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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

A Publication of
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IDMA BULLETIN

Vol. No. 52 Issue No. 34 08 to 14 September 2021

IDMA representation to NPPA on Need to extend revised ceiling prices of Heparin Injection fixed under Para 19 of DPCO-2013 - reg.

IDMA has submitted the following representation on 8th September 2021 to Shri Kamlesh Kumar Pant, Chairman, National Pharmaceuticals Pricing Authority, Department of Pharmaceuticals, Ministry of Chemical & Fertilizers on the above subject:

Respected Sir,

Greetings from Indian Drug Manufacturers' Association (IDMA).

IDMA on behalf of the Pharmaceutical industry appreciates your understanding of the ongoing concerns of exorbitant prices of Heparin Sodium ("API") which constitutes to be a quintessential portion of the input cost. NPPA by invoking its extraordinary powers in public interest issued a Notification no. S.O. 2151 (E) dated 30.06.2020 ("Notification") and increased the ceiling prices of Heparin Injection 1000IU/ml and Heparin Injection 5000IU/ml ('Product") by 50% which proved to be a saviour to many manufacturers of the said Product. Being an essential medicine for treatment in the ongoing pandemic situation, NPPA decided to continue with the increased ceiling price and the said Notification was extended vide another notification no. S.O. 4333 (E) dated 03.12.2020 till 31.03.2021 and further extended vide notification no. S.O. 1236 (E) dated 17.03.2021 till 30.09.2021.

IDMA has received several representations from the Pharmaceutical Industry requesting IDMA to represent and request your good offices to extend the validity of the revised ceiling price of the Product beyond the notified period i.e. 30.09.2021 so as to sustain themselves during the ongoing pandemic situation. The said Product has proved to be an essential treatment in the ongoing pandemic situation. Apart from being an essential treatment in the Covid-19 scenario, the Product still remains the front line drug and lifesaving drug used for dialysis in case of kidney failure. This in turn has resulted in a higher demand for the Product.

Pertinently, it was only due to NPPA's thoughtful step of granting extension of revised ceiling price of the Product that enabled the manufacturers to put up with such high demand.

It would be relevant to note that the issue of high prices of API continues to haunt the manufacturers of the Product due to which many of the manufacturers are unable to sustain in this particular scenario where the demand of the Product is equally high. Besides, many of the manufacturers of the Product are still operating at a huge loss to manufacture and supply the Product due to the continuing increase in the import price of API imported from China.

Needless to mention that the pandemic has brought extreme hardship to the entire industry and the impact of the pandemic situation is anticipated to stay in the market for some time before the situation moves towards normalcy.

As an association, we believe that striking a balance between the availability of the Product and extending requisite support to the manufacturers is the panacea for ensuring the well-being of our population.

Therefore, in order to ensure consistent availability of the Product in a scenario where the demand for the Product, as well as the prices of API from China are also high, there is a dire need to extend the revised ceiling price of the Product beyond 30.09.2021 till 31st March 2022.

Thanking you and assuring you of our best attention at all times.

Yours Sincerely,
For Indian Drug Manufacturers' Association

Mahesh H Doshi
National President

Encl: As above

Extension of ceiling prices fixed under Para 19 of DPCO-2013 for Heparin Injection - reg.

S.O. 4333(E), dated 3rd December 2020

1. The ceiling prices of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml fixed under Para 19 of the DPCO, 2013 vide notification S.O. 2151(E) dated 30.06.2020 issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India are extended upto 31.03.2021.

2. All the notes and other contents mentioned in the original order S.O. 2151(E) dated 30.06.2020 shall remain the same and are applicable except that in Para 6, Notes (a) and Note (k) for the phrase "31st December 2020" it is to be read as "31st March 2021".

[PN/213/81/2020/F
F. No. 8(81)/2020/DP/NPPA-Div.-II]

Prasenjit Das, Asstt. Director, National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, New Delhi.

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Extension of ceiling prices fixed under Para 19 of DPCO-2013 for Heparin Injection - reg.

S.O. 1236(E), dated 17th March 2021

1. The ceiling prices of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml fixed under Para 19 of the DPCO, 2013 vide notification S.O. 2151(E) dated 30.06.2020 and extended upto 31.03.2021 vide S.O. 4333(E) dated 03.12.2020, issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India are further extended upto 30.09.2021 or until further order, whichever is earlier.

2. All the notes and other contents mentioned in the original order S.O. 2151(E) dated 30.06.2020 read with extension order S.O. 4333(E) dated 03.12.2020 shall remain the same and are applicable except that in Para 6, Notes (a) and Note (k) for the phrase "31st March 2021" it is to be read as "30th September 2021 or until further order, whichever is earlier".

[PN/216/84/2021/F /
F. No. 8(84)/2021/D.P./NPPA-Div.-II]

Prasenjit Das, Deputy Director, National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, New Delhi.

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Regarding Ceiling prices under Para 19 of DPCO-2013 for Heparin Injection

S.O. 2151(E), dated 30th June 2020

1. Whereas the National Pharmaceutical Pricing Authority (NPPA) was established vide the Resolution of the Government of India in the Ministry of Chemicals and Fertilizers No. 33/7/97-PI.I dated 29th August, 1997, inter-alia, to fix prices and notify the changes therein, if any, of bulk drugs and formulations, monitor the prices of non-scheduled drugs and formulations and oversee the implementation of the provisions of the Drugs (Price Control) Order (DPCO).

2. And whereas the Ministry of Chemicals and Fertilizers vide S.O.1394 (E) dated the 30th May, 2013, in exercise of the powers conferred by Section 3 and 5 of Essential Commodities Act, 1955 has delegated the powers in respect of specified paras of the DPCO, 2013, including para 19 of the said Order to be exercised by the NPPA on behalf of the Central Government.

3. And whereas NPPA had received applications from several companies having major market share for upward revision of ceiling prices of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml under para 19 of DPCO 2013 citing reasons that the cost of APIs which constitute major portion of the input cost and mainly imported from China, has risen to a considerable extent making the companies entirely unviable to continue manufacture the formulations. The companies also contended that over the years the regulated price have decreased whereas there is consistent increase in the price of imported price of APIs thereby making commercially unviable for the drug manufacturers to manufacture the said product.

4. And whereas, Ministry of Health and Family Welfare (MoH&FW) has included Heparin injection 5000IU/ml as an essential medicine for treatment of COVID-19 patients. Further, reports of shortage have also been received for Heparin Injection.

5. And whereas, the Committee constituted to monitor export/import trends of APIs, formulations and medical devices needed for COVID-19 vide its report communicated through letter dated 19th June, 2020 has informed that there has been considerable increase in the price of API Heparin when compared to base year of September 2018. Accordingly, the Committee recommended short term upward price revision of Heparin Injection.

6. And whereas, the NPPA considered the aspect of availability of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml, a scheduled formulation, especially during the pandemic situation of COVID-19 and opined that any situation of shortage due to price control needs to be seen from a public interest perspective. Accordingly, NPPA invoked extra ordinary powers in public interest under para 19 of DPCO 2013 for upward revision of the ceiling prices of Heparin Injection 1000IU/ ml and Heparin Injection 5000IU/ ml by giving one time increase of 50% from the present ceiling price to be applicable upto 31st December 2020.

7. Therefore, in exercise of extra ordinary powers in public interest, conferred by paragraph 19 of the Drugs (Prices Control) Order, 2013, read with S.O. No. 1394(E) dated the 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) S.O. Number and date specified in column no. 6(a) & 6(b) mentioned in the table below, the National Pharmaceutical Pricing Authority, hereby fixes the prices as specified in column (5) of the Table below as ceiling prices exclusive of goods and services tax applicable, if any in respect of the Scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE

Sr. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)	Existing S.O. No. & Date	
1.	Heparin	Injection 1000 IU/ml	1 ml	24.39	1213(E) Sl. No. 403	25.03.2020
2.	Heparin	Injection 5000 IU/ml	1 ml	60.54	1213(E) Sl. No. 404	25.03.2020

Note:

(a) The ceiling price as specified in column (5) in respect of the formulations with dosage & strength mentioned in column (2) and (3) respectively would be applicable upto 31st December 2020.

(b) All manufacturers of scheduled formulation, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government,

shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

(c) The provisions of para 13(2) of DPCO 2013 would not be applicable on the ceiling price specified in column (5) in respect of the formulations with dosage & strength mentioned in column (2) and (3) respectively.

(d) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.

(e) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(f) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(g) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

(h) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

(i) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.

(j) Consequent to the issue of ceiling price of such formulation as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

(k) The price of Heparin Sodium API would be monitored on a monthly basis upto 31st December 2020.

PN/208/76/2020/F
F. No. 8(76)/2020/ DP/Div-II/NPPA

Prasenjit Das, Asst. Director, National Pharmaceuticals Pricing Authority, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, New Delhi.

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MoEF MATTERS

Uploading of Environment Clearance (EC) conditions –reg.

Office Memorandum dated 7th September, 2021

To

1. Chairman, Central Pollution Control Board,

2. All ADGs of Integrated Regional Office; MoEF&CC,

3. All Chairman and Member Secretaries of SEIAAISEAC;

4. All Chairman/Members of SPCB/UTPCC;

5. Sr. Director, NIC, MOEFCC.

1. This is to inform that Ministry is in the process of setting up of "Centralized Processing Centre-Green (CPC-Green)", a transparent, technology-driven, non-intrusive monitoring system which would provide a "single window" solution for an environmental regulation (Environment clearances, Forest Clearances, Wildlife clearances, Coastal Regulation Zone etc) administered in the Ministry of Environment, Forest and Climate Change.

2. Ministry vide OM (No. 04/01/2021-IA III) dated 04th August, 2021 requested all the project proponents to upload EC conditions alongwith other desired information on the PARIVESH portal within a period of two weeks. Progress on EC conditions uploaded by the Project Proponents, for both Cat A and B project proposals, were reviewed in the Ministry. It has been observed that many of the project proponents are yet to upload the desired information. This has been viewed seriously by the competent authority.

3. In view of the above, all the project proponents who have not yet uploaded the desired information are once again requested to do so at the earliest and latest by 13th September 2021.

4. It is informed that above direction of the Ministry is to be strictly complied. In case of any technical issue, users may register their complaint through "complaint" button on Parivesh. Users may also contact the NIC technical team in the Ministry at 011 24695407/monitoring-ec@nic.in. Further, Project Proponent may also refer to the user manual, available on the PARIVESH portal, for uploading of EC conditions.

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

F. No. 4/1/2021-IA.III [E-148683]

Sharath Kumar Pallerla,
Scientist 'F', Ministry of Environment,
Forest and Climate Change, (IA. III Division), New Delhi.

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GOVERNMENT NOTIFICATION

Draft Rules Notification wrt Registration certificate - reg.

G.S.R. 618(E), dated 7th September, 2021

The following draft of certain rules further to amend the Drugs Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by sub-section (1) of section 12 and subsection (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published after consultation with the Drugs Technical Advisory Board for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of thirty days from the date on which copies of the Gazette of India containing these draft rules are made available to public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 434, C Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

(1) (i) These rules may be called the Drugs (..... Amendment) Rules, 2021.

(ii) These rules shall, unless specified otherwise, come into force on the date of their final publication in the Official Gazette.

(2) In the Drugs Rules, 1945 (hereinafter referred to as said rules), in rule 24, in sub-rule (3), the words “or for a duplicate copy of the license issued under this rules, if the original is defaced, damaged or lost” shall be omitted.

(3) In the said rules, in rule 24A, in sub-rule (7), the words “or for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost” shall be omitted.

F.No. X.11014/8/2021-DR

Dr. Mandeep K Bhandari, Joint Secretary, Ministry of Health and Family Welfare, Department of Health and Family Welfare, New Delhi.

***Note:** The Principal Rules were published in the Gazette of India vide notification number F.28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification number G.S.R. ….(E), dated the ……. 2021.*

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Draft New monographs, Proposed Amendment list and revised general chapters on IPC website - reg.

Dear Stakeholder's,

As you are aware, Indian Pharmacopoeia Commission is continuously involved in up-gradation of monographs and general chapters in Indian Pharmacopoeia.

Further to develop IP standards, IPC has uploaded 60 new monographs, proposed Amendment list and 03 revised general monographs under "Stakeholder comments" section available on IPC website www.ipc.gov.in for public comments.

The list is as follows:

New Monographs

1.	2-Deoxy-D-glucose
2.	2-Deoxy-D-glucose Sachet
3.	Alpha Lipoic Acid
4.	Amlodipine and Valsartan Tablets
5.	Apremilast
6.	Apremilast Tablets
7.	Aprotinin Injection
8.	Azithromycin Eye Drops
9.	Biotin
10.	Bosutinib
11.	Bosutinib Tablets
12.	Calcium Citrate Maleate
13.	Chromium Picolinate
14.	Ciprofloxacin and Tinidazole Tablets
15.	Copper Gluconate
16.	Desogestrel
17.	Desogestrel and Ethinyl Estradiol tablets
18.	Dextropropoxyphene Hydrochloride and Paracetamol Tablets
19.	Diclofenac Potassium
20.	Diclofenac Potassium Tablets
21.	Epalrestat
22.	Epalrestat Tablets
23.	Estradiol Hemihydrate
24.	Ethyl Acetate
25.	Ethynodiol Diacetate and Ethinyl Estradiol Tablets
26.	Fexofenadine and Pseudoephedrine ER tablet
27.	Glipizide and Metformin Tablets
28.	Glutamic Acid
29.	Inositol
30.	Itraconazole
31.	Itraconazole Capsule
32.	Lenvatinib
33.	Lenvatinib Capsules
34.	Liposomal Amphotericin B for Injection
35.	Lutein
36.	Lysine HCl
37.	Mesna Tablets
38.	Phenylalanine
39.	Prasugrel Hydrochloride and Aspirin Capsules
40.	Repaglinide and Voglibos Tablet
41.	Ribavirin Capsules
42.	Rocuronium Bromide
43.	Rocuronium Bromide Injection
44.	Selenomethionine
45.	Selenous Acid
46.	Sofosbuvir
47.	Sofosbuvir and Daclastasvir Tablets
48.	Sofosbuvir Tablets
49.	Sugur Spheres

50.	Threonine
51.	Tofacitinib Citrate
52.	Tofacitinib Citrate Tablets
53.	Triamterene and Hydrochlorothiazide Tablets
54.	Tryptophan
55.	Valacyclovir Hydrochloride

56.	Valacyclovir Hydrochloride Tablets
57.	Valine
58.	Vildagliptin and Metformin Hydrochloride Tablets
59.	Zanamivir
60.	Zinc Citrate

Revised General chapters

1. 2.4.14. Liquid Chromatography
2. 2.4.42. Inductively Coupled Plasma Spectrometry
3. 5.9 IP Reference Substances (IPRS)
4. Inhalation Preparations

All are requested to kindly provide your comments/ suggestions on the new monographs/ amendments and revised general chapters by writing to us at : lab.ipc@vsnl.net.

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CDSCO MATTERS

Special Condition under which the permission for import of drug with residual shelf life less than 60% is allowed - reg.

File No. DCGI/Misc/2020 (110), dated 13th September 2021

To
All Port offices of CDSCO.

In light of representation received and Covid-19 pandemic situation, the effective date of the circular of even no. dated 17.04.2020, 10.07.2020, 18.12.2020 and 13.04.2021 issued on subject cited above is extended up to 30.04.2022 or till further order whichever is earlier.

Dr V G Somani, Drugs Controller General (India), Central Drugs Standard Control Organization, (DCGI Secretariat), Directorate General of Health Services, New Delhi.

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Data required by Department of Revenue - reg.

ATTENTION MEMBERS

IDMA has received email communication from Dr. Sumit Garg, IRS, Deputy Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers dated 25th August 2021 and 7th September 2021 that the Department of Revenue is examining various Customs Duty exemptions and has referred two lists of drugs on which either there is NIL Customs duty or concessional Customs duty.

Although this exercise was done during the budget time as well but D/o Revenue requires specific information in the excel sheet attached.

Members are requested to kindly go through the excel sheet as reproduced below and provide the data as requested to IDMA Secretariat at idma2@idmaindia.com / actadm@idmaindia.com

Your prompt and positive response will be appreciated.

Thanks & regards,

Daara B Patel
Secretary - General

	Description	Domestic Production (in suitable units)	Import dependence (% share of imports in demand)
S. No	**List 3 (See S. No 166 of Table)**		
1	Amikacin		
2	Amphotericin-B		
3	Amrinone		
4	Aprotinin		
5	Baclofen		
6	Bleomycin		
7	Busulphan		
8	BCG vaccine , Iopromide,Iotrolan		
9	Chlorambucil		
10	Chorionic Gonadotrophin		
11	Clindamycin		
12	Cyclophosphamide		
13	Dactinomycin		
14	Daunorubicin		
15	Desferrioxamine		
16	Dimercaprol		
17	Disopyramide phosphate		
18	Dopamine		
19	Eptifibatide		
20	Glucagon		
21	Hydroxyurea		
22	Isoprenaline		
23	Isoflurane		

24	Lactulose		
25	Lomustine		
26	Latanoprost		
27	Melphalan		
28	Mesna		
29	Methotrexate		
30	MMR (Measles, mumps and rubella) vaccine		
31	Mustin Hydrochloride		
32	Pancuronium Bromide		
33	Praziquantel		
34	Protamine		
35	Quinidine		
36	Sodium Cromoglycate spincaps and cartridges		
37	Sodium Hyalauronate sterile 1% and 1.4% solution		
38	Somatostatin		
39	Strontium Chloride (85 Sr.		
40	Thioguanine		
41	Tobramycin		
42	Tetanus Immunoglobin		
43	Typhoid Vaccines :		
(i)	VI Antigen of Salmonella Typhi, and		
(ii)	Ty 2la cells and attenuated non-pathogenic strains of S. Typhi		
44	Tretinoin		
45	Tribavirin/Ribavirin		
46	Urokinase		
47	Ursodeoxycholic Acid		
48	Vancomycin		
49	Vasopressin		
50	Vecuronium Bromide		
51	Zidovudine		
52	5-Fluorouracil		
53	Pegulated Liposomal Doxorubicin Hydrochloride injection		
54	Ketoanalogue preparation of essential amino acids		
55	Pergolide		
56	Kit for bedside assay of Troponin-T		
57	Solution for storing, transporting, flushing donor organs for transplant		
58	Miltefosine		
59	Milrinone Lactate		
60	Methoxy Isobutile Isonitrile (MIBI		
61	Haemophilus Influenzae Type b Vaccine		
62	Mycophenolate Sodium		
63	Verteporfin		
64	Daclizumab		
65	Ganciclovir		
66	Drotrecogin alfa (activated		

67	Eptacog alfa activated recombinant coagulation factor VIIa		
68	Muromonab CD3		
69	Japanese encephalitis vaccine		
70	Valganciclovir		
71	Low molecular weight heparin		
72	Efavirenz		
73	Emtricitabine		
74	Azathioprine		
75	Antinomycin D		
76	Cytosine Arabinoside (Cytarabine		
77	Vinblastine Sulphate		
78	Vincristine		
79	Eurocollins Solution		
80	Everolimus tablets/dispersible tablets		
81	Poractant alfa		
82	Troponin-I whole blood test kit		
83	Blower/mister kit for beating heart surgery		
84	Fluoro Enzyme Immunoassay Diagnostic kits		
85	Tablet Telbivudine		
86	Injection Exenatide		
87	DTaP-IPV-Hib or PRP-T combined Vaccine		
88	Pneumococcal-7 Valent Conjugate Vaccine (Diphtheria CRM197 Protein)		
89	Injection Thyrotropin Alfa		
90	Injection Omalizumab		
91	Abatacept		
92	Daptomycin		
93	Entacevir		
94	Fondaparinux Sodium		
95	Influenza Vaccine		
96	Ixabepilone		
97	Lapatinib		
98	Pegaptanib Sodium injection		
99	Suntinib Malate		
100	Tocilizumab		
101	Agalsidase Beta		
102	Anidulafungin		
103	Caspofungin acetate		
104	Desflurane USP		
105	Heamostatic Matrix with Gelatin and human Thrombin		
106	Imiglucerase		
107	Maraviroc		
108	Radiographic contrast media (Sodium and Meglumine ioxitalamate, Iobitridol and Sodium and meglumine ioxaglate		
109	Sorafenib tosylate		

110	Varenciline tartrate		
111	90Yttrium		
112	Nilotinib		
113	Pneumococcal acchride Conjugate vaccine adsorbed 13-valent suspension for injection		
114	Micafungin sodium for injection		
115	Bevacizumab		
116	Raltegravir potassium		
117	Rotavirus Vaccine (Live Oral Pentavalent		
118	Pneumococcal Polysaccharide Vaccine		
119	Temsirolimus Concentrate for infusion for injection		
120	Natalizumab		
121	Octreotide		
122	Somatropin		
S.No	**List 4 (See S. No. 167 and 607 of the Table)**		
1	Aurothiomalate Sodium		
2	Asparaginase		
3	Agglutinating Sera		
4	Anti-Diphtheria Normal Human Immunoglobulin		
5	Anti-human lymophocyte immunoglobulin IV		
6	Anti-human thymocyte immunoglobulin IV		
7	Anti-Pertussis Normal Human Immunoglobulin		
8	Anti-Plague serum		
9	Anti-Pseudomonas Normal Human Immunoglobulin		
10	Basiliximab		
11	Beractant Intra-tracheal Suspension		
12	Blood group sera		
13	Botulinum Toxin Type ‘A’		
14	Burn therapy dressing soaked in gel		
15	Bovine Thrombin for in vitro test for diagnosis in Haemorrhagic disorders		
16	Bovine Albumin		
17	Bretyleum Tossylate		
18	Calcium Disodium Edetate		
19	Carmustine		
20	Cesium Tubes		
21	Calcium folinate		
22	Cholestyramine		
23	Christmas Factor Concentrate (Coagulation factor IX prothrombin complex concentrate		
24	Cobalt-60		
25	Corticotrophin		
26	Cyanamide		
27	Diagnostic Agent for Detection of Hepatitis B Antigen		
28	Diagnostic kits for detection of HIV antibodies		
29	Diphtheria Antitoxin sera		
30	Diazoxide		

31	Edrophonium		
32	Enzyme linked Immunoabsorbent Assay kits ELISA KITS		
33	Epirubicin		
34	Fibrinogen		
35	Floxuridine		
36	Flucytosin		
37	Flecainide		
38	Fludarabine Phosphate		
39	Foetal Bovine Serum (FBS		
40	Gadolinium DTPA Dimeglumine		
41	Gallium Citrate		
42	Gasgangrene Anti-Toxin Serum		
43	Goserlin Acetate		
44	Hepatitis B Immunoglobulin		
45	Hexamethylmelamine		
46	Hydralazine		
47	Idarubicine		
48	Idoxuridine		
49	Immunoassay kit for blood Fibrinogen degradation product for direct estimation for diagnostic test in D.I.C.		
50	Inactivated rabies vaccine Human diploid cell		
51	Inactivated rabies vaccine Vero-cell		
52	Intravenous amino acids		
53	Intravenous Fat Emulsion		
54	Iopamidol		
55	Iohexol		
56	(a) Indium 113 in brain scanning kit (b) Indium 113 Sterile generator and elution accessories (c) Indium 113 in brain scanning kit (d) Indium 113 in liver scanning kit		
57	Iscador, CLIA diagnostic kits		
58	Levodopa with benserazine		
59	Lenograstim		
60	Meningococcoal A and C combined vaccine with diluant solvent		
61	Methicillin		
62	Metrizamide Inj with diluant		
63	Monocomponent insulins		
64	Mycophenolate Mofetil		
65	Normal Human plasma		
66	Normal Human immunoglobulin		
67	Nuclear magnetic resonance contrast agent		
68	Normal Human serum Albumin		
69	Penicillamine		
70	Pentamidine		
71	Penicillinase		
72	Poliomyelitis vaccine (inactivated and live		

73	Potassium Aminobenzoate		
74	Porcine Insulin Zinc Suspension		
75	Prednimustine		
76	Porcine and Bovine insulin		
77	Purified Chick Embryo Cell Rabies Vaccine		
78	Pyridostigmine		
79	Pneumocystis carinii IF kits		
80	Prostaglandin E 1 (PGE1		
81	Radio-immunoassay kit for hormones (T3, T4, TSH Insulin, Glucogen, Growth Hormone, Cortisol, L.H., FSH and Digoxin		
82	Radioisotope TI 201		
83	(a) Rabbit brains thromboplastin for PT test (b) Reagent for PT tests (c) Human Thrombin for TT tests		
84	Rabies immunoglobulin of equine origin		
85	Sevoflurane		
86	Rocuronium Bromide		
87	Septopal beads and chains		
88	Sodium Arsenate		
89	Freeze Dried Form of Human Follicle Stimulating and Luteinising Hormones		
90	Solution of Nucleotides and Nucliosides		
91	Specific Desensitizing Vaccine		
92	Sterile Absorbable Haemostat for control of surgical vessel bleeding		
93	Strontium SR-89 Chloride		
94	Suxamethonium Chloride		
95	Selenium-75		
96	Teicoplanin		
97	Tetrofosmin		
98	Ticarcillin		
99	Tranexamic Acid		
100	Tocainide		
101	Tri-iodothyronine		
102	Triethylene Tetramine		
103	Thrombokinase		
104	Teniposide		
105	Trans-1- diamino cyclohexane Oxalatoplatinum		
106	Ticarcillin Disodium and Potassium Clavulanate combination		
107	Vindesin Sulphate		
108	X-ray diagnostic agents, the following: (i) Propylidone (ii) Ethyl iodophenylun decylate (iii) Iodipammide methyl glucamine (iv) Lipidoll utra fluid (v) Patent blue		
109	Zalcitabine		
110	Zoledronic Acid		
111	Anti-Haemophilic Factor Concentrate (VIII and IX)		

Possible Early Harvest of India-Canada Comprehensive Economic Partnership Agreement (CEPA) – request for comments from stakeholders on the Canada's wish list - reg.

F.No. 35022/14/2020-Policy, dated 14th September, 2021

To
IPA, IDMA, Pharmexcil, AIMED, MTAI and EEPC.

1. I am directed to refer to the above-mentioned subject and to convey that the Wish List of the Canadian Side in its final version is attached. You are requested to examine the specific tariff lines of Canada's wish list and indicate the specifically (Yes No) whether the product can be considered for tariff concessions under the CEPA along with comments; in case indicated as 'No', specific reason may be mentioned.

2. In view of above, it is requested to provide the requisite information latest by 17.09.2021 positively.

Encl: As above.

Sanjay Meena,
Section Officer,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers,
New Delhi.

Note : Enclosure not reproduced for its details please contact IDMA Secretariat

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DGFT MATTERS

Clarification on last date of import in continuation of Notification No. 20/2015-20 dated 24.08.2021 - reg.

Notification No.S.O. 25/2015-2020, dated 13th September, 2021

In exercise of powers conferred by Section 3 read with Section 5 of FT (D&R) Act, 1992 and paragraph 1.02 and 2.01 of the Foreign Trade Policy, 2015-2020, as amended from time to time, the Central Government hereby amends the provision in Para 3 of Notification No. 20/2015-20 dated 24.08.2021 as under:-

The last date of import, 31.10.2021, as mentioned in Para 3 of Notification number 20 dated 24.8.2021, is amended to read as " Last date of shipment or Bill of Lading date (in case of permitted seaports) or Lorry Receipt date (in case of LCS Petrapole)" shall be 31.10.2021 or until further orders, whichever is earlier. Further, import consignments of these items with Bill of Lading/Lorry Receipt issued on or before 31st October, 2021 shall not be allowed by Customs beyond 31st January 2022.

Effect of the Notification: For imports under Notification 20/2015-20 dated 24.08.2021, the last date of shipment or date of issuance of the Bill of Lading or Lorry Receipt date is 31.10.2021. Import consignments of these items with Bill of Lading/Lorry Receipt issued on or before 31st October, 2021 shall not be allowed by Customs beyond 315' January 2022.

This issues with the approval of Minister of Commerce & Industry.

F.No.M-5012/300/2002/PC-2[A]/Part-VIII/E-29098

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

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PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA

(Set up by Ministry of Commerce and Industry, Government of India)

PXL/HO/Cir-072/2021-22 Date: 07.09.2021

Hyderabad

IDMA (Indian Drug Manufacturer's Association)

Dear Sir/Madam,

Subject: Opportunities in the Biotechnology Sector - Cuba

You are kindly aware that the Ministry of Commerce & Industry, Government of India in close coordination with our missions around the globe are engaged in exploring opportunities for growth of the Indian Pharmaceutical sector. Pharmexcil is in receipt of communication from Embassy of India in Havana, Cuba regarding establishment of a new joint venture for the development and commercialization of innovative biotechnology products in the Mariel Special Development Zone, Cuba.

The joint venture named IncuBIO SA is established between Center of Molecular Immunology (Cimab SA) - Cuba and Neuronic Mexicana SA - Mexico designed to attract venture capital for financing of clinical trials in underdeveloped country markets. First of such products scheduled to undergo trial would be NeuroEPO - a promising drug manufactured by Center of Molecular Immunology (Cimab SA) - Cuba used for treatment for various neurodegenerative diseases such as Alzheimer's, Parkinson & Ataxia.

Mariel Special Development Zone is the first of its type in Cuba and enjoys a privileged geographic location i.e in the center of the Caribbean Sea and at the crossroads of the main maritime commercial traffic routes in the Western Hemisphere. The Office of Mariel Special Development Zone provides information to investors and facilitates companies set up, registration and licensing. The regulatory framework establishes approval within 60 days from the submission of the file.

Cuba has a well-developed scheme in the Biotechnology sector and it is believed that a joint venture/ commercial agreement with such a quality institution could be an opportunity to explore untapped markets in the sector. Member companies looking forward to invest/partner in the initiative may write back with their queries directly to sspol.havana@mea.gov.in with a copy to regulatory@pharmexcil.com & rodelhi@pharmexcil.com

With regards,

Uday Bhaskar
Director General

In Lok Sabha & In Rajya Sabha

Rajya Sabha

COVID-19 waste Management

Rajya Sabha Unstarred Question No. 1471

Dr. Narendra Jadhav:

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

(a) the number of biomedical waste treatment facilities in India;

(b) the number of biomedical waste treatment facilities in India which have or are updating their waste handling data on the COVID19BWM app from July 2020 to June 2021, State-wise and month-wise;

(c) India's biomedical waste treatment capacity per day;

(d) the number of waste generators registered, State-wise; and

(e) the number of waste generators which have or are updating their waste handling data on the COVID19BWM app from July 2020 to June 2021, State-wise and month-wise?

Answered on 02nd August 2021

A. (a): The Central Pollution Control Board (CPCB) has reported that 202 Common Biomedical Waste Treatment Facilities (CBWTFs) are operational in the country.

(b) The details of CBWTFs updating data on the COVID19 BWM app, State-wise and Month-wise, are placed at Annexure-A.

(c) The CPCB has reported that 1185 Tons per day of bio-medical waste (BMW) incineration and autoclaving capacity is available in the country.

(d)&(e) The details of waste generators registered, State-wise,and the details of data uploaded on the on COVID19 BWM app, month-wise, are placed at Annexure-B.

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

Annexure-A

Annexure Referred to in Part (B) of Rajya Sabha Unstarred Question No. 1471 Due for Reply on 02/08/2021 Regarding 'Covid-19 Waste Management' Raised by Dr. Narendra Jadhav

Details of CBWTFS Registered and Reporting Data in Covid19 BWM App

State/Union Territory	Registered CBWTFs	CBWTFs reporting data
Andaman and Nicobar Islands	0	0
Andhra Pradesh	12	12
Arunachal Pradesh	0	0
Assam	1	1
Bihar	4	4
Chandigarh	1	1
Chhattisgarh	4	4
Daman Diu & Dadar Nagar Haveli	BMW handed over to Gujarat facility	
Delhi	2	2
Goa	0	0
Gujarat	20	20
Haryana	11	11
Himachal Pradesh	2	2
Jammu and Kashmir and Ladakh	4	4
Jharkhand	3	2
Karnataka	27	22
Kerala	1	1
Lakshadweep	0	0
Madhya Pradesh	12	12
Maharashtra	30	30
Manipur	1	1
Meghalaya	1	1
Mizoram	0	0
Nagaland	0	0

Odisha	6	5
Puducherry	1	1
Punjab	5	5
Rajasthan	8	8
Sikkim	0	0
Tamil Nadu	8	8
Telangana	11	11
Tripura	1	0
Uttarakhand	2	2
Uttar Pradesh	18	18
West Bengal	6	6
TOTAL	**202**	**194**

Month-wise details of data reported by CBWTFs on COVID19 BWM app

Month and Year	No. of CBWTFs reporting data
July, 2020	150
August, 2020	165
September, 2020	174
October, 2020	181
November, 2020	184
December, 2020	184
January, 2021	184
February, 2021	184
March, 2021	184
April, 2021	186
May, 2021	193
June, 2021	194

Annexure-B

Annexure Referred to in Part (D) and (E) of Rajya Sabha Unstarred Question No. 1471 Due for Reply on 02/08/2021 Regarding 'Covid-19 Waste Management' Raised By Dr. Narendra Jadhav

Details of Waste generators registered and reporting data in COVID19 BWM app

State/Union Territory	No. of waste generators registered and reporting data
Andaman and Nicobar Islands	11
Andhra Pradesh	1025
Arunachal Pradesh	1
Assam	88
Bihar	92
Chandigarh	23
Chhattisgarh	166
Daman Diu & Dadar Nagar Haveli	4
Delhi	619
Goa	99
Gujarat	983
Haryana	477
Himachal Pradesh	411
Jammu and Kashmir and Ladakh	139
Jharkhand	42
Karnataka	742
Kerala	2291
Lakshadweep	0
Madhya Pradesh	362
Maharashtra	2108
Manipur	7
Meghalaya	37
Mizoram	33
Nagaland	0
Odisha	330
Puducherry	52
Punjab	449
Rajasthan	284
Sikkim	8
Tamil Nadu	1015
Telengana	635
Tripura	27
Uttarakhand	115
Uttar Pradesh	454
West Bengal	242
TOTAL	**13371**

Month-wise details of data reported by Waste generators on COVID19 BWM app:

Month	No. of waste generators registeredand reporting data
July, 2020	3477
August, 2020	5070
September, 2020	6556

October, 2020	7549
November, 2020	7904
December, 2020	8178
January, 2021	8338
February, 2021	8449
March, 2021	8584
April, 2021	9370
May, 2021	12542
June, 2021	13371

Waste management in the light of COVID -19

Rajya Sabha Unstarred Question No. 1486

Dr. Amar Patnaik:

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

(a) whether the usage of covid protection gear like Personal Protection Equipment (PPE) kits and masks has led to a strain on the country's waste management systems pertaining to medical waste;

(b) if so, the details of measures that Government is following to combat this;

(c) whether the increased generation of biomedical waste has caused hindrance to the cleanliness goals in the country agreed to as a part of the Paris Agreement; and

(d) if so, the details of mechanism by which Government aims to overcome this?

Answered on 02nd August 2021

A. (a) & (b) The COVID-19 waste has increased the quantum of BMW generated in the country for treatment and disposal. The waste arising out of COVID-19 pandemic situation viz. Personal Protective Equipment (PPEs) like goggles, face-shield, plastic coverall, Hazmat suite, nitrile gloves, masks etc. are identified as biomedical waste (BMW) and required to be dealt under the provisions of Bio-Medical Waste Management Rules, 2016 (BMWM Rules, 2016). The Central Pollution Control Board (CPCB) has come up with separate guidelines for 'Handling, Treatment & Disposal of biomedical waste generated during Treatment/Diagnosis/Quarantine of COVID-19 patients'. The guidelines prescribe the following w.r.t. PPEs:

- PPEs such as goggles, face-shield, splash proof apron, Plastic Coverall, Hazmat suit, nitrile gloves may be segregated into 'Red bag'
- PPEs such as used mask (including Triple layer mask, N95 mask etc.), head cover/ cap, shoe-cover, disposable linen Gown, non-plastic or semi-plastic coverall are required to be segregated in 'Yellow bags'

Additionally, a mobile application has been developed by CPCB to track and compile the COVID-19 BMW generation, collection, treatment and final disposal by CBWTFs. The app has recorded 56898.14 Tons of BMW generation between June, 2020 to June, 2021. A High Level Task Team headed by CPCB Chairman is also constituted to review the status of COVID-19 waste management in the country.

(c)&(d) The Paris Agreement pertains to the issue of climate change and not bio-medical waste management or cleanliness. The cleanliness goals of the country are addressed through various legal and promotional measures. The legal measures are implemented through Central and State Acts and Rules/ Notifications issued there under, such as the comprehensive set of waste management rules issued by Ministry of Environment, Forest and Climate Change under Environment (Protection) Act, 1986. Similarly, the promotional measures include various flagship programs and schemes of the Government such as the Swachh Bharat Mission, Smart Cities Programme, Atal Mission for Rejuvenation and Urban Transformation etc.

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

Common Bio-medical Waste Treatment and Disposal Facilities (CBWTFs)

Rajya Sabha Unstarred Question No. 1488

Shri John Brittas:

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

(a) whether Government plans to increase the number of Common Bio-medical Waste Treatment Facility (CBWTF) in the country for treatment and disposal of bio-medical waste produced due to the pandemic;

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

(c) whether Government plans to enhance capabilities of already existing CBWTFs; and

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

Answered on 02nd August 2021

A. (a)to(d) The State/ Union Territory Governments are mandated to implement the Bio-Medical Waste Management Rules, 2016 (BMWM Rules, 2016) in Healthcare Facilities(HCFs) and Common Bio-medical Waste Treatment Facilities(CBWTFs) falling under their jurisdiction, including undertaking need assessment for infrastructure/ facilities required for the purpose. The Central Pollution Control Board (CPCB) has reported that, at present, 202 CBWTFs are operational and 35 CBWTFs are under construction. The operational CBWTFs are handling the incremental bio-medical waste (BMW) generated due to pandemic in line with the CPCB guidelines on- 'Handling, Treatment and Disposal of Waste Generated during Treatment/Diagnosis/Quarantine of COVID-19 Patients'. Further, in the matter of O.A. 710/2017 before the Hon'ble National Green Tribunal, the CPCB has recommended for setting up of CBWTFs in following States/ Union Territories (UTs):

- States - Arunachal Pradesh, Goa, Mizoram, Nagaland, Sikkim and Tripura
- UTs - Andaman and Nicobar Islands and Lakshadweep

The CPCB guidelines have prescribed for extended operation of CBWTFs (in terms of hours)to treat and dispose-off BMW generated in the country. The guidelines also prescribe for disposal of yellow color-coded (incinerable) BMW through Hazardous Waste incinerators in existing Treatment, Storage and Disposal Facilities or captive industrial incinerators beyond the capacity of existing CBWTFs and captive BMW incinerators. The State Pollution Control Boards/ Pollution Control Committees have been authorised for permitting such cases duly ensuring separate arrangement for COVID19 BMW handling and waste feeding.

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

Lok Sabha

Regulate Product Labels

Lok Sabha Unstarred Question No. 2995

Shri Saptagiri Sankar Ulaka:

Dr. Mohammad Jawed:

Shri Santokh Singh Chaudhary:

Dr. Amar Singh:

Shri Benny Behanan:

Shri K. Muraleedharan:

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

(a) whether the Government proposes to regulate product labels for mandatory declaration of animal and animal by-product ingredients used in them along with declaration of ingredients that have been tested on animals;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

Answered on 06th August 2021

A. (a) to (c): Food Safety and Standards Authority of India (FSSAI) has informed that as per sub-regulation 5(4) of Food Safety and Standards (Labelling & Display) Regulations, 2020, every package of non-vegetarian food containing ingredients including food additives and processing aids of animal origin, shall bear a declaration to this effect made by a symbol which is brown colour filled triangle inside a square with brown outline (copy of the image is placed at annexure). The symbol shall be prominently displayed on the package having contrast background on principal display panel, just close in proximity to the name or brand name of the production front of pack.

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

Annexure

Symbol which is brown colour filled triangle inside a square with brown outline

Panel to frame new drugs, cosmetics and medical device laws

It is scheduled to submit draft document by Nov. 30

The Central government has constituted a committee for framing/preparing new drugs, cosmetics and medical device laws. The eight-member panel, headed by Drug Controller General of India V.G. Somani, is scheduled to submit a draft document by November 30.

According to the order issued by the Ministry of Health and Family welfare, dated August 27: "The government has decided to constitute a committee for framing/preparation of New Drugs, Cosmetics and Medical Devices Bill so that New Drugs, Cosmetics and Medical Devices Act can be framed."

The other members of the panel are Rajiv Wadhawan (director, Ministry of Health and Family Welfare), Dr. S.E. Reddy (member) A.K. Pradhan (joint drug controller), drugs controllers of Haryana, Gujarat, Maharashtra and IAS officer NL Meena. The committee is allowed to co-opt member(s) if it requires.

The order further states that the committee shall undertake pre-legislative consultations and examine the present Act, previously framed Drugs and Cosmetics Bills and submit a draft document for a de-novo Drugs, Cosmetics and Medical Devices bill.

The order is titled 'Constitution of Committee for Framing of New Drugs, Cosmetics and Medical Devices Act'.

Rajiv Nath, forum coordinator, Association of Indian Medical Device Industry, said medical devices have outgrown the joint family home shared too long with pharma.

'A good step'

"The separate rules were a good step to allow us to have our own home but Central Drugs Standard Control Organisation [CDSCO] is not letting go. If food can have FSSAI, we need something similar for devices, which are engineering goods undergoing constant innovation," Mr.Nath stated.

The NITI Aayog Bill to regulate devices separately from drugs and decriminalise minor non-compliances was in the right direction, he noted.

The composition of the committee was a serious conflict of interest and unprecedented. "Involving stakeholders like manufacturers, scientists, doctors and patient groups would have been beneficial," he added.

Source: Bindu Shajan Perappadan, The Hindu, 08.09.2021

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Covaxin may get WHO nod this week: Expert

On July 12, Bharat Biotech announced that it submitted all documents required for EUL to WHO on July 9. Bharat Biotech also attended a pre-submission meeting with representatives of WHO on June 23.

People register to receive Covid-19 vaccine dose, at MotiLal Nehru Medical College, in Prayagraj on Monday. (PTI)

Bharat Biotech's Covaxin is likely to receive the emergency use listing (EUL) by the World Health Organization (WHO) this week, a top expert in India's official vaccination planning body has said.

The EUL will pave the way for a wider recognition of Covaxin in documentation sought by many countries that have made an inoculation mandatory for entry into their borders. In the past, students who sought to study abroad were left in the lurch because Covaxin is recognised as a coronavirus vaccine only in few countries.

"I hope this week we get the WHO EUL. The company has submitted all the relevant documents; the vaccine safety data has also been submitted to WHO. So, we are hoping this week we should get it," said Dr NK Arora, chairman, Covid-19 working group of National Technical Advisory Group on Immunisation.

On July 12, Bharat Biotech announced that it submitted all documents required for EUL to WHO on July 9. "The review process has now commenced with the expectation that we will receive EUL from WHO at the earliest ," said Krishna Ella, chairman and managing director of Bharat Biotech, in a statement earlier.

Bharat Biotech also attended a pre-submission meeting with representatives of WHO on June 23.

While the Indian regulator has approved six coronavirus vaccines for emergency use, Covaxin and Serum Institute of India-manufactured Covishield are the mainstay of the country's inoculation campaign. Covishield, the India-manufactured version of the Oxford-AstraZeneca vaccine AZD1222, accounts for close to 90% of the 750 million doses administered till Monday. Covishield has already received a WHO EUL.

Covaxin has been developed by the Hyderabad-based vaccine major and the Indian Council of Medical Research.

According to people familiar with the matter, WHO began a rolling review of Covaxin on July 6, 2021, and even though the review is still 'ongoing', it is a matter of time before an approval is granted.

According to the UN health body, WHO EUL is a risk-based procedure for assessing and listing unlicensed vaccines, therapeutics and in vitro diagnostics with the ultimate aim of expediting the availability of these products to people affected by a public health emergency.

This will assist interested UN procurement agencies and member states in determining the acceptability of using specific products, based on an essential set of available quality, safety, and efficacy and performance data.

On June 22, the subject expert committee of the central drugs standards control organisation (CDSCO) assessed Bharat Biotech's phase 3 clinical trials data of Covaxin, and found the inactivated whole virion vaccine to be 77.8% efficacious in preventing symptomatic Covid-19.

Source: Rhythma Kaul, Hindustan Times, 14.09.2021

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SoftBank walks away from negotiations to pick a stake in 'pricey' PharmEasy

SoftBank Group has walked away from negotiations to acquire a stake in IPO-bound PharmEasy due to disagreement over valuation. API Holdings Pvt Ltd, which owns the Indian online pharmacy chain PharmEasy, was seeking a valuation of at least $5.6 billion in a new funding round.

SoftBank was in talks with API Holdings to invest $150-200 million but a deal has not resulted, said sources close to the development.

Another source said that SoftBank was interested in the company because it had a good network, however, "the valuation that PharmEasy is seeking is too high for SoftBank for the stake in return."

It was reported in July that PharmEasy had approached SoftBank for a stake sale after the former acquired diagnostics laboratories chain Thyrocare for $611 million.

An email query to PharmEasy remained unanswered while SoftBank declined to comment.

IPO listing

According to recent reports, PharmEasy is likely to file draft prospectus with SEBI for an IPO in October. API has commissioned JM Financial and Kotak Investment Banking for the DRHP (draft red herring prospectus) process. In May, PharmEasy acquired rival Medlife. In June, it also acquired Thyrocare. API has already integrated 'lab tests' on its portal.

PharmEasy was founded in 2015 by Dharmil Sheth and Dhaval Shah as a subsidiary of Ascent Health. Since its inception, it has managed to deliver in over 1,000 cities and towns covering 22,000+ pin codes.

Over the last few months, SoftBank has been scouting the Indian healthcare space for making investments. In July, *Business Line* had reported that SoftBank was in

preliminary talks to acquire a stake in Apollo Hospitals Enterprise Ltd's pharmacy arm, Apollo HealthCo, as part of the Japanese company's focus on India's healthcare market. But this deal has also not fructified.

Source : Forum Gandhi, The Hindu Business Line, 13.09.2021

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Clinical trials of Gennova, Bio E vax pick up pace

The government has agreed to supply Covishield doses to the firms for a comparator study

Currently, only SII and Bharat Biotech have continued to supply vaccines en mass in India's immunization drive

Clinical trials of the two Indian vaccine candidates—the mRNA jab from Gennova and the Receptor Binding Protein (RBD) vaccine by Biological E—are expected to speed up after the government agreed to supply doses of Covishield vaccines to these companies for a comparator study, people aware of the development said.

Both companies had been stuck with their vaccine development as they were unable to get doses from Serum Institute of India's Covishield and Bharat Biotech's Covaxin to proceed with their late-stage trials.

According to information put up by the companies in the clinical trial registry, Biological E's Corbevax covid vaccine has entered phase 3 trials. A total of 2,140 volunteers have been recruited between ages 18 and 80, with one set of participants given Corbevax and the other set Covishield. They will be compared for levels of antibodies produced.

In the case of Gennova, a total of 4,000 subjects will be enrolled in the trial across phases 2 and 3, with 3,000 given HGCO19 (its underdevelopment vaccine candidate) and 1,000 Covishield.

"We had to push the government really hard to get the comparator vaccines as it was getting difficult to access them," said an official at a vaccine company who did not want to be named due to the sensitivity of the issue.

Biological E and Gennova did not respond to email queries by Mint.

With four approved vaccines in the market, companies that started their trials early this year have been forced to use an approved vaccine in place of a placebo to compare the efficacy of their vaccines as recruiting trial participants was becoming ethically and logistically challenging.

Globally, too, new covid-19 vaccine candidates have hit a roadblock as vaccine makers such as Pfizer, Moderna and J&J are not sharing doses for comparator clinical trials.

"While the number of doses of comparator vaccine needed to support clinical trials is small, covid-19 vaccines remain scarce, and they are not available for purchase in the open market," said Melanie Saville, director of vaccine research and development at the Norway-based Coalition of Epidemic Preparedness Innovations (CEPI), which funds vaccines for neglected diseases and now also covid.

Saville pointed out that pre-purchase agreements between vaccine makers and countries restrict the latter's use of vaccines to only mass vaccination campaigns, banning their use for clinical trials.

Vaccine makers, too, are not ready to change this agreement "threatening to bring vital covid-19 vaccine R&D to a standstill," CEPI said.

It urged governments, developers and vaccine manufacturers to urgently offer solutions to unlock supplies of comparator vaccines in order to speed up trials and end a shortage of vaccines in low- and middle-income countries.

In India, despite the country making progress with its vaccination drive, the erratic supply of vaccines has made room for new vaccine candidates to be included in the immunization drive.

Currently, only SII and Bharat Biotech have continued to supply vaccines en mass in India's immunization drive. And with only Covishield having approval from the WHO, the supply pressure rests on SII.

Source: Divya Rajagopal, HTMint, 14.09.2021

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Personalized Healthcare with Digital Twin

In the healthcare systems computing becomes the foundation of care delivery services and mainly driven by an industrial concept called the Digital Twin.

We human are the biggest repository of data. Everything we say or do generates data that can be further used to drive new healthcare models. Data is expressed in everything from biochemical changes in cells to physiological shocks, such as a stroke or heart failure and the emotionally intense

moments in our lives. Today much of this data is escaping capture by healthcare systems and is not being put to the best use possible because we do not organize our technologies to do so. In the healthcare systems computing becomes the foundation of care delivery services and mainly driven by an industrial concept called the Digital Twin. The main purpose of such computational power is to characterize every individual or patient that is under the care of the health system. This form of "patient typing" encompasses not just digital phenotyping but all the other evolving typing methodologies, to support efficiently deliver patient-centric care.

The best way to understand the digital twin is to compare to a Airplane Engine digital replica. It is routine for most Jet engines to have a replica in the lab that continuously monitor and collect every single detail about the engine's condition. Using this real time data and a machine learning model, the engine manufacturer can predict every single problem that the engine may face in the future.

Potential of Digital Twin in healthcare

In the healthcare context, a patient's digital twin would similarly enable data collection at the finest granularity of individual cells working together in the various organs of the body. Along with the genome data, the clinical longitudinal data and the wellness data, this digital twin can create a unique data model for each individual. Artificial intelligence can then predict advent of many factors that in future would lead to disease like conditions. In the Indian context, the data would enable better understanding of subpopulations at a regional and district level. With cloud and 5G networks, along with Telehealth the routine doctor interaction can become a health tune up activity.

Need to overcome the roadblocks

Digital twins in healthcare are still very much an opportunity that is further away. In India specifically the digitization of health records is very low. Even though the pandemic is raising awareness, the first set of enablers are going to be around digital tools and technologies that capture the patient record and make it available to the Patient. Along with the same, a comprehensive data repository of a larger population can create a knowledge graph of the genetic mutations, the specific variants and molecular pathways. For example, Indian Cancer Genome Atlas is collecting and curating data for all mutations in the Indian population that have implications on cancerous conditions.

Healthcare data integration

The next level of enablers will have to come around availability of even more computational power. To create a multidimensional and complete twin model, all the forms of data modalities would need to be combined. This would include images from CT scans, MRI, PET scans all the way to pathology data from digital slides. While science is now enabling understanding of cell mechanisms at the single cell level, the scaling of this to routine therapy in the clinic is going to require more simplification and standardization of the involved techniques. At the same time the digital twin could be approached in multiple stages going gradually from 30,000 feet to 10,000 feet to 5000 and to ground level. In technical terms this would be equivalent to start to understand the disease preventive mechanisms in a population at a organ level, going to a tissue and cellular level.

Need of holistic digital health ecosystem in India

India is unfortunately a leader in most of the chronic disease conditions. Even though the population is large and majorly rural, the possibilities presented by Telehealth will raise the effectiveness of the healthcare expenditure. Efforts are underway to create a health blueprint and unified health interface for systems involved in providing healthcare. As UPI made digital payments ubiquitous, the hope is Universal Health Interface, UHI will join the large population to the variety of health services that can be made available remotely and digitally.

This will lead to more digital data in the hands of the patients who can then choose to share the same with healthcare partners investing in future of personalized and precision medicine specific to Indian conditions. With the right technology accelerators, the Indian health system can leapfrog the western counterparts by directly implementing health and wellness measures that are based on a digital twin model. Given the large segments of similar individuals this would overcome the usual challenges of smaller datasets within large data and lead to the digital modelling for the uniquely Indian Health Atlas.

The ultimate aim for the Digital twin is to achieve the triple aim of improving care, improving health at an effective cost. The most detailed individual model can reduce onset of diseases and focus effort on conditions that result from genetic conditions. This would create equitable allocation of costs at the same time improving health outcomes. The technology can also enable remote

adoption and delivery thereby addressing the challenge related to penetration of health services in India.

Shreekanth Joshi -Vice President - Healthcare Life Science at Persistent Systems Ltd.

Source: Shreekanth Joshi, ETHealthworld News, 14.09.2021

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Top medical institutes urge immediate action on front-of-pack labels to address India's NCDs crisis

India's top medical experts cited the exponential rise in the consumption of packaged food as the key contributor to the obesity epidemic and upsurge in non-communicable diseases (NCDs) in India.

New Delhi: Experts from top Indian medical colleges called for mandatory front-of-pack food labels (FOPL) with all the details about the nutritional value of the pack to raise consumer awareness and avert the NCDs and obesity crisis. They asserted that millions of lives will be saved if India establishes scientific cut-off limits for salt, sugar, saturated fats and mandates clear warning labels on packaged products.

India's top medical experts cited that an exponential rise in the consumption of ultra-processed foods containing high levels of sugars, sodium and saturated fats is a key contributor to this obesity epidemic and upsurge in the prevalence of non-communicable diseases (NCDs).

Unhealthy, ultra-processed foods and sugary drinks have only expanded their market in the past few years with the sale of ultra-processed food going up to 6 kg per capita in 2019 from 2 kg in 2005. This consumption has further risen during the Covid pandemic.

Leaders from All India Institute of Medical Sciences (AIIMS), Post Graduate Institute of Medical Education and Research (PGIMER), Institute of Liver and Biliary Sciences, Indian Association of Preventive and Social Medicine (IAPSM), Indian Public Health Association (IPHA), Indian academy of Paediatrics and Epidemiological Foundation of India (EFI), along with doctors from other top medical institutes marked their presence at the event organised by AIIMS Rishikesh and agreed upon the argument presented against junk food.

Medical experts were of the view that front-of-package warning labelling is a key component of a comprehensive strategy to promote healthier lives as it enables consumers to identify products that are high in nutrients of concern associated.

Talking about the impact of not having access to nutrient information of a product, Dr. Suneela Garg, President, Indian Association of Preventive and Social Medicine (IAPSM) said, "All of these conditions such as diabetes, obesity, heart disease or cancers are closely linked to excessive intake of energy-dense and nutrient poor foods and beverages. World over, countries are recognising that consumers have the right to accurate health information regarding these products as part of their right to health. Having incomprehensible or misleading information about a food product puts them at a higher risk of making uninformed choices that lead to overweight, obesity and other diet-related conditions."

All the experts present have agreed to send set of recommendations to the Ministry of Health and hope to work with the government of India towards a healthier and accountable food system. They said it is encouraging to note that the FSSAI has revived FOPL related consultations. In 2018 the Food Safety Standards Authority India (FSSAI) published draft regulation for FOPL which was subsequently withdrawn for further deliberation. In 2019 December, FSSAI delinked FOPL from general labelling regulations and is currently seeking inputs from consumer rights organizations, industry and nutrition experts for a viable model for India.

Source: ET Healthworld News, 14.09.2021

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Covid vaccine boosters not 'appropriate' at this stage: Lancet study

Covid-19 vaccine booster shots are not appropriate at this stage in the pandemic, according to a report in The Lancet published on Monday.

An expert review of scientific evidence to date has concluded that vaccines are effective enough at preventing severe Covid-19 and that there is no need at the moment for the general population to be given third doses.

The conclusion by scientists, including those from the World Health Organisation (WHO) and the US Food and

Drug Administration (FDA), show that vaccination had 95% efficacy against severe disease both from the Delta variant and from the Alpha variant, and over 80 per cent efficacy at protecting against any infection from these variants.

"Although the idea of further reducing the number of Covid-19 cases by enhancing immunity in vaccinated people is appealing, any decision to do so should be evidence-based and consider the benefits and risks for individuals and society," the study said.

"Current evidence does not appear to show a need for boosting in the general population, in which efficacy against severe disease remains high," it added.

According to the study, even if some gain can ultimately be obtained from boosting, it will not outweigh the benefits of providing initial protection to the unvaccinated.

If vaccines are deployed where they would do the most good, they could hasten the end of the pandemic by inhibiting further evolution of variants, it said.

The Lancet study concluded that the current variants had not developed sufficiently to escape the immune response provided by vaccines currently in use.

The Lancet study comes at a time when the US is moving closer to offering booster shots to large segments of the population even as it struggles to persuade Americans to get vaccinated in the first place.

The head of the WHO, Tedros Adhanom Ghebreyesus has insisted that rich countries with large supplies of Covid-19 vaccines should hold off on offering booster shots through the end of the year and make the doses available to poorer countries.

John Nkengasong, director of the Africa Centers for Disease Control and Prevention, said that "we have not seen enough science" to drive decisions on when to administer booster shots.

"Without that, we are gambling," he said, and urged countries to send doses to countries facing "vaccine famine" instead.

US health officials have defended the administration's plan to offer Americans' additional protection against the virus with another vaccine dose, even as others await initial shots, noting that United States has also donated more vaccine doses internationally than every other country combined.

Countries like France have started distributing third jabs to the elderly and people with compromised immune systems, while Israel has gone further, offering children 12 and older a third dose five months after full vaccination.

According to a report in Bloomberg, Israel is making preparations to ensure it has sufficient vaccine supply in case a fourth round of Covid-19 shots is needed.

India crosses 75 crore Covid vaccine doses

Meanwhile, India has crossed the landmark of administering 75 crore Covid vaccine doses.

So far, all adult people in six states and Union territories -- Sikkim, Himachal Pradesh, Goa, Dadra and Nagar Haveli, Ladakh and Lakshadweep -- have received at least one dose of the vaccine.

India took 85 days to touch the 10-crore vaccination mark, 45 more days to cross the 20-crore mark and 29 more days to reach 30 crore, Union Health Minister Mansukh Mandaviya said.

The country took 24 days to reach 40 crore from 30 crore doses and then 20 more days to cross the 50-crore vaccination mark on August 6.

Source : ET Healthworld News, 14.09.2021

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Only 2% of Maharashtra's 20L pregnant women jabbed

Only around 40,700 women have taken the shot so far in Maharashtra, shows data. Considering the state has an estimated 20 lakh women in this category, it means barely 2% have taken the jab. In Mumbai, home to about 1.5 lakh pregnant women, only 1,278 have taken it. Nationally, over 6 lakh had taken it till September 7.

Vaccination against Covid for pregnant women started in mid-July, but it is still to pick up in the state.

Only around 40,700 women have taken the shot so far in Maharashtra, shows data. Considering the state has an estimated 20 lakh women in this category, it means barely 2% have taken the jab. In Mumbai, home to about 1.5 lakh pregnant women, only 1,278 have taken it. Nationally, over 6 lakh had taken it till September 7.

Doctors believe fear, misconception and lack of local data on pregnancy outcomes for the mother and the child may be keeping women away.

'More data, awareness can push pregnant women to take shot'

The low rate of vaccination despite mounting evidence that pregnant women face a higher risk of severe Covid has the medical fraternity calling for more awareness and confidence-building campaigns.

BMC data shows that only one woman of the nearly 1,200 vaccinated had a serious adverse event that required a few days of hospitalisation. Data for adverse events recorded could not be obtained at the state level.

In the first wave, pregnant women were relatively less impacted. Dr Tushar Palve, superintendent of Cama and Albless Hospital, said less than five pregnant women needed oxygen support out of nearly 700 admissions. That changed drastically in the second wave as nearly 30% (120) required oxygen support out of 450-odd admissions. "Morbidity was higher in the second wave, so we highly recommend vaccination to our patients," he said.

Dr Palve said they counsel pregnant women when they come for antenatal visits. As they wait in a common hall for their turn to see the doctor, a senior nurse or a doctor counsels them in groups about the benefits of vaccination outweighing risks for women who are pregnant or breastfeeding.

"Few get convinced to take the vaccine and walk up to the vaccination centre on our premises," he said, adding that only 21 have taken the vaccine at Cama, a dedicated women's hospital, till now.

Vaccination is avoided by most in the first trimester although it has been approved any time during pregnancy. Dr Hrishikesh Pai, president-elect of Federation of Obstetric and Gynaecological Societies of India (FOGSI), said repeated counselling is needed to allay fears of miscarriage. "There is strong hesitancy, but that's understandable," he said. Dr Pai thinks the numbers may see an uptick next year, provided more data is available.

Globally, there is robust data on the safety of mRNA vaccines for pregnant women. Dr Pai said the government must collect local data, including on Covaxin and Covishield. One way to do that would be to study pregnancy outcomes in women, particularly healthcare and frontline workers, who may have inadvertently taken the vaccine in January-February.

Source : ET Healthworld News, 13.09.2021

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Multi-vitamin supplement sales drop as Covid cases reduce

A drop in the number of Covid cases has been reflected in the sales of multi-vitamin supplements that were once widely sold. A report by TOI says that sales of Zincovit, A to Z and Becosules have fallen since the number of cases declined in May-June.

Recently, there has been a drop in the number of Covid cases across the country, this has been reflected in the sales of multi-vitamin supplements that were once widely sold. A report by TOI says that sales of Zincovit, A to Z and Becosules have fallen since the number of cases declined in May-June.

In comparison to the same period (July-August) last year, purchases have almost halved, a TOI report said, on the basis of data culled by a pharma research firm. Immunity supplements have also seen a fall in sales as they went from being present in 92% of bills in June 2020 to around 49% in August this year.

Last October Zincovit managed to cross the highest selling drug Human Mixtard (insulin). It achieved its highest ever sales in May (Rs 80 crore) which then fell by over 60% in July. Experts have said that in a market where anti-diabetic therapies reign, a strong need to strengthen one's immunity is understood, especially during a pandemic. During May, other supplements like Becosules (Pfizer), A to Z (Alkem) and Shelcal (Torrent) also recorded high sales of Rs 30- 50 crore, according to healthcare service provider IQVIA. Vitamin D plain & combinations, and Vitamin C also witnessed high sales after the resurgence of Covid this year.

Pronto Consult founder Karishma Atul Shah said to TOI, "There was a nearly 58% drop in the purchases of immunity boosters in August as compared to the corresponding period last year. However, there was an increase in antibacterials and derma-related brands. Chronic brands were also purchased, but lower as compared to August last year."

The pharma retail market has risen by nearly 14% to Rs 1.73 lakh crore (12-year period ended July), on the back of higher sales of acute therapies of anti-infectives

and respiratory drugs, and certain chronic medication including anti-diabetics.

Source: ET Healthworld News, 13.09.2021

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India worried about complacency over second dose of COVID-19 vaccine

The country has reported 33.26 million infections and 442,874 deaths. The government estimated in July that more than two-thirds of India's 1.35 billion had contracted the virus.

India is worried that growing complacency as COVID-19 infection rates and deaths decline could lead to people skipping their second vaccine shots, leaving communities vulnerable to the coronavirus, said two health experts briefed on the matter.

India has administered more than 744 million vaccine doses - with 60% of its 944 million adults getting a first shot and 19% fully vaccinated with the required two shots.

India has the most partly immunized people in the world, according to the Our World in Data website, mainly due to a long gap of between 12 and 16 weeks between doses, as prescribed by the government.

"There's a concern among the highest quarters of an impending vaccine hesitancy, in view of most taking a single dose already and disease incidence at its lowest," said one of the sources, both of whom declined to be identified.

Large numbers of people skipping their second dose would be particularly problematic in areas with low numbers of previously infected people, meaning more people with fewer antibodies so those communities would be more vulnerable, the first expert said.

The second expert said the health ministry had told states to encourage people to get their second doses as soon as possible, so on the 12th week after their first dose, rather than waiting for the latest date, in a bid to ensure people don't miss the second shot.

The Health Ministry did not immediately respond to a request for comment.

The government told a news conference last week that data gathered between April and August - when the Delta variant was spreading rapidly - showed one dose alone was 96.6% effective in preventing deaths, while two gave a 97.5% protection.

But one of the experts said that message could inadvertently put people off getting their second shot, especially as for many poor workers time spent at the vaccination centre means a smaller pay packet.

After being hit by the world's biggest surge in coronavirus cases and deaths in April and May, India's daily infections have settled at around 40,000 and deaths have come down sharply.

India has reported 33.26 million infections and 442,874 deaths. The government estimated in July that more than two-thirds of India's 1.35 billion had contracted the virus.

Source: ET Healthworld News, 13.09.2021

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Digital Therapeutics: Revolutionizing the virtual healthcare industry

The value of the global DTx market is estimated at USD 1.8 billion in 2018, which is expected to reach USD 7.1 billion by 2025.

Constant innovation and technological advancement across healthcare applications from use of AI, ML to health monitoring have been helping stakeholders of the industry address the vast data pool while providing them with valuable insights.

Individuals with chronic health conditions have always required a regular interaction with doctors/health care providers & healthcare systems. Patients are constantly on the lookout for digitally enabled solutions that can help provide personalized and on-demand care. While the providers are implementing various digital tools for real-time monitoring and improved patient-platform engagement at affordable pricing, the Pandemic has accelerated the adoption of virtual care with a rising focus on affordable and preventive care digital solutions.

Digital Therapeutics (DTx) is one such growing subspeciality of digital healthcare, which denotes a collection of products, technologies and services across healthcare and wellness industries.

The value of the global DTx market is estimated at USD 1.8 billion in 2018, which is expected to reach USD 7.1 billion by 2025. A recent report estimates the biggest

applications for DTx to be for diabetes and weight loss programs, with other applications likely to be observed in conditions such as chronic obstructive pulmonary disorder (COPD), developmental disorders, with the use of computer games, as well as post- traumatic stress disorder (PTSD), with the use of virtual reality (VR).

Difference and Benefits

The fundamental difference between DTx and general wellness applications is that the DTx applications are developed for a specific disease condition, particularly chronic diseases such as diabetes, cardiovascular conditions such as hypertension and pulmonary diseases like COPD.

DTx comprises a system of applications that help treat diseases through management in patient's lifestyle activities or behavior and monitoring remotely to get a positive health outcome.

These systems of applications are devised to achieve positive health outcomes; for example, they can motivate patients to adhere to a particular lifestyle such as diet and exercise routines or drug regimens.

A number of DTx applications are emerging for the treatment of mental health conditions. The digital application of cognitive-behavioral therapy (CBT) is showing promising results in the management of depression and anxiety disorders. Products for treatment of conditions such as schizophrenia and insomnia are also under development. For example, one of the online self-care programs based on CBT for insomnia has demonstrated improvement in both insomnia symptoms and mental well-being.

DTx is also utilising VR technology to help reduce costs. It has shown an important use as a key application in providing exposure therapy for PTSD. Evidence based studies to assess its potential use in other areas, including depression, anxiety, phobias, obsessive-compulsive disorder (OCD), eating disorders, addiction, and psychosis, are also underway. The VR technology in DTx uses simulation to enable people to learn by getting an experience of real-world situations. For example, through VR, patients experience a situation and learn how to think, feel, and act differently.

Importance of DTx adoption in Traditional Healthcare

DTx has the potential to improve health care practice. A major advantage of DTx is that it offers physicians an option to provide treatment remotely, in real time and at scale, removing the physical borders of a clinic or a hospital. It aids health care professionals / physicians to make timely, informed, and accurate clinical diagnoses and patient care decisions to prevent future complications. Its ability to monitor and track response to the prescribed therapies, provide an opportunity for individualised/personalized treatment.

The American Diabetes Association recently reported on the efficacy of one such app using digital therapeutics in imparting behavioral adjustments necessary for diabetes lifestyle treatment. Similarly, for conditions such as depression and anxiety, DTx can assist physicians in personalizing therapy and monitoring outcomes.

Couple of real life examples will help in understanding the positive health outcomes after using the DTx.

A 40 year individual, overweight with unhealthy dietary pattern & sedentary lifestyle got a surprise with his blood reports (FBS 184, PPBS 245) with HbA1c 8.5 & a deranged lipid profile. The individual received a prescription of LSM (Diet+Exercise) along with oral anti diabetic medications for his physician. Post enrolling in a LSM program (based on a DTx) he got educated about various healthy dietary patterns along with appropriate exercises personalised for his health situation along with monitoring of blood sugar through digital device of glucometer. Over a period of 6-8 months, by virtue of his adherence to personalised LSM (diet & exercises) along with medications was able to improve his sugar control.

Another such instance was a 55 year person with a case of T2DM (diagnosed over the last 5 years) with multiple oral anti-diabetic medications. Post his enrolment in a LSM DTx program, he got educated about various dietary patterns and exercise modules along with various stress reduction techniques/meditation etc. Remote monitoring of blood glucose, personalised LSM techniques (healthy balanced diet + exercise) led to improvement in his sugar control.

The point here is that by virtue of diabetes education, remote monitoring of health parameters, better adherence to LSM (diet + exercise), these individuals were able to achieve better disease control which led to better quality of life along with prevention of future complications.

Limitations of DTx

The solutions provided by DTX to certain medical / clinical situations and early evidence have proved their clinical value, yet, DTx entities have not significantly

entered the mainstream healthcare system. The two main obstacles to broader adoption of DTx we see are:

1. Difficulty in separating DTx from the more general health applications in the digital health market
2. Uneven incentives in the healthcare environment

Today, DTx offers a variety of information and modifications to the workflows of a healthcare provider, thus adding to the physician's burden by an overload of data and required interpretation.

Rigorous evidence based investigation is required through randomized clinical trials (RCTs) to get reliable supporting evidence on the safety and efficacy of DTx. Apart from regulatory approvals, there is also a need for defining the standards of safety and efficacy for collaboration among stakeholders.

DTx is an emerging approach in the management of health conditions, ready to tackle chronic and other clinical / medical conditions. DTx is here to stay and grow. Though it is expected to influence healthcare delivery and its consumption across the globe, the widespread adoption of DTx may take longer than the industry had hoped for. Solutions to the main challenges are still evolving and growing R&D investment will definitely show the enormous potential impact of DTx soon.

Rohan Verma, Co-founder, CEO, Breathe Well-being

Source: ET Healthworld News,14.09.2021

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Vax for 12 to 17-yr kids with comorbidities from Oct-Nov

The government plans to begin Covid vaccination of children in the 12-17 age group who have co-morbidities like obesity, heart disorders, or immunodeficiency by October-November, official sources said.

The government plans to begin Covid vaccination of children in the 12-17 age group who have co-morbidities like obesity, heart disorders, or immunodeficiency by October-November, official sources said.

The plan keeps in mind that supplies of Zydus Cadila's DNA vaccine ZyCoV-D — the only one to have received emergency authorisation for use in children in the country so far — are likely to begin in October.

"We are waiting for Zydus to begin supplies. Once that starts we will initiate vaccination among children. This year, only those with co-morbidities will receive the vaccine doses, rest will start getting it from the first quarter of next year," a senior official told TOI.

Around 20-30 lakh children with co-morbidities will be eligible for the first round of vaccination, according to government estimates.

Zydus is expected to supply around 40 lakh doses in the first lot, and scale it up to one crore every month going forward. The government is expecting that the company will be able to supply around 4-5 crore doses by December. ZyCoV-D is a three dose vaccine. The government expects to further expand coverage among children by March next year, when more vaccines are available for them.

Bharat Biotech's Covaxin is also being tested for use in children and clinical trials are nearing completion, according to regulatory officials. Once Covaxin gets emergency authorisation for use in children, it can be administered to all those above two years. There are also other vaccine candidates from Biological E and Serum Institute of India that have recently got approval for clinical trials in children.

Full report on www.toi.in

Source: Sushmi Dey, TNN (ET Healthworld News), 14.09.2021

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Delta breaches China less than month after previous outbreak

China is experiencing yet another Delta outbreak, with dozens of infections detected in the southeastern province of Fujian less than a month after the nation's last flare-up was contained. The cluster was detected during a routine testing in local schools, where two students tested positive on Friday. Their father, who returned from Singapore in early August, was also found to have been infected. Officials believe he is the likely source of the latest outbreak, which now stretches to over 60 people in three cities.

The man did three weeks of quarantine and took 10 tests with no signs of infection before returning to the community, underscoring how difficult it can be to identify every case. China's so-called Covid Zero policy relies on aggressive testing and contact tracing. At least 19 of the infected are under the age of 12, a group that China's vaccine campaign has yet to reach. A task force has been sent to the city of Putian, where most of the cases have been found. Other patients were detected in the port cities of Quanzhou and Xiamen. The latest wave comes less than a month after China contained its broadest outbreak since initial emergence in Wuhan, with curbs that included regional lockdowns and train and flight suspension. Similar curbs have been imposed in Fujian.

Source : Times of India, 14.09.2021

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INTERNATIONAL NEWS

Britain begins world's largest trial of blood test for 50 types of cancer

LONDON, (Reuters) - Britain's state-run National Health Service will on Monday begin the world's biggest trial of Grail Inc's (GRAL.O) flagship Galleri blood test that can be used to detect more than 50 types of cancer before symptoms appear.

The Galleri test looks at the DNA in a patient's blood to determine if any come from cancer cells. Earlier diagnosis of cancers leads to dramatically increased survival rates.

The NHS said it wanted to recruit 140,000 volunteers in England to see how well the test worked as part of a randomised control trial. Half of the participants will have their blood sample screened with the Galleri test right away.

"We need to study the Galleri test carefully to find out whether it can significantly reduce the number of cancers diagnosed at a late stage," said Peter Sasieni, professor of cancer prevention at King's College London.

"The test could be a game changer for early cancer detection and we are excited to be leading this important research."

Lung cancer is by far the most common cause of cancer death in the United Kingdom, accounting for around a fifth of all cancer deaths. Lung, bowel, prostate and breast cancers account for 45% of the United Kingdom's cancer deaths, the NHS said.

U.S. life sciences company Illumina Inc. (ILMN.O) said last month it had completed its $7.1 billion acquisition of Grail. Illumina said it will operate Grail separately from its existing business.

Source: Reporting by Guy Faulconbridge; Editing by Mike Harrison, Reuters, 13.09.2021

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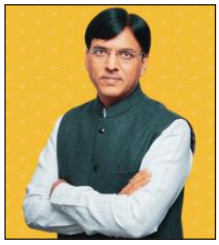
FEATURE

75 crore vaccine doses a global beacon in fight against Covid-19

Shri. Mansukh Mandaviya

Union Minister for Health & Family Welfare, and Chemicals and Fertilisers

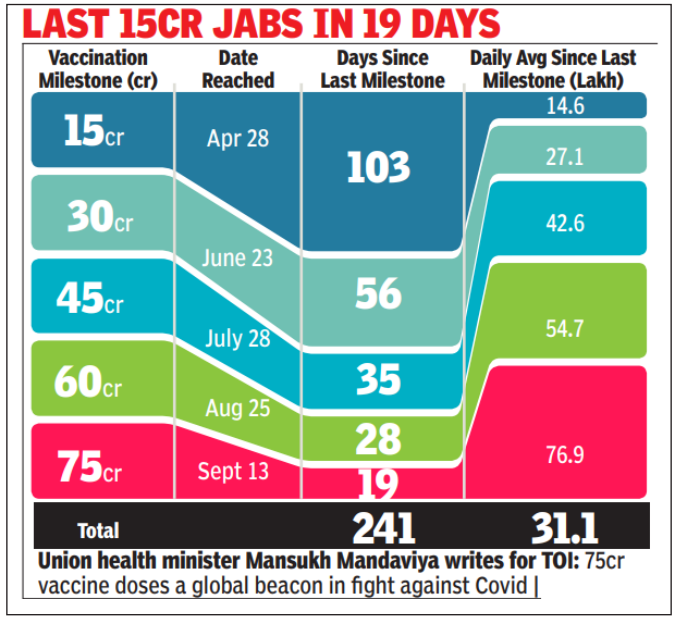


It is a day to rejoice! As India prepares to celebrate the 75th anniversary of Independence, we have another reason to celebrate. Having delivered a landmark 75 crore Covid-19 vaccine doses under the visionary leadership of Prime Minister Narendra Modi, India is well on its way to vaccinating the entire adult population soon. If there was ever a measure of progress by a country that has harnessed its science, R&D, human resources of health workers, doctors, nurses and medical staff, it is this milestone.

What makes the achievement more significant in this 75th year of Independence is that almost all these vaccines have been manufactured in India by our scientists in a relatively short span of time.

India has a proven track record of strong pharma and vaccine manufacturing capabilities. The first indigenously developed Covid-19 vaccine, Covaxin, led by ICMR in collaboration with Bharat Biotech; Serum Institute's Covishield; Sputnik (in private hospitals), have been rolled out across the country. Zydus Cadila's ZyCoV-D, the world's first placid DNA vaccine, has received EUA, and many other candidates from Indian companies are in advanced stages of trials.

Despite challenges in terms of a large population and at-risk groups, India has done remarkably well in managing



the Covid-19 pandemic. India was quick to identify gaps and rapidly provided innovative solutions for surveillance and testing. Our government ramped up testing capacity, diagnostic centres and supply of critical equipment and medicines. With ICMR's rapid intervention, India has more than 2,900 Covid testing labs, more than 541 million samples have been tested,1.5 million tests are conducted every day. The department of biotechnology (DBT) has launched a pan-India 1000 SARS – CoV-2 RNA genome sequencing programme. Our Covid-19 vaccination drive has shown the strength of India's vaccine manufacturing capabilities for inoculating such a large population of which many reside in the remotest of villages.

With the massive support of state governments, India has been able to accelerate and expand its Covid-19 vaccination drive. The promise made by our PM of free vaccines for all is being met by Centre that is supporting all states and UTs with free of cost vaccines. We are administering an average of 76.45 (Sep 21) lakh Covid-19 vaccine doses per day. We have administered more than 1

crore doses on several days recently. This is a figure larger than the entire population of several nations.

Nearly 60% of India's adult population has now been vaccinated with at least one-dose of the Covid-19 vaccine. Almost 19% have been administered both the doses. More importantly, today over 67% of our elderly and 68% of those who are 45-59 years have received at least one dose of the vaccine.

It is encouraging to see states like HP, Sikkim, Dadra & Nagar Haveli, Daman & Diu and Goa having vaccinated 100% of eligible population with the first dose of Covid-19 vaccine. UP, Gujarat, Karnataka, MP and Haryana are administering Covid-19 vaccines faster than some leading nations of the world. It is impressive that the digital vaccination platform CoWin has been scaled up to deliver digital vaccine certificates for all those who are vaccinated.

These vaccination numbers have been made possible not only because of the efforts of governments, but by the relentless hard work of our scientists, doctors, healthcare workers, paramedical staff -- the nation's Covid warriors. I join the rest of the nation in congratulating them for their selfless dedication, spirit, and commitment. Special acknowledgement is needed for our ASHAs, ANMs, Anganwadi workers and women's Self Help Groups (SHGs) for their contributions in the vaccination drive.

As we rejoice successes achieved thus far, we should not let complacency get the better of us. The increasing rate of coronavirus cases in states like Kerala and Maharashtra is a real concern. As new variants of the Covid-19 virus emerge, we must stay vigilant and not drop our guard. India, with its 'aatmavishwas' and 'aatmanirbharta', has been able to stand tall against Covid-19. All Indians should take pride and enthusiastically participate in the world's largest and fastest vaccination drive.

Source: Times of India, 13.09.2021

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IDMA BULLETIN

PUBLISHED ON 7th, 14th, 21st and 30th of Every Month

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