ITC available hence No additional cost.
- GST rates on Miscellaneous goods of paper like cards, catalogue, printed material (Chapter 49 of tariff) increased from 12% to 18%.
- Relaxation in the requirement of filing FORM GST ITC-04 - Requirement of filing FORM GST ITC-04 under rule 45 (3) of the CGST Rules has been relaxed as under:
  a. Taxpayers whose annual aggregate turnover in preceding financial year is above Rs. 5 crores shall furnish ITC-04 once in six months;
  b. Taxpayers whose annual aggregate turnover in preceding financial year is upto Rs. 5 crores shall furnish ITC-04 annually.

The GST Council's 45th meeting was held yesterday on 17th September 2021 in Lucknow under the chairmanship of the Union Finance & Corporate Affairs Minister Smt. Nirmala Sitharaman. The GST Council has made the **following recommendations relating to changes in GST rates on supply of goods and services and changes related to GST law and procedure:**

I. Recommendations relating to GST rates on goods and services

A. <u>COVID-19 relief measure in form of GST rate concessions</u>

1. Extension of existing concessional GST rates (currently valid till 30th September, 2021) on following Covid-19 treatment drugs, up to 31st December, 2021, namely-

i. Amphotericin B -nil

ii. Remdesivir – 5%

iii. Tocilizumab -nil

iv. Anti-coagulants like Heparin – 5%

2. Reduction of GST rate to 5% on more Covid-19 treatment drugs, up to 31st December, 2021, namely-

i. Itolizumab

ii. Posaconazole

iii. Infliximab

iv. Favipiravir

v. Casirivimab & Imdevimab

vi. 2-Deoxy-D-Glucose

vii. Bamlanivimab & Etesevimab

B. Major recommendations on GST rate changes in relation to Goods [w.e.f 1.10.2021 unless otherwise stated]

S. No.	Description	From	To
	GST rate changes		
1	Retro fitment kits for vehicles used by the disabled	Appl. rate	5%
2	Fortified Rice Kernels for schemes like ICDS etc.	18%	5%
3	Medicine Keytruda for treatment of cancer	12%	5%
4	Biodiesel supplied to OMCs for blending with Diesel	12%	5%
5	Ores and concentrates of metals such as iron, copper, aluminum, zinc and few others	5%	18%
6	Specified Renewable Energy Devices and parts	5%	12%
7	Cartons, boxes, bags, packing containers of paper etc.	12%/18%	18%
8	Waste and scrap of polyurethanes and other plastics	5%	18%
9	All kinds of pens	12%/18%	18%
10	Railway parts, locomotives & other goods in Chapter 86	12%	18%
11	Miscellaneous goods of paper like cards, catalogue, printed material (Chapter 49 of tariff)	12%	18%
12	IGST on import of medicines for personal use, namely *i. Zolgensma* for Spinal Muscular Atrophy *ii. Viltepso* for Duchenne Muscular Dystrophy iii. Other medicines used in treatment of muscular atrophy recommended by Ministry of Health and Family Welfare and Department of Pharmaceuticals.	12%	Nil
13	IGST exemption on goods supplied at Indo-Bangladesh Border haats	Appl. rate	Nil
14	Unintended waste generated during the production of fish meal except for Fish Oil	Nil (for the period 1.7.2017 to 30.9.2019)	

C. Other changes relating to GST rates on goods

1. Supply of mentha oil from unregistered person has been brought under reverse charge. Further, Council has also recommended that exports of Mentha oil should be allowed only against LUT and consequential refund of input tax credit.

2. Brick kilns would be brought under special composition scheme with threshold limit of Rs. 20 lakhs, with effect from 1.4.2022. Bricks would attract GST at the rate of 6% without ITC under the scheme. GST rate of 12% with ITC would otherwise apply to bricks.

D. Correction in Inverted Duty structure in Footwear and Textiles sector

GST rate changes in order to correct inverted duty structure, in footwear and textiles sector, as was discussed in earlier GST Council Meeting and was deferred for an appropriate time, will be implemented with effect from 01.01.2022.

E. In terms of the recent directions of the Hon'ble High Court of Kerala, the issue of whether specified

petroleum products should be brought within the ambit of GST was placed for consideration before the Council. After due deliberation, the Council was of the view that it is not appropriate to do so at this stage.

F. Major GST changes in relation to rates and scope of exemption on Services [w.e.f 1.10.2021 unless otherwise stated]

No.	Description	From	To
1	Validity of GST exemption on transport of goods by vessel and air from India to outside India is extended upto 30.9.2022.	-	Nil
2	Services by way of grant of National Permit to goods carriages on payment of fee	18%	Nil
3	Skill Training for which Government bears 75% or more of the expenditure [presently exemption applies only if Govt funds 100%].	18%	Nil
4	Services related to AFC Women's Asia Cup 2022.	18%	Nil
5	Licensing services/ the right to broadcast and show original films, sound recordings, Radio and Television programmes [to bring parity between distribution and licencing services]	12%	18%
6	Printing and reproduction services of recorded media where content is supplied by the publisher (to bring it on parity with *Colour printing of images from film or digital media*)	12%	18%
7	Exemption on leasing of rolling stock by IRFC to Indian Railways withdrawn.		
8	E Commerce Operators are being made liable to pay tax on following services provided through them.		
	i. transport of passengers, by any type of motor vehicles through it [w.e.f. 1st January, 2022]		
	ii. restaurant services provided through it with some exceptions [w.e.f. 1st January, 2022]		
9	Certain relaxations have been made in conditions relating to IGST exemption relating to import of goods on lease, where GST is paid on the lease amount, so as to allow this exemption even if (i) such goods are transferred to a new lessee in India upon expiry or termination of lease; and (ii) the lessor located in SEZ pays GST under forward charge.		

G. Clarification in relation to GST rate on Goods

1. Pure henna powder and paste, having no additives, attract 5% GST rate under Chapter 14.
2. Brewers' Spent Grain (BSG), Dried Distillers' Grains with Soluble [DDGS] and other such residues, falling under HS code 2303 attract GST at the rate of 5%.
3. All laboratory reagents and other goods falling under heading 3822 attract GST at the rate of 12%.
4. Scented sweet supari and flavored and coated illachi falling under heading 2106 attract GST at the rate of 18%
5. Carbonated Fruit Beverages of Fruit Drink" and "Carbonated Beverages with Fruit Juice" attract GST rate of 28% and Cess of 12%. This is being prescribed specifically in the GST rate schedule.
6. Tamarind seeds fall under heading 1209, and hitherto attracted nil rate irrespective of use. However, henceforth they would attract 5% GST rate (w.e.f. 1.10.2021) for use other than sowing. Seeds for sowing will continue at nil rate.
7. External batteries sold along with UPS Systems/ Inverter attract GST rate applicable to batteries [28% for batteries other than lithium-ion battery] while UPS/inverter would attract 18%.
8. GST on specified Renewable Energy Projects can be paid in terms of the 70:30 ratio for goods and services, respectively, during the period from 1.7.2017 to 31.12.2018, in the same manner as has been prescribed for the period on or after 1st January 2019.

9. Due to ambiguity in the applicable rate of GST on Fibre Drums, the supplies made at 12% GST in the past have been regularised. Henceforth, a uniform GST rate of 18% would apply to all paper and paper board containers, whether corrugated or non-corrugated.

10. Distinction between fresh and dried fruits and nuts is being clarified for application of GST rate of "nil" and 5%/12% respectively;

11. It is being clarified that all pharmaceutical goods falling under heading 3006 attract GST at the rate of 12% [not 18%].

12. Essentiality certificate issued by Directorate General of Hydrocarbons on imports would suffice; no need for taking a certificate every time on inter-state stock transfer.

H. <u>Clarification in relation to GST rate on services</u>

1. Coaching services to students provided by coaching institutions and NGOs under the central sector scheme of 'Scholarships for students with Disabilities" is exempt from GST

2. Services by cloud kitchens/central kitchens are covered under 'restaurant service', and attract 5% GST [without ITC].

3. Ice cream parlor sells already manufactured ice- cream. Such supply of ice cream by parlors would attract GST at the rate of 18%.

4. Overloading charges at toll plaza are exempt from GST being akin to toll.

5. The renting of vehicle by State Transport Undertakings and Local Authorities is covered by expression 'giving on hire' for the purposes of GST exemption

6. The services by way of grant of mineral exploration and mining rights attracted GST rate of 18% w.e.f. 01.07.2017.

7. Admission to amusement parks having rides etc. attracts GST rate of 18%. The GST rate of 28% applies only to admission to such facilities that have casinos etc.

8. Alcoholic liquor for human consumption is not food and food products for the purpose of the entry prescribing 5% GST rate on job work services in relation to food and food products.

II. On the issue of compensation scenario, a presentation was made to the Council wherein it was brought out that the revenue collections from Compensation Cess in the period beyond June 2022 till April 2026 would be exhausted in repayment of borrowings and debt servicing made to bridge the gap in 2020-21 and 2021-22. In this context various options, as have been recommended by various committees/ forums were presented. The Council deliberated at length on the issue. The Council decided to set up a GoM to examine the issue of correction of inverted duty structure for major sectors; rationalize the rates and review exemptions from the point of view of revenue augmentation, from GST. It was also decided to set up a GoM to discuss ways and means of using technology to further improve compliance including monitoring through improved e-way bill systems, e-invoices, FASTag data and strengthening the institutional mechanism for sharing of intelligence and coordinated enforcement actions by the Centre and the States.

III. Recommendations relating to GST law and procedure

I. <u>Measures for Trade facilitation</u>:

1. Relaxation in the requirement of filing FORM GST ITC-04:

Requirement of filing **FORM GST ITC-04** under rule 45 (3) of the CGST Rules has been relaxed as under:

c. Taxpayers whose annual aggregate turnover in preceding financial year is above Rs. 5 crores shall furnish ITC-04 once in six months;

d. Taxpayers whose annual aggregate turnover in preceding financial year is upto Rs. 5 crores shall furnish ITC-04 annually.

2. In the spirit of earlier Council decision that interest is to be charged **only** in respect of net cash liability, section 50 (3) of the CGST Act to be amended retrospectively, w.e.f. 01.07.2017, to provide that interest is to be paid by a taxpayer on "**ineligible ITC availed and utilized**" and not on "ineligible ITC availed". It has also been decided that interest in such cases should be charged on ineligible ITC **availed and utilized** at 18% w.e.f. 01.07.2017.

3. Unutilized balance in CGST and IGST cash ledger may be allowed to be transferred between distinct persons (entities having same PAN but registered in different states), without going through the refund procedure, subject to certain safeguards.

4. Issuance of the following circulars in order to remove ambiguity and legal disputes on various issues, thus benefiting taxpayers at large:

a. Clarification on scope of "intermediary services";

b. Clarification relating to interpretation of the term "merely establishment of distinct person" in condition (v) of the Section 2 (6) of the IGST Act 2017 for export of services. A person incorporated in India under the Companies Act, 2013 and a person incorporated under the laws of any other country are to be treated as separate legal entities and would not be barred by the condition (v) of the sub-section (6) of the section 2 of the IGST Act 2017 for considering a supply of service as export of services;

c. Clarification in respect of certain GST related issues:

i. W.e.f. 01.01.2021, the date of issuance of debit note (and not the date of underlying invoice) shall determine the relevant financial year for the purpose of section 16(4) of CGST Act, 2017;

ii. There is no need to carry the physical copy of tax invoice in cases where invoice has been generated by the supplier in the manner prescribed under rule 48(4) of the CGST Rules, 2017;

iii. Only those goods which are actually subjected to export duty i.e., on which some export duty has to be paid at the time of export, will be covered under the restriction imposed under section 54(3) of CGST Act, 2017 from availment of refund of accumulated ITC.

5. Provision to be incorporated in in CGST Rules, 2017 for removing ambiguity regarding procedure and time limit for filing refund of tax wrongfully paid as specified in section 77(1) of the CGST/ SGST Act and section 19(1) of the IGST Act.

J. <u>Measures for streamlining compliances in GST</u>

1. Aadhaar authentication of registration to be made mandatory for being eligible for filing **refund claim and application for revocation of cancellation of registration**.

2. Late fee for delayed filing of **FORM GSTR-1** to be auto-populated and collected in next open return in **FORM GSTR-3B**.

3. Refund to be disbursed in the bank account, which is linked with same PAN on which registration has been obtained under GST.

4. Rule 59(6) of the CGST Rules to be amended with effect from 01.01.2022 to provide that a registered person shall not be allowed to furnish **FORM GSTR-1**, if he has not furnished the return in **FORM GSTR-3B** for the preceding month.

5. Rule 36(4) of CGST Rules, 2017 to be amended, once the proposed clause (aa) of section 16(2) of CGST Act, 2017 is notified, to restrict availment of ITC in respect of invoices/ debit notes, to the extent the details of such invoices/ debit notes are furnished by the supplier in **FORM GSTR-1/ IFF and are** communicated to the registered person in **FORM GSTR-2B**.

K. GST Council has also recommended amendments in certain provisions of the Act and Rules.

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Taxation and other Laws (Relaxation and Amendment of Certain Provisions) Act, 2020 - reg.

S.O. 3814(E), dated 17th September, 2021

In exercise of the powers conferred by sub-section (1) of section 3 of the Taxation and Other Laws (Relaxation and Amendment of Certain Provisions) Act, 2020 (38 of 2020) (hereinafter referred to as the said Act), and in partial modification of the notifications of the Government of India in the Ministry of Finance, (Department of Revenue) No. 93/2020 dated the 31st December, 2020, published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-section (ii), vide number S.O. 4805(E), dated the 31st December, 2020 and No. 10/2021 dated the 27th February, 2021, published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-section (ii),vide number S.O. 966(E) dated the 27th February, 2021 and No. 20/2021 dated the 31st March, 2021, published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-section (ii), vide number S.O 1432(E) dated the 31st March, 2021and No. 74/2021 dated 25th June, 2021, published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-section (ii), vide number S.O. 2580(E) dated the 25th June, 2021, (hereinafter referred to as the said notifications), the Central Government hereby specifies for the purpose of sub-section (1) of section 3 of the said Act, that,—

(A) where the specified Act is the Income-tax Act, 1961 (43 of 1961) (hereinafter referred to as the Income-tax Act) and, —

(a) the completion of any action, referred to in clause (a) of sub-section (1) of section 3 of the said Act, relates to passing of any order for imposition of penalty under Chapter XXI of the Income-tax Act, —

(i) the 30th day of March, 2022 shall be the end date of the period during which the time limit specified in, or prescribed or notified under, the Income-tax Act falls for the completion of such action; and

(ii) the 31st day of March, 2022 shall be the end date to which the time-limit for completion of such action shall stand extended;

(b) the compliance of any action, referred to in clause (b) of sub-section (1) of section 3 of the said Act, relates to intimation of Aadhaar number to the prescribed authority under sub-section (2) of section 139AA of the Income-tax Act, the time-limit for such the compliance of such action shall stand extended to the 31st day of March, 2022.

(B) where the specified Act is the Prohibition of *Benami* Property Transaction Act, 1988, (45 of 1988) (hereinafter referred to as the *Benami* Act) and the completion of any action, as referred to in clause (a) of sub-section (1) of section 3 of the said Act, relates to issue of notice under sub-section (1) or passing of any order under sub-section (3) of section 26 of the *Benami* Act,—

(i) the 30th day of June, 2021 shall be the end date of the period during which the time-limit specified in or prescribed or notified under the *Benami* Act falls, for the completion of such action; and

(ii) the 31st day of March, 2022 shall be the end date to which the time-limit for completion of such action shall stand extended.

Notification No. 113/2021/
F. No. 370142/35/2020-TPL-Part 1]

Shefali Singh,
Under Secretary,
Central Board of Direct Taxes,
Tax Policy and Legislation Division,
Department of Revenue,
Ministry of Finance,
New Delhi.

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Last Date for Submitting applications for Scrip based FTP Schemes and validity period of Duty Credit Scrips- reg.

DGFT Notification No.26/2015-2020, dated 16th September 2021

1. 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 and the enabling para 3.13 of the FTP, the Central Government hereby inserts the following in the Foreign Trade Policy 2015-20 with immediate effect:

2. The following paragraphs are inserted in the FTP 2015-20 after paragraph 3.13:

"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 December 2021 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 in 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 31.12.2021, 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 31.12.2021 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

3.13B: Validity Period of Scrips

a. In supersession of existing laid down provisions regarding validity of a Duty Credit Scrip in Hand Book of Procedures (HBP) 2015-20, the new validity period of a Duty Credit Scrip issued on or after 16.09.2021 shall be 12 months from the date of issue, for scrip based Schemes under chapter 3 and chapter 4 of the Foreign Trade Policy (FTP) 2015-20 or the earlier FTPs"

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) has been notified to be 31.12.2021, in supersession of any such provision in the Hand Book of Procedures, 2015-20 going forward. Further, the validity of any scrip issued under FTP from the date of this Notification have been notified to be 12 months from the date of issue, in supersession of validity provisions in the Handbook of Procedures, 2015-20.

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

Amit Yadav, Director General of Foreign Trade, Ex officio Additional Secretary, Ministry of Commerce & Industry, Department of Commerce, New Delhi.

Amendment of policy condition no. 5 of Chapter 27 of ITC (HS), 2017, Schedule-I (Import Policy)

DGFT Notification No.27/2015-2020 dated 16/09/2021

1. In exercise of powers conferred by Section 3 read with Section 5 of FT (D&R) Act, 1992, read with paragraph 1.02 and 2.01 of the Foreign Trade Policy, 2015-2020, as amended from time to time, the Central Government hereby amends policy condition no.5 of Chapter 27 of ITC (HS), 2017, Schedule - I (Import Policy) as under:

Existing Policy Condition	Revised Policy Condition
Import allowed through IOC subject to para 2.20 of Foreign Trade Policy, except for the companies who have been granted rights for marketing of transportation fuels in terms of Ministry of P and NGs Resolution No. P23015/1/2001-MKT.Dated 8.3.2002 including HPCI, BPCI, and IBP who have been marketing transportation fuels before this date.	Import allowed through IOC subject to para 2.20 of Foreign Trade Policy, except for the who have been granted rights for marketing of transportation fuels in terms of MoP&NG Resolution No.P-23015/1/2001-MKT dated 08.03.2002 for products excluding gasoline conforming to standard IS 2796 (ITC HS Code: 27101241) and Automotive diesel fuel, not containing biodiesel, conforming to standard IS 1460 (ITC HS Code 27101944) which would be allowed to be imported by entities in terms of MoPNG Resolution No. P-12029(11)/2/2018-OMC-PNG dated 08.11.2019"

2. Effect of the Notification: Policy condition no.5 of Chapter 27 of ITC (HS), 2017, Schedule - I (Import Policy) amended in terms of Government Resolution No. P-12029(11)/2/2018-OMC-PNG dated 08.11.2019.

This is issued with the approval of Minister of Commerce & Industry.

File No. 01/93/180/03/AM-10/PC-2[A]/e-1426

Amit Yadav,
Director General of Foreign Trade,
Ex officio Additional Secretary,
Ministry of Commerce & Industry,
Department of Commerce,
New Delhi.

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De-Activation of IECs not updated on the DGFT

Trade Notice 18/2021-2022, dated 20th September 2021

To,
1. All IEC Holders/Members of Trade,
2. DGFT Regional Authorities,
3. Export Promotion Councils/Commodity Boards/ other Industry Associations.

1. This Trade Notice is being issued in reference to the Notification No. 58/2015-2020 dated 12.02.2021, 11/2015-2020 dated 01.07.2021 and 16/2015-2020 dated 09.08.2021 whereby it was mandated by DGFT to all IEC holders to ensure that details in their IEC is updated electronically every year during April-June period (for which no user charges will be borne by the IEC holder). Based on representations received from the IEC holders who had not updated their IECs, the period of updation was extended upto 31st July 2021 and subsequently to 31st August 2021.

2. In continuation to the aforementioned notification and as per para 2.05(e) of the Foreign Trade Policy (FTP), IECs which are not yet updated shall now

be de-activated. This de-activation activity is being initiated in a phased manner.

3. **All IECs which have not been updated after 01.01.2005 shall be de-activated with effect from 06.10.2021.** The list of such IECs may be seen at the given link (https://www.dgft.gov.in/CP/?opt=dgft-ra). The concerned IEC holders are provided one final opportunity to update their IEC in this interim period till 05.10.2021, failing which the given IECs shall be de-activated from 06.10.2021. Any IEC where an online updation application has been submitted but are pending with the DGFT RA for approval shall be excluded from the de-activation list.

4. **It may further be noted that any IEC so de-activated, would have the opportunity for automatic re-activation** without any manual intervention or a physical visit to the DGFT RA. For IEC re-activation after 06.10.2021, the said IEC holder may navigate to the DGFT website and update their IEC online. Upon successful updation the given IEC shall be activated again and transmitted accordingly to Customs system with the updated status.

   This issues with the approval of the competent authority.

File No. 01/02/30/AM-22/EG&TF

Md. Moin Afaque, Deputy Director General of Foreign Trade, Ministry of Commerce and Industry, Department of Commerce, Directorate General of Foreign Trade, Udyog Bhawan, New Delhi.

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Food Safety and Standards (Labelling and Display) First Amendment Regulations, 2021 - reg.

F. No. Std/SP-08/A-1.2019/N-02, dated 10th September, 2021

Whereas the draft of certain regulations, namely: -

(i) the Food Safety and Standards (Packaging and Labelling) Amendment Regulations, 2020, *vide* notification number File No. 1/Stds/Notification/Sweeteners-labelling/FSSAI-2019, dated the 16th September, 2020; and

(ii) the Food Safety and Standards (Packaging and Labelling) Amendment Regulations, 2020, *vide* notification number F. No. Std/SP-08/A-1.2019/N-02 dated the 10th November, 2020, were published as required under sub-section (1) of section 92 of the Food Safety and Standards Act, 2006 (34 of 2006) in the Gazette of India, Extraordinary, Part III, Section 4 inviting objections and suggestions from persons likely to be affected thereby before the expiry of period of sixty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the said two Gazette notifications were made available to the public on the 18th September, 2020 and 18th November, 2020, respectively;

And whereas the objections and suggestions received from the public in respect of the said two draft regulations have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by clause (k) of sub-section (2) of section 92 read with section 23 of the Food Safety and Standards Act, 2006(34 of 2006), the Food Safety and Standards Authority of India with the previous approval of the Central Government hereby makes the following regulations to amend the Food Safety and Standards (Labelling and Display) Regulations, 2020, namely: -

Regulations

1. (1) These regulations may be called the Food Safety and Standards (Labelling and Display) First Amendment Regulations, 2021.

(2) They shall come into force on the date of their publication in the Official Gazette and Food Business Operator shall comply with all the provisions of these regulations by 17th November, 2021.

2. In the Food Safety and Standards (Labelling and Display) Regulations, 2020 (herein after refer as the said regulations), in regulation 7, under sub-regulation (1), the following proviso shall be inserted, namely: -

"Provided that in case of food package having surface area upto 30cm^2 containing caloric or non caloric sweetener or mixture thereof, the size of numerals and letters for the declarations or specific requirements specified in Schedule -II shall not be less than 1mm based on the letter l."

3. In the said regulations, in Schedule-II,

(1) in clause 1, -

(a) under sub-clause (1), in the table, after S. No. 4 and the entries relating thereto, the following shall be inserted, namely: -

Sr. No.	Ingredients/additives	Declarations
"5.	10 per cent. or more Sorbitol and Sorbitol syrup	May have laxative effect, cause bloating and diarrhea in children; and reduce calcium absorption in post- menopausal women.";

(b) under sub-clause (3), in the table,

(i) for S. No. 3 and the entries relating thereto, the following shall be substituted, namely:-

Sr. No.	Articles of food	Declarations
"3.	Aspartame (Methyl ester), Acesulfame Potassium, Aspartame-Acesulfame salt, Sucralose, SACCHARINS, Neotame, Steviol Glycoside and Polyols marketed as "Table TopSweetener"	(i) Contains..... (Name of sweetener with purity and weight percent of marker compound) (ii) Not recommended for phenylketonurics; for children suffering from seizure disorders; pregnant and lactating mothers (in case of Aspartame (Methyl ester)) (iii) Not recommended for children; pregnant and lactating mothers (in case of Acesulfame Potassium) (iv) Not recommended for phenylketonurics; for children; pregnant and lactating mothers (in case off Aspartame-Acesulfame salt) (v) Not recommended for children" (in case of SACCHARINS) (vi) Polyols may have laxative effect (in case of Polyols) (vii) May have laxative effect, cause bloating and diarrhea in children; and reduce calcium absorption in post-menopausal women (in case of Sorbitol and Sorbitol syrup).";

(ii) S. No. 4 and the entries relating thereto shall be omitted;

(c) under sub-clause (4), in the table, for S. No. 1, 2 and 3 and the entries relating thereto, the following shall be substituted, namely: -

Sr. No.	Ingredients/additives	Declarations
"1.	Sweeteners mentioned under Appendix A of Food Safety and standards (Food Products standards and Food Additive) Regulations, 2011	(i) This contains..... (name of the sweetener). (ii) *Not recommended for phenylketonurics; for children suffering from seizure disorders; pregnant and lactating mothers (if Aspartame is added) (iii) *Not recommended for children; pregnant and lactating mothers" (if Acesulfame potassium is added) (iv) *Not recommended for phenylketonurics; for children; pregnant and lactating mothers (if Aspartame-Acesulfame salt is added) (v) *Not recommended for children (if SACCHARINS is added)
2	Mixture of Sweeteners mentioned under Appendix A of Food Safety and Standards (Food Products Standards and Food Additive) Regulation, 2011	This ……..... (name of food) contains an admixture of (name of the sweeteners). Provided that in addition to the above declaration every package of food containing mixture of sweeteners shall declare the labelling requirement prescribed under these regulations for the individual sweeteners present in the mixture; **Note:** In case of food package having surface area upto 100cm^2, the size of numerals & letters for such declarations shall not be less than 1.5 mm.

3.	Every package of food which is permitted to contain non-caloric sweetener mentioned in Food Safety and Standards (Food Products standards and Food Additive) Regulations, 2011	CONTAIN NON-CALORIC SWEETENER”;

(2) in clause 2, relating to “Specific requirements/ restrictions on manner of labelling”, in sub-clause 2.1,-

(a) after item (2), following shall be inserted, namely: -

“2A. In case rice bran oil which is physically refined is used as one of the ingredients in Vanaspati, it shall be declared in the ingredient list on the label as „Physically Refined Rice Bran Oil.”;

(b) for item (4), the following shall be substituted, namely: -

“(4) Every package containing an admixture of edible oils shall carry the following label declaration in bold capital letter immediately below its brand name or trade name on the front of pack, namely: -

“MULTI-SOURCE EDIBLE OIL”

(Name and nature* of edible oil) ……per cent. by weight (Name and nature* of edible oil) ……per cent. by weight

(*i.e. in raw or refined form)

For pack size less than one litre, the font size of the label declaration “MULTI-SOURCE EDIBLE OIL”, shall not be less than 3 mm with the length of declaration statement as 35 mm minimum and for label declaration “Name and Nature of edible oil per cent. by weight”, font size shall not be less than 2 mm.

For pack size one litre to below 5 litre, the font size of the label declaration “MULTI-SOURCE EDIBLE OIL” shall not be less than 4 mm with the length of declaration statement as 45 mm minimum and for label declaration “Name and Nature of edible oil per cent. by weight” font size shall not be less than 2.5 mm.

For pack size five litre and above, the font size of the label declaration “MULTI-SOURCE EDIBLE OIL” shall not be less than 10 mm and for label declaration “Name and Nature of edible oil.....per cent. by weight” font size shall not be less than 3 mm.

There shall also be the following declaration in bold capital letters along with the name of product on front of pack,-

NOT TO BE SOLD LOOSE.”

[ADVT.-III/4/Exty./256/2021-22]

Arun Singhal, Chief Executive Officer, Food Safety And Standards Authority of India, New Delhi.

Note: *The Food Safety and Standards (Labelling and Display) Regulations,2020 were published in the Gazette of India, Extraordinary, Part III, Section 4 vide notification number F. No. 1-94/FSSAI/ SP (Labelling)/2014(Pt-2), dated the 17th November, 2020.*

In Lok Sabha & In Rajya Sabha

Lok Sabha

COVID-19 Vaccine Production

Lok Sabha Unstarred Question No. 3045

Shri P.C. Mohan:

Dr. T. Sumathy (A) Thamizhachi Thangapandian:

Q. Will the Minister of Health and Family Welfare be pleased to state:

(a) the total capacity of vaccine manufacturing/ production in the country;

(b) the details of COVID-19 Vaccines produced in the country during the last one year;

(c) whether the Government has taken effective steps to increase the production of COVID-19 vaccines in the country; and

(d) if so, the details thereof?

Answered on 06th August 2021

A. (a) & (b): ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) (COVISHIELD) is manufactured by M/s Serum Institute of India Pvt., Ltd., Pune, while the Whole Virion Inactivated Corona Virus Vaccine (COVAXIN) is manufactured by M/s Bharat Biotech International Limited, Hyderabad.

As communicated by the manufacturers, the monthly vaccine production capacity of Covishield is planned to be increased from 11 crore doses per month to more than 12 crore doses per month and the production capacity of Covaxin is planned to be increased from 2.5 crore doses per month to around 5.8 crore doses per month.

From 16th January, 2021 to 5th August, 2021, 44.42 crore doses of Covishield have been supplied by M/s Serum Institute of India and 6.82 crore doses of Covaxin have been supplied by M/s Bharat Biotech International Limited for the National Covid Vaccination Programme.

(c) & (d): Central Drugs Standard Control Organisation, Ministry of Health and Family Welfare has taken various steps for fast track approval of COVID-19 Vaccines, as below:

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

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

(iii) CDSCO has granted permission for manufacturing of Gam-COVID-Vac Combined vector vaccine (SPUTNIK-V) using Ready to fill bulk to M/s Ra (biologicals) Panacea Biotec Ltd., New Delhi for restricted use in emergency situation on 02.07.2021 and manufacturing license was issued on 05.07.2021.

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

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

Under the mission, facility augmentation of Bharat Biotech and 01 State Public Sector Enterprise and 02 Central Public Sector Enterprises (PSEs) including Haffkine Biopharmaceutical Corporation Ltd, Mumbai; Indian Immunologicals Limited (IIL), Hyderabad and Bharat Immunologicals

Biologicals Limited (BIBCOL), Bulandshahr; for production of Covaxin have been supported.

In addition, Technology transfer of Covaxin production to Gujarat COVID Vaccine Consortium (GCVC), including Hester Biosciences and OmniBRx Biotechnologies Pvt Ltd, led by Gujarat Biotechnology Research Centre (GBRC), Department of Science and Technology, Govt. of Gujarat has also been facilitated.

Further, Government of India has also extended financial assistance to one of the domestic manufacturers for 'At-risk manufacturing', advance payment against the supply orders placed with M/s Serum Institute of India and M/s Bharat Biotech, and streamlining of regulatory norms for approval of vaccines.

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

Research Under Indian Council of Medical Research

Lok Sabha Unstarred Question No.3084

Shri Raja Amareshwara Naik:

Dr. Sukanta Majumdar:

Shri Rajveer Singh (Raju Bhaiya):

Shrimati Sangeeta Kumari Singh Deo:

Shri Bhola Singh:

Shri Vinod Kumar Sonkar:

Dr. Jayanta Kumar Roy:

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

(a) whether Indian Council of Medical Research (ICMR) conducts research in the field of medical sciences, if so, the details of research projects undertaken funds spent and revenue generated during the last three years, lab-wise;

(b) whether the Government has collaborated with FICCI for commercialization of technologies developed by ICMR;

(c) if so, the details of achievements made including number and cost of technology commercialized so far;

(d) whether the Government has reviewed the working of ICMR, if so, the details and the outcome thereof indicating the posts lying vacant in various labs of ICMR; and

(e) the other steps taken/being taken by the Government to improve the functioning of ICMR?

Answered on 06th August 2021

A. Indian Council of Medical Research (ICMR), an autonomous body under the Department of Health Research (DHR), is a medical research organization in the country which spearheads planning, formulation, coordination, implementation and promotion of biomedical and health research. Through its 27 research institutes across India as well as through extramural funding to promote research in institutes other than ICMR, medical colleges, Universities and non-governmental organizations, ICMR undertakes research in the area of various communicable as well as non-communicable diseases such as malaria, Japanese encephalitis, tuberculosis, HIV/AIDS, Kala-azar, Filariasis, Leprosy, Poliomyelitis, cancer, diabetes, hypertension, cardiovascular diseases and stroke. Also, it caters to the research questions pertaining to current public health concerns including nutrition, reproduction and maternal and child health, occupational and environmental health and health systems research.

Major areas of research undertaken by ICMR Institutes in the last three years can be accessed at ICMR's website at the link https://main.icmr.nic.in/sites/default/files/upload_documents /ICMR_Achievement_last_3yrs.pdf Details of the funds allocated on intramural and extramural research by ICMR in last three years are attached as **Annexure-I.**

Details of revenue generated in last three years are attached as **Annexure II.**

(b) A Memorandum of Understanding (MoU) has been executed between ICMR & FICCI for commercialization of ICMR technologies.

(c) ICMR-FICCI Health Technology Accelerated Commercialization (HTAC) program was conceived to facilitate the growth of the ICMR research as a technology provider to nation. The outcome of this program is as under:

(i) : Capacity Building and Value creation through tech transfer & commercialisation workshops.

(ii) : Technology Assessment & Commercialization whereby 20 technologies have been identified for commercialization.

(iii): Participation in Global Research and Development Summit and Exposition-2019 to display the technologies at the exposition held at this summit.

(iv): Business Development status

Technologies titled *'AV Magnivisualiser';Fly ash-based mosquito larvicidal formulations* and *A novel Salmonella Typhi protein* as subunit vaccine is under process of commercialisation.

(d): The working of ICMR has been reviewed by a Review Committee constituted by Government of India under the Chairmanship of Professor (Dr.) M. K. Bhan, Former Secretary, Department of Biotechnology, Government of India.

It, inter alia recommended strengthening the DHR and ICMR linkages; administrative reorganization of the existing institutes by merger of ICMR institutes and centres doing similar work or those having fewer than 10 scientists, or those having low productivity of less than one publication per scientist per year; enhancing Human Resource Capacities; foster Multi-Sector Collaboration; undertaking flagship research programmes in mission mode aligned to national priorities; etc.

7 small institutes of ICMR have since been merged into existing institutes. The mandates of the smaller institutes have been included in that of the parent institutes thus broadening their research expertise and complementing each other's capacities. Also, a number of fellowships have been initiated to nurture clinical scientists.

Presently, in ICMR, there are 211 posts vacant in Health Research Scientists Cadre, 228 posts in Administrative Cadre including Hindi Cadre posts and 1151 posts in Technical Cadre.

(e) A number of organizational, governance, scientific and policy level changes have been made towards augmenting capacity strengthening, infrastructure and mission mode target oriented research, as follows:

- Merger of small Institutes/Centres of ICMR has improved the work efficiency as well as helped in re-appropriating the administrative and financial resources.
- Implementation of DASHBOARD Darpan Portal for analytical review of projects for wider publicity and public awareness. Similarly, Electronic Project Proposal Management System (e-ppms) has been implemented for submission, processing, review of scientific research proposals & release of grants.
- Treasury Single Account (TSA) system was implemented in 2018-19 as part of pilot run by O/o CGA, Ministry of Finance under which entire grant of ICMR is released in RBI as Assignment rather than actual release. TSA has been resumed since April, 2021.

Time bound mission mode projects with national public health priorities in focus have been identified and initiated.

Annexure I

Details of the funds allocated by ICMR for intramural research during the last three years are as follows:

Sr. No.	Name of Institutes	Grant in Aid (2018-19) Rs. In Crore	Grant in Aid (2019-20) Rs. In Crore	Grand in Aid (2020-21) Rs. In Crore
1	Regional Medical Research Centre, Gorakhpur	3.48	4.85	4.93
2	National AIDS Research Institute, Pune	15.55	17.35	21.75
3	National Institute of Cholera and Enteric Diseases, Kolkatta	39.53	34.80	43.49
4	National Institute of Epidemiology, Chennai	25.85	32.60	34.05
5	National Institute of Malaria Research, New Delhi	66.15	80.25	78.05
6	National Institute of Medical Statistics, New Delhi	11.50	15.00	17.55

7	National Institute for Research in Tuberculosis, Chennai	68.34	81.00	83.54
8	National Institute of Virology , Pune	104.00	89.20	111.04
9	National JALMA Institute for Leprosy and other Mycobacterial Diseases Agra	34.60	34.20	32.90
10	Regional Medical Research Centre, Bhubaneswar	14.20	16.95	21.20
11	Regional Medical Research Centre, Port-Blair	6.16	7.80	9.75
12	National Institute for Research in Tribal Health, Jabalpur	25.80	29.70	27.55
13	Rajendra Memorial Research Institute of Medical Sciences, Patna	19.37	23.20	24.55
14	Vector Control Research Centre, Puducherry	30.80	34.95	38.56
15	Desert Medicine Research Centre, Jodhpur	13.25	15.55	15.80
16	National Institute of Cancer Prevention and Research , Noida	14.78	17.70	22.30
17	National Institute of Occupational Health, Ahmadabad	42.80	42.05	36.99
18	National Institute for Research in Environmental Health, Bhopal	7.12	9.70	11.98
19	National Centre for Disease Informatics and Research, Bengalure	20.18	17.20	18.88
20	National Institute of Immuno-haemotology , Mumbai	15.24	17.40	20.86
21	National Institute of Pathology, New Delhi	16.24	18.70	19.47
22	National Institute of Traditional Medicine, Belagavi	5.45	6.20	6.86
23	National Institute of Nutrition, Hyderabad	69.04	85.20	80.50
24 #	Bhopal Memorial Health Research Centre, Bhopal	0.00	0.00	131.65
25	National Animal Resource Facility for Biomedical Research , Hyderabad	10.50	9.70	6.80
26	National Institute for Research in Reproductive Health, Mumbai	41.77	49.20	53.82
27	RMRC, Dibrugarh	49.00	28.00	32.00
Grand Total	**770.70**	**818.45**	**1006.82**	

Transferred from the Department of Health Research (DHR) to Indian Council of Medical Research (ICMR) with effect from November, 2019.

Details of the funds allocated by ICMR for extramural research during the last three years are as follows:

Financial Year	Funds allocated (Rupees inCrore)
2018-19	76.27
2019-20	182.25
2020-21	56.48

Annexure II

Sr. No.	Name of Institute / Center	2018-19	2019-20	2020-21 *	Total
1	NIOH, Ahmedabad	0.31	0.32	0.97	1.60
2	RMRC, Dibrugarh	0.19	0.60	0.32	1.11
3	NIRRH, Mumbai	0.37	0.23	0.23	0.83
4	NIRTH, Jabalpur	0.34	0.27	0.12	0.73
5	NCDIR, Bengaluru	0.02	0.03	0.02	0.07
6	RMRC, Gorakhpur	0.00	0.01	0.01	0.02
7	RMRC, PortBlair	0.15	0.04	0.01	0.20
8	NIMR, Delhi	0.23	0.25	0.21	0.69
9	NIE, Chennai	0.20	0.61	0.13	0.94
10	NIN, Hyderabad	0.77	1.24	0.73	2.74
11	NIMS, New Delhi	0.06	0.07	0.37	0.50
12	NJIL&OMD, Agra	0.10	0.19	0.14	0.43
13	NIRT, Chennai	1.37	1.32	1.14	3.83
14	RMRC, Bhubaneswar	0.08	0.16	0.09	0.33
15	NARI, Pune	0.17	0.05	0.09	0.31
16	NICPR, Noida	0.66	0.15	0.10	0.91
17	NIOP, New Delhi	0.09	0.10	0.28	0.47
18	NIV, Pune	0.70	0.19	0.31	1.20
19	NIIH, Mumbai	0.49	0.30	0.09	0.88
20	RMRIMS, Patna	0.19	0.46	2.81	3.46
21	VCRC Puducherry	0.24	0.16	0.37	0.77
22	NICED, KOLKATA	4.84	0.42	0.37	5.63
23	NARF, Hyderabad	0.60	0.05	1.22	1.87
24	NIREH, Bhopal	0.04	0.00	0.01	0.05
25	NITM, Belagavi	0.06	0.04	0.06	0.16
26	NIIRNCD, Jodhpur	0.05	0.03	0.02	0.10
27 #	BMHRC Bhopal	0.00	0.00	4.24	4.24
	Total	**12.30**	**7.30**	**14.46**	**34.05**

Note - (*) Revenue for F.Y. 2020-21 are subject to Audit of Annual Accounts. (#)Transferred from the Department of Health Research (DHR) to Indian Council of Medical Research (ICMR) with effect from November, 2019.

Research and Development in Private Sector

Lok Sabha Unstarred Question No.3104

Col. Rajyavardhan Rathore:

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

(a) whether the Government has identified areas where private sector companies are in a better position to conduct scientific research and development and if so, the details thereof;

(b) whether the Government has any plans to offer tax incentives, loans, procurement commitments, or any other measures as incentives for private sector companies to conduct research on such target areas and if so, the details thereof;

(c) whether the Government has considered commercializing inventions which result from Government-aided private sector research and development ventures and if so, the details thereof; and

(d) the steps taken by the Government to double the gross expenditure in research and development every five years as per the policy objectives of the draft Science, Technology and Innovation Policy 2020?

Answered on 06th August 2021

A. (a) Yes, Sir. New Millennium Indian Technology Leadership Initiative (NMITLI) program of CSIR has identified areas viz. Agriculture & Plant Biotechnology, General Biotechnology, Bioinformatics, Drugs & Pharmaceuticals, Chemicals, Materials, Information and Communication Technology and Energy for conducting research. Considering the problems posed by corona pandemic, NMITLI called for R&D proposals on COVID-19 interventions. Six projects are under implementation. Biotechnology Industry Research Assistance Council (BIRAC), a not-for-profit Section 8- PSU under DBT undertake strategic research & innovation in the areas of affordable health care and wellness, agriculture, food and nutritional

security, environmental safety, clean energy, biofuel and bio-manufacturing. translating knowledge into technology led affordable and globally competent product development.

(b) Under NMITLI program of CSIR, soft loan @3% interest is being provided to industry to carry out research and development and the partnering public institutions are provided grant-in-aid. BIRAC, a not for profit section 8 company under DBT offers several funding schemes, programs to facilitate biotech startups, medium and large scale companies. It has funded 1000+ entrepreneurs and Startups so far. It also supports setting up of incubation centres in both public and private sector. DBT has also set up a dedicated Make in India Cell for Biotechnology at BIRAC. Make in India Cell, under the close monitoring of Department for Promotion of Industry & Internal Trade (DPIIT), has introduced and prioritized multiple initiatives including Startup India to promote innovation, capacity building, strategic growth in Industrial sector, foreign direct investment, promotion for technology adoption, manufacturing, Intellectual Property rights, employment generation and others. The Make In India Cell at BIRAC connects with stakeholders and provides critical inputs for Tax/ Fiscal incentives to Industry. It also operates Fund of Funds – AcE to support biotech startups by partnering with SEBI registered Venture Funds. BioAngels initiative is also to attract participation of private equity in biotech sector. A dedicated portal 'Biotech Showcase Portal' showcasing the complete profile of innovative products developed by biotech start-ups.

(c) BIRAC supports the startups across the value chain of product development i.e. from proof of concept (PoC) to commercialization of the innovative technologies. It also provides assistance for field validation of technologies in the Test Beds in order to promote public procurement working at the State level. The organization has released catalogues and compendium to promote the commercialization of innovative products. These booklets give complete information about the product, ranging from its market price, IP Status, awards to product positioning and its relevancy in National & International Market.

(d) The draft Science, Technology and Innovation Policy 2020 is under consideration.

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

Inspection of Industrial Units by CPCB

Lok Sabha Unstarred Question No. 3106

Shrimati Poonamben Madam:

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

(a) whether the Central Pollution Control Board (CPCB) has inspected many industrialunits;

(b) if so, the details thereof; and

(c) the action taken so far against the industrial units which have not followed theinstructions issued after inspection?

Answered on 06th August 2021

A. (a) to (c) For strengthening monitoring mechanism and effective compliance through self- regulatory mechanism, Central Pollution Control Board (CPCB) directed all 17 categories of highly polluting industries, to install Online Continuous Effluent/ Emission Monitoring Systems (OCEMS) for constant vigil on pollution levels.

CPCB carries out inspection-cum-monitoring of industries on random-basis, selected on the basis of the real time data received through OCEMS installed in industries. Since, August, 2018, CPCB has carried out inspection of 291 industries, out of which 117 units were found non-complying with prescribed environmental norms to whom show-cause notices and closure directions were issued under the provisions of Environment (Protection) Act, 1986. So far, out of 117 non-complying units, 99 units have complied with CPCB directions and for remaining 18 units, directions of CPCB are still in-force. State-wise status of inspected industries is given at **Annexure-I.**

CPCB has engaged third party technical institutes for carrying out inspections of GPIs jointly with officials from concerned State Pollution Control Boards/ Pollution Control Committes, State Mission Clean Ganga (SMCGs) and District Ganga Committee (wherever constituted). Accordingly, during 2020, out of 2740 GPIs, 2109 GPIs were found operational and 631 non-operational. Out of 2109 operational GPIs, 1512 were found complying and 597 non-complying. Out of 597 non-complying, show cause notices were issued to 562 GPIs and remaining 35 GPIs (Grossly Polluting Industries) were issued closure directions by concernedSPCBs. The state-wise status of-GPIs is given at **Annexure-II.**

ANNEXURE - I

Annexure - I referred in reply to the Lok Sabha Unstarred Question No. 3106 due for answer on 06.08.2021 regarding 'Inspection of Industrial Units of CPCB'

State-wise compliance status of 17 categories of industries inspected on random-basis, selected based on the real time data received from OCEMS

Sr. No.	State/UT	Total no. of industries Inspected	No. of industries found Non-Complying	No. of industries complied withCPCB directions	No. of industries for which CPCB directions are still in-force
1	Andhra Pradesh	14	3	3	0
2	Assam	21	7	5	2
3	Bihar	3	1	1	0
4	Chhattisgarh	17	2	2	0
5	Delhi	1	0	0	0
6	Goa	3	0	0	0
7	Gujarat	25	17	17	0
8	Haryana	11	3	3	0
9	Himachal Pradesh	2	1	1	0
10	Jammu & Kashmir	7	4	3	1
11	Jharkhand	14	5	4	1
12	Karnataka	9	5	4	1
13	Kerala	2	2	2	0
14	Madhya Pradesh	15	6	4	2
15	Maharashtra	25	14	13	1
16	Meghalaya	9	4	2	2
17	Odisha	17	11	11	0
18	Puducherry	1	0	0	0
19	Punjab	6	0	0	0
20	Rajasthan	18	1	1	0
21	Sikkim	3	1	0	1
22	Tamil Nadu	18	11	10	1
23	Telangana	10	3	3	0
24	Tripura	3	0	0	0
25	Uttar Pradesh	18	8	4	4
26	Uttarakhand	4	2	1	1
27	West Bengal	15	6	5	1
	Total	**291**	**117**	**99**	**18**

ANNEXURE - II

Annexure - II referred in reply to the Lok Sabha Unstarred Question No. 3106 due for answer on 06.08.2021 regarding 'Inspection of Industrial Units of CPCB'

State-wise compliance status of GPIs

S. No.	State	Total No of GPIs	Complied	Temporary Close	Permanent Close	Non-Complied	Show Cause Notice (Non Complied)	Closure Direction (Non Complied)
1	Bihar	53	42	5	0	6	6	0
2	Uttar Pradesh	1464	853	262	51	298	265	33
3	Uttarak hand	65	54	6	1	4	4	0
4	West Bengal	54	31	8	0	15	15	0
5	Jharkhand	5	4	0	0	1	1	0
6	Haryana	832	391	104	117	220	219	1
7	Delhi	267	137	25	52	53	52	1
Total		**2740**	**1512**	**410**	**221**	**597**	**562**	**35**

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

Rajya Sabha

Production of vaccines for COVID-19

Rajya Sabha Starred Question No. 2113

Shri M.V. Shreyams Kumar:

Q. Will the Minister of Chemicals and Fertilizers be pleased to state:

(a) the cost of production of various vaccines for COVID-19 produced by Indian pharmaceutical companies;

(b) the steps taken by Government to increase the production of COVID-19 vaccines in India and to ensure adequate and timely supply to all the States;

(c) the steps taken by Government to make available vaccines for COVID-19 in the domestic market;

(d) whether steps have been taken by Government to ensure that the entire population is fully vaccinated by December, 2021; and

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

Answered on 06th August 2021

A. (a): The manufacturing cost of medicine/vaccine is dependent of factors such as development cost, Intellectual Property Rights (IPR) cost, technology, vaccine platform & scale of production in different companies.

(b) to (c): Department of Biotechnology has informed that under "Mission COVID Suraksha- the Indian COVID-19 Vaccine Development Mission", being implemented by Biotechnology Industry Research Assistance Council (BIRAC), a Public Sector Undertaking (PSU) of DBT, facility augmentation of Bharat Biotech and 3 Public Sector Enterprises (PSEs) including Haffkine Biopharmaceutical Corporation Ltd, Mumbai; Indian Immunologicals Limited (IIL); Hyderabad; Bharat Immunologicals Biologicals Corporation Limited (BIBCOL), Bulandshahr; is being supported, for augmented production of Covaxin. Further, Technology transfer of Covaxin production to Gujarat COVID Vaccine Consortium (GCVC), comprising Hester Biosciences, OmniBRx Biotechnologies Pvt Ltd and Gujarat Biotechnology Research Centre (GBRC), Department of Science and Technology, Govt. of Gujarat; is being facilitated

by the Department of Biotechnology, with a view to enhance the production of Covaxin in the coming months.

Ministry of Health and Family Welfare has provided 100% advance to domestic vaccine manufacturers in respect of procurement order placed with them. These funds can be used by such manufacturers for their capacity augmentation. Government has also provided financial assistance to one of the vaccine manufacturer i.e. M/s Biological E for 'At-risk manufacturing' of COVID-19 vaccine.

Further, the Central Drug Standards and Control Organisation (CDSCO) under the Ministry of Health and Family Welfare has put in place a system for fast track processing of application for clinical trial & approval for COVID-19 Vaccines.

(d) to (e): Ministry of Health and Family Welfare, Government of India has ensured improved accessibility of safe COVID-19 vaccination services for eligible beneficiaries irrespective of their socio-economic status. This has been done through increase in vaccination centres, citizen friendly upgradation of Co-WIN establishment of 24x7 national call center helpline to address queries from general public on COVID-19 and the vaccination process.

Government of India is also providing 15 days advance visibility of vaccine availability to States/ UTs with an advice to prepare and publicize in advance district-wise and COVID-19 Vaccination Centers wise (CVCs) plan for accelerating the coverage of COVID-19 vaccination and for convenience of citizens. Further, a communication strategy is in place which is being implemented across all States/UTs with a focus to sustain vaccine confidence and address vaccine hesitancy. Accessibility to vaccination is being facilitated by involving Private CVCs, workplace CVCs & 'Near to Home' CVCs. Government of India regularly reviews the progress of National COVID-19 Vaccination Programme with all States/UTs to expedite its progress.

Government of India has made all arrangements to secure COVID-19 vaccines for the eligible beneficiaries as per production and the availability of COVID-19 vaccines in the country. It is expected that adequate quantity of COVID vaccine will be available between January 2021 to December 2021 to vaccinate eligible beneficiaries aged 18 years and above.

Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

MRP in comparison with manufacturing cost

Rajya Sabha Unstarred Question No. 2116

Shri Anil Desai:

Q. Will the **Minister of Chemicals and Fertilizers** be pleased to state:

(a) whether it is a fact that the Maximum Retail Price (MRP) written on medicines are excessively on the higher side in comparison with manufacturing cost;

(b) whether there is any law which prohibit excessive profits by marking higher MRP;

(c) whether Government will consider a law to ensure reasonable MRP on medicine to save common consumer from this organised loot; and

(d) the role of Drug Controller in this regard?

Answered on 06th August 2021

A. (a) to (c): National Pharmaceuticals Pricing Policy (NPPP), 2012 has one of its key principles as Market Based Pricing for regulation of prices of drugs. Based on NPPP, 2012 and subsequent Drugs (Prices Control) Order, 2013 (DPCO, 2013), the National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals fixes the ceiling price of scheduled medicines specified in the first schedule of the DPCO, 2013.

Maximum Retail Price (MRP) of a scheduled formulation is fixed by the manufacturers on the basis of ceiling price notified by NPPA plus applicable Goods and Service Tax. NPPA monitors the MRP of the scheduled formulations to ensure that the same are within the range of ceiling price. In case of non-scheduled formulation, NPPA ensures that MRP does not increase by more than 10% of MRP during the preceding twelve months. In case of any violation, the manufacturers are liable to deposit the overcharged amount along with interest thereon from the date of overcharge in addition to the penalty. Further, DPCO, 2013 provides for fixation of ceiling price or retail price of any drug in case of extraordinary circumstances, in public interest.

(d): The compliance of MRPs fixed under provisions of DPCO, 2013, is to be ensured by State Drug Controllers.

Minister in the Ministry of Chemicals and Fertilizers (Shri Mansukh Mandaviya)

Two-tier drug pricing

Rajya Sabha Unstarred Question No.2118

Smt. Jharna Das Baidya:

Q. Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether the pharmaceutical firms have urged Government to have two-tier drug pricing in the country; and

(b) if so, the details thereof, State-wise?

Answered on 06th August 2021

A. (a) and (b): No, Sir. As per available records, no request has been received by the Department of Pharmaceuticals from any pharmaceutical firm for two tier drug pricing in the country.

Minister in The Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

Shortage of antiviral drugs

Rajay Sabha Unstarred Question No. 2119

Dr. Amee Yajnik: Shri Ripun Bora:

Q. Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether Government has taken cognizance of shortages of antiviral drugs such as Remdesivir and Tocilizumab;

(b) if so, the details thereof and actions taken to address this shortage;

(c) whether Government, exercising its powers under Patents Act, intends to issue compulsory licenses to generic pharmaceutical companies for manufacturing low-cost versions of Remdesivir and Tocilizumab;

(d) if so, the details thereof, if not, the reasons therefor;

(e) the export details of Remdesivir and Tocilizumab between March 2020 till date, including volumes exported, month-wise; and

(f) the number of Remdesvir and Tocilizumab manufacturing units set up between March 2020 and June 2021?

Answered on 06th August 2021

A. (a) & (b): Yes, Sir. Shortages were noticed in the months of April and May, 2021 in case of Remdesivir and Tocilizumab due to the sudden surge in demand of these drugs for managing COVID-19 patients. It may be noted that both these drugs are patented drugs. Remdesivir is manufactured in India whereas Tocilizumab is available in India through imports only. To address the shortages, government immediately started working on augmenting supply of these drugs by augmenting domestic production in case of Remdesivir and by making efforts for increased quantity of imports in case of Tocilizumab. Due to collective efforts made in this direction by seven domestic manufacturers of Remdesivir and with the grant of expeditious approvals by Drug Controller General of India, the number of licensed manufacturing sites of Remdesivir in India increased from 22 in mid-April, 2021 to 62 at present. The domestic production capacity of Remdesivir increased from 38 lakh vials per month in mid-April, 2021 to 122 lakh vials per month now. Similarly, in case of Tocilizumab, the imported quantity was maximized due to persistent efforts of the Government with the sole manufacturer of Tocilizumab.

Further, in order to secure domestic supply of Remdesivir, the export of Remdesivir Injection and Remdesivir API (Active Pharmaceutical Ingredient) was prohibited from 11th April, 2021. In addition, Department of Pharmaceuticals (DoP) and Ministry of Health and Family Welfare (MoH&FW) jointly undertook an exercise for allocation of available stocks of Remdesivir and Tocilizumab to all the States/UTs of the country in a move to mitigate shortage and to ensure fair and equitable distribution across the country. The total supply of these two drugs to States/UTs and Central Institutions as on 01.08.2021 is given as under: -

Sr. No.	Name of the drug	Supply (number of vials)
1.	Remdesivir Injection	1,00,44,144
2.	Tocilizumab Injection	67,439

In addition to the above mentioned commercial supplies, the MoHFW has also supplied Remdesivir and Tocilizumab, free of cost, to the States/UTs and Central Institutions. The total supply of free Remdesivir and Tocilizumab as on 01.08.2021 is given as under: -

Sr. No.	Name of the drug	Supply (number of vials)
1.	Remdesivir Injection	30,10,798
2.	Tocilizumab Injection	27,381

As on date, the demand of Remdesivir has come down considerably and the demand supply gap has reversed in the sense that supply is much more than the demand. Accordingly, Remdesivir has been moved from Prohibited to Restricted Category of Exports on 14th June, 2021. Similarly, the demand-supply position for Tocilizumab has stabilized considerably and some States are not placing purchase orders with the company marketing Tocilizumab as per quantities allocated by Central Government to them. The States and UTs have been advised to procure buffer stocks to deal with any future requirements.

(c) to (d): No sir. There is no application filed for invoking compulsory licensing under Section 84 of the Patents Act with central Government by manufacturer or party intending to manufacture Remdesivir or Tocilizumab. Further, the manufacturing capacity of Remdesivir, a patented drug has been ramped up from 38 lakh vials per month to 1.22 crore vials per month now, by the seven domestic manufacturers that have been licensed in 2020 by Gilead Sciences Inc, a USA based multinational company, holding the patent for Remdesivir. Tocilizumab is also a patented drug of Hoffman La Roche, a Switzerland based multinational company and is not manufactured in India. It is pertinent to note that the Central Drugs Standard Control Organisation (CDSCO) under MoHFW, has on 12th May, 2021 given permission to one Indian pharmaceutical company for conducting phase three clinical trials for a bio-similar drug.

(e): The month-wise data of exports of Remdesivir and Tocilizumab, as shared by the Central Board of Indirect Taxes and Customs (CBIC), Department of Revenue between March, 2020 and July, 2021 is given in the Annexure.

(f) : CDSCO has informed that between March 2020 and June, 2021, 62 manufacturing sites have been approved for manufacturing Remdesivir injection in the country. As far as Tocilizumab is concerned, it is not manufactured in India but marketed in India only by way of imports.

Annexure

Month-wise data of exports of Remdesivir and Tocilizumab

Month andYear	Quantity exported Remdesivir		Quantity exported Tocilizumab
	(vials/packs/ bottles/ pieces)	(Kgs)	(vials/packs/ bottles/ pieces)
March, 2020	Nil	Nil	223
April, 2020	Nil	Nil	146
May, 2020	350	Nil	156
June, 2020	5000	1	435
July, 2020	1,26,604	3	Nil
August, 2020	2,64,956	573	Nil
September, 2020	3,26,178	11	Nil
October, 2020	6,26,737	14	Nil
November, 2020	4,55,429	66	26
December, 2020	8,05,244	510	14
January, 2021	4,04,634	36	25
February, 2021	3,57,991	5	21
March, 2021	7,16,287	82	Nil
April, 2021	86,599	10	Nil
May, 2021	Nil	Nil	Nil
June, 2021	80,003	Nil	Nil
July, 2021	19,79,632	75	Nil

Minister in the Ministry of Chemicals & Fertilizers (Shri Mansukh Mandaviya)

Recommendations of 45th GST Council Meeting Several people centric decisions taken by GST Council

dated 17 SEP 2021

Life-saving drugs Zolgensma and Viltepso used in treatment of Spinal-Muscular Atrophy exempted from GST when imported for personal use. Extension of existing concessional GST rates on certain COVID-19 treatment drugs upto 31stDecember 2021. GST rates on 7 other medicines recommended by Department of Pharmaceuticals reduced from 12% to 5% till 31st December 2021. GST rate on Keytruda medicine for treatment of cancer reduced from 12% to 5%. GST rates on Retro fitment kits for vehicles used by persons with special abilities reduced to 5%. GST rates on Fortified Rice kernels for schemes like ICDS reduced from 18% to 5%. Council also recommends major changes in GST rates and scope of exemption on Services. Recommends several clarifications in relation to GST rates on Goods and Services Council recommends several measures relating to GST law and procedure Council decides to set up 2 GoMs to examine issue of correction of inverted duty structure for major sectors and for using technology to further improve compliance, including monitoring.

The GST Council's 45th meeting was held today in Lucknow under the chairmanship of the Union Finance & Corporate Affairs Minister Smt. Nirmala Sitharaman. The GST Council has *inter-alia* made the **following recommendations relating to changes in GST rates on supply of goods and services and changes related to GST law and procedure:**

I. Recommendations relating to GST rates on goods and services

A. COVID-19 relief measure in form of GST rate concessions

1. Extension of existing concessional GST rates (currently valid till 30th September, 2021) on following Covid 19 treatment drugs, up to 31st December, 2021, namely-

i. Amphotericin B -nil

ii. Remdesivir – 5%

iii. Tocilizumab -nil

iv. Anti-coagulants like Heparin – 5%

2. Reduction of GST rate to 5% on more Covid-19 treatment drugs, up to 31st December, 2021, namely-

i. Itolizumab

ii. Posaconazole

iii. Infliximab

iv. Favipiravir

v. Casirivimab & Imdevimab

vi. 2-Deoxy-D-Glucose

vii. Bamlanivimab & Etesevimab

B. <u>Major recommendations on GST rate changes in relation to Goods [w.e.f 1.10.2021 unless otherwise stated</u>

S. No.	Description	From	To
	GST rate changes		
1.	Retro fitment kits for vehicles used by the disabled	Appl. rate	5%
2.	Fortified Rice Kernels for schemes like ICDS etc.	18%	5%
3.	Medicine Keytruda for treatment of cancer	12%	5%
4.	Biodiesel supplied to OMCs for blending with Diesel	12%	5%
5.	Ores and concentrates of metals such as iron, copper, aluminum, zinc and few others	5%	18%
6.	Specified Renewable Energy Devices and parts	5%	12%
7.	Cartons, boxes, bags, packing containers of paper etc.	12% /18%	18%
8.	Waste and scrap of polyurethanes and other plastics	5%	18%

9.	All kinds of pens	12%/18%	18%
10.	Railway parts, locomotives & other goods in Chapter 86	12%	18%
11.	Miscellaneous goods of paper like cards, catalogue, printed material (Chapter 49 of tariff)	12%	18%
12.	IGST on import of medicines for personal use, namely i. *Zolgensma* for Spinal Muscular Atrophy ii. *Viltepso* for Duchenne Muscular Dystrophy iii. Other medicines used in treatment of muscular atrophy recommended by Ministry of Health and Family Welfare and Department of Pharmaceuticals.	12%	Nil
13.	IGST exemption on goods supplied at Indo-Bangladesh Border *haats*	Appl. rate	Nil
14.	Unintended waste generated during the production of fish meal except for Fish Oil	Nil (for the period 1.7.2017 to 30.9.2019)	

C. Other changes relating to GST rates on goods

1. Supply of mentha oil from unregistered person has been brought under reverse charge. Further, Council has also recommended that exports of Mentha oil should be allowed only against LUT and consequential refund of input tax credit.
2. Brick kilns would be brought under special composition scheme with threshold limit of Rs. 20 lakhs, with effect from 1.4.2022. Bricks would attract GST at the rate of 6% without ITC under the scheme. GST rate of 12% with ITC would otherwise apply to bricks.

D. Correction in Inverted Duty structure in Footwear and Textiles sector

GST rate changes in order to correct inverted duty structure, in footwear and textiles sector, as was discussed in earlier GST Council Meeting and was deferred for an appropriate time, will be implemented with effect from 01.01.2022.

E. In terms of the recent directions of the Hon'ble High Court of Kerala, the issue of whether specified petroleum products should be brought within the ambit of GST was placed for consideration before the Council. After due deliberation, the Council was of the view that it is not appropriate to do so at this stage.

F. Major GST changes in relation to rates and scope of exemption on Services [w.e.f 1.10.2021 unless otherwise stated]

No.	Description	From	To
1.	Validity of GST exemption on transport of goods by vessel and air from India to outside India is extended upto 30.9.2022.	-	Nil
2.	Services by way of grant of National Permit to goods carriages on payment of fee	18%	Nil
3.	Skill Training for which Government bears 75% or more of the expenditure [presently exemption applies only if Govt funds 100%].	18%	Nil
4.	Services related to AFC Women's Asia Cup 2022.	18%	Nil
5.	Licensing services/ the right to broadcast and show original films, sound recordings, Radio and Television programmes [to bring parity between distribution and licencing services]	12%	18%
6.	Printing and reproduction services of recorded media where content is supplied by the publisher (to bring it on parity with *Colour printing of images from film or digital media*)	12%	18%
7.	Exemption on leasing of rolling stock by IRFC to Indian Railways withdrawn.		
8.	E Commerce Operators are being made liable to pay tax on following services provided through them i. transport of passengers, by any type of motor vehicles through it [w.e.f. 1st January, 2022] ii. restaurant services provided through it with some exceptions [w.e.f. 1st January, 2022]		

9.	Certain relaxations have been made in conditions relating to IGST exemption relating to import of goods on lease, where GST is paid on the lease amount, so as to allow this exemption even if (i) such goods are transferred to a new lessee in India upon expiry or termination of lease; and (ii) the lessor located in SEZ pays GST under forward charge.

G. Clarification in relation to GST rate on Goods

1. Pure henna powder and paste, having no additives, attract 5% GST rate under Chapter 14.
2. Brewers' Spent Grain (BSG), Dried Distillers' Grains with Soluble [DDGS] and other such residues, falling under HS code 2303 attract GST at the rate of 5%.
3. All laboratory reagents and other goods falling under heading 3822 attract GST at the rate of 12%.
4. Scented sweet supari and flavored and coated illachi falling under heading 2106 attract GST at the rate of 18%
5. Carbonated Fruit Beverages of Fruit Drink" and "Carbonated Beverages with Fruit Juice" attract GST rate of 28% and Cess of 12%. This is being prescribed specifically in the GST rate schedule.
6. Tamarind seeds fall under heading 1209, and hitherto attracted nil rate irrespective of use. However, henceforth they would attract 5% GST rate (w.e.f. 1.10.2021) for use other than sowing. Seeds for sowing will continue at nil rate.
7. External batteries sold along with UPS Systems/ Inverter attract GST rate applicable to batteries [28% for batteries other than lithium-ion battery] while UPS/ inverter would attract 18%.
8. GST on specified Renewable Energy Projects can be paid in terms of the 70:30 ratio for goods and services, respectively, during the period from 1.7.2017 to 31.12.2018, in the same manner as has been prescribed for the period on or after 1st January 2019.
9. Due to ambiguity in the applicable rate of GST on Fibre Drums, the supplies made at 12% GST in the past have been regularised. Henceforth, a uniform GST rate of 18% would apply to all paper and paper board containers, whether corrugated or non-corrugated.
10. Distinction between fresh and dried fruits and nuts is being clarified for application of GST rate of "nil" and 5%/12% respectively;
11. It is being clarified that all pharmaceutical goods falling under heading 3006 attract GST at the rate of 12% [not 18%].
12. Essentiality certificate issued by Directorate General of Hydrocarbons on imports would suffice; no need for taking a certificate every time on inter-state stock transfer.

H. Clarification in relation to GST rate on services

1. Coaching services to students provided by coaching institutions and NGOs under the central sector scheme of 'Scholarships for students with Disabilities" is exempt from GST
2. Services by cloud kitchens/central kitchens are covered under 'restaurant service', and attract 5% GST [without ITC].
3. Ice cream parlor sells already manufactured ice-cream. Such supply of ice cream by parlors would attract GST at the rate of 18%.
4. Overloading charges at toll plaza are exempt from GST being akin to toll.
5. The renting of vehicle by State Transport Undertakings and Local Authorities is covered by expression 'giving on hire' for the purposes of GST exemption
6. The services by way of grant of mineral exploration and mining rights attracted GST rate of 18% w.e.f. 01.07.2017.
7. Admission to amusement parks having rides etc. attracts GST rate of 18%. The GST rate of 28% applies only to admission to such facilities that have casinos etc.
8. Alcoholic liquor for human consumption is not food and food products for the purpose of the entry prescribing 5% GST rate on job work services in relation to food and food products.

II. On the issue of compensation scenario, a presentation was made to the Council wherein it was brought out that the revenue collections from Compensation Cess in the period beyond June 2022 till April 2026 would be exhausted in repayment of borrowings and debt servicing made to bridge the gap in 2020-21 and 2021-22. In this context various options, as have been recommended by various committees/ forums were presented. The Council deliberated at length on the issue. The Council decided to set up a GoM to examine the issue of correction of inverted duty structure for major sectors; rationalize the rates and

review exemptions from the point of view of revenue augmentation, from GST. It was also decided to set up a GoM to discuss ways and means of using technology to further improve compliance including monitoring through improved e-way bill systems, e-invoices, FASTag data and strengthening the institutional mechanism for sharing of intelligence and coordinated enforcement actions by the Centre and the States.

III. <u>Recommendations relating to GST law and procedure</u>

I. <u>Measures for Trade facilitation</u>:

1. Relaxation in the requirement of filing FORM GST ITC-04:

Requirement of filing **FORM GST ITC-04** under rule 45 (3) of the CGST Rules has been relaxed as under:

a. Taxpayers whose annual aggregate turnover in preceding financial year is above Rs. 5 crores shall furnish ITC-04 once in six months;

b. Taxpayers whose annual aggregate turnover in preceding financial year is upto Rs. 5 crores shall furnish ITC-04 annually.

2. In the spirit of earlier Council decision that interest is to be charged **only** in respect of net cash liability, section 50 (3) of the CGST Act to be amended retrospectively, w.e.f. 01.07.2017, to provide that interest is to be paid by a taxpayer on "**ineligible ITC availed and utilized**" and not on "ineligible ITC availed". It has also been decided that interest in such cases should be charged on ineligible ITC **availed and utilized** at 18% w.e.f. 01.07.2017.

3. Unutilized balance in CGST and IGST cash ledger may be allowed to be transferred between distinct persons (entities having same PAN but registered in different states), without going through the refund procedure, subject to certain safeguards.

4. Issuance of the following circulars in order to remove ambiguity and legal disputes on various issues, thus benefiting taxpayers at large:

a. Clarification on scope of "intermediary services";

b. Clarification relating to interpretation of the term "merely establishment of distinct person" in condition (v) of the Section 2 (6) of the IGST Act 2017 for export of services. A person incorporated in India under the Companies Act, 2013 and a person incorporated under the laws of any other country are to be treated as separate legal entities and would not be barred by the condition (v) of the sub-section (6) of the section 2 of the IGST Act 2017 for considering a supply of service as export of services;

c. Clarification in respect of certain GST related issues:

i. W.e.f. 01.01.2021, the date of issuance of debit note (and not the date of underlying invoice) shall determine the relevant financial year for the purpose of section 16(4) of CGST Act, 2017;

ii. There is no need to carry the physical copy of tax invoice in cases where invoice has been generated by the supplier in the manner prescribed under rule 48(4) of the CGST Rules, 2017;

iii. Only those goods which are actually subjected to export duty i.e., on which some export duty has to be paid at the time of export, will be covered under the restriction imposed under section 54(3) of CGST Act, 2017 from availment of refund of accumulated ITC.

5. Provision to be incorporated in in CGST Rules, 2017 for removing ambiguity regarding procedure and time limit for filing refund of tax wrongfully paid as specified in section 77(1) of the CGST/ SGST Act and section 19(1) of the IGST Act.

J. Measures for streamlining compliances in GST

1. Aadhaar authentication of registration to be made mandatory for being eligible for filing **refund claim and application for revocation of cancellation of registration**.

2. Late fee for delayed filing of **FORM GSTR-1** to be auto-populated and collected in next open return in **FORM GSTR-3B**.

3. Refund to be disbursed in the bank account, which is linked with same PAN on which registration has been obtained under GST.

4. Rule 59(6) of the CGST Rules to be amended with effect from 01.01.2022 to provide that a registered person shall not be allowed to furnish

FORM GSTR-1, if he has not furnished the return in **FORM GSTR- 3B** for the preceding month.

5. Rule 36(4) of CGST Rules, 2017 to be amended, once the proposed clause (aa) of section 16(2) of CGST Act, 2017 is notified, to restrict availment of ITC in respect of invoices/ debit notes, to the extent the details of such invoices/ debit notes are furnished by the supplier in **FORM GSTR-1/ IFF and are** communicated to the registered person in **FORM GSTR-2B**.

K. GST Council has also recommended amendments in certain provisions of the Act and Rules.

Note: The recommendations of the GST Council have been presented in this release containing major item of decisions in simple language for information of all stakeholders. The same would be given effect through relevant Circulars/ Notifications/ Law amendments which alone shall have the force of law.

Source: PIB Delhi, 17.09.2021

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GST MATTERS

Clarification on doubts related to scope of "Intermediary"– reg.

Circular No. 159/15/2021-GST, dated 20th September, 2021

To,
The Principal Chief Commissioners/Chief Commissioners/ Principal Commissioners/ Commissioners of Central Tax (All)
The Principal Directors General/ Directors General (All).

1. Representations have been received citing ambiguity caused in interpretation of the scope of "Intermediary services" in the GST Law. The matter has been examined. In view of the difficulties being faced by the trade and industry and to ensure uniformity in the implementation of the provisions of the law across field formations, the Board, in exercise of its powers conferred by section 168 (1) of the Central Goods and Services Tax Act, 2017 (hereinafter referred to as "CGST Act"), hereby clarifies the issues in succeeding paragraphs.

2. Scope of Intermediary services

2.1 'Intermediary' has been defined in the sub-section (13) of section 2 of the Integrated Goods and Services Tax Act, 2017 (hereinafter referred to as "IGST" Act) as under–

"Intermediary means a broker, an agent or any other person, by whatever name called, who arranges or facilitates the supply of goods or services or both, or securities, between two or more persons, but does not include a person who supplies such goods or services or both or securities on his own account."

2.2 The concept of 'intermediary' was borrowed in GST from the Service Tax Regime. The definition of 'intermediary' in the Service Tax law as given in Rule 2(f) of Place of Provision of Services Rules, 2012 issued vide notification No. 28/2012-ST, dated 20-6-2012 was as follows:

"intermediary" means a broker, an agent or any other person, by whatever name called, who arranges or facilitates a provision of a service (hereinafter called the 'main' service) or a supply of goods, between two or more persons, but does not include a person who provides the main service or supplies the goods on his account;"

From the perusal of the definition of "intermediary" under IGST Act as well as under Service Tax law, it is evident that there is broadly no change in the scope of intermediary services in the GST regime vis-à-vis the Service Tax regime, except addition of supply of securities in the definition of intermediary in the GST Law.

3. Primary Requirements for intermediary services

The concept of intermediary services, as defined above, requires some basic pre- requisites, which are discussed below:

3.1 Minimum of Three Parties: By definition, an intermediary is someone who arranges or

facilitates the supplies of goods or services or securities between two or more persons. It is thus a natural corollary that the arrangement requires a minimum of three parties, two of them transacting in the supply of goods or services or securities (the main supply) and one arranging or facilitating (the ancillary supply) the said main supply. An activity between only two parties can, therefore, NOT be considered as an intermediary service. An intermediary essentially "arranges or facilitates" another supply (the "main supply") between two or more other persons and, does not himself provide the main supply.

3.2 Two distinct supplies: As discussed above, there are two distinct supplies in case of provision of intermediary services;

(1) Main supply, between the two principals, which can be a supply of goods or services or securities;

(2) Ancillary supply, which is the service of facilitating or arranging the main supply between the two principals. This ancillary supply is supply of intermediary service and is clearly identifiable and distinguished from the main supply.

A person involved in supply of main supply on principal to principal basis to another person cannot be considered as supplier of intermediary service.

3.3 Intermediary service provider to have the character of an agent, broker or any other similar person: The definition of "intermediary" itself provides that intermediary service provider *means a broker, an agent or any other person, by whatever name called*….". This part of the definition is not inclusive but uses the expression "means" and does not expand the definition by any known expression of expansion such as "and includes". The use of the expression "arranges or facilitates" in the definition of "intermediary" suggests a subsidiary role for the intermediary. It must arrange or facilitate some other supply, which is the main supply, and does not himself provides the main supply. Thus, the role of intermediary is only supportive.

3.4 **Does not include a person who supplies such goods or services or both or securities on his own account:** The definition of intermediary services specifically mentions that intermediary "*does not include a person who supplies **such** goods or services or both or securities on his own account". Use of word "**such**"* in the definition with reference to supply of goods or services refers to the main supply of goods or services or both, or securities, between two or more persons, which are arranged or facilitated by the intermediary. It implies that in cases wherein the person supplies the main supply, either fully or partly, on principal to principal basis, the said supply cannot be covered under the scope of "intermediary".

3.5 **Sub-contracting for a service is not an intermediary service:** An important exclusion from intermediary is sub-contracting. The supplier of main service may decide to outsource the supply of the main service, either fully or partly, to one or more sub-contractors. Such sub-contractor provides the main supply, either fully or a part thereof, and does not merely arrange or facilitate the main supply between the principal supplier and his customers, and therefore, clearly is not an intermediary. For instance, 'A' and 'B' have entered into a contract as per which 'A' needs to provide a service of, say, Annual Maintenance of tools and machinery to 'B'. 'A' subcontracts a part or whole of it to 'C'. Accordingly, 'C' provides the service of annual maintenance to 'A' as part of such sub-contract, by providing annual maintenance of tools and machinery to the customer of 'A', i.e. to 'B' on behalf of 'A'. Though 'C' is dealing with the customer of 'A', but 'C' is providing main supply of Annual Maintenance Service to 'A' on his own account, i.e. on principal to principal basis. In this case, 'A' is providing supply of Annual Maintenance Service to 'B', whereas 'C' is supplying the same service to 'A'. Thus, supply of service by 'C' in this case will not be considered as an intermediary.

3.6 The specific provision of place of supply of 'intermediary services' under section 13 of the IGST Act shall be invoked **only when** either the location of supplier of intermediary services or location of the recipient of intermediary services is outside India.

4. Applying the above mentioned guiding principles, the issue of intermediary services is clarified through the following illustrations:

Illustration 1

'A' is a manufacturer and supplier of a machine. 'C' helps 'A' in selling the machine by identifying client 'B' who wants to purchase this machine and helps in finalizing the contract of supply of machine by 'A' to 'B'. 'C' charges 'A' for his services of locating 'B' and helping in finalizing the sale of machine between 'A' and 'B', for which 'C' invoices 'A' and is paid by 'A' for the same. While 'A' and 'B' are involved in the main supply of the machinery, 'C', is facilitating the supply of machine between 'A' and 'B'. In this arrangement, 'C' is providing the ancillary supply of arranging or facilitating the 'main supply' of machinery between 'A' and 'B' and therefore, 'C' is an intermediary and is providing intermediary service to 'A'.

Illustration 2

'A' is a software company which develops software for the clients as per their requirement. 'A' has a contract with 'B' for providing some customized software for its business operations.

'A' outsources the task of design and development of a particular module of the software to 'C', for which "C' may have to interact with 'B', to know their specific requirements. In this case, 'C' is providing main supply of service of design and development of software to 'A', and thus, 'C' is not an intermediary in this case.

Illustration 3

An insurance company 'P', located outside India, requires to process insurance claims of its clients in respect of the insurance service being provided by 'P' to the clients. For processing insurance claims, 'P' decides to outsource this work to some other firm. For this purpose, he approaches 'Q', located in India, for arranging insurance claims processing service from other service providers in India. 'Q' contacts 'R', who is in business of providing such insurance claims processing service, and arranges supply of insurance claims processing service by 'R' to 'P'. 'Q' charges P a commission or service charge of 1% of the contract value of insurance claims processing service provided by 'R' to 'P'. In such a case, main supply of insurance claims processing service is between 'P' and 'R', while 'Q' is merely arranging or facilitating the supply of services between 'P' and 'R', and not himself providing the main supply of services. Accordingly, in this case, 'Q' acts as an intermediary as per definition of sub-section of section 2 of the IGST Act.

Illustration 4

'A' is a manufacturer and supplier of computers based in USA and supplies its goods all over the world. As a part of this supply, 'A' is also required to provide customer care service to its customers to address their queries and complains related to the said supply of computers. 'A' decides to outsource the task of providing customer care services to a BPO firm, 'B'. 'B' provides customer care service to 'A' by interacting with the customers of 'A' and addressing/ processing their queries / complains. 'B' charges 'A' for this service. 'B' is involved in supply of main service 'customer care service' to 'A', and therefore, ''B' is not an intermediary.

5. The illustrations given in para 4 above are only indicative and not exhaustive. The illustrations are also generic in nature and should not be interpreted to mean that the service categories mentioned therein are inherently either intermediary services or otherwise. Whether or not, a specific service would fall under intermediary services within the meaning of sub-section (13) of section 2 of the IGST Act, would depend upon the facts of the specific case. While examining the facts of the case and the terms of contract, the basic characteristics of intermediary services, as discussed in para 3 above, should be kept in consideration.

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

7. Difficulty, if any, in the implementation of this Circular may be brought to the notice of the Board. Hindi version will follow.

F.No. CBIC-20001/8/2021-GST

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

Clarification in respect of certain GST related issues - reg.

Circular No. 160/16/2021-GST, dated the 20th September, 2021

To
The Pr. Chief Commissioners / Chief Commissioners / Principal Commissioners / Commissioners of Central Tax (All)
The Principal Directors General / Directors General (All).

Various representations have been received from taxpayers and other stakeholders seeking clarification in respect of certain issues pertaining to GST laws. The issues have been examined. In order to ensure uniformity in the implementation of the provisions of the law across field formations, the Board, in exercise of its powers conferred by section 168(1) of the Central Goods and Services Tax Act, 2017 (hereinafter referred to as "CGST Act"), hereby clarifies each of these issues as under:

S. No.	Issue	Clarification
1.	Section 16 (4), as amended with effect from 01.01.2021, provides that a registered person shall not be entitled to take input tax credit in respect of any invoice or debit note for supply of goods or services or both after the due date of furnishing of the return under section 39 for the month of September **following the end of financial year to which such invoice or debit note pertains** or furnishing of the relevant annual return, whichever is earlier. Doubts have been raised seeking following clarification: 1. Which of the following dates are relevant to determine the 'financial year' for the purpose of section 16(4): (a) date of issuance of debit note, or (b) date of issuance of underlying invoice.	1. With effect from 01.01.2021, section 16(4) of the CGST Act, 2017 was amended *vide* the Finance Act, 2020, so as to delink the date of issuance of debit note from the date of issuance of the underlying invoice for purposes of availing input tax credit. The amendment made is shown as below: *"A registered person shall not be entitled to take input tax credit in respect of any invoice or debit note for supply of goods or services or both after the due date of furnishing of the return under section 39 for the month of September following the end of financial year to which such invoice or* ~~***invoice relating to such***~~ *debit note pertains or furnishing of the relevant annual return, whichever is earlier."* As can be seen, the words "invoice relating to such" were omitted w.e.f. 01.01.2021. 2. The intent of law as specified in the Memorandum explaining the Finance Bill, 2020 states that "*Clause 118 of the Bill seeks to amend sub-section (4) of section 16 of the Central Goods and Services Tax Act so as to* ***delink the date of issuance of*** *IDMA Bulletin LII (35) 15 to 21 September 2021* 44

	2. Whether any availment of input tax credit, on or after 01.01.2021, in respect of debit notes issued either prior to or after 01.01.2021, will be governed by the provisions of the amended section 16(4), or the amended provision will be applicable only in respect of the debit notes issued after 01.01.2021?	***debit note from the date of issuance of the underlying invoice for purposes of availing input tax credit.*** 3. Accordingly, it is clarified that: a) w.e.f. 01.01.2021, in case of debit notes, the date of issuance of debit note (not the date of underlying invoice) shall determine the relevant financial year for the purpose of section 16(4) of the CGST Act. b) The availment of ITC on debit notes in respect of amended provision shall be applicable from 01.01.2021. Accordingly, for availment of ITC on or after 01.01.2021, in respect of debit notes issued either prior to or after 01.01.2021, the eligibility for availment of ITC will be governed by the amended provision of section 16(4), whereas any ITC availed prior to 01.01.2021, in respect of debit notes, shall be governed under the provisions of section 16(4), as it existed before the said amendment on 01.01.2021. ***Illustration 1***. A debit note dated 07.07.2021 is issued in respect of the original invoice dated 16.03.2021. As the invoice pertains to F.Y. 2020-21, the relevant financial year for availment of ITC in respect of the said invoice in terms of section 16(4) of the CGST shall be 2020-21. However, as the debit note has been issued in FY 2021-22, the relevant financial year for availment of ITC in respect of the said debit note shall be 2021-22 in terms of amended provision of section 16(4) of the CGST Act.

		Illustration 2. A debit note has been issued on 10.11.2020 in respect an invoice dated 15.07.2019. As per amended provision of section 16(4), the relevant financial year for availment of input tax credit on the said debit note, on or after 01.01.2021, will be FY 2020-21 and accordingly, the registered person can avail ITC on the same till due date of furnishing of FORM GSTR-3B for the month of September, 2021 or furnishing of the annual return for FY 2020-21, whichever is earlier.
2.	Whether carrying physical copy of invoice is compulsory during movement of goods in cases where suppliers have issued invoices in the manner prescribed under rule 48 (4) of the CGST Rules, 2017 (i.e. in cases of e-invoice).	1. Rule 138A (1) of the CGST Rules, 2017 *inter-alia,* provides that the person in charge of a conveyance shall carry— (a) the **invoice or bill of supply or delivery challan**, as the case may be; and (b) a copy of the e-way bill or the e-way bill number, either physically or mapped to a **Radio Frequency Identification Device** embedded on to the conveyance in such manner as may be notified by the Commissioner. 2. Further, rule 138A (2) of CGST Rules, after being amended *vide* notification No. 72/2020-Central Tax dated 30.09.2020, states that "*In case, invoice is issued in the manner prescribed under sub-rule (4) of rule 48, the Quick Reference (QR) code having an embedded* ***Invoice Reference Number (IRN)*** *in it, may be produced electronically, for verification by the proper officer in lieu of the physical copy of such tax invoice*" 3. A conjoint reading of rules 138A (1) and 138A (2) of CGST Rules, 2017 clearly indicates that there is no requirement to carry the physical copy of tax invoice in

		cases where e-invoice has been generated by the supplier. After amendment, the revised rule 138A (2) states in unambiguous words that whenever e-invoice has been generated, the Quick Reference (QR) code, having an embedded **Invoice Reference Number (IRN)** in it, may be produced electronically for verification by the proper officer **in lieu of the physical copy of such tax invoice.** 4. **Accordingly, it is clarified that there is no need to carry the physical copy of tax invoice in cases where invoice has been generated by the supplier in the manner prescribed under rule 48(4) of the CGST Rules and production of the Quick Response (QR) code having an embedded Invoice Reference Number (IRN) electronically, for verification by the proper officer, would suffice.**
3.	Whether the first proviso to section 54(3) of CGST / SGST Act, prohibiting refund of unutilized ITC is applicable in case of exports of goods which are having NIL rate of export duty.	1. The term '**subjected to export duty'** used in first proviso to section 54(3) of the CGST Act, 2017 means where the goods are actually leviable to export duty and suffering export duty at the time of export. Therefore, goods in respect of which either NIL rate is specified in Second Schedule to the Customs Tariff Act, 1975 or which are fully exempted from payment of export duty by virtue of any customs notification or which are not covered under Second Schedule to the Customs Tariff Act, 1975, cannot be considered to be subjected to any export duty under Customs Tariff Act, 1975. 2. **Accordingly, it is clarified that only those goods which are actually subjected to export duty i.e., on which some export duty has to be paid at the time of export,**

		will be covered under the restriction imposed under section 54(3) from availment of refund of accumulated ITC. Goods, which are not subject to any export duty and in respect of which either NIL rate is specified in Second Schedule to the Customs Tariff Act, 1975 or which are fully exempted from payment of export duty by virtue of any customs notification or which are not covered under Second Schedule to the Customs Tariff Act, 1975, **would not be covered by the restriction imposed under the first proviso to section 54(3) of the CGST Act for the purpose of availment of refund of accumulated ITC.**

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

3. Difficulty, if any, in the implementation of this Circular may be brought to the notice of the Board. Hindi version will follow.

F. No. CBIC-20001/8/2021-GST

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

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Clarification relating to export of services-condition (v) of section 2(6) of the IGST Act 2017–reg.

Circular No. 161/17/2021-GST, dated 20th September, 2021

To
The Pr. Chief Commissioners / Chief Commissioners / Principal Commissioners/Commissioners of Central Tax (All),
The Principal Directors General / Directors General (All).

1. Various representations have been received citing ambiguity caused in interpretation of the Explanation 1 under section 8 of the IGST Act 2017 in relation to condition (v) of export of services as mentioned in sub-section (6) of the section 2 of the IGST Act 2017. Doubts have been raised whether the supply of service by a subsidiary/ sister concern/ group concern, etc. of a foreign company in India, which is incorporated under the laws in India, to the foreign company incorporated under laws of a country outside India, will hit by condition (v) of subsection (6) of section 2 of IGST Act.

2. The matter has been examined. In view of the difficulties being faced by the trade and industry and to ensure uniformity in the implementation of the provisions of the law across field formations, the Board, in exercise of its powers conferred by section 168 (1) of the Central Goods and Services Tax Act, 2017 (hereinafter referred to as "CGST Act"), hereby clarifies the issue in succeeding paragraphs.

Relevant legal provisions:

3.1 The export of services has been defined in sub-section (6) of the section 2 of the IGST Act 2017 as under:

(6) "export of services" means the supply of any service when,—

(i) the supplier of service is located in India;

(ii) the recipient of service is located outside India;

(iii) the place of supply of service is outside India;

(iv) the payment for such service has been received by the supplier of service in convertible foreign exchange; and

(v) the supplier of service and the recipient of service are not merely establishments of a distinct person in accordance with Explanation 1 in section 8;

3.2 Explanation 1 of the Section 8 of the IGST Act provides for the conditions wherein establishments of a person would be treated as establishments of distinct persons, which is reproduced as under:

Explanation 1.—For the purposes of this Act, where a person has,—

(i) an establishment in India and any other establishment outside India;

(ii) an establishment in a State or Union territory and any other establishment outside that State or Union territory; or

(iii) an establishment in a State or Union territory and any other establishment being a business vertical registered within that State or Union territory, then such establishments shall be treated as establishments of distinct persons.

As per the above Explanation, an establishment of a person in India and another establishment of the said person outside India are considered as establishments of distinct persons.

3.3 Reference is also invited to the Explanation 2 of Section 8 of IGST Act, which is reproduced below:

"Explanation 2.—A person carrying on a business through a branch or an agency or a representational office in any territory shall be treated as having an establishment in that territory."

3.4 Reference is also invited to the definition of "person" as provided under CGST Act 2017, made applicable to IGST Act vide section 2(24) of IGST Act 2017. "Person" has been defined under sub-section (84) of the section 2 of the CGST Act 2017, as under:

(84) "person" includes—

(a) an individual;

(b) a Hindu Undivided Family;

(c) a company;

(d) a firm;

(e) a Limited Liability Partnership;

(f) an association of persons or a body of individuals, whether incorporated or not, in India or outside India;

(g) any corporation established by or under any Central Act, State Act or Provincial Act or a Government company as defined in clause (45) of section 2 of the Companies Act, 2013;

(h) any body corporate incorporated by or under the laws of a country outside India;

(i) a co-operative society registered under any law relating to co-operative societies;

(j) a local authority;

(k) Central Government or a State Government;

(l) society as defined under the Societies Registration Act, 1860;

(m) trust; and

(n) every artificial juridical person, not falling within any of the above;

3.5. The definitions of company and foreign company have been provided under section 2 of Companies Act 2013, as under:

(20) "company" means a company incorporated under this Act or under any previous company law;

(42) "foreign company" means any company or body corporate incorporated outside India which—

(a) has a place of business in India whether by itself or through an agent, physically or through electronic mode; and

(b) conducts any business activity in India in any other manner.

Analysis of the issue:

4.1 Clause (v) of sub-section (6) of section 2 of IGST Act, which defines "export of services", places a condition that the services provided by one establishment of a person to another establishment of the same person, considered as establishments of distinct persons as per Explanation 1 of section 8 of IGST Act, cannot be treated as export. In other words, any supply of

services by an establishment of a foreign company in India to any other establishment of the said foreign company outside India will not be covered under definition of export of services.

4.2 Further, perusal of the Explanation 2 to section 8 of the IGST Act suggests that if a foreign company is conducting business in India through a branch or an agency or a representational office, then the said branch or agency or representational office of the foreign company, located in India, shall be treated as establishment of the said foreign company in India. Similarly, if any company incorporated in India, is operating through a branch or an agency or a representational office in any country outside India, then that branch or agency or representational office shall be treated as the establishment of the said company in the said country.

4.3. In view of the above, it can be stated that supply of services made by a branch or an agency or representational office of a foreign company, not incorporated in India, to any establishment of the said foreign company outside India, shall be treated as supply between establishments of distinct persons and shall not be considered as "export of services" in view of condition (v) of sub-section (6) of section 2 of IGST Act. Similarly, any supply of service by a company incorporated in India to its branch or agency or representational office, located in any other country and not incorporated under the laws of the said country, shall also be considered as supply between establishments of distinct persons and cannot be treated as export of services.

4.4 From the perusal of the definition of "person" under sub-section (84) of section 2 of the CGST Act, 2017 and the definitions of "company" and "foreign company" under Section 2 of the Companies Act, 2013, it is observed that a company incorporated in India and a foreign company incorporated outside India, are separate "person" under the provisions of CGST Act and accordingly, are separate legal entities. Thus, a subsidiary/ sister concern/ group concern of any foreign company which is incorporated in India, then the said company incorporated in India will be considered as a separate "person" under the provisions of CGST Act and accordingly, would be considered as a separate legal entity than the foreign company.

Clarification:

5.1 In view of the above, it is clarified that a company incorporated in India and a body corporate incorporated by or under the laws of a country outside India, which is also referred to as foreign company under Companies Act, are separate persons under CGST Act, and thus are separate legal entities. Accordingly, these two separate persons would not be considered as "merely establishments of a distinct person in accordance with Explanation 1 in section 8".

5.2 Therefore, supply of services by a subsidiary/ sister concern/ group concern, etc. of a foreign company, which is incorporated in India under the Companies Act, 2013 (and thus qualifies as a 'company' in India as per Companies Act), to the establishments of the said foreign company located outside India (incorporated outside India), would not be barred by the condition (v) of the sub-section (6) of the section 2 of the IGST Act 2017 for being considered as export of services, as it would not be treated as supply between merely establishments of distinct persons under Explanation 1 of section 8 of IGST Act 2017 . Similarly, the supply from a company incorporated in India to its related establishments outside India, which are incorporated under the laws outside India, would not be treated as supply to merely establishments of distinct person under Explanation 1 of section 8 of IGST Act 2017. Such supplies, therefore, would qualify as 'export of services', subject to fulfilment of other conditions as provided under sub-section (6) of section 2 of IGST Act.

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

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

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

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India's weekly Covid-19 cases drop 15%, lowest in 6 months

India recorded a 15% drop in fresh Covid-19 detected in the week ending Sunday, the lowest weekly count in more than six months, with Kerala numbers declining by a steep 21%. The country reported over 2.14 lakh new cases in the week (September 13-19), down from 2.51 lakh in the previous seven days. This was the lowest number of cases reported in 27 weeks since March 8-14 (for weeks ending Sunday).

VACCINE TRACKER

State/UT	% Of 18+ Population Covered	
	Both Shots	At least one shot
India	21.7	64
Himachal Pradesh	40	100
Kerala	36.7	89
Gujarat	34	81.5
Uttarakhand	33.6	89.5
Delhi	31.8	74.2
Jammu & Kashmir	30.3	76.2
Andhra Pradesh	29.8	64.2
Karnataka	29.7	76.4
NE minus Assam	28.7	64.7
Rajasthan	27.6	76.2
Haryana	26.6	74.4
Maharashtra	22.5	57.6
Madhya Pradesh	22.4	81.8
Odisha	21.9	62.5
Telangana	21.6	56.4
Chhattisgarh	21	60.8
West Bengal	20.2	49.5
Assam	19.2	73.4
Punjab	19.1	58.8
Tamil Nadu	15.1	56.6
Jharkhand	13.9	50.2
Bihar	12.6	55.4
Uttar Pradesh	11.3	52.6

Source: Health ministry for vaccination, Census projections for population. As of 7 am on Sep 12

This was the second consecutive week of a substantial decline in Covid numbers. Last week, cases in the country had seen a 13% drop, while in the previous seven days, numbers were mainly flat with a drop of just 0.6%.

The sharp fall in infections were mainly due to numbers dropping in Kerala, which still accounted for 62% of all cases in the country during the week. Kerala reported 1.33 lakh fresh cases, a drop of 20.6% from the previous week's tally of over 1.67 lakh. Two week earlier, Kerala's weekly case count had crossed 2 lakh, as the latest wave of the pandemic in the state peaked.

Source : TNN, 20.09.2021

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Plain-clothed Health Minister hit by security guard during surprise visit to Safdarjung hospital

Mansukh Mandaviya said that he dawned the disguise to find out the real condition of the hospital

File image of Union health minister Mansukh Mandaviya. News18

Union Health Minister Mansukh Mandaviya said that he was assaulted by a guard at Delhi's Safdarjung hospital when he made a surprise visit as a general patient.

He revealed the story during the inauguration of four health facilities at Safdarjung Hospital on Thursday. He inaugurated a child abuse care and elder abuse care centre in the new block, the third PM-CARES Pressure Swing Adsorption Oxygen Plant with capacity 1 MT, and a new makeshift hospital at the hospital premises. He released a booklet 'Quality ki Baat' and presented the hospital its entry-level NABH accreditation certificate as well.

Mandaviya said that during his surprise visit, a security guard chided him and hit him for trying to sit on a bench.

Speaking at the function, he also said he noticed several patients facing problems in getting stretchers and other medical assistance at the hospital. He gave an example of a 75-year-old woman who was pleading with the guards to get a stretcher for her son but couldn't find one.

Not pleased with the guard's behaviour, he asked why even after 1,500 guards being stationed at the hospital, not a single guard helped the elderly woman. Reminding paramedics and other staff of their role, Mandaviya said hospital and medical staff are the two sides of the same coin and they should work as a team.

Mandaviya said he has informed the Prime Minister about the incident, who too was upset upon hearing it and asked whether the guard was suspended. Mandaviya replied that he wasn't as he was trying to improve the system and not just one person.

Source : First Post, 19.09.2021

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Impact of Nutraceutical Sector Post Covid

Once considered a curative cure, the sector and its products are now being consumed as preventive cure. This change started last year when the pandemic hit the world, making everyone worried about their health and immunity to fight the virus.

The nutraceutical sector has always been present in the market and has been running for a long time. Having its roots deep within Ayurveda and science, nutraceuticals have been a choice for the consumers for a healthy lifestyle. Initially this sector and the products were taken as a curative cure and was seen specifically for those who are indulging in heavy workout sessions and diets. But as time has changed and we are facing many critical health issues, this perception towards the sector has completely changed.

Once considered a curative cure, the sector and its products are now being consumed as a way of preventive cure. This change started last year when the pandemic hit the world, taking everybody through a rush of worry. This worry has now become a big concern which led people in search of ways to boost their immunity to fight against the virus. This wave of awareness among people and the arising need to stay fit has brought tremendous growth to the sector of nutraceuticals. Since the pandemic, people are consuming more supplements to make sure they are taking all the necessary nutrients that their body needs to keep it healthy.

Parents who often struggle to make their small kids eat all the green leafy vegetables are now opting for the chewable nutritious supplements which are available in different shapes and flavors to appeal the young little consumers. Given these changes in the lifestyle requirements, the Nutraceutical sector is expected to see exponential growth till the end of 2025 as it has been growing at a steady pace of 17%. In the sector, almost 65% market is of dietary supplements that are being consumed a lot especially in the time of pandemic to stay healthy due to the renewed attention on the preventive healthcare measures.

Due to the awareness among people, related to boosting their immunity and eating healthy, consumer behavior and the buying pattern has seen a major shift. Many people are now buying various healthcare products available as vitamin capsules, gummies, and chewable tablets or strips. The supplements dominating the demands are Vitamin C and Zinc supplements as these are prescribed by the doctors for those who have been caught by the virus. So, to avoid the effect of the virus, people are consuming these beforehand to strengthen their system.

The sector is showing great potential in turning into a necessity from just a choice in the economy. Given this, even though the effect of the pandemic has cooled down to a certain bit, these supplements will become an integral part of people's everyday life as they will continue to consume them, not wanting to show any leniency towards their health given the situation and risks involved with it.

So, given all the facts and information, we can say that the nutraceutical sector is being driven due to the following factors:

1. The change in consumer preferences: For better health, people are now relying more on the available nutrition supplements and other forms available.
2. Now, as per the trend, the nutraceutical is seen crossing the bar of age groups as it is being considered for all age groups. From children to old-aged people, everybody is consuming nutraceuticals in various forms suitable for their age based on the ease of consumption.

To conclude, we can say that the sector of nutraceuticals is ready to see a big and significant growth in the upcoming days. It will grow rapidly as per the estimates and it is said that itwon't be surprising if it surpasses the old and strongly established industry of pharmaceuticals in the coming days due to its growing demand in the market.

Nihaal Mariwala, Founder & CEO, Setu India

Source: Nihaal Mariwala, ETHealthworld News, 19.09.2021

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India administers over 80 crore vaccines; daily positivity rate drops below 2%

Over 5.16 crore unutilised doses are still available with the states and UTs while 1.16 doses are now in the pipeline.

The total vaccine doses crossed 80 Crore (80,43,72,331) mark as India administered 85,42,732 vaccine doses in the last 24 hours. Out of the total doses administered in the last 24 hours, the maximum of over 38 crore doses have gone to the 18-44 age group followed by people from the 45-59 age group.

States and UTs had provided over 78.58 crore doses via central government and through direct procurement. After total vaccine administration till now, over 5.16 crore unutilised doses are still available with the states and UTs while 1.16 doses are now in the pipeline.

A total of 3,26,71,167 patients have recovered since the beginning of the pandemic out of which 38,945 patients recovered in the last 24 hours. India's recovery rate now stands at 97.68 percent.

The number of new cases reported went slightly above 30,000 with 30,773 new cases being reported in the last 24 hours. This addition takes the active caseload to 3,32,158 which constitutes 0.99 percent of the total positive cases reported in the country.

A total of 15,59,895 tests were conducted in the last 24 hours taking the total number of tests conducted so far to over 55.23 Cr.

The daily positivity rate stands at 1.97 percent. The weekly positivity rate slightly increased from the previous day to 2.04 percent.

Source : ET Healthworld News, 19.09.2021

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Accelerating digitization in the health and life science sector in the right way

Significant strides are being made for merging the latest digital outcomes in the healthcare and life sciences field, but there surely is disconnectedness of data which can prove to be a major drag in the system. It can turn productive collaboration much tougher.

The healthcare organizations are ramping up their digital activities, however, the efforts remain disconnected and disparate, misguided, and misplaced. The leaders/management must focus on how to derive new value using data as an asset to drive transformation and optimization for more effectiveness.

The dynamics of the healthcare ecosystem are witnessing a robust wakening as the Covid 19 pandemic has cast unparalleled demands on the industry. While all other business is at a stall at the moment, the healthcare industry is continuously going through unprecedented adoption and innovation, demonstrating its resilience over time.

These innovations must stand the test of time and save human lives. An effective healthcare response during the pandemic commands catering to overall healthcare needs. The system is now overwhelmed by COVID-19 cases and should gear up for routine medical services that are being delayed or canceled.

The pandemic has proven to be the epitome of a multidimensional and multidisciplinary problem, which needs a concrete digital makeover integrating science and technology. The application of digital technologies in pandemic management and response, highlighting ways in which successful countries have adopted and integrated digital technologies for pandemic planning, surveillance, testing, contact tracing, quarantine, and healthcare.

Digital health technology can facilitate pandemic strategy and response in ways that are difficult to achieve manually. However, due to the ongoing pandemic, healthcare and life sciences have accelerated their digital advancements. The players in this field would generally map and implement their digital strategy over one-to-years depending on the initiatives. However, these policies and regulations were being executed within a matter of days or weeks.

Advancement in the sciences and healthcare sector is constantly evolving. The results if packaged into a strategy and pushed into execution in a haste can have damaging effects. An article in Gartner stated, "Optimization and

modernization are the foundation for digital advancement. Healthcare and life science CEOs and boards of directors want to digitally transform and innovate and have learned that they cannot achieve their business growth goals using outdated technology. Legacy technology, when not well-integrated with systems of record and innovative IT applications, is a constraint on digital progress."

There has to be a balance and systems should be in place for healthcare staff to be able to deal with digitalization. How soon are the medical practitioners able to embrace the digital changes in their workflow is also a key reason for the slow assimilation of digital technologies in the healthcare regimen. This pushes the disengagement process between technology, healthcare staff and patients a bit further, leaving gaps still to be filled. Most of these changes are long lasting, so it has to be done eventually through training sessions, workshops of the medical staff and most importantly by monitoring the implementation system as it can have bearing effects on the healthcare system.

Significant strides are being made for merging the latest digital outcomes in the healthcare and life sciences field, but there surely is disconnectedness of data which can prove to be a major drag in the system. It can turn productive collaboration much tougher. There have been situations when hospital administration could not leverage data analytics to provide greater care to serious patients.

Another huge gap that is split wide open due to digitalization in the healthcare sphere, is adherence to privacy regulations. Though crores of rupees are being invested for rapid advancements for digitalization of medical organizations, interoperability is still not there today. This is critical as technology cannot enable communication between healthcare organizations, medical staff and the patients.

An article in Gartner expressed, "Value-based care is not just a payment mechanism -- it is a fundamental systemwide shift from isolated health interventions to comprehensive population health. To succeed, CIOs must use technology to make care and population health management efforts person-centric. This includes, in some countries, bridging gaps between national health policy and funding models by taking cues from exemplar countries' successes in personalizing services to address consumers' social determinants of health."

The article further said, "Life science CIOs operate in a challenging environment fraught with rising development costs, volatile regulations and rampant medical innovations. CIOs' engagement with business leaders is critical to ensure that IT's efforts are result-focused and deliver the value of digital technology across the enterprise. Life science CIOs must optimize the deployment of value-oriented solutions, while also remaining compliant."

The value of digital technology is nothing but 'disruptive technology'. This can complicate, rather than simplify, the fundamental patient care and medical treatment process. This needs to be addressed. For medical practitioners and healthcare providers managing multiple technologies, platforms and access credentials etc can prove to be a headache if it is not user friendly, if it does not have required data access and if it doesn't exchange analysis. The very foundation of the healthcare system is the "wealth of data" that is produced daily in different regions and geographies. Implementation of technologies, digitization etc are all useless if this data is not harnessed, anaylzed and transformed into usable information eventually.

This sector needs practical technologies that help streamline communication between medical practitioners and patients, identify and provide information from its processes in the disparate health systems, and help channelize the volume of clinical data that is being captured at different platforms. These technologies should also accommodate the patients who need access easy-to-understand clinical records and access resources before engaging in self-care treatment programs.

The digital technologies will keep communication in the healthcare sector disconnected if it doesn't allow reliable connectivity virtually anytime anywhere. This aspect is definitely lacking at the moment. According to a research survey by Accenture, "Healthcare organizations need to become more collaborative in creating new digital healthcare experiences to help customers feel engaged, important and informed." About 45% of surveyors who were part of the Accenture survey said that rapid advancements in new technologies and scientific innovations are positioned to disrupt the industry. In other words it should be understood that digital technologies should make people feel comfortable that they feel safe and secure with their healthcare experience and data.

Gaurav Aggarwal, Vice President, Global Lead - Everything on Azure Solution Strategy & GTM at Avanade

Source: Gaurav Aggarwal, ETHealthworld News, 20.09.2021

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Pharma units in AP, TS continue to put up stellar performance

The sector has provided employment to 19,172 people

Exports during 2019-20 stood at ₹15,027 crore. During 2020-21 the total business to the order of `20,500 crore was recorded in both the States Visakhapatnam:

DESPITE the long spell of pandemic and its fallout on various sectors, the pharma industry has remained unscathed in Andhra Pradesh and Telangana.

In both the Telugu-speaking States, the pharma sector has put up a spectacular performance, said Visakhapatnam Special Economic Zone-Duvvada Development Commissioner A Rama Mohan Reddy in a chat with Bizz Buzz.

VSEZ has 58 units (Telangana 22 and AP 36). All major pharma companies operate from VSEZ viz., Aurobindo, Divi's, Dr Reddy's, Biocon, GVK, Laurus Labs, Mylan, Sanofi, Hetero, Lee Pharma, Gland Pharma and Cornelius Pharma.

During 2021-22, the total exports rose to Rs 8,971 crore, which is 9.4 per cent higher than last year. AP contributed Rs 4,203 crore up to August 31 and Telangana Rs 4,768 crore. The performance is almost in the ratio of 46: 54.

The pharma giants operating in both States are more or less the same. Telangana has APIIC SEZ at Jadcherla and AP has pharma SEZ at Parwada known as Ramky SEZ, Hetero at Nakkapalli and Divi's in Visakhapatnam, Reddy's at Pydibheemavaram in Srikakulam, AurobindoPharma at Naidupeta and GMR SEZ in Hyderabad,.

"We have many other units in multi-product SEZs. SEZs across VSEZ make a number of drugs related to Covid namely Fabipiravir, Molupiravir, Remdessivir, Sputnic vaccine in Hetero, 2G3D in Laurus Labs. In India AP had been the pharma hub of the country," Reddy said.

Exports during 2019-20 stood at Rs 15,027 crore. During 2020-21 the total business to the order of Rs 20,500 crore was recorded in both the States. VSEZ, which has achieved a growth of 40 per cent during last year with exports of Rs 20,500 crore. It is 9 per cent up to August 31 with a business amounting to Rs 8,971 crore. Reddy said they are confident of putting up a good show during the current year with many undertaking expansion activities.

The sector has provided employment to 19,172. Laurus Labs was as in news for supplying HCQs (Hydroxychloroquine) of 35 mi. tabs to the USA, South Africa, Singapore, Malawi and Belgium. As on date, VSEZ, has 62 SEZs (out of a total of 265 in India) fully operational with 569 units. The zone has jurisdiction over AP, Telangana, Chhattisgarh and Yanam. VSEZ has achieved a total exports to the tune of Rs 96,886 crore from all sectors during 2019-20.

During 2020-21, the exports made from the zone was to the tune of Rs 1,13,975crore. VSEZ recorded an increase in exports of 14.50 per cent and recorded growth in merchandise (26.95 per cent) and in the services sector (9.61 per cent). So far, an investment of Rs 75,055 crore has been made in the zone employment to 4.32 lakh on a regular basis.

VSEZ has broken all the records in 32 years by achieving the highest-ever exports since inception. Reddy said during the current year, despite lockdown, VSEZ has achieved exports to the tune of Rs 44,080 crore (Rs14,904crore merchandise and Rs 29.176 crore in services), up to August 31, which is 25 per cent higher than last year during the corresponding period. Merchandise recorded a growth of 26 per cent and services of 24 per cent this year.

Source: Santosh Patnaik, Hans India Bizz, 20.09.2021

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JB Chemicals new formulations for growth

JBCPL has seven worldclass manufacturing facilities, certified by leading regulators across the world

Poised for growth

Backed by a state-of-the-art manufacturing infrastructure, strong product portfolio with high growth brands, improving marketing capability and a strong balance sheet, JBPCL is well poised for growth and organisational improvement on a variety of parameters

JB Chemicals & Pharmaceuticals Ltd (JBCPL), one of the leading Indian pharmaceutical companies which specialises in branded formulations, has been in the process of re-strategising itself in the market ever since US private equity firm KKR acquired a controlling stake of 54 per cent for around Rs. 3,100 crore in the family-owned business, in July last year. Showing its aggressive intent, the new management has already initiated a series of measures to transform the entire business.

The Rs. 2,000-crore company, the owner of marquee brands such as Rantac, Metrogyl and Cilacar, has a strong portfolio in the cardiac, gastrointestinal and anti-infective therapeutic categories across the branded formulations market. The company, previously controlled by the Mody family (that currently holds 1.9 per cent stake), has put forth an accelerated growth strategy where it looks to not only build upon its core competencies but also leverage its strengths to enter into new therapeutic areas. Backed by 4,000 employees including a 2,100-strong sales force, JBCPL has put in place a new 'go-to-market' model, where it is evaluating new growth opportunities to further drive its productivity.

The company, founded by J.B. Mody in 1976 as an API maker, has clocked a market-beating performance even during the Covid-afflicted scenario. JBCPL (head office in Mumbai) is one of the fastest-growing companies amongst the top 10 players in the covered market, and has improved its IPM ranking recently to 28th in FY21 from 32nd in FY20.

Having registered a growth of 15 per cent in its revenue to Rs.2,043 in FY21, JBCPL which has five brands among the top 300 brands (flagship brands: Cilacar, Cilacar-T (Cardiac, calcium channel blocker), Metrogyl (AI,amoebicides), Nicardia (cardiac, calcium channel blocker) and Rantac (gastro, anti-peptic anti-ulcerant) in the Indian formulation market, has recorded more impressive performance during Q1FY22, growing by 16 per cent to Rs606 crore.

Market beating performance

In fact, the domestic formulation business (contributing around 50 per cent to the total revenue) of the company has clocked a market-beating performance, growing at 39 per cent in the first quarter ended June 2021, even as the international business remained flat on account of Covid-related challenges. The company exports to over 40 countries across the world and earns half its revenue from its international business where it has a front-end presence in South Africa and Russia.

As per IQVIA MAT, in June 2021, the company's growth was 24 per cent versus the market growth of 19 per cent for the IPM market. In 2021, JBCPL achieved a growth of 21 per cent as against the IPM market growth of 4.5 per cent. As per IQVIA MAT June 2021 data, all the big five brands that contribute over 75 per cent to the company's domestic formulation business, recorded an average growth of over 20 per cent.

The company, which is among the top five manufacturers of medicated and non-medicated lozenges in the world, exporting to over 30 countries, has recently expanded its portfolio foraying into the new therapeutic categories of diabetes, nephrology, respiratory, paediatric and virology.

In the first quarter of FY22, it diversified into nephrology with the launch of new dedicated division, RENOVA, to cater to the needs of chronic kidney disease patients in the country. The division consists of a 40-member team and has already launched six products in the segment.

It has also launched its NOVA division (with a 350-strong team) with a focus on the paediatric and respiratory segments in India. The division, which focusses on antivirals, corticosteroids, anti-allergic and nicotine replacement therapies, has launched six products during the quarter. Both these divisions are expansions aligned with the company's core strengths. With the addition of these two divisions, the company, which earlier had four divisions (two each in chronic and acute), will have, in total, six divisions to cater to the domestic formulation market.

Chopra: pursuing a new go-to-market model

As part of moving into newer therapies and expanding its existing portfolio, JBCPL has entered the fastest-growing category of the Indian pharmaceutical market with the launch of DPPIV and SGLT2 inhibitor molecules. It has extended its lozenges expertise to Nicotine Replacement Therapy in India with the introduction of NOSMOK lozenges. It also entered the trade generics segment in the last quarter.

All these expansions and diversifications are well backed by seven world-class manufacturing facilities (across Panoli and Ankleshwar in Gujarat and Daman) including a dedicated manufacturing facility for medicated

lozenges. The manufacturing facilities are certified by leading regulators across the world.

"JBCPL, as a business, possesses immense potential and we are now backed by a number of new initiatives. We are all prepared to leverage this untapped potential as part of our transformation journey that we have started recently. We want to leverage our strengths and core competencies pursuing our new 'go-to-market model'. We will continue to evaluate several new growth opportunities that will further drive productivity on a relatively stable cost base. In the next three years, we want to increase our market share by being among the top 20 companies in the IPM market," says Nikhil Chopra, 47, CEO and wholetime director, JBCPL.

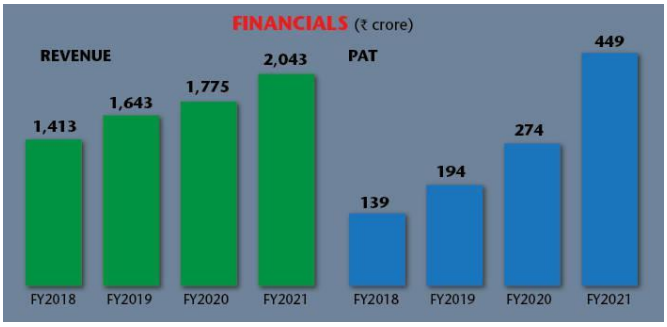
Foraying into newer therapies

"Under the new strategy, our major focus is to strengthen our core therapy segments ie hypertension, respiratory, gastroenterology, nephrology, cardiology, dentistry, and paediatrics. In FY21, we realigned our structure and portfolio to ensure sustainable growth and focussed strongly on the lifecycle management of our flagship brands. The next priority is to scale up R&D and business development initiatives towards building a progressive portfolio for the US, Russia, South Africa, API and contract manufacturing businesses. We will focus on consolidating our business areas through a deeper presence in existing geographies and this will be aided by multiple new launches over the next two to three years," adds Chopra.

Chopra joined JBCPL in October last year. The board of directors of the company have appointed him whole-time director and Chief Executive Officer of the company for a period of five years. Having taken the rein from JB Mody, the previous CMD of the company, he has been mandated to lead the KKR-controlled entity's new growth strategy and transform the entire business into a more vibrant organisation. It may be noted that JBCPL, despite being in the business for over four decades, has been regarded as a slow-moving company dependent on traditional businesses. The company has now inducted new management and expanded the board.

Prior to this, Chopra was executive vice president and CEO for the India business of pharmaceutical major Cipla Ltd. During his tenure in Cipla spanning over two decades, he played a key role in the development and growth of Cipla's India business. He also drove the ideas around greater access to high quality care for patients, and is credited with innovations and competitive advantage in areas like respiratory, urology, paediatric, cardio-metabolic and HIV care.

Chopra has always emphasised a 'beyond the pill' marketing approach in the Indian pharmaceutical industry, which involved organic and inorganic initiatives to enhance patient awareness, education, diagnosis and adherence through various 'phygital' initiatives. His other areas of expertise include digitalisation of the pharma field force and engagement with doctors, nurturing talent and creating cross-functional collaborations. He is a strong propagator of technology towards improving healthcare access and awareness. Chopra is a gold medallist from Gujarat University's School of Science, and has a master's degree in organic chemistry.



In a short span of time, the JBCPL CEO has brought about multiple initiatives in his current assignment. He is looking to replicate some of its past proven experience as he says: "We are investing in 'beyond the pill' initiatives, tech-enabled solutions, and a 'phygital' approach to innovatively meet the diverse needs of internal stakeholders, employees, associates, and healthcare professionals."

"JBCPL is a holistic pharmaceutical company built on a strong foundation of ethics, teamwork and the belief of 'always putting patients first'." We are looking ahead and accelerating towards our 50th year in 2025 and on this journey, we will focus on strengthening our core capabilities and also building an organisation that is agile and resilient to uncertain times. Our purpose is to contribute to healthcare globally, support healthcare providers and enrich the lives of patients. Featured as one of the fastest-growing companies in the Indian pharmaceutical market, we are on a journey of sustained growth and value creation by developing products that increase health-spans, not just lifespans," adds Chopra.

Analysts believe that all these initiatives are crucial to help the company transform into a more agile organisation and get into its next growth phase with more opportunities and avenues. They are of the firm view that in the domestic

market, the company's portfolio needs to be adjusted as just five flagship brands (around 30 SKUs) contribute over 75 per cent to its domestic formulations business and there is a need to broaden and diversify the portfolio with the inclusion of more products within the existing therapies as also newer products from newer therapies.

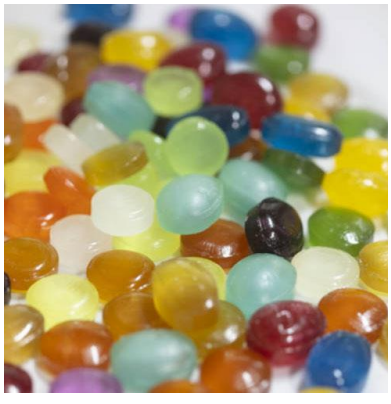
The company has all the required ingredients (world class manufacturing capabilities/infrastructure, team, etc) to become a much larger business. Analysts are of the view that KKR's presence will provide the company the much-needed wherewithal and expertise to help it commence its next growth phase in a more structured manner.

Already, the newly set up core management team and its aggressive intents are showing up in terms of encouraging results as the company is posting impressive financials. The capital market has also approved these events quite positively as the prices of JBPCL stock, in the last one year have surged over 120 per cent. Currently, the stock is hovering around Rs1,750.

"KKR's investment reflects our strong belief in India's pharmaceutical industry as Indian consumers increasingly seek out high-quality medicines and wellness products. JB provides us with a unique growth platform to target this opportunity, with its leadership position in its core products in India, a diversified portfolio of trusted brands, and high-quality manufacturing facilities," says Prashant Kumar, managing director of KKR's private equity team.

New management

"We are supporting JB's CEO Nikhil Chopra and his experienced management team in capitalising on these strengths, and accelerating its growth and expansion into new areas. By combining KKR's extensive global pharmaceutical and healthcare expertise with JB's core capabilities, we look forward to helping the company achieve its growth aspirations, serve its doctor-partners and patients better, actively shape a fulfilling workplace for JB's employees, and create value for its public shareholders," adds Kumar.



JBCPL is among the top five manufacturers of medicated and non-medicated lozenges

In the newly-constituted JBCPL board of eight directors, KKR is represented by four directors, led by the KKR India chairman, Sanjay Nayar, who is non-executive director. Nayar joined KKR in 2009 and was partner & CEO of KKR India until January 2021. Prior to joining KKR, he served as CEO of Citigroup's Indian and South Asian operations and was a member of Citigroup's Management Committee and Asia Executive Operating Committee from 2002–2009. Nayar also served in Citibank/Citigroup for 25 years in various positions in India, UK and USA.

Other KKR representatives include non-executive directors like, Gaurav Trehan, partner and head of the private equity business for KKR India; Prashant Kumar, managing Director at KKR's private equity team and Ananya Tripathi, Director with KKR Capstone, who leads the team's value-creation efforts across KKR India's private equity portfolio companies.

Ranjit Shahani is the chairman and independent director of JBCPL. He is a global business leader with over 40 years of experience in industries such as healthcare, pharmaceuticals, health technology, and speciality chemicals. He served as vice-chairman and managing director of Novartis, India. Sumit Bose, ex IAS (former revenue secretary, GoI) and Padmini Khare Kaicker, the managing partner of BK Khare & Co, are the other two independent directors.

As part of its new strategy, the management, in the next two-three years, is aiming to improve the company's IPM ranking to 20th from the current 28th in the domestic formulation market. The company is looking to increase its share of the domestic formulation business from around 50 per cent to 60 per cent of its total revenue by expanding the contribution of chronic therapies.

"For the company, the domestic formulations business remains a key focus area and it has been consistently growing at better than industry growth rate over the last several years. While India has historically been a market dominated by acute therapies, the trend has been shifting to a larger contribution from chronic drugs in the consumption base. As per IQVIA IMS data, the share of chronic therapies in the Indian pharmaceutical market has expanded from 31 per cent to 36 per cent in the period between FY13 and FY21. This is in line with the trend in several global economies that have seen a larger incidence of lifestyle diseases on the back of improved diagnoses and better compliance by patients," states the JBCPL CEO.

There are now concerted efforts to expand the portfolio of top brands from five brands (across two-three therapies) in the top 300 brands in the IPM market to eight to nine sizeable brands across four-five therapies.

All these years, the company has been quite conservative and would launch one to two new products annually. However, under its new strategy, it has decided to be more aggressive and aims to launch six to eight products annually, which will provide the desired growth momentum and improve its share in the domestic formulation market. In fact, during the last fiscal, the company launched 10 new products across angiotensin receptor blocker, anti-diabetic, calcium channel blocker, hypotensive, anti-peptic ulcerant, anti-viral and anti-parasitic segments – all of which have shown good traction in the market.

While doing so, it has been felt that there is a need to augment the prescriber relationship by expanding the reach to specialists (cardiologists, nephrologists, etc). Currently, the prescriber relationship is primarily focused on physicians. In order to achieve the desired results, the company has taken a conscious decision to improve the productivity of its 2,000-odd field force in the domestic market. In fact, it aims to ramp up workforce productivity by 12-14 per cent from the current level.

A dedicated facility for lozenges

A dedicated facility for lozenges

JBCPL's international business, which contributes around 50 per cent of the total revenue, comprises three segments: export formulations, API and contract manufacturing. The company operates distinct operating models across multiple international businesses with a direct presence in Russia and South Africa as well as distributor relationships in the US and a large number of markets across Asia, Africa and Latin America.

It also has a leading global position in the contract manufacturing market driven by marquee client relationships. The company supplies lozenges (manufacturing capacity: two billion units per annum) and tablets (capacity: 7.6 billion) to MNC clients like Johnson & Johnson and Procter & Gamble. It is now consciously looking to ramp up its contract manufacturing business (which currently contributes around 10 per cent to the overall revenue) and expand its partnerships with new MNC clients. Besides, the management is contemplating launching a few of these wellness lozenges in the Indian market under its own label.

Overseas business

Overall, the company's international business derives strong visibility from its wide geographical presence, increased focus on ANDA filings, new product introductions in the markets of Russia and South Africa, a focus on the lucrative contract manufacturing business backed by state-of-the-art manufacturing facilities and a wide range of products across injectables, solids and semi-solids.

The company's overall consolidated formulations exports during FY21 (at around Rs1,007crore) were 19.1 per cent higher over the previous year. Despite many markets in the Rest of the World business (other than Russia-CIS) remaining subdued due to Covid-19, exports to these markets delivered revenues of Rs565 crore and achieved a robust growth of over 24 per cent on the back of the strong growth of 63 per cent delivered by the US market. The company holds 19 ANDAs and two ANDAs are pending approval by US FDA.

"In our international business, our presence is strategically dominant, both in our home markets (Russia, South Africa) as well as in the 30+ countries where we operate. We will remain focused on consolidating existing business areas through a deeper presence in existing geographies, aided by new launches and dossier buyouts. Strengthening and scaling up R&D and business development initiatives towards building a progressive portfolio will be a continued objective," says Chopra.

With all these developments in place, JBPCL is all geared up to commence its next growth phase. The new management, backed by KKR has put forth multiple initiatives to get some much-needed momentum into the entire business. Backed by a state-of-the-art manufacturing infrastructure, strong product portfolio with high growth brands, improving marketing capability and a strong balance sheet, it is well poised for growth and organisational improvement on a variety of parameters. Besides, it enjoys a positive business outlook both in domestic and international markets.

Source : Arbind Gupta, Business India, 20.09.2021

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Mode	Number	Cum. Contact Hours
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