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IDMA BULLETIN

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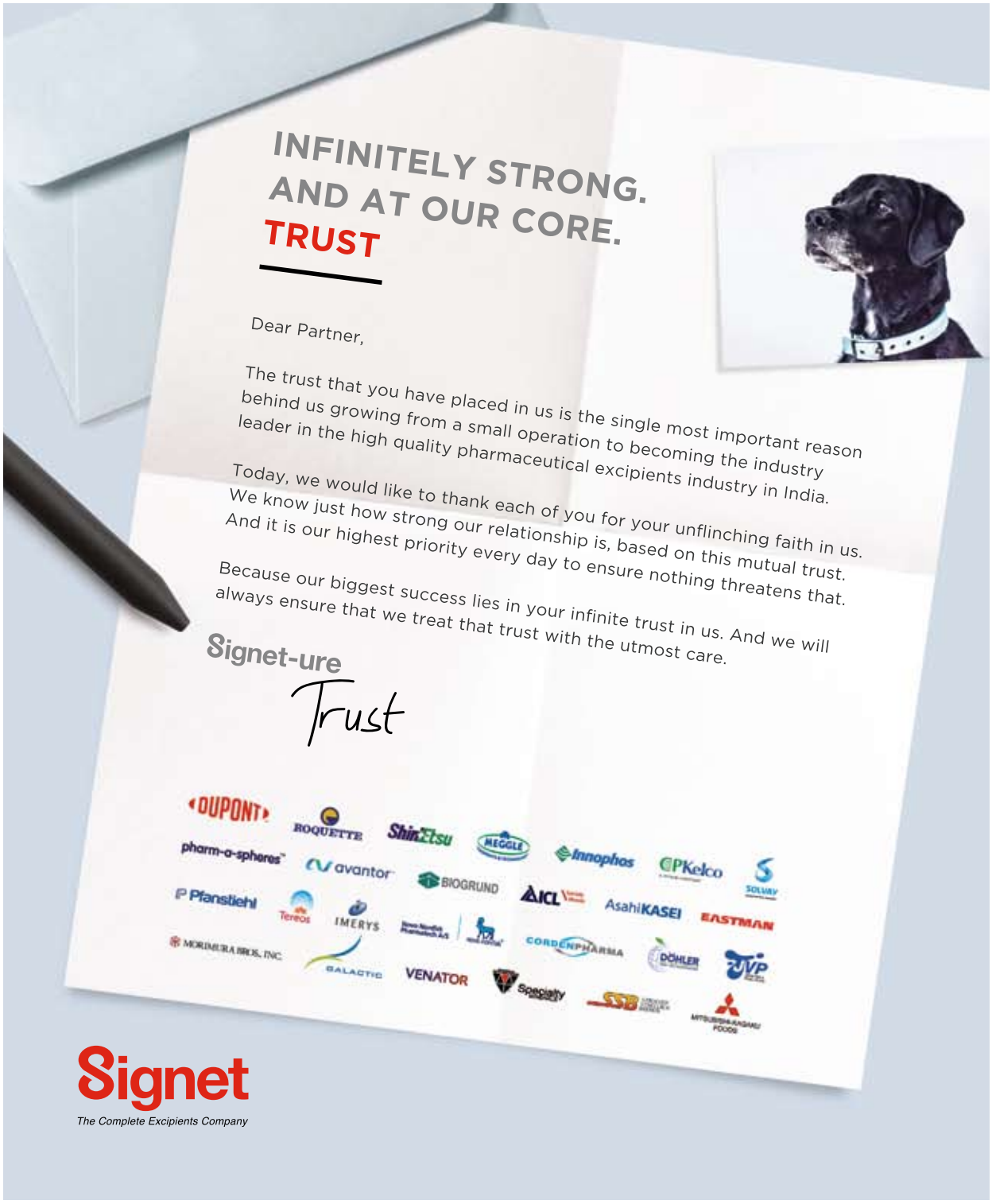
Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS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Dear Partner,
The trust that you have placed in us is the single most important reason behind us growing from a small operation to becoming the industry leader in the high quality pharmaceutical excipients industry in India.
Today, we would like to thank each of you for your unflinching faith in us. We know just how strong our relationship is, based on this mutual trust. And it is our highest priority every day to ensure nothing threatens that.
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IDMA BULLETIN

Vol. No. 51 **Issue No. 25** **01 to 07 July 2020**

Meeting with stakeholders for discussion on formulation of guidelines for labelling of performance enhancing drugs (Doping drugs) on 23.06.2020: IDMA Submission – reg.

The Association has made the following submission on 27th June 2020 to Shri Arun Pradhan, Deputy Drugs Controller, Central Drugs Standard Control Organisation, New Delhi for discussion on formulation of Guidelines for labelling of performance enhancing Drugs (Doping Drugs) subsequent to the webinar-meeting with stakeholders on 23rd June 2020:

"We are thankful for your esteemed office mail dated 16th June 2020 granting us the opportunity to partake in the webinar on 23rd June, 2020.

On the aforesaid subject, we wish to submit that Performance enhancing drugs (Doping Drugs) or Prohibited Drugs, are published by World Anti-Doping Agency (WADA) and National Anti-Doping Agency (NADA) on NADA website, under the aegis of Ministry of Youth affairs and Sports website. NADA and various sports bodies in India such as Indian Olympic association, BCCI, All India Tennis Association (AITA) etc undertake extensive awareness programs with sports persons on these prohibited drugs. With reference to the objective of the stakeholders meeting to discuss possibility of changing the labelling requirements for performance drugs, as detailed in the prohibited list of NADA, it is our strong belief that this is not warranted, for the following reasons:

1) All these Performance Drugs (barring illegal substances) are prescription drugs, either in Schedule H, H1 or X or NDPS (where in the labelling requirement is NRx). These are prescription only drugs and hence, the question of awareness to general public such as parents, teachers, students, sports persons etc does not arise.

2) There is adequate information on the label to state that "for prescription only" and to further distinguish the same, as performance drugs does not serve any purpose.

3) Strict enforcement of prescription based performance enhancement drugs and availability, by prescription only is a better solution to the problem.

4) The prohibited drugs under NADA and WADA are prescribed by RMPs, only. Hence, awareness to RMPs should be done through Medical Council of India to ensure that these are not misused.

5) It is pertinent to mention that there have been too many changes in the labelling requirements and the label is already very crowded. For example, it is not practical to include anything on a small volume injection ampoule. IDMA has submitted a representation dated 21st June, 2018 for simplification of the labelling requirements (Copy attached)*. This needs to be reviewed in context of the current proposition.

6) Labelling changes should be reviewed, changed and notified, once in 5 years and implemented after giving adequate time of 12 months, for managing packaging inventory. Industry typically has 9-12 months packaging inventory, at any given point of time and any adhoc implementation of labelling changes impact availability of medicines and disruption in the supply chain, as designing, artwork, printing, current inventory of packaging material has to be managed.

7) The prohibited list is dynamic and is revised by WADA on an annual basis. This would be difficult to implement and enforce if the labelling requirement and changes are dynamic in nature. This would create huge impediments for Industry and Trade.

We do hope our opinion and suggestions as above are considered favourably. Warm regards".

*(*Not reproduced here)*

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Exorbitant increase in Air-freight affecting Exports and Imports: IDMA Representation

The Association has made the following representation on 30th June 2020 to Dr P D Vaghela, IAS, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi on the above subject: Similar representations have been made to Dr Anup Wadhawan, IAS, Secretary,

Department of Commerce, Ministry of Commerce & Industry and Shri Pradeep Singh Kharola, IAS, Secretary, Ministry of Civil Aviation, New Delhi.

"Greetings from Indian Drug Manufacturers' Association.

Indian Drug Manufacturers' Association (IDMA) has been, since its inception in 1961, the engine leading the Indian Pharmaceutical Industry to greater heights and glory and ensuring near self-sufficiency of affordable quality medicines for our people. IDMA has a strong membership of more than 1000 manufacturers (of APIs and Formulations) throughout the country, comprising Small, Medium and Large-scale companies.

Pharma Units manufacturing life-saving drugs were adversely affected by the various logistic issues faced during lockdown to combat COVID-19. Exorbitant increases in air freight rates have further added to misery for Indian Pharma Industry. During the last three months air freight for international cargo has gone up 2 to 3 times. For instance, Air Freight rate to the USA for a normal cargo increased four times to Rs.768 per KG in May 2020 from Rs.189 per KG in February 2020. Attached **Annexure 1** shows an increase in export air freight to various regions of the world. This increase is adversely impacting businesses' commercial viability of some shipments.

We understand this is because of the supply demand situation. There could also be cartelization by the airlines. To combat this situation, we request you to consider the following measures:

1. Air India may be asked for more cargo flights to/from different international destinations.
2. Freely permit international airlines to run cargo flights to/from India.
3. Ask IATA to prevent cartelization by airlines.

Pharmaceutical industry is willing to work with the state airlines for giving them the details of the cargo required to be moved to/from various destinations. We request your kind help in the matter. Thanking you and with regards."

Encl: Annexure 1

Annexure 1

Export Air Freight during COVID 19

Sector	Shipment Type	February Min	February Max	February Avg/Kg	March Min	March Max	March Avg/Kg	April Min	April Max	April Avg/Kg	May Min	May Max	May Avg/Kg
USA	15-25°C	189	196	199	190	530	269	228	728	560	358	768	669
	2-8°C		252	252	252	1143	299	712	1562	1093	519	1002	805
	Narcotics		232	232	237	561	397	-	1538*	1538	723	850	799
								*UA Freighter Narc + Nor		el Total value $4.13 mill =			
EUROPE	15-25°C	120	155	128	120	290	148	298	426	352	321	463	367
	2-8°C		794	794		209	209					493	493
	Narcotics										585	586	585
CANADA	15-25°C	200	246	213	200	236	206	668	839	791	708	838	
	2-8°C								1979	1978		865	865
	Narcotics		495	495									
	DGR		273	273		257	257		805	805			
ANC	15-25°C	104	160	123	107	138	126	668	879	699	648	807	652
	2-8°C		384	384		201	201					1627	1627
	Narcotics												
	DGR												

Source: IPA Companies
Data collated basis various airlines such as United, Lufthansa, Emirates

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Industries covered under Public Liability Insurance (PLI) Act, 1991: Subscription - reg.

MoEF&CC Communication Ref.File No. 10/1/2020-HSMD, dated 28th February, 2020

(Letter from MoEF&CC received on 29th June 2020)

To
The President,
Indian Drug Manufacturers' Association (IDMA), Mumbai.

The Public Liability Insurance (PLI) Act, 1991 came into force in 1991 and was amended in 1992 with the objective of providing immediate relief to the victims of accidents that might occur while handling hazardous substance(s). This Ministry is administrating the Act. The owner is required to pay specified amounts to the victims as interim relief based on *'no fault liability'* under the Act. It is mandatory for every owner engaged in handling listed hazardous substance(s) above the threshold quantity to take out insurance policy(ies).

The liability of the insurance companies is limited as per the Act, though the owner's liability continues to be unlimited. An Environmental Relief Fund (ERF) has been established under the PLI Act with the contribution, equivalent to the premium paid by the owner(s) through insurance companies. This fund is dedicated to meet the requirement of immediate relief to the victims as and when required.

The named threshold quantity of 179 listed hazardous chemicals under the PLI Act is enclosed*. However, certain chemicals (liquid/gas) like Acetylene, LPG, Solvents, etc would fall under part II of the list as per the interpretation of material safety data sheets of the different chemicals, (i.e. Flammable substances) which are over and above the listed 179 chemicals.

The PLO Act and rules there-under are in place since 1992. However, it is observed that contribution to Environment Relief Fund is dwindling year-after-year which indicates that companies are not renewing their PLI policies.

It is requested that member industries may be sensitized adequately to subscribe to PLI policies and renew them in time.

Dr Dharmender Kumar Gupta, Director (S), Ministry of Environment, Forest and Climate Change, (HSM Division), Government of India, New Delhi.

Encl: Annexure/List as above.

Ministry of Environment and Forest Notification No.S.O.227(E), dated 24th March 1992

In exercise of the powers conferred by clause (d) of Section 2 of the Public Liability Insurance Act, 1991 (6 of 1991), the Central Government hereby specifies the quantities shown in column 3 of the Table below for which or exceeding which every owner handling the hazardous substance mentioned in the corresponding entry in column 2 thereof shall take out insurance policy as per the provisions of the said Act.

TABLE

***LIST OF CHEMICALS WITH QUANTITIES FOR APPLICATION OF PUBLIC LIABILITY INSURANCE ACT**

Sr. No.	Name of hazardous substances	Quantity	CAS Chemical Abstract Service Number
1	2	3	4
PART - 1			
GROUP 1 - TOXIC SUBSTANCES			
1	Aldicarb	100 kg	116-06-3
2	4-Aminodiphenyl	1 kg	96-67- 1
3	Amiton	1 kg	78-53-5

4	Anabasine	100 kg	494-52-0
5	Arseinc pentoxide, Arsenic (V) acid & salts	100 kg	
6	Arsenic trioxide, Arscius (III) acid & salts	100 kg	
7	Arsine (Arsenic hydride)	10 kg	7784-42- 1
8	Azinphos-ethyl	100 kg	2642-71-9
9	Azinphos-methyl	100 kg	86-50-0
10	Benzidine	1 kg	92-87-5
11	Benzidine salts	1 kg	
12	Beryllium (powders, compounds)	10 kg	
13	Bis (2-chloroethyl) sulphide	1 kg	505-60-2
14	Bis (chloromethyl) ether	1 kg	542-88-1
15	Carbophuran	100 kg	1563-66-2
16	Carbophenothion	100 kg	786-19-6
17	Chlorefenvinphos	100 kg	470-90-6
18	4-(Chloroformyl) morpholine	1 kg	15159-40
19	Chloromethyl methyl ether	1 kg	107-30-2
20	Cobalt (metal, oxides, carbonates, sulphides, as powders)	1 t	
21	Crimidine	100 kg	535-89-7
22	Cynthoate	100 kg	3734-95-0
23	Cycloheximide	100 kg	66-81 -9
24	Demeton	100 kg	806548-3
25	Dialifos	100 kg	10311-84-9
26	OO-Diethyl S-ethylsulphinylmethyl phosphorothiate	100 kg	2588-05-8
27	OO-Diethyl S-ethylsulphonylmethyl phosphorothioate	100 kg	2588-06-9
28	OO-Diethyl S-ethylthiomethyl Phosphorothioate	100 kg	2600-69-3
29	OO-Diethyl S-isopropylthiomethyl phosphorodithioate	100 kg	78-52-4
30	OO-Diethyl S-propylthiomethyl phosphorodithioate	100 kg	3309-68-0
31	Dirnefox	100kg	115-264
32	Dimethylcarbamoyl chloride	1 kg	79-44-7
33	Dimelhylnitrosamine	1 kg	62-75-9
34	Dimethyl phosphoramidocynicidic acid	1 t	6391741-9
35	Diphacinone	100kg	82-66-6
36	Disulfoton	100 kg	298-04-4
37	EPN	100 kg	2104-64-5
38	Ethion	100 kg	563-12-2
39	Fensulfothion	100 kg	115-90-2
40	Fluenetil	100 kg	4301-50-2
41	Fluroacetic acid	1 kg	14449-0
42	Fluoroacetic acid, salts	1 kg	
43	Ruoroacetic acid, esters	1 kg	
44	Fluoroacetic acid, amides	1 kg	
45	4-Fluorobutyric acid	1 kg	62-23-7
46	4-Fluorobutyric acid, salts	1 kg	
47	4-Fluorobutyric acid, esters	1 kg	
48	4-Fluorobutyric acid, amides	1 kg	
49	4-Florocrotonic acid	1 kg	37759-72- 1
50	4-Fluorocrotonic acid, salts	1 kg	
51	4-Fluorocrotonic acid, esters	1 kg	

52	4-Fluorocrotonic acid, amides	1 kg	
53	4-Fluoro-2-hydroxybutyric acid, amides	1 kg	
54	4-Fluoro-2-hydroxybutyric acid, salts	1 kg	
55	4-Fluoro-2-hydroxybutyric acid, esters	1 kg	
56	4-Fluoro-2-hydroxybutyric acid, amides	1 kg	
57	Glycolonitrile (Hydroxyacetoni trile)	100kg	107-164
58	1, 2, 3, 7, 8, 9-Hexachlorodibenzo-p-dioxin	100g	194-8-74-3
59	Hexamethyl phosphoramide	1 kg	680-31-9
60	Hydrogen selenide	10 kg	7783-07-5
61	Isobenzan	100 kg	297-78-9
62	Isodrin	100 kg	465-73-6
63	Juglone (S-Hydroxynaphithalene 1,4 dione)	100 kg	481-39-0
64	4, 4-Methylenebis (2-chloroniline)	10 kg	101-14-4
65	Mthyl isocynate	150 kg	624-83-9
66	Mevinphos	100 kg	7786 34-7
67	2-Naphthylamine	1 kg	91-59-8
68	2-Nickel (metal, oxides, carbonates,	1 t	
69	Nickel tetracarbonyl	10kg	13463-39-3
70	Oxygendisulfoton	100 kg	2497-07-6
71	Oxygen difuoride	10kg	7783-41-7
72	Paraxon (Diethyl 4-n;trophenyl phosphate)	100 kg	31145-5
73	Parathionf	100 kg	56-38-2
74	Parathion-methyl	100 kg	298-00-0
75	Pentaborane	100 kg	19624-22-7
76	Phorate	100 kg	298-02-2
77	Phosacetim	100 kg	4104-14-7
78	Phosgene (carbonyl chloride)	750 kg	7544-5
79	Phospharnidon	100 kg	13171-21-6
80	Posphine (Hydrogen phosphide)	100 kg	7803-51 -2
81	Promurit (1-(3, 4-dichlorophenyl) 3-triazenelhiocarboxamide)	100kg	5836-73-7
82	1, 3-Propanesullone	1 kg	1120-714
83	1-Propcn-2-chloro-1, 3-diol diacetate	10 kg	10118-72-6
84	Pyrazoxon	100 kg	108-34-9
85	Selenium hexalluoride	10 kg	7783-79-1
86	Sodium selenite	100 kg	10102-18-8
87	Stibine (Antimony hydride)	100 kg	7803-52-3
88	Sulfotep	100 kg	3689-24-5
89	Sulphur dichloride	1 t	10545-99-0
90	Tellurium hexafluroride	100 kg	7783-80-4
91	TEPP	100 kg	107-49-3
92	2, 3, 7, 8-Telrachlorodibenzo-p-dioxin (TCDD)	1 kg	1746-01 -6
93	Telramethylenedisulphototramine	1 kg	80-12-6
94	Thionazin	100 kg	297-97-2
95	Tirpate (2, 4-Dimethyl-1, 3-di thiolane-2-calboxaldehyde O-methylcarbamoyloxime)	100 kg	26419-73-8
96	Trichloromethanesulphenyl chloride	100 kg	594-42-3
97	1-Tri (cyclohexyl) stannyl-l H-l, 2, 4-triazole	100 kg	41083-11-8

98	Triethylenemelamine	10 kg	51-18-3
99	Warfarin	100 kg	81-81-2
GROUP 2-TOXIC SUBSTANCES			
100	Acetone cyanohydrin (2-Cyanopropan-2-01)	200 t	75-86-5
101	Acrolein (2-Propenal)	20 t	107-02-8
102	Acrylonitrile	20 t	107-13-1
103	Allyl alcohol (Propen-1-01)	200 t	107-18-6
104	Alylamine	200 t	107-11-9
105	Ammonia	50 t	7664-41 -7
106	Bromine	40 t	7726-95-6
107	Carbon disulphide	20 t	75-15-0
108	Chlorine	10 t	7782-50-5
109	Dipneyl ethane di-isocynate (MDI)	20 t	101-68-8
110	Ethylene dibromide (1, 2-Dibromocthanc)	5 t	106-93-4
111	Ethyloncimine	50 t	151-56-4
112	Formaldehyde (concentration <90%)	5 t	50-00-0
113	Hydrogen cynide	5 t	74-90-8
114	Hydrogen chloride (liquified gas)	25	7647-01-0
115	Hydrogen fluoride	5 t	7664-39-3
116	Hydrogen sulphide	5 t	7783-064
117	Methyl bromide (Bromomethane)	20 t	74-83-9
118	Nitrogen oxides	50t	11104-93-1
119	Propylineimine	50t	75-55-8
120	Sulphur dioxide	20t	7446-09-5
121	Sulphur trioxide	15t	7446-11-9
122	Tetraethyl lead	5 t	78-00-2
123	Tetramethyl lead	5 t	75-74- 1
124	Toluene di-isocynate (TDI)	10 t	584-84-9
			75-01 -4
GROUP 3-HIGHLY REACTIVE SUBSTANCES			
125	Acetylene (ethyne)	5 t	74-86-2
126	a. Ammonium nitrate (I)	350 t	6484-52-2
	b. Ammonium nitrate in form of fertiliser (2)	1250 t	
127	2, 2-Bis (tcrt-butylperoxy) butane) (concentration # 70%)	5 t	2167-23-9
128	1, 1-Bis (tert-butylperoxy) cyclohexane (concentration # 80%)	5 t	3006-86-8
129	tert-Butyl proxyacetate (concentration # 70%)	5 t	107-71-1
130	tert-Butyl peroxyisobutyrate (concentration # 80%)	5 t	109-13-7
131	tert-Butyl peroxy isopropY1 carbonate (concentration -- # 80%)	5 t	2372-21-6
132	tert-Butyl peroxymalcate (concentration- # 80%)	5 t	1931 -62-0
133	tert-Butyl peroxypivalate (concentration # 77%)	50 t	927-07-1
134	dibenzyl peroxydicarbonate (concentration # 90%)	5 t	2144-45-8
135	Di-sec-butyl peroxydicarbonate (concentration # 80%)	5 t	19910-65-7
136	Diethyl peroxydicarbonate (concentration # 30%)	50 t	14666-78-5
137	2, 2-dihydroperoxypropanc (concentration # 30%)	5 t	2614-76-08
138	di-isobutyryl peroxide concentration # 50%)	50 t	3437-84- 1
139	Di-n-propyl peroxydicarbonate (concentration # 80%)	5 t	16066-38-9

140	Ethylene oxide	5 t	75-21 -8
141	Elyl nilrat	50 t	625-58-1
142	3, 3, 6, 6, 9, 9Hcxamcthyl-1, 2, 4, 5-tertoxacyclononane (concentration # 75%)	50 t	22397-33-7
143	Hydrogen	2 t	1333-74-0
144	Liquid Oxygen	200 t	7782-41 -7
145	Melhyl ethyl ketone peroxide (concentration 260%)	5 t	1338-93-4
146	Methyl isobutyl ketone peroxide (concentration 260%)	50 t	37206-20-5
147	Peracetic acid (concentration 260%)	50 t	79-21-0
148	Propylene oxide	5 t	75-56-9
149	Sodium chlorate	25 t	7775-09-9
GROUP 4 EXPLOSIVE SUBSTANCES			
150	Barium azide	50 t	18810-58-7
151	Bis (2,4, 6-trinitrophenyl) amine	50 t	131 -073-7
152	Chlorotrinitro benzene	50 t	28260-61 -9
153	Cellulose nitrate (containing 12.6% Nitrogen)	50 t	9004-70-0
154	Cyclotetramethylenctcranitramine	50 t	2691-41 -0
155	Cyclotrimethylenetiranitramine	50 t	121-82-1
156	Diazodinitsphenol	10 t	7008-81-3
157	Dicthylene glycol dinitrate	10 t	693-21 -0
158	Dinitrophenol, salts	50 t	
159	Ethylene glycol dinitrate	10 t	628-96-6
160	l-Gyanyl4-nitrosaminoguanyl- 1 -tetrazene	10 t	109-27-3
161	2, 2', 4, 4,' 6, 6'-Hexanirostilbene	50 t	20062-22-0
162	Hydrazine nitrate	50 t	13464-9 / -6
163	Lead azide	50 t	13424-46-9
164	Lead styphnate (Lead 2, 4, 6-trinitroresorcinoxide)	50 t	15245-44-0
165	Mercury fuliminate	10 t	20820-45-5
			628-86-4
166	N-Mcthyl-N,2, 4, 6-tetranitroanilinc	50 t	479t45-8
167	Nitroglycerine	10 t	55-63-0
168	Pentacrylhrilol tetranitrate	50 t	78-11-5
169	Picric acid (2, 3, 6-Trinitrophenol)	50 t	88-89- 1
170	Sodium picramate	50 t	831 -52-7
171	Styphnic acid (2, 4, 6-TriniLroresorcinol	50 t	82-71 -3
172	1, 3, 5-Triamino-2, 4. 6-trinitrobenzene	50 t	3058-38-6
173	Trinitroaniline-	50 t	26952-42- 1
174	2, 4, 6-Trinitroanisole	50 t	605-35 9
175	Trinitrobenzene	50 t	25377-32-6
176	Trinitrobenzoic acid	50 t	35860-50-5
			129-66-8
177	Trinitrocresol	50 t	28905-71 -7
178	2,4, 6-Trinitrophenitole	50 t	4732-4-3
179	2,4, 6-Trinitrotulene	50 t	118-96-7

F.No. 18(13)/91-PL-HSMD

K M Chadha, Joint Secretary, Ministry of Environment, Forest and Climate Change, HSM Division, New Delhi.

Union Health Ministry issues updated Clinical Management Protocol for managing COVID-19 cases

Updated Protocol includes use Dexamethasone as an alternative to Methylprednisolone for managing moderate to severe cases

MoH&FW Press Release dated 27th June 2020

Keeping pace with evolving knowledge about COVID-19, especially in terms of effective drugs, the Union Ministry of Health & Family Welfare has released an updated Clinical Management Protocol for managing COVID-19 cases. The updated protocol includes the advice to use Dexamethasone as an alternative choice to Methylprednisolone for managing moderate to severe cases of COVID-19. The change has been made after considering the latest available evidence and expert consultation.

Dexamethasone is a corticosteroid drug used in a wide range of conditions for its anti-inflammatory and immunosuppressant effects. The drug has been tested in hospitalized patients with COVID-19 in the RECOVERY Clinical Trial and was found to have benefits for critically ill patients and has been shown to reduce mortality by about one third for patients on ventilators, and by about one fifth for patients being maintained on oxygen therapy. The drug is also a part of the National List of Essential Medicines (NLEM) and is widely available.

The Union Health Secretary, Ms Preeti Sudan has forwarded the updated protocol with all States/UTs to make necessary arrangements for availability and use of the updated protocol and drug Dexamethasone at the institutional level also. The guidance document has also been made available online on the website of the Health Ministry at:

https://www.mohfw.gov.in/pdf/lManagement Protocol forCOVID19dated27062020.pdf

The last update to the Clinical Management Protocol was done on 13th June, 2020.

Source: PIB, MoH&FW Press Release, 27.06.2020

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NPPA is monitoring price increase of critical medical equipments for COVID-19 Pulse Oximeter and Oxygen Concentrators and also ensuring sufficient availability of the same in the country

MoC&F Press Release dated 2nd July 2020

In the wake of COVID-19 pandemic, Government is striving to ensure sufficient availability of critical medical equipments for clinical management of COVID-19 in the country. Ministry of Health & Family Welfare (MoH&FW) has identified list of critical medical equipments for the same and has requested National Pharmaceutical Pricing Authority (NPPA) to ensure availability of the same in the country.

The Government is committed for availability of life saving drugs/devices at affordable prices to the consumers. All the medical devices have been notified as Drugs and have come under regulatory regime of the Drugs & Cosmetics Act, 1940 and Drugs (Prices Control Order), 2013 w.e.f. 1st April 2020. In order to keep check on the price rise of critical medical equipments, NPPA, in exercise of powers conferred under DPCO, 2013, has

called for price related data from manufacturers/importers of (i) Pulse Oximeter and (ii) Oxygen Concentrator to ensure that prices existing as on 1st April 2020 should not be increased more than 10% in a year.

A Stakeholders Consultation with Medical Devices Industry Associations and Civil Society Group was held in NPPA on 1st July 2020 wherein it was stressed that all the manufacturers/importers of critical medical equipments shall ensure sufficient availability of the same in the country. It has been reiterated that all the Medical Devices have come under price regulation under DPCO, 2013 w.e.f. 1st April 2020, accordingly, price increase of medical devices would be monitored under Para 20. Chairman, NPPA also urged the Industry that it is not "Business as usual" and not the time to profiteer in the public health emergency. The Medical Devices Industry Associations have been urged to bring down the retail price of critical medical equipments in larger public interest in the prevailing situation as has been done by the manufacturers/importers of N-95 masks.

Source: PIB, NPPA, MoC&F Press Release, 02.07.2020

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Government launches Drug Discovery Hackathon 2020 (DDH2020), a first of its kind National Initiative for supporting drug discovery process

Dr Harsh Vardhan: "in-silico drug discovery which utilizes computational methods such as Machine Learning, AI (Artificial Intelligence) and Big Data will help in accelerating this process"

"This Hackathon will help India establish new model for expediting drug discovery process": Prof K Vijay Raghavan

Ministry of Science & Technology Press Release dated 2nd July 2020

The Union Government launched Drug Discovery Hackathon in the presence of Union Minister for Science and Technology Dr Harsh Vardhan and Union Minister for Human Resource Development Shri Ramesh Pokhriyal 'Nishank'. This Drug Discovery Hackathon is a joint initiative of MHRD's Innovation Cell (MIC), All India Council for Technical Education (AICTE) and Council of Scientific and Industrial Research (CSIR) and supported by Centre for Development of Advanced Computing (CDAC), MyGov as well as private players.

Minister of State for HRD Shri Sanjay Dhotre, Principal Scientific Advisor Prof Vijay Raghavan, DG CSIR, Dr Shekhar Mande, Chairman, AICTE, Prof Anil Sahasrabudhe, President, Pharmacy Council of India (PCI) Prof B Suresh and Chief Innovation Officer, MHRD, Dr Abhay Jere were also present during the online launch program.

This Hackathon is first of its kind National initiative for supporting drug discovery process and will see participation from professionals, faculty, researchers and students from varied fields like Computer Science, Chemistry, Pharmacy, Medical Sciences, Basic Sciences and Biotechnology.

Dr Harsh Vardhan, Minister for S&T said, "We need to establish the culture of Computational Drug Discovery in our country. In this initiative, MHRD's Innovation cell and AICTE will focus on identifying potential drug molecules through the Hackathon while CSIR will take these identified molecules forward for synthesis and laboratory testing for efficacy, toxicity, sensitivity and specificity." Pointing out that drug discovery is a complex, expensive, arduous and time-consuming process, Dr Harsh Vardhan said, "While we pursue clinical trials of few repurposed drugs for COVID-19, as they are faster and can quickly be launched, it is also important that we find other suitable repurposed drugs while at the same time continue working on new drug discovery to develop specific drugs against COVID-19". He added, "in-silico drug discovery which utilizes Computational methods

such as Machine Learning (ML), AI and Big Data will help in accelerating this process".

Shri Ramesh Pokhriyal 'Nishank', HRD Minister said, "MHRD and AICTE have huge experience in organizing Hackathons but for the first time, we are using hackathon model for tackling a great scientific challenge. More importantly, this initiative is open for researchers/faculty across the globe as we are keen on attracting international talent to join and support our efforts."

Minister of State for HRD Shri Sanjay Dhotre also appreciated the concept and said, "Our Government has kick-started Hackathon culture in this country which is very critical for challenging our youngsters to solve some of the daunting problems faced by our nation."

Prof K Vijay Raghavan, PSA, Government of India said, "I wish to thank MHRD, AICTE and CSIR and all our partners for supporting this Hackathon which will help India establish new model for expediting drug discovery process. The Hackathon consists of challenges that are posted as problem statements and, are based on specific drug discovery topics which, are open to the participants to solve. It will have three phases of three months each and the whole exercise is to be completed by April-May 2021. At the end of each phase, successful teams will be rewarded. The 'lead' compounds identified at the end of phase 3 will be taken forward for experimental level at CSIR and other interested organizations.

During the launch function, Dr Abhay Jere, Chief Innovation Officer explained the concept of Drug Discovery Hackathon, while Prof Anil Sahasrabudhe extended all the support from AICTE and appealed all technical institutions to participate in this initiative in big numbers. Dr Shekhar Mande extended all the required commitment from CSIR's side for this initiative. He also expressed satisfaction on the quality and variety of problem statements released.

Background Information and Methodology of Hackathon:

- The Hackathon consists of challenges that are posted as problem statements and, are based on specific drug discovery topics which, are open to the participants to solve. A total of 29 Problem Statements (PS) have been identified.
- My Gov portal is being used and any Indian student can participate.
- Professionals and Researchers from anywhere in the world can participate.
- The Hackathon will have three Tracks. **Track 1 will primarily deal with drug design for anti-COVID-19 hit/lead generation:** this is done using tools such as molecular modelling, pharmacophore optimization, molecular docking, hit/lead optimization, etc.
- Track 2 **will deal with designing/optimizing new tools and algorithms** which will have an immense impact on expediting the process of in silico drug discovery.
- There is also a **third track called "Moon shot** "which allows for working on problems which are 'out of the box' nature.

Source: PIB, MoS&T Press Release, 02.07.2020

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NPPA notifies upward price revision of Heparin injection under Para 19 of DPCO 2013 - reg.

NPPA Notification No.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 (₹)	Existing S.O. No. & Date	
(1)	(2)	(3)	(4)	(5)	6(a)	6(b)
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, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi.

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CBDT Notification on Income-Tax (13th Amendment) Rules, 2020 – reg.

Gazette Notification No.G.S.R.415(E), dated 26th June 2020

In exercise of the powers conferred by sub-section (2) of section 115 BAC read with section 295 of the Income-tax Act, 1961 (43 of 1961), the Central Board of Direct Taxes hereby makes the following rules further to amend the Income-tax Rules, 1962, namely:

1. **Short title** and commencement:

(1) These rules may be called **the Income-Tax (13th Amendment) Rules, 2020.**

(2) They shall come into force from the 1st day of April, 2021 and shall accordingly apply in relation to the Assessment Year 2021-22 and subsequent Assessment Years.

2. In the Income-Tax Rules, 1962:

(a) in rule 2BB, after sub-rule (2), the following sub-rule shall be inserted, namely:

"(3) Notwithstanding anything contained in sub-rule (1) and (2), an employee, being an assessee, who has exercised option under sub-section (5) of section 115 BAC shall be entitled to exemption only in respect of the allowances mentioned in sub-clauses (a) to (c) of sub-rule (1) and at Serial No.11 of the Table below sub-rule (2) to the extent and subject to the conditions, if any, specified therein.";

(b) in rule 3, in sub-rule (7), in clause (iii), after the proviso, the following proviso shall be inserted, namely:

3. "Provided further that the exemption provided in the first proviso in respect of free food and nonalcoholic beverage provided by such employer through paid voucher shall not apply to an employee, being an assessee, who has exercised option under sub-section (5) of section 115 BAC".

Notification No. 38/2020
F.No.370142/15/2020-TPL.

Note: *The Principal Rules were published in the Gazette of India, Extraordinary, Part-II, Section-3, Sub-section (ii) vide number S.O.969(E), dated the 26th March, 1962 and last amended by the Income-Tax (12th Amendment) Rules, 2020, vide Notification Number G.S.R.338(E) dated 29.05.2020.*

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IPAB stays revocation of Pharmacyclics' patent on anti-cancer drug Ibrutinib

The Intellectual Property Appellate Board (IPAB) has granted an interim stay on an order issued by the Indian Patent Office removing a patent of Pharmacyclics for anti-cancer drug Ibrutinib.

Ibrutinib sold by Pharmacyclics Inc, a Silicon Valley-based biopharmaceutical company and part of AbbVie under the brand name 'Imbruvica' is used to treat adults with mantle cell lymphoma (MCL), chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL), Waldenström's macroglobulinemia (WM), Marginal Zone Lymphoma (MZL), and chronic Graft Versus Host Disease (cGVHD).

N R Meena, Joint Controller of Patents and Designs, in an order issued on March 4, 2020 revoked the patent based on a post-grant opposition filed by Laurus Labs. The patent office observed the claims made by Pharmacyclics are obvious to an ordinary person skilled in the art and that the drug lacks any inventive step that would make it superior to other existing formulations.

According to Pharmacyclics, ibrutinib is a small molecule that works by inhibiting an enzyme called protein kinase, which controls the rate at which certain cells multiply. It claims that the drug works differently from existing chemotherapy and immunotherapy solutions. It is a once-daily, first-in-class Bruton's Tyrosine Kinase (BTK) inhibitor administered orally, and has been jointly developed and commercialised by Pharmacyclics and Janssen Biotech, Inc.

Pharmacyclics filed a patent application for ibrutinib in 2009 and received a patent on September 25, 2014. Laurus filed a post-grant challenge on September 24, 2015 citing lack of novelty and lack of inventive steps among others. Natco Pharma launched a generic version of the drug in December 2019 at Rs. 38,000 per month, as opposed to Rs. 4 lakh course for Imbruvica. Natco tied up with Laurus Labs.

On December 18, 2019 Pharmacyclics sued Natco and Laurus Labs before the Delhi High Court for allegedly infringing its patent Ibrutinib. Based on Patent Office order rejecting patent of Pharmacyclics in March, Natco and Laurus sought dismissal of the patent infringement suit filed by the US drugmaker in Delhi High Court.

Pharmacyclics said it would file an appeal before the IPAB within the next two weeks, and on that basis, asked for adjournment. The High Court passed a conditional order stating that the suit shall be dismissed with liberty to be revived or reinstituted if the IPAB doesn't pass an interim stay order by the next date of hearing. The IPAB, which was taking up only urgent matters due to the outbreak of COVID-19, resumed its functioning, via video conferencing from May 26, 2020, and took this matter up on June 12, 2020. There, the IPAB passed the stay order against the Joint Controller of Patents and Designs' revocation of the patent, on apprehension of "irreparable damage to the petitioner (Pharmacyclics)", and set the final date of appeal on July 9, 2020.

This also prevented Pharmacyclics' suit from being dismissed at the Delhi High Court. The IPAB decision was given by its Chairperson (Retd.) Justice Manmohan Singh and the Board's Sole Technical Member Dr Onkar Nath Singh.

The IPAB stated that the appellants have made a strong prima facie case in its favour by arguing that (i) the Delhi High Court case would be dismissed, (ii) that the Patent Office did not submit additional evidence filed by the parties to the opposition board, as instructed by the High Court in the order dated November 20, 2019, and (iii) that the Patent Office decided on obviousness without application of mind.

The board in the present case decided in favour of granting a stay essentially only on the basis of the applicant's allegations against the Patent office's order, since no representation was made on its behalf on the day of the hearing. This has opened the doors for generic companies to approach the IPAB for an interim stay on similar grounds, on Patent Office upholding of a patent, said patent experts.

Source: Laxmi Yadav, Pharmabiz, 24.06.2020

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Madras University gets two patents for inventing phyto-chemical compound to treat cancer and diabetes

The Centre for Advanced Studies in Botany (CASB) at the Madras University has got two patents for extracting a phyto-chemical compound from the leaves of the plant Manilkara zapota, commonly called sapodilla sapota, chikoo or naseberry, for developing a potent drug for treating cancer and diabetes, or both.

Christened as 'Mazapotin', the new compound, a novel flavonoid, is claimed to have anti-cancer, anti-diabetic, anti-oxidative and anti-angiogenic properties. The university received the patents on June 26, 2020 for which the applications were filed in December 2012.

According to university sources, the invention of the pharmaceutical composition, which comprises Mazapotin, was carried out by a two-member group led by the Former Director of the CASB, Prof Dr N Raaman and his student Dr C Shivaraj.

Considering protection of Intellectual Property (IP), the office of the Indian Patent Office, after due process and examination has granted the two patents. One is for the process, "A Process for Extracting a Novel Flavonoid from Manilkara Zapota' and another one is for the product, "Mazapotin".

While briefing Pharmabiz, Dr Raaman who was also the HoD of the Department of Herbal Sciences at the University, said his team conducted the cell line study which proved that Mazapotin was more powerful than that of the Quercetin, a flavonoid used to treat cancer. The process involved extraction of dried powder of Manilkara zapota leaves and mixed it with methanol to get methanol crude extract. After various laboratory processes, Mazapotin is eluted.

He said the university is now looking for some pharmaceutical companies to undertake further studies to develop it into a pharmaceutical formulation. "After a comprehensive study on its mechanism of action, animal studies and clinical trials, this new pharmaceutical compound can be developed into a potent drug to treat cancer, diabetes and patients with diabetes and cancer", he said. Dr Raaman has executed more than 25 research projects and guided 41 Ph.D. scholars. He has published 150 research papers and 4 books.

Source: Peethaambaran Kunnathoor, Pharmabiz, 02.07.2020

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Study is first to identify potential therapeutic targets for COVID-19

Researchers profile the body's immune response in critically ill patients

Dr Douglas Fraser led a research team that identified a unique pattern of six molecules that could be used as therapeutic targets to treat the COVID-19 virus.

A team from Lawson Health Research Institute and Western University are the first in the world to profile the body's immune response to COVID-19. By studying blood samples from critically ill patients at London Health Sciences Centre (LHSC), the research team identified a unique pattern of six molecules that could be used as therapeutic targets to treat the virus. The study is published this week in Critical Care Explorations.

Since the pandemic's start there have been reports that the immune system can overreact to the virus and cause a cytokine storm - elevated levels of inflammatory molecules that damage healthy cells. "Clinicians have been trying to address this hyperinflammation but without evidence of what to target," explains Dr Douglas Fraser, lead researcher from Lawson and Western's Schulich School of Medicine & Dentistry and Critical Care Physician at LHSC. "Our study takes away the guessing by identifying potential therapeutic targets for the first time."

The study included 30 participants: 10 COVID-19 patients and 10 patients with other infections admitted to LHSC's intensive care unit (ICU), as well as 10 healthy control participants. Blood was drawn daily for the first seven days of ICU admission, processed in a lab and then analyzed using statistical methods and Artificial Intelligence (AI).

The research team studied 57 inflammatory molecules. They found that six molecules were uniquely elevated in COVID-19 ICU patients (tumor necrosis factor, granzyme B, heat shock protein 70, interleukin-18, interferon-gamma-inducible protein 10 and elastase 2). The team also used AI to validate their results. They found that inflammation profiling was able to predict the presence of COVID-19 in critically ill patients with 98 percent accuracy. They also found that one of the molecules (heat shock protein 70) was strongly associated with an increased risk of death when measured in the blood early during the illness.

"Understanding the immune response is paramount to finding the best treatments," says Dr Fraser "Our next step is to test drugs that block the harmful effects of several of these molecules while still allowing the immune system to fight the virus."

The study was made possible with donor support to London Health Sciences Foundation's COVID-19 Response Fund. It also received additional funding from Lawson, Western and the AMOSO Innovation Fund.

Source: Lawson Health Research Institute, EurekAlert/World Pharma News, 25.06.2020 (Excerpts)

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Researchers identify multiple molecules that shut down SARS-Cov-2 polymerase reaction

SARS-CoV-2, the coronavirus causing the global COVID-19 pandemic, uses a protein called polymerase to replicate its genome inside infected human cells. Terminating the polymerase reaction will stop the growth of the coronavirus, leading to its eradication by the human host's immune system.

Researchers at Columbia Engineering and the University of Wisconsin-Madison have identified a library of molecules that shut down the SARS-CoV-2 polymerase reaction, a key step that establishes the potential of these molecules as lead compounds to be further modified for the development of COVID-19 therapeutics. Five of these molecules are already FDA-approved for use in the treatment of other viral infections including HIV/AIDS, cytomegalovirus, and hepatitis B. The new study was published on June 18, 2020, in Antiviral Research.

The Columbia team initially reasoned that the active triphosphate of the hepatitis C drug sofosbuvir and its derivative could act as a potential inhibitor of the SARS-CoV-2 polymerase based on the analysis of their molecular properties and the replication requirements of both the hepatitis C virus and coronaviruses. Led by Jingyue Ju, Samuel Ruben-Peter G. Viele Professor of Engineering, Professor of Chemical Engineering and Pharmacology, and Director of the Center for Genome Technology & Biomolecular Engineering at Columbia University, they then collaborated with Robert N Kirchdoerfer, Assistant Professor of Biochemistry and an expert in the study of coronavirus polymerases at University of Wisconsin-Madison's Institute for Molecular Virology and the Department of Biochemistry.

In an earlier set of experiments testing the properties of the polymerase of the coronavirus that causes SARS, the researchers found that the triphosphate of sofosbuvir was able to terminate the virus polymerase reaction. They then demonstrated that sofosbuvir and four other nucleotide analogues (the active triphosphate forms of the HIV inhibitors Alovudine, Zidovudine, Tenofovir alafenamide, and Emtricitabine) also inhibited the SARS-CoV-2 polymerase with different levels of efficiency.

Using the molecular insight gained in these investigations, the team devised a strategy to select 11 nucleotide analogue molecules with a variety of structural and chemical features as potential inhibitors of the polymerases of SARS-CoV and SARS-CoV-2. While all 11 molecules tested displayed incorporation, six exhibited immediate termination of the polymerase reaction, two showed delayed termination, and three did not terminate the polymerase reaction.

Prodrug medications of five of these nucleotide analogues (Cidofovir, Abacavir, Valganciclovir/Ganciclovir, Stavudine, and Entecavir) that terminate the SARS-CoV-2 polymerase reaction are FDA-approved for the treatment of other viral infections and their safety profiles are well established. Once the potency of the drugs to inhibit viral replication in cell culture is demonstrated in future investigations, then the candidate molecules and their modified forms may be evaluated for the development of potential COVID-19 therapies.

"In our efforts to help tackle this global emergency, we are very hopeful that the structural and chemical features of the molecules we identified, in correlation with their inhibitory activity to the SARS-CoV-2 polymerase, can be used as a guide to design and synthesize new compounds for the development of COVID-19 therapeutics," says Ju. "We are extremely grateful for the generous research support that enabled us to make rapid progress on this project. I am also grateful for the outstanding contributions made by each member of our collaborative research consortium."

Source: Columbia University School of Engineering and Applied Science, Science Daily, 01.07.2020 (Excerpts)

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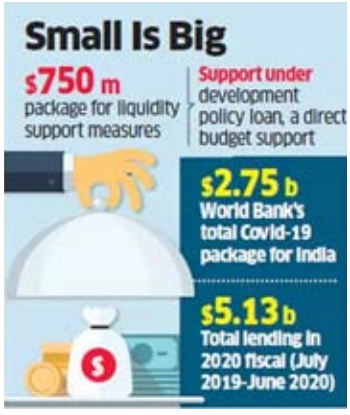
NATIONAL NEWS

World Bank unveils $750m Package for Indian MSMEs hit by Pandemic

Latest package takes commitment for its Covid-19 fight in the country to $2.75b



The World Bank announced a $750 million package for India's Medium and Small Enterprises, which have been severely impacted by Covid-19 pandemic and lockdown imposed to contain it.

The latest package takes the multilateral lender's commitment to India for its Covid-19 fight to $2.75 billion with total lending in fiscal 2020 (July 2019-June 2020) to $5.13 billion, highest in a decade. The MSME Emergency Response programme, launched on Wednesday, 01.07.2020 to support increased flow of finance to MSMEs will address the immediate liquidity and credit needs of some 1.5 million enterprises in the category to help them withstand the impact of the current shock and protect millions of jobs. "The MSME sector is central to India's growth and job creation and will be key to the pace of India's economic recovery, post Covid-19," said Junaid Ahmad, World Bank Country Director in India. This is the first step among a broader set of reforms that are needed to propel the MSME sector over time, the World Bank said in a statement.

Ahmad said the immediate need is to ensure that the liquidity infused into the system by the Government is

accessed by MSMEs. This funding is under the multilateral lender's Development Policy Loan, which is a direct budget support, he said.

"Equally important is to strengthen the overall financing ecosystem for MSMEs," he said, adding that this operation seeks to achieve both these objectives by furthering the role of NBFCs and small credit banks as effective financial intermediaries and leveraging fintech to broaden the reach of finance into the MSME sector.

Source: The Economic Times, 02.07.2020

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Customs begins clearing stuck Chinese shipments

No physical check if bills of entry filed till June 30

Indian customs began clearing shipments of Chinese origin that had been stuck at ports for the past 10 days after border tensions escalated. Consignments started moving Wednesday, 01.07.2020 after several representations by multiple industry bodies to various Ministries including Finance, Commerce and Industry, Chemicals and Fertilisers and MSME as well as the Prime Minister's Office (PMO).

India Inc had petitioned the PMO as delays were hurting the process of normalization that had begun June 1 with Unlock 1.0. Indian industry relies heavily on inputs from China for its factories and the development threatened to disrupt production.

"Goods are being cleared now... All ports are clearing without 100% physical checking," a Government official told. Shipments for which documents were filed up to June 30 will be cleared in this round and no call has been taken on bills of entry submitted after that, he said.

List of Companies given to Customs:

Officials at customs brokers' associations in New Delhi, Chennai and Mumbai confirmed the development. However, clearances will continue for imports by US and South Korean companies even after June 30, said a person with knowledge of the development. Officials said a list of companies had been provided to the customs authorities for clearing their consignments without physical checks.

Indian customs authorities at all ports and customs freight stations made 100% physical checks mandatory for all Chinese imports from June 22, bringing clearances to a halt. While there was no official instruction to this effect, authorities said checks were being carried out based on intelligence alerts about narcotics.

The exercise began at Chennai, which receives a bulk of Chinese telecom equipment coming into India besides medical devices and auto components, and soon spread to other ports. The move, soon after the border incident, was seen by industry watchers as a signal by the Government to industry to diversify its supply base.

Relaxations were first allowed for US companies such as Apple, Dell, HP and Cisco as well as South Korea's Samsung. This was later extended to importers of Active Pharmaceutical Ingredients.

It is likely that these relaxations will continue for shipments after June 30 as well, a person familiar with the development said. Physical checks can be cumbersome and a costly affair for the industry as goods can get damaged in the re-packaging process. India imported goods worth $62.4 billion from China in the April-February period of FY20 compared with $70.3 billion in FY19.

Source: Deepshikha Sikarwar, The Economic Times, 02.07.2020

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COVID-19 hugely alters work environment for pharma & healthcare as re-skilling takes centrestage: Sumit Kumar

The COVID-19 pandemic has drastically changed the world of work in the last 3 months making Pharma and healthcare to have a re-look at their business models with a focus on automation and digitization, said Sumit Kumar, Vice President, NETAP, TeamLease Services.

Processes are being re-worked to adapt during the ongoing pandemic. The intent is to prepare for businesses to be able to scale-up post the pandemic. Here, we see when organizations reorient, it is the workforce which is the central point of the change strategy. The workforce

transformation happens not just with skilling but a need for behavioral change along with an undue importance to health and safety that will enable people adapt to the new normal, he added.

Both Pharma and Healthcare are witnessing a rapid change as the pandemic has accelerated the need for automation and digitization. As workplace distancing and restricted workforce becomes a new norm, organizations are opting for multi-shifts to ensure the desired production capacity. In many areas, productivity is affected which has compelled midsized organizations for a rapid adoption of automation as large ones ramp up their existing systems, Kumar told.

Even in automation, organizations need skilled people to be able to adjust to the new systems like managing robots, troubleshooting, complex testing, maintenance-repair of equipment, safety procedures, creative thinking, and have strong communication skills to interact with the development teams.

Hence the demand for skilled workforce is on the rise and accessing trained human resources is a challenge as the current vocational education does not stress on automation and digitization. This has led organizations to invest in skilling to address the challenge. Here companies can hire fresh graduates and skill them through 'learning by doing' programmes to create a pool of productive human resources.

Apprenticeships are also ideal for talent creation. Indian industry is experiencing migration of labour and the scare of the Coronavirus disease has led to scarcity of workforce. Companies need to restore the confidence in their labour force, ensure their safety and welfare to woo them back. At the same time resorting to skilling programmes would offset the shortfall, he noted.

On the healthcare front, the demand during the pandemic is for doctors, paramedics, nurses, home care professionals and lab technicians. Need for skilled professionals in healthcare will see a spike. As per WHO, India does not meet the requirement of 44.5 skilled workers per 10,000 population. In fact, the current scenario has widened the gap despite hiring for an estimated 5 million healthcare workers.

The medical technology front is also scouting for candidates with expertise in artificial intelligence (AI). The aim is to spur diagnosis and decrease the time to market of medicines from drug discovery phase to clinical trials in a transparent, high quality standard and efficient manner. It is also estimated that to overcome the shortage, India needs to increase the healthcare spend which is 1.29% of the GDP as against China's 2.9%.

The count of infected people is rapidly growing each day as there is need for a cure and hospitalization. This has increased the demand for medical insurance claims processing by the TPAs (third party administrators) which will require people to manage the disbursements. Here too job opportunities have increased in data management and documentation.

Source: Nandita Vijay, Pharmabiz, 30.06.2020

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ICMR invites research proposals under GACD on primary and secondary prevention of cancer

The Indian Council of Medical Research (ICMR) has invited research proposals under Global Alliance for Chronic Diseases (GACD) for implementation research on primary and secondary prevention of cancer.

The aim of the programme is to adapt and scale-up the implementation of these interventions in accessible, affordable and equitable ways in order to improve the prevention and early diagnosis of cancer in real-life settings. It should meet conditions and requirements of the local health and social system context and address any other contextual factors identified as possible barriers. The scope of this call is to focus on implementation research for the primary and secondary prevention of cancer in Low-and Middle-Income Countries (LMICs) and/or in populations facing conditions of vulnerability in High-Income Countries (HICs).

Proposals must build on evidence-based interventions (including cost-effectiveness) for the respective population groups under defined contextual circumstances. Research activities should focus on their implementation in real-life settings. The proposed interventions should be gender-responsive.

Research proposals are focused on implementation research addressing prevention or early diagnosis strategies derived from existing knowledge about effective interventions and to test the proposed model of intervention and to address the socioeconomic and contextual factors of relevance to the targeted region and community.

Another area of the research includes understanding of key barriers and facilitators at local, national and/

or international level that affect prevention and/or early diagnosis of cancer and to align with the priorities in national/regional cancer control programme, if any.

It is estimated that 30 to 50 percent of all cancers are preventable. Around 25 percent of cancer incidence in LMICs is attributable to vaccine-preventable infections (HPV and HBV). Within HICs, similar patterns are seen in populations experiencing conditions of vulnerability. Researchers, public and/or patient and community groups or other relevant stakeholder groups are eligible for these proposals. The last date for submitting the application is July 31, 2020.

Source: Neethikrishna, Pharmabiz, 30.06.2020

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Commerce Ministry launches beta version of iVEDA portal to facilitate company registration & data upload for tracking drug supply

The Union Commerce and Industry Ministry has launched the beta version of Integrated Validation of Exports of Drugs from India and its Authentication (iVEDA) portal. This will facilitate manufacturer exporters and merchant exporters register with portal and file the company profiles and update the facility/site information.

iVEDA is a project of Commerce Ministry Developed by Pharmexcil with technical support from Centre for Development of Advanced Computing (C-DAC) for facilitating the implementation of track and trace for pharmaceutical products. iVEDA will replace Drugs Authentication and Verification Application (DAVA) portal which has hit technical glitches hampering manufacturers and exporters from uploading data on barcode on secondary and tertiary packs of drugs meant for export and maintenance of parent-child relationship between them.

Launched by Shyamal Misra, Joint Secretary, Commerce Ministry on June 24, 2020, the beta version (test run) will help manufacturer exporters and merchant exporters easily register with iVEDA portal and upload the company profiles and update the site information. It enabled bulk upload of XML files.

Data uploading in XML formats can be commenced by member exporters on the portal. Exporters can continue to use the serialization codes provided by GS1 or can opt for any service provider for the serialization numbers. The C-DAC can be requested to provide the serial numbers for affixing on the different packaging levels. The beta version integrates software between the companies and iVEDA platform. The parent-child/aggregation will be optional as the new system is flexible. The parent child aggregation, if opted, will be on secondary package levels (the lowest one as last saleable pack) and tertiary level. The step by step process for company registration, Excel to XML conversion, bulk data upload, coding system, serialization etc., has been provided in the user manuals for the ready reference and kind information of the companies at iVEDA web portal: www.iveda-india.in. During this beta version period, all the functionalities will be tested in real time and issues if any arising during the registration process/ data upload process will be responded and addressed by the CDAC and Pharmexcil team.

The beta version is available for the companies for a period of one month from June 25, 2020 and Pharmexcil has appealed to all the companies to register with the web portal by July 25, 2020 and start uploading the data. This time period is kept purposefully for familiarizing with the web portal and its templates, software integration and also addressing the issues and challenges if any while uploading the data, said Pharmexcil Director General Uday Bhaskar. The user fees will be intimated to companies through a separate circular by July 20, 2020, said Bhaskar. The data pertaining to every export consignment starting from June 1, 2020 pertaining to the finished drug formulations is to be uploaded by the manufacturer-exporter and merchant exporters, traders of finished formulations on beta version of iVEDA and thereafter on final version.

The Directorate General of Foreign Trade (DGFT) has extended the date of implementation of track and trace system for drug formulations with respect to maintaining the parent-child relationship in packaging levels and its uploading on central portal till October 1, 2020 for both SSI and non-SSI manufactured drugs amid the coronavirus outbreak. The Commerce Ministry, through C-DAC, was supposed to launch iVEDA portal from April 1, 2020.

Source: Laxmi Yadav, Pharmabiz, 29.06.2020

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Union Government should set up drug regulatory & pollution control board offices within Pharma Parks for speedy approvals: Experts

Experts in the industry are of the opinion that the Union Government should set up small offices of pollution

control board and drug regulatory within the Pharma Parks to expedite the required clearances in a time bound manner.

Experts' suggestion in this regard comes at a time when the Government has recently made announcements to establish Pharma Parks at different locations in the country to incentivise and give a boost to domestic manufacturing of active pharmaceutical ingredients, key starting materials and intermediates in the country. The Pharma industry sees the need for Government departments of drug regulatory and environment control to be also stationed within the Pharma Parks as it would bring about ease of coordination and transparency.

Further, the industry sees the need for a world class Pharma Park infrastructure with uninterrupted power and water supply, allowing the companies to produce to their full capacities without interruptions of any sort and also be able to go through successful global audits, noted the Pharma Chiefs at a webinar 'CII PHARMASCOPE: A Step Towards *Atamnirbhar* Bharat - Made In India, Made for the World'.

The Government's clarion call for a self-reliant India to stay away from imports must be converted into a viable and profitable opportunity, said Dr Dinesh Dua, Chairman, CII Northern Regional Committee on Life Sciences and Biotech, Chairman Pharmexcil & Executive Director, Nectar Lifesciences. The industry can optimise its techno-capability to manufacture not just paracetamol but other products as it did in the past. What China took 20 years to achieve, India can generate the momentum to become self-sufficient in APIs within the next 5 years, added Dr Dua.

Delving on the strategies to make India a global hub for API manufacturing, Dr S Eswara Reddy, Joint Drugs Controller (India), CDSCO, said that any disruption of drug supply during this COVID-19 pandemic will adversely impact patient care. The reality is that India imports 70 percent APIs valued at Rs. 42,000 crore. Such excessive dependence on China is a concern. Moreover, China's fluctuating and exorbitant pricing for APIs cannot be justified as it drained India's foreign exchange and created the balance of trade deficit.

"China has been able to monopolies the API market because of its massive manufacturing capacity, low cost of utilities and export incentives. Its interest rate is 4-6 percent as against India's 8.5 to 11 percent. Power tariff is Rs. 4 to 6 per KW and India's is Rs. 7. In China, adoption of advanced technology is extensive while it is under-utilised in India. The Effluent Treatment Plant (ETP) charges are Rs. 102 per KL against India's Rs. 1,920 KL. While China imposes a business tax of 25 percent, India's is 26-34 percent. Further, in China industry-academia partnership is promoted with tax benefits to accelerate R&D, which is unheard of in India. Now in an effort to ensure Indian Pharma capitalises its inherent strength, our Government is now supporting end-to end manufacturing operations through Productivity Linked Incentives and bulk drugs parks, Dr Reddy noted.

The other members of the panel included B R Sikri, Co-Chairman, CII Northern Regional Committee on Lifesciences & founder, ABS Group of Companies, VV Krishna Reddy, President, Bulk Drug Manufacturers Association of India, Arjun Juneja, Director, Operations, Mankind Pharma, Sanjay Suri, CMD, Morpen Labs and Pranav Gupta, Co-Chairman of PHD Chamber of Commerce & Industry and Managing Director, Parabolic Drugs.

Source: Nandita Vijay, Pharmabiz, 29.06.2020

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Relief for Pharma firms as customs starts clearing of consignments with China origin-APIs, status quo on the rest

After days of delay, customs officials have begun to clear Chinese-origin consignments containing Active Pharmaceutical Ingredients (APIs) across ports, sources in the know told. Customs officials have now started to issue orders to clear these consignments, after Pharma companies raised concerns that the delays may lead to hamper production of essential life-saving drugs. Shipments for Dr Reddy's Labs and Aurobindo Pharma already received clearances on Tuesday, 30.06.2020.

Customs officials and other agents involved in handling China-origin cargo, including CFSes, port and airport authorities are acting on unofficial instructions to hold back these shipments for a 100 percent physical examination at the item-level, including those containers which have received an Out of Charge Order.

However, sources say, even after being stranded for over a week, a vast majority of the containers have still not been opened up for an examination, as clearing agents cite inordinate delays and a total lack of probable clearance time-lines. These shipments will start to rack up penalties in the form of port charges, warehouse charges, ground rent and demurrages if the delays continue.

However, for the ninth day running, there are no instructions yet for clearance of other consignments. Since Monday, 29.06.2020 customs officials permitted AEO - Tier 3 complaint importers to have their shipments cleared without a full examination. However, these importers are minuscule in number and in some cases, such as Toyota Kirloskar Motor, do not have direct sourcing from China.

Sources say some bills of entry are now also getting generated at the Kolkata port, but for all other ports, the situation remain status-quo. Most Chinese import orders are pre-paid as the country rarely ships orders on credit. Add to that the penalties on delays that importers will have to pay shipping lines and Container Freight Stations (CFSes), if these are not explicitly waived off by a Government Order. Container Freight Stations and shipping lines are privately operated. Industry bodies have highlighted that prolonged delays will hamper production by affecting the supply chain. "We fear that if the supply chain is broken, then there will be severe shortage of essential communication, equipment required for health, work-from-home and online education goods such as smart-phones, tablets and laptops since alternative supplies are not available in the local and global markets amidst the COVID-19 outbreak," electronics body ICMEA said in its letter to the Finance Ministry and customs authority. ICMEA said that opening finished products could lead to their getting soiled and becoming unfit for sale.

Source: cnbctv18.com, 01.07.2020

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Cipla and Boehringer Ingelheim forge Partnership to co-market three oral anti-diabetic drugs

- *Partnership will help co-market three anti-diabetic drugs Oboravo (Empagliflozin), Oboravo Met (Empagliflozin+Metformin) and Tiptengio (Empagliflozin+Linagliptin).*
- *Empagliflozin has potential for addressing Cardiovascular disease (CVD) risk along with effective blood sugar control in eligible Indian patients with type 2 diabetes.*
- *Tiptengio has a strong blood sugar lowering effect and at the same time addresses multiple pathophysiological defects in type 2 diabetes.*

Cipla Limited (BSE: 500087; NSE: CIPLA EQ; hereafter referred to as "Cipla") and Boehringer Ingelheim India Pvt Ltd (BI) announced their partnership in India to co-market three new oral anti-diabetics drugs Oboravo (Empagliflozin), Oboravo Met (Empagliflozin+Metformin) and Tiptengio (Empagliflozin+Linagliptin)

Empagliflozin is approved for glucose-control in patients with type-2 diabetes; it is also approved for reducing the risk of cardiovascular death, in patients with type-2 diabetes and established cardiovascular disease. The Empagliflozin + Metformin combination Oboravo Met can be given to newly diagnosed patients of type-2 diabetes who have higher baseline HbA1c levels.

The Empagliflozin + Linagliptin combination Tiptengio is the world's first approved combination of an SGLT-2 inhibitor and DPP4 inhibitor. In addition to a strong effect on lowering blood sugar levels, it also addresses multiple pathophysiological defects in type 2 diabetes, and is a big step towards improved management of type 2 diabetes. It will also help in reducing the pill burden for patients and help improve adherence to the prescribed treatment.

As per the International Diabetes Federation, India is home to 77 million adults aged between 20 and 79 years with diabetes, ranking second behind China; and is poised to reach 134.2 million patients by 2045. Fortunately, while the number of patients is increasing, so is the awareness among the public to address it. The Indian diabetes market is valued at INR 1,45,451 million and is growing at 10.35% (IMS MAT May 2020) with the oral anti-diabetic market being valued at INR 1,07,354 million and growing at 11.34% (IMS MAT May 2020).

Commenting on the Partnership, Nikhil Chopra, Executive Vice President & CEO - India Business, Cipla said, "We are committed to providing access to innovative medications that address unmet patient needs. Diabetes continues to be a focus area for Cipla and with a strategic partnership with Boehringer Ingelheim coupled with our strong brand building, patient access and reach capabilities, we will be at the forefront of providing holistic diabetes care." Commenting on the expanded partnership, Mr Sharad Tyagi, Managing Director - Boehringer Ingelheim India said, "We are excited about the expansion of our partnership with Cipla to provide pioneering medicines through the new oral anti-diabetics drugs. As a dedicated organization to the field of diabetes, we aim to provide wider access and innovative solutions to the medical fraternity and patients with one of the most comprehensive Diabetes portfolios in the country."

Source: Cipla.com Press Release, 30.06.2020

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Chinese import restrictions: Pharma companies seek more time to meet export orders from foreign clients

Department of Pharmaceutical made an SOS call to Finance Ministry and PMO regarding this matter

Indian businesses continue to face hurdles due to import restrictions on consignments of Chinese origin. Some of the worst-hit sectors such as Pharmaceuticals, Automobiles and Auto-ancillary, Fertilizers, Chemicals, etc have made a slew of representations to the Government, seeking early clearances. Pharma industry sources have told that individual companies have now started writing to their domestic and international clients seeking more time to meet export orders, citing longer customs clearance of imported raw material as a prime reason for the delay in meeting order obligations.

Meanwhile, Senior Government sources added that "Department of Pharmaceutical made an SOS call to Finance Ministry and PMO, seeking immediate clearance of Active Pharmaceutical Ingredient (APIs), Key Starting Raw Materials (KSM's) and intermediates. Post which, customs authorities from June 30 started clearing imports across Indian ports".

Clearances, however, are happening for consignments post proper checks, inspections as desired by the customs latest protocols. The Pharma companies and their industry bodies have written afresh yesterday, 30.06.2020 to Finance Minister Nirmala Sitharaman, Cabinet Secretary-Rajiv Guaba, Health Secretary Preeti Sudan, Commerce Minister Piyush Goyal, Principal Secretary to PM requesting for expediting clearance of import consignments.

"There has been a huge disruption on account of inordinate delay in Customs Clearing from last one week" and non-clearance of imported Pharma Key Starting Raw Materials (KSM's), Intermediates & API's, COVID related medical devices, as well as diagnostics from ports particularly Nhava Sheva & Delhi Airport, are hurting the industry, said the letter. "There are many international commitments, Indian Pharma companies have export orders in advance from a lot of countries in Africa, EU, etc, were not meeting these commitments, there are serious penal provisions. Many Pharma companies have global tie-ups where drugs and medicines need to be supplied from India and they get branded and marketed in those countries, so now Pharma companies are forced to reach to their clients, seeking an extension of order timelines caused due to the import restrictions. Holland, Germany have already sounded that in the next one or two years they will start Pharma manufacturing in their own country and reduce their reliance on India. So there is hardly enough opportunity left and such man-made barriers impact the international reputation of Indian manufacturers," said Dinesh Dua, Chairman, Pharmexcil.

Source: cnbctv18.com, 01.07.2020

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COVID-19 crisis unleashed the potential of India's life sciences sector: Dr Kiran Mazumdar-Shaw

The COVID-19 crisis has unleashed the potential of India's life sciences sector. The challenge or adversity the pandemic has created is seen to be an opportunity for the Indian Pharma, biotech and the medical devices companies, said Dr Kiran Mazumdar-Shaw, Executive Chairperson, Biocon.

Early March when coronavirus disease struck, the life sciences industry in the country responded rapidly to manage the situation. The urgent need was to test for the virus, ensure early detection and faster access to treatment. Obviously, there was shortage of RT-PCR kits across India. Also the testing capacity was low. We saw the Government hospitals perform 10,000 tests a day for the entire country. The surge of patients and the rationing of tests led India's biotech sector produce indigenous RT-PCR kits to conduct the test. The production capacity of these kits is currently 2 million a day.

However, India at this point of time lacks the much-needed laboratory infrastructure to conduct the tests, said Shaw while speaking at the Dassault Systèmes 'The World After - From Things to Life' virtual event.

Similarly in the case of PPEs, masks and sanitizers, Shaw said that India stood up to meet the challenge. From producing 40,000 PPEs a day, the industry ramped up the capacity to manufacture 1 lakh a day. In the case of ventilators too, from 40,000 we proved our capability. The local manufacture came in from across the country. Even PM Cares funded 50,000 ventilators a month. Therefore, this was the country's assiduous workforce in biomedical technology field that proved themselves during the pandemic. India is well known for its medical expertise, engineering skills and research capability, she said.

On the pharmaceutical front, India is the third largest generic drug manufacturer in terms of volumes. Drugs like

Hydroxychloroquine (HCQ) to the recent dexamethasone apart from other widely used generic drugs across the world are all manufactured and marketed by Indian companies.

Even in the area of vaccine production, India chips in 60 percent to the supplies of WHO-GAVI needs. The country's vaccine production capacity is 3 billion of which one billion is for domestic use and the remaining 2 billion is for the global market. The success of India here lies in its scale of production. Even for COVID-19, the global strategy is to partner with Indian vaccine makers which is a huge opportunity for India to succeed. Post COVID-19, the requirements for vaccines will be massive. Hence what better opportunity is sighted for India in the global markets for generics, biosimilars and its vaccine offerings, she noted.

Going bythe wide distribution of population and disease burden, the prospects are also immense for clinical trials and clinical research where we could provide large scale data. After the success in information technology in India, the Pharma and Biotech are the country's knowledge engines.

Source: Nandita Vijay, Pharmabiz, 24.06.2020

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Healthcare providers in Hyderabad come up with innovative & affordable 'Home Care' packages to treat mild COVID-19 patients

With Telangana state witnessing huge spike in COVID-19 cases every passing day, a few private healthcare providers have come up with an innovative 'Home Care' packages to treat corona infected patients by keeping them under home isolation in Hyderabad.

As already, healthcare experts have suggested and advised that corona positive patients with mild COVID-19 symptoms can keep themselves under home quarantine and isolation rather than admitting to hospitals. Taking this as an opportunity, some private healthcare providers in Hyderabad have come forward to offer 'Home Care' packages for patients suffering from corona infection.

As already the COVID-19 designate hospitals in Telangana are full and the healthcare authorities at these hospitals turning down to admit more patients with mild COVID symptoms and advising them to confine to home isolation, a few private healthcare providers have offered 'Home Care' package' wherein they will not only provide treatment for the patients while they are in home isolation but also give them healthcare suggestions and monitor their vital health parameters from time to time through virtual video consultation.

The home care providers are also offering the COVID patients in home isolation a medical kit which includes digital oximeter, digital thermometer, spirometer, N95 masks, sanitizers, waste disposal bags and gloves and also providing guidance regarding home isolation.

According to Dr V Ramana Prasad, a leading pulmonologists from Hyderabad, virtual home care particularly for those patients who prefer to stay in home isolation and want their health condition to be monitored on a daily basis is great opportunity. "Just because a person is tested positive with corona, there is no need for him to get admitted to a hospital unless he has a medical history or his symptoms are causing severe healthcare issues. As per the ICMR guidelines, asymptomatic and persons with mild COVID symptoms can also be kept under home isolation and necessary treatment can be provided under proper guidance of health experts," observed Dr Ramana Prasad.

It is also leant that the Home care providers will give complete guidance regarding home isolation, care and disinfection as per the standard guidelines. Expert physicians through video consultation will also monitor the vital health parameters of the patients such as oxygen etc and if there is any serious condition, then they will also provide ambulance service and shift the patient immediately to a hospital for emergency treatment facilities.

"Instead of rushing to a hospital and spending lakhs of Rupees for treatment, COVID positive patients with mild symptoms can get their health assessed regularly during the isolation period through the innovative home care facilities. With just a package of Rs. 20,000 per 15 days, the COVID positive patients can not only get treatment but also two sessions of physiotherapy classes and important medical equipments as part of their medical kit for monitoring the patient's health on a regular basis," opined Dr Prasad.

Source: A Raju, Pharmabiz, 24.06.2020

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NRDC develops low-cost PPE 'Nav Rakshak', licenses to four MSMEs for mass production amid Covid-19 pandemic

The Indian Navy has recently developed low cost Personal Protective Equipment (PPE) named NavRakshak

and it has been successfully patented by the Defense Ministry in association with the National Research Development Corporation (NRDC), an enterprise under the Ministry of Science and Technology for rapid mass production amid the Coronavirus pandemic.

NRDC has licensed the manufacturing know-how of this PPE kit being named as NavRakshak to five Ministry of Micro, Small and Medium Enterprises (MSME) clients Greenfield Vintrade Pvt Ltd, Kolkata, Vaishnavi Global Pvt Ltd, Mumbai, Bharat Silks, Bengaluru, Sure Safety (India) Ltd Vadodara and Swaps Couture, Mumbai to meet the ongoing countrywide demand of quality PPE kits.

These five manufacturers put together are planning to mass-produce more than 10 million PPEs per year. The manufacturing know-how of NavRakshak PPE has been developed at the Innovation Cell of the Institute of Naval Medicine, INHS Asvini Hospital (Mumbai) of the Indian Navy.

It said the technology has also been tested and validated by a testing lab approved by the Indian Council of Medical Research (ICMR).

The PPE has been tested and certified at the Institute of Nuclear Medicine & Allied Sciences (INMAS), DRDO which is one of the nine NABL accredited labs authorised by Ministry of Textile currently in India for PPE prototype sample testing as per the prevailing ISO standards and Ministry of Health & Family Welfare/Ministry of Textile Guidelines and has been found to meet the synthetic blood penetration resistance criteria for both the fabric, suit, and seam.

It is low cost breathable PPE suite and also available for commercialization to startups and industry. The PPE suit is available in single-ply as well as double-ply versions as per the need of the end use conditions. It also comes with a head gear; face mask and shoe cover up to the mid-thigh level.

NavRakshak has been designed by a naval doctor incorporating personal experience in using the PPE for the comfort and protection of the doctors. The enhanced breathability factor in the PPE suit makes it an attractive proposition to be used by the frontline health workers who are required to wear these suits for long hours and face extreme discomfort while working.

Source: Pharmabiz, 24.06.2020

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Pharma MSMEs awaiting clearance of their dues pending with PSUs since years

Even though the Central Government has recently announced that all Public Sector Undertakings (PSU) will pay outstanding of Micro, Small and Medium Enterprises (MSMEs) in 45 days, Pharma MSMEs facing liquidity crisis caused by COVID-19 pandemic are still awaiting clearance of their dues pending with these PSUs. While announcing stimulus measures under the Rs. 20 lakh crore economic package last month, Union Finance Minister Nirmala Sitharaman had said that pending dues of MSMEs would be cleared in 45 days to increase liquidity.

The Finance Ministry on May 20, 2020 advised all concerned administrative ministries of Central Public Sector Enterprises (CPSEs) to direct their respective CPSEs to release the pending payments to MSMEs immediately in line with the Government announcement made recently, said Sitharaman in a tweet.

Prime Minister Narendra Modi also directed that clearance of all dues pending with PSUs should take place within 45 days to provide relief to MSMEs in distress due to the pandemic. MSME Minister Nitin Gadkari has also requested all the state Governments, their PSUs and other departments to release their pending dues at the earliest.

Despite central Government's directive, Pharma PSUs such as Indian Drugs and Pharmaceuticals Ltd (IDPL), Hindustan Antibiotics Ltd (HAL), Rajasthan Drugs and Pharmaceuticals Ltd (RDPL) under Department of Pharmaceuticals (DoP) are yet to initiate the process of clearing dues of Pharma MSMEs. MSMEs struggling to survive amid huge losses caused by the Coronavirus pandemic have been waiting for clearance of their dues pending with Pharma PSUs since years.

Jocund India Limited which supplied raw material to IDPL, Rishikesh in 2011 is awaiting dues worth Rs.1,07,14,497.50 since February 2011 and earlier. Medicamen Biotech Limited which supplied raw material to HAL is yet to receive dues of more than Rs.one crore from the Pharma PSU.

Pharmchem is also awaiting dues worth Rs.3,424,453 from RDPL since March 2014. RDPL also owes dues of more than Rs.11 lakh to Medicamen Organics Ltd. Besides the four drug units, there are scores of MSME suppliers waiting for their dues from Pharma PSUs. When contacted, Rajneesh Tingal, Joint Secretary (PSU, NIPER,

Scheme), Department of Pharmaceuticals about Pharma PSUs' pending MSME dues said "If individual company will approach us with dues pending with Pharma PSUs, we will look into it."

However, Dr P D Vaghela, Secretary, Department of Pharmaceuticals and A K Sharma, Secretary, Union Ministry of Micro, Small & Medium Enterprises did not respond despite repeated requests. HAL is the first public sector drug manufacturing company set up by the Government in March 1954. IDPL is the PSU with plants at Rishikesh, Gurugram and Hyderabad and two subsidiary units at Chennai and Muzaffarpur.

Earlier in 2016 Union Cabinet meeting chaired by Prime Minister Modi gave its nod for the need-based sale of surplus land of four Pharma PSUs—IDPL, RDPL, HAL and Bengal Chemicals and Pharmaceuticals Ltd (BPCL) and settle outstanding liabilities of the PSUs from the sale proceeds. Following this, the operation of IDPL and RDPL will be closed down and HAL and BCPL will then be assessed for a strategic sale. It was not materialised due to lack of interest of investors.

Source: Laxmi Yadav, Pharmabiz, 23.06.2020

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Nearly 35% of operations of Pharma Companies need to be shifted to digital marketing: C Com Digital survey

There is an urgent need for the Pharmaceutical Organizations thriving on age-old business models to embrace the world of digital marketing and leverage technology to their optimum advantage. Nearly 35% of the operations of the Pharma companies need to be shifted to digital marketing, according to a survey conducted by C Com Digital, a full-service digital marketing agency.

The survey, conducted study to explore the impact of COVID-19 on the Indian Pharmaceutical Industry, was carried out in collaboration with some of the leading decision makers and business consultants from across India to gauge the impact of COVID-19 on their organizations as well as the whole of the Pharma Industry. Most of the respondents that participated in the survey experienced complacency in the industry with respect to heavy dependency on the out-of-date B2B model and hesitance to adopt changes due to ROI centricity prevailing for decades.

The study also saw that, pharmaceutical companies are considering dedicating about 5% to 10% of their marketing budget towards creating webinars and online communications.

"It's time for Pharma companies to respond positively to digitization; since it's here to stay for a long while now. In general, when we are talking about the 'new normal', we must understand that employees can work remotely with utmost productivity, but the key remains to prepare ourselves, as an organization, to adjust and adopt new changes quickly as per the changing environment, so that there's victory at the end of the dark tunnel. And now, as we analyze the report of the survey, it's clear that to tackle the existing challenges in the Pharma industry, we must let the best options and capabilities walk up to the table," said Chandan Bagwe, Founder and Managing Director, C Com Digital.

The online digital survey said that majority of the top management officials believed that COVID-19 has already brought about a strategic shift in the way Pharma companies function and engage with physicians and other clients on a day to day basis. Teleconsultation and online consultation has seen a steady spikeinfact, around 42% of patients are taking prescriptions by teleconsultation and doctor visits had dropped by almost 5% during the period of March to April 2020.

To add, the biggest concern for most of these organizations remains to undertake measures for continued remote working facilities and minimizing direct engagement by establishing digital routes.

Moreover, the report identifies that many large-scale Pharma companies are now looking to place their bet on online patient education and online training of field staff through the means of comprehensive soft skill modules and dedicated e-learning programmes from a perspective of sustainable development goals. In fact, few of the companies are already leveraging AI-driven models to gain a competitive advantage over others and to build engagement with their clients from newsletters.

Pharma companies are slowly picking up the pace to go digital, primarily by looking at social media for communication and engagement. In the days to come, it is certain that most of these businesses will find an alternative to demonstrate their offerings, either through applications or video content. Clearly, the position of the industry and the present-day scenario points out that more and more Pharma companies will dedicate a larger portion of their

budgets towards digital marketing as against advertising or branding. Perhaps, the progress and success post-COVID-19 will be primarily reliant on agile working models, sagacious strategies, and adaptable workforces.

Source: Pharmabiz, 27.06.2020

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Exporters hail CBIC's initiative to introduce paperless documentation for exporters

In a bid to save time and cost of compliance for the trade, the Central Board of Indirect Taxes and Customs (CBIC) has introduced end-to-end paperless documentation for exporters. With this, exporters will now have to present only digital copies of shipping bills bearing final let export order (LEO) and gatepass to customs authorities.

In its continuing endeavour to promote 'faceless, contactless, paperless customs', the board has decided to rely upon digital copies of the shipping bill and do away with the requirement of taking bulky printouts from the service centre or maintenance of voluminous physical dockets in the custom houses, said a circular issued by CBIC.

The board directed that only the digital copy of the shipping bill bearing the final LEO would be electronically transmitted to the exporter and the present practice of printing copies of the said document for the exporters and also for maintaining a docket in the customs house would stand discontinued with effect from June 22, 2020, stated the circular.

This reform complements the introduction of a digital PDF Out-of-Charge (OoC) copy of the bill of entry and gatepass with effect from April 15, 2020 and the launch of the first phase of faceless assessment at Chennai and Bengaluru with effect from June 8, 2020. The digitization of end to end export documentation is being carried out in a phased manner.

This reform will yield immense benefits in terms of saving the time and cost of compliance for the trade, thereby enhancing the ease of doing business, while providing enhanced security features for verification of authenticity and validity of the electronic document, said Ananth Rathakrishnan, Deputy Secretary (Customs).

Currently, the shipping bill is being printed in duplicate, namely customs copy and exporter copy. The shipping bill is also being printed in many instances, based on the request of the exporters. This necessitates the exporter/customs broker to take physical printouts in the service centre and present it to the customs officer. In many locations, physical signing of the printouts is also insisted upon.

To promote a paperless environment, the board has decided to do away with the taking the printouts. Instead, the Directorate General of Systems will send the PDF version of the final LEO copy of the shipping bill to the customs broker and exporter, if registered via email. This electronic final LEO copy can serve multiple purposes such as being shared with DGFT, banks etc.

The PDF version will bear a digitally signed and encrypted QR code which can be scanned to verify the authenticity of the document using mobile app ICETRAK. The QR code is tamper proof, which is digitally signed by CBIC to ensure the authenticity. Key details like Shipping Bill (SB) no, SB date, Free on Board (FOB) value, package details are available in the secured QR code.

The shipping bill printout is also being used extensively by the logistics operators during the movement of export goods, including transhipment, by road or rail or during the loading of cargo into vessels, aircrafts etc as a proof of export. Taking cognizance of the logistics needs, the Directorate General of Systems would henceforth communicate through email, the eGatepass PDF copy of the shipping bill to the customs broker and the exporter, if registered. The electronic document provides key summary details like container/packages related to logistics movement and facilitates authentic, easy and quick verification by the custodian, at the point of entry/exit.

In the issued circular, the board has also mentioned that for exports, all the supporting documents mandatorily need to be uploaded on eSanchit. However, anticipating a situation where printouts of shipping bills are required, the board desires that such scenarios should be informed by exporters immediately and the respective Principal Commissioners/Commissioners of Customs would analyse the situation and take a decision on allowing printouts. Although, this is applicable only in exceptional situations.

Appreciating the CBIC's digitization initiative, Sahil Munjal, Vice Chairman, Pharmexcil said, "With this, there is no requirement of paper work in export and import custom clearing process. Customs clearance is being done 24 x 7 in all customs across India. If any amendment is required in bill of entry or shipping bill, importer/exporter

can do the same online. Also facility of e-payment of customs duty, e-gate pass and e-out of charge is being provided by customs. Now all import and export customs clearance process is faster, flexible and free from human intervention."

Commenting on the move, Dr Viranchi Shah, National Vice President, Indian Drug Manufacturers' Association said "It is a welcome step. The paperless customs processing through PDF copies of shipping bills and eGatepass will make clearance of exports faster and lower transaction time and costs. It will boost ease of doing business." Mr Nipun Jain, Chairman of Small and Medium Pharma Manufacturers' Association (SMPMA) said "It is a positive step at a time of COVID-19 pandemic emphasizing physical distancing and minimal interface. It will save time and expedite the entire export process."

Source: Laxmi Yadav, Pharmabiz, 26.06.2020

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India's Zydus Cadila to make Gilead's potential COVID-19 Drug Remdesivir

Indian drugmaker Zydus Cadila said on Friday, 03.07.2020 it signed a non-exclusive licensing pact with Gilead Sciences Inc to manufacture and market antiviral drug Remdesivir, the first treatment to show improvement in COVID-19 trials. Zydus, listed as Cadila Healthcare, joins other Indian pharmaceutical companies Cipla Ltd, Jubilant Sciences Ltd and privately held Hetero Labs Ltd in signing non-exclusive pacts with Gilead for the drug.

Clinical studies involving the drug are being closely watched as nations look for treatments for the disease that has infected more than 7 million people and killed over 400,000 globally. The drug, intravenously administered in hospitals, has already been approved for emergency use in severely-ill patients in the United States, India and South Korea. As part of the pact, Zydus will get the manufacturing know-how from Gilead to manufacture the Active Pharmaceutical Ingredient for Remdesivir and the finished product. Zydus will market it in 127 countries, including India.

India's novel Coronavirus cases on Friday, 03.07.2020 jumped by a record 10,956 from the previous day, and the death toll reached 8,498. Worldwide death toll was 420,950 on Friday, 03.07.2020.

Source: Reuters/The Economic Times, 04.07.2020 (Excerpts)

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Pharma major Mylan gets go-ahead to make Remdesivir for 'restricted emergency use'

After Hetero and Cipla another pharmaceutical major Mylan was given permission by India's drug regulator on Thursday, 02.07.2020 to manufacture and market the anti-viral drug Remdesivir for "restricted emergency use" on hospitalised COVID-19 patients, official sources said.

Written informed consent of each patient is required before the use of the drug while active post-marketing surveillance data and reporting of serious adverse events have to be submitted. On June 21, Hetero and Cipla were given permission to manufacture and market the drug on the same conditions.

The Union Health Ministry in its 'Clinical Management Protocols for COVID-19' recommended the use of the drug in COVID-19 patients with moderate stages of the illness (those on oxygen support). The drug has been included as an investigational therapy? only for restricted emergency use purposes. It is not recommended for those with severe renal impairment and high level of liver enzymes, pregnant and lactating women, and those below 12 years, the document stated.

The drug, administered in the form of an injection, should be given at a dose of 200 mg on day one followed by 100 mg daily for five days. "The approval was given by the CDSCO on Thursday, 02.07.2020" an official source in the know of the developments told. Mylan had already entered into non-exclusive licensing agreements with Gilead Sciences, which is the patent holder of the drug Remdesivir.

US Pharma giant, Gilead Sciences, had applied to the Indian drug regulatory agency, Central Drugs Standard Control Organisation (CDSCO), for import and marketing of Remdesivir on May 29. After due deliberations, permission under emergency use authorisation was granted by Drug Controller General of India (DCGI) on June 1 in the interest of patient safety and obtaining further data.

On June 21, Hetero and Cipla were given permission to manufacture the drug. Besides, Jubilant, BDR and Dr Reddy's Labs have also applied to CDSCO for permission to manufacture and market the drug in India and are still awaiting due permission.

Source: PTI, The Economic Times, 03.07.2020

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Rising costs of raw materials from China: NPPA to allow Pharma companies to raise Heparin price by 50%

The National Pharmaceutical Pricing Authority (NPPA) has decided to allow pharmaceutical companies to increase the price of essential blood thinner heparin by 50 percent until December, citing shortages and rising costs of the raw materials from China used to make it. The price hike also comes as heparin was among several drugs flagged by the Health Ministry as essential medicines that needed to remain in stock while the country battled the ongoing Covid-19 pandemic.

Meanwhile, other pharmaceutical companies have also approached the drug pricing watchdog seeking price increases for various other essential medicines like Paracetamol Formulations and antibiotics on similar grounds. The development also comes at a time when tensions between India and China have been on the rise. While there had been issues with delayed clearances of consignments from China at Indian ports over the last fortnight, shipments of pharmaceutical products have begun to get released this week, as per Pharmaceuticals Export Promotion Council of India Chairman Dinesh Dua.

NPPA had received applications from "several" companies with major market share of heparin injections seeking an upward price revision. In doing so, the firms had submitted that the cost of the heparin sodium Active Pharmaceutical Ingredient (API) used to make the drug had risen "to a considerable extent", making it "entirely unviable" for them to continue manufacturing it.

The costs of the API constitute a "major" portion of the input cost for the drug and the API is "mainly imported from China," the firms had submitted to NPPA, according to a Notification dated June 30. "The Authority further noted that Heparin injection 5000IU/ml has also been included in list of medicine essential for patients admitted in ICU and Hospitalization due to COVID-19 circulated by Ministry of Health & Family Welfare (MoH&FW). Uninterrupted supply of such medicines is essential for management of COVID-19," stated the minutes of NPPA's June 22 Authority meeting, where this matter was discussed. "Further, reports of shortage have also been received for Heparin Injection."

A committee headed by Central Drugs Standard Control Organisation Joint Drug Controller Dr S Eswara Reddy had informed the Authority that there has been a 211 percent increase in the price of heparin's API when compared to the base year of September 2018, according to the minutes.

The committee had opined that "NPPA may consider to increase the ceiling price of Heparin Injection 5000IU/ml by 50 percent to ensure continuous availability of the essential drugs in public interest. The committee also recommends that increase in ceiling price may be considered for only a fixed duration, say for about six to nine months, after which the situation may be reviewed and further necessary action can be taken as deemed fit."

Apart from heparin, submissions for price increases have also been made over the past two months for other drugs under price control, ranging from Paracetamol products and antibiotics to vitamins. According to pharmaceutical associations in the country, the costs of APIs imported from China and used to make essential medicines have on average risen 20-35 percent in the last 3-6 months, with a majority of the increase being brought in during the pandemic.

Antibiotic azithromycin, for instance, has seen a "substantial" increase in API costs, according to Indian Pharmaceutical Alliance Secretary General Sudarshan Jain. **Paracetamol products, according to Indian Drug Manufacturers' Association Secretary General Daara B Patel, have also experienced similar hikes in cost as the key starting materials for them come mainly from China.**

"During the pandemic, the overall cost of operations, especially transportation and APIs, have gone up substantially," said Jain, adding that firms had separately approached the regulator with information regarding increasing costs of APIs, a majority of which come from China. "Wherever it is viable and the companies have applied for price revision with proper data, NPPA should consider it and give an increase where it is required," he told.

Chinese manufacturers of these products seem to be trying to recover the costs of not being able to operate their facilities back in January, according to Patel. "China also experienced a lockdown, so manufacturers there had to shut operations for a while as well," he said. "Because of this pandemic, prices have gone up for all imported items. We have requested NPPA to consider this on a case to case basis," he said.

Source: Prabha Raghavan, The Indian Express, 03.07.2020

Initial COVID-19 infection rate may be 80 times greater than originally reported

Many epidemiologists believe that the initial COVID-19 infection rate was undercounted due to testing issues, asymptomatic and alternatively symptomatic individuals, and a failure to identify early cases. Now, a new study from Penn State estimates that the number of early COVID-19 cases in the US may have been more than 80 times greater and doubled nearly twice as fast as originally believed.

In a paper published in the journal *Science Translational Medicine*, researchers estimated the detection rate of symptomatic COVID-19 cases using the Centers for Disease Control and Prevention's Influenza-Like Illnesses (ILI) surveillance data over a three week period in March 2020.

"We analyzed each state's ILI cases to estimate the number that could not be attributed to influenza and were in excess of seasonal baseline levels," said Justin Silverman, Assistant Professor in Penn State's College of Information Sciences and Technology and Department of Medicine. "When you subtract these out, you're left with what we're calling excess ILI - cases that can't be explained by either influenza or the typical seasonal variation of respiratory pathogens."

The researchers found that the excess ILI showed a nearly perfect correlation with the spread of COVID-19 around the country. Said Silverman, "This suggests that ILI data is capturing COVID cases, and there appears to be a much greater undiagnosed population than originally thought."

Remarkably, the size of the observed surge of excess ILI corresponds to more than 8.7 million new cases during the last three weeks of March, compared to the roughly 100,000 cases that were officially reported during the same time period.

"At first I couldn't believe our estimates were correct," said Silverman. "But we realized that deaths across the US had been doubling every three days and that our estimate of the infection rate was consistent with three-day doubling since the first observed case was reported in Washington state on January 15."

The researchers also used this process to estimate infection rates for each state, noting that states showing higher per capita rates of infection also had higher per capita rates of a surge in excess ILI. Their estimates showed rates much higher than initially reported but closer to those found once states began completing antibody testing.

In New York, for example, the researchers' model suggested that at least 9% of the state's entire population was infected by the end of March. After the state conducted antibody testing on 3,000 residents, they found a 13.9% infection rate, or 2.7 million New Yorkers. Excess ILI appears to have peaked in mid-March as, the researchers suggest, fewer patients with mild symptoms sought care and states implemented interventions which led to lower transmission rates. Nearly half of US states were under stay-at-home orders by March 28. The findings suggest an alternative way of thinking about the COVID-19 pandemic.

"Our results suggest that the overwhelming effects of COVID-19 may have less to do with the virus' lethality and more to do with how quickly it was able to spread through communities initially," Silverman explained.

"A lower fatality rate coupled with a higher prevalence of disease and rapid growth of regional epidemics provides an alternative explanation of the large number of deaths and overcrowding of hospitals we have seen in certain areas of the world." Other collaborators on the project included Nathaniel Hupert of Cornell University and the New York-Presbyterian Hospital, and Alex Washburne of Montana State University.

(Materials provided by Penn State. Original written by Jordan Ford. Note: Content may be edited for style and length).

Source: Penn State, Science Daily/World Pharma News, 23.06.2020 (Excerpts)

FEATURE

Manufacture of vaccines in India

Aakarsh Nashier & Pallavi Puri

With a large part of the population under quarantine and the economy reeling from the effects of COVID-19, feverish efforts are underway worldwide to develop a vaccine. The British Pharma giant AstraZeneca, in partnership with Oxford University and the US based biotechnology giant Moderna, shows promise of an imminent breakthrough as their combined research for the coveted vaccine reaches the later stages of human trials.

The development of a vaccine is, however, only one-half of the battle; the other major requirement entails making the vaccine available to the entire world. This is where India can be a major player. Being the largest provider of generic drugs worldwide, the Indian pharmaceutical sector meets close to 50 percent of the global demand for various vaccines. Pharmaceuticals exports from India stood at $19.14 billion in FY19.

The manufacture of vaccines in India is strictly controlled by a hierarchy of regulatory bodies. Guidelines provided by the Indian Council of Medical Research (ICMR) set the rules of conduct for clinical trials. These guidelines address ethical issues that arise during Phases I-IV of every vaccine study.

The manufacture of any vaccine in India requires various licenses/permissions to be obtained under the Drugs and Cosmetics Act, 1940 (Act). Typically, the procedure for approvals starts with procuring a license for the import of small quantities of the strain for testing and analysis. This is followed by seeking permission to manufacture experimental batches of the said vaccine.

The sample strain is then submitted for pre-clinical studies at the Central Drugs Laboratory (CDL) for tests that check batch consistency. Once the results of the preclinical studies and the certificate of analysis from CDL are obtained, an application and protocol are tabled with the regulator, i.e., Central Drugs Standard Control Organization (CDSCO), for conducting Phases I/II/III of the clinical study with the experimental batches of vaccines. Clinical study reports are furnished to CDSCO after the completion of each phase of the trial along with the experimental batches of the vaccine. Upon successful completion of all three phases of the trials, a market authorization application is filed by the manufacturer, as per Rule 122B of Drugs and Cosmetics Rules 1945 (Rules). On receipt of the market authorization, an application for a manufacturing license for the vaccine needs to be filed with the Central and the State Licensing Authority.

However, to meet the exigencies of the current pandemic, the Government of India by way of a notification dated March 20, 2020, has relaxed the standards under the Act and the Rules for vaccines for Covid-19. Taking its cue from this concern for an early remedy of the growing malaise, the Ministry of Health and Family Welfare has deferred its stipulated regulations in the case of the Serum Institute's tie-up with AstraZeneca for the manufacture of its potential COVID-19 vaccine.

A comprehensive review conducted by the WHO in December 2019 paved the way for easy export of vaccines produced in the country. Now, the National Regulatory Authority of India and its affiliated institutions meet World Health Organization (WHO) efficacy indicators for a functional vaccine regulatory system.

Once all the requisite licenses and permissions are in place, a manufacturer (in India) then enters into a licensing agreement with the patent holder, allowing the manufacturer to mass-produce the vaccine. As per the terms of this agreement, a patent owner gives the necessary license to the manufacturer to use, sell, and extract benefits from his patented invention for a royalty. Negotiating parties have a wide choice of patent licensing agreements, such as exclusive licenses, non-exclusive licenses, and compulsory licenses. Gilead Sciences recently entered into non-exclusive licensing agreements with four domestic Pharma companies for the manufacture and distribution of Remdesivir, a drug that has the potential to combat the Coronavirus.

The primary form of license in today's scenario is a compulsory license, which is provided under Sections 84 and 92 Indian Patent Act, 1970 (Patent Act). A Compulsory License is granted after three years of a patent's pendency, on certain grounds such as a surge in public demand and in price. However, in extraordinary situations, the Central Government is empowered to bypass the elaborate procedure laid down under the Patent Act and grant a Compulsory License to a manufacturer, thereby facilitating the availability of the drug or vaccine at the lowest possible price.

This will test the alacrity of the Indian Pharma sector, which is expected to witness a phenomenal growth in the coming decade. The ever-increasing ease of ordering medicines through e-commerce platforms is opening various new avenues such as alternative medicines, movable clinics, and healthcare data collectors. Further, with the introduction of 'Pharma Vision 2020', the Central Government aims to make India a major player in the global competition for drug manufacture and boost investments in its Pharma market.

Source: Express Pharma, 30.06.2020

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SPECIAL IPR FEATURE

Needed: a pandemic patent pool

Justice Prathiba M Singh

(The author is Judge of the Delhi High Court and was a Member of the IP think tank that drafted India's Intellectual Property Rights Policy)

Every April 26, we celebrate World Intellectual Property Day. This year, it was not a day for celebration, but one for reflection and dedication. It provided us an opportunity to reflect upon the role of Intellectual Property (IP) in the ongoing health crisis and dedicate IP to finding a solution.

A long road ahead:

The purpose of creating and recognizing patent rights is for the common public good, i.e., innovation should be made public in exchange for a limited monopoly. Thus, patents need to be disclosed to the public in order to enable further research. Should pandemics such as COVID-19 be an exception to this?

For human life to become normal again, vaccines or medicines are the only permanent solutions. However, even by conservative estimates, it will take at least 6-10 months for any vaccine/drug to be available. Even when approval for marketing of a vaccine/drug is granted, it will be impossible for it to be made instantly available across the world. This is because even after approval for commercial production is granted, say, in one country, in order for the product to be available to the rest of the world, approvals will be required in each and every country. Then countries will have to gear up for instant manufacturing and marketing of the drug. For this to happen, continuous dialogue has to take place among innovators, manufacturers and supply chains. This requires massive efforts by private players, Governments and international organisations. With the outbreak of COVID-19, there are several innovations. All these innovations may be the subject matter of patent applications around the world. It will be a few years before patents are even granted. However, friction already exists among various stakeholders. For instance, one country made attempts to obtain exclusive rights to a vaccine being developed. On the other hand, there are also collaborations taking place. However, the spirit of collaborative solutions is only on the anvil. The question that arises is whether the exclusivity that is recognised by patent rights will be detrimental to society. Will patents create roadblocks or is there a solution? Pandemics need disruptive solutions. Governments and international organisations need to arrive at a consensus in advance to ensure that the system is ready. Procrastination would be disastrous. Creating hindrances through exclusivity claims, in the wake of a pandemic, will result in dividing countries, corporations and international organisations. This will not benefit patients and the world as a whole. If patent owners create impediments on the strength of patent rights, the world will start despising patents and that is not a situation IP owners ought to be in. Under the TRIPS (Trade-Related Aspects of Intellectual Property Rights) regime, there are several tools such as compulsory licensing that are available to ensure access to medicines. However, beyond the laws, society needs to respect innovation. To protect the sanctity and integrity of patent systems, and in order to ensure that an anti-IP sentiment is not generated globally, answers need to be found within the existing regime. In exceptional circumstances such as these, there is a likelihood that societies may resort to extreme steps to protect themselves. Before such ideas are floated, solutions should be created.

Creating a patent pool:

One method by which aggregation and dissemination of innovative products can be ensured is by creating a patent pool. Patent pools are usually effective in aggregating,

administering and licensing patents related to specific areas of technology. Such pools are usually managed by a central agency and the patents which become part of the pool are readily made available for licensing. Some pools even publish the royalty rates payable for such licences. Anyone who wishes to obtain a licence will be able to approach the pool, agree to the terms, and begin to manufacture and sell the products. Such pools are prevalent in, for instance, standard essential patents related to telecom and digital innovations.

At the moment, individual efforts are being made by research organisations to create their own pools. A more fruitful endeavour would be to create a global pool of COVID-19- related innovations, or innovations related to rare pandemics, in respect of vaccines and medicines. This could be managed by a trustworthy international organisation. All countries ought to have the right to implement these innovations without further permission from the patent-holders and without resorting to provisions such as compulsory licensing, state acquisition, etc. Even if royalties are at a minimal level, the revenues would still be in billions of dollars owing to the large swathes of the population affected by the pandemic, who will need to be administered these products. Creation of a pool and immediate licensing will ensure that there are hundreds of manufacturers across the world. As a result, vaccines and medicines will be quickly available. Some part of the royalties could then be disbursed to patent owners on a periodic basis and some part could be retained to fund further research to deal with such pandemics in future.

Such a pool needs the cooperation of not just countries and international organisations but also the hundreds of researchers, innovators, companies and universities involved. Concerns relating to patents and profits to be earned there from should be put aside. The world has to come out of this crisis quickly and patents ought to accelerate rather than impede the path. Combating the crisis and earning collectively is the need of the hour. Pooling of patent resources is also in line with the Doha Declaration on Public Health which is a part of the TRIPS agreement. This declaration recognises the need for taking measures to 'protect public health' and 'promote access to medicines'. Public-Private Partnerships (PPP) need to be scaled up. Creation of the 'PPP-pandemic patent pool' at a global level, to pool all innovations, is the way forward. Let us not wait any longer.

Source: The Hindu, 01.05.2020 (Excerpts)

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