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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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102-B, 'A-Wing', Poonam Chambers,
Dr. A.B. Road, Worli, Mumbai - 400 018
Tel : 022-2494 4624 / 2497 4308 **Fax:** 022-2495 0723
e-mail: mail_ idma@idmaindia.com/
admin@idmaindia.com/ Website: www.idma-assn.org

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IDMA BULLETIN

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RESEARCH AND PATENTING IN COVID TIMES

Dr Gopakumar G Nair, *Editor, Indian Drugs*

Dear Reader,

Government of India is currently negotiating a limited trade deal with USA which is likely to be signed after the US elections. Although, the current negotiations do not cover the Intellectual Properties (IP) or Pharmaceuticals, a limited deal if concluded successfully is expected to be followed by a full Trade Deal (FTA), which will include IP and Pharmaceuticals too.

In spite of all the negative (or positive?) consequences of COVID-19, the SARS-2-COV virus has provided humanity with a great learning experience. Repurposing of known drugs, bio-natural products, biologicals and vaccines such as TB, Leprosy, BCG have all been undertaken in the desperate search for prophylactic, therapeutic as well as preventive options. However it is interesting to note and appreciate that except for pre-existing patent rights (ex:-Remdesivir), there have hardly been any emphases on protecting the Covid remedies through patenting.

Balancing of rights and obligations have always been an integral aspect of Patent Laws ever since the Paris Convention was adopted in 1883. The TRIPs (Trade Related Aspects of Intellectual Property Rights) has incorporated and adopted all the provisions of Paris conventions as per Article 2 of TRIPs. Further, under the Objective and Principle of TRIPs, it is explicitly stated in Article 7 and 8, which respectively refer to "transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare, and to a balance of rights and obligations" and also "Members may adopt measures necessary to protect public health and nutrition and to promote public interest….". As such, member countries like India do provide such balancing provisions in the National Patent laws such as the Patents Act 1970 of India. However, in developed countries such as USA, the patent provisions are constantly evolving based on juridical judgments from the US Courts. The US Patent law, 35 US code is very brief unlike Patents Act, 1970 of India, where the balance has moved substantially in favor of the Inventors and the Patent owner. Consequently, USA has been extensively critical of Indian Patent provisions leading to USTR (United Sates Trade Representative) issuing Super 301 Trade notifications over the last few years. India's

Dr Gopakumar G Nair is a Ph.D in Organic Chemistry (1966) from National Chemical Laboratory, Pune (Pune University). He was a Post-Doctoral fellow at IIT Bombay, Powai (1967) before joining the Pharma Industry. He was Director of Bombay Drug House P. Ltd., later Chairman of BDH Industries Ltd. as well as CMD of Bombay Drugs & Pharma Ltd., which was merged with Strides Arcolab Ltd. in 2001. Dr. Nair served IDMA as office bearer for many years from 1972 onwards and was Chairman of various Committees for nearly 4 decades. He was the President of IDMA in 1999/2000. Currently, Dr. Nair is the Chairman of the IPR Committee in IDMA.

Having moved into the Intellectual Property field, he was the Dean of IIPS (Institute of Intellectual Property Studies) at Hyderabad in 2001/2002. Later, he set up his own boutique IP firm, Gopakumar Nair Associates, as well as Gnanlex Hermeneutics Pvt. Ltd., having done his L.L.B. from Mumbai University. He is also CEO of Patent Gurukul and President of Bharat Education Society, Kurla, Mumbai, managing many educational institutions in and around Mumbai.

response has been more defensive, though our Trade negotiators have successfully explained our position on the balance of rights and obligations. However, it is time now, especially in view of the global pandemic, for us to convince the developed countries like USA to provide needful emphasis on healthcare protection in preference to patent protection.

Indian patent provisions as per Patents Act, 1970 has been challenging for Indian Inventors and their Patent Agents/Attorneys. India's unique permission under Sec 3 "What are not inventions" "What are not patentable" [Sec 3 (d) for example] has been a real hurdle unlike USA, over and above the tough "Obviousness" criteria adopted by the Indian Examiners.

Pricing of pharmaceuticals has been tightly controlled under NPPA (National Pharmaceutical Pricing Authority) except for patented molecules, most of which are either wholly imported or exclusively licensed with terms and conditions. As such, Indian Patents and healthcare providers have been under an advantage vis-à-vis affordable access and generic options widely being available without market monopolies.

Indian Pharmaceutical researchers and manufacturers in the field of natural products have been facing the additional challenge from the Biodiversity Act, 2002 and the Rules 2004, which had been prematurely promulgated ahead of the Nagoya Protocol and which had been very tardily drafted. To add insult to injury, the procedural provisions have all along been harsh and narrowly interpreted. While world over (ex-China, Japan, Asian countries) the pharmaceutical industry has been looking at integrating options through products of natural origin, Indian researchers have been extremely stifled in their options for herbal remedies due to the NBA (National Biodiversity Authority). A simple example is cited to explain the dilemma. A distinguished academic pharma Research Professor came up with a novel invention of an antifertility agent and formulation from the extract of the seeds of Annona Squamosa (Seetaphal). Not only did the NBA demand 5% royalty on all income generated from the invention, but the Biodiversity Authorities insisted on the inventor disclosing the original origin of the seed geographically for benefit sharing. Paradoxical indeed.

Coming back to the subject of R&D in COVID times, the only option should be to invent or reinvent through repurposing effective remedies and cures for the virus infection and treatment thereof. Even the Remdesivir patent had to be saved from Compulsory License by liberal Voluntary Licensing by Gilead. It is a common man's concern. "Will the vaccines for COVID be patented?" "No way", let us comfort ourselves, atleast not in India. Fortunately, India is in forefront of Vaccine development and manufacturing at extremely affordable pricing.

In the meantime, planning for growth by the pharma industry needs an integrated approach. Leading Indian manufacturers like Zydus Cadila and Cipla have grown exemplarily through an integrating approach by adopting organic as well as inorganic routes. While APIs and building blocks will continue to grow and receive much deserved attention, the formulation industry is bound to expand horizontally and vertically in technology options keeping the consumers benefit in mind. For example, Cipla who started aerosol business in 1976 is becoming a global leader through acquisition of respiratory device manufacturing companies both in India as well as overseas. The announcement of a Rs.1000 crore acquisition of a leading US inhaler manufacturing company is a crowning glory for an Indian Pharmaceutical giant. After reaching a critical mass, the Indian Pharmaceutical manufacturers need to look at strengthening the operations by adopting an integrated approach through development or acquisition of technologies. Emphasis in future will be on "Innovation" and "Novel" technologies and healthcare solutions.

Courtesy: Indian Drugs, Editorial, Vol. 57 (08) August 2020

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NPPA extends validity of revised price of Heparin Injection based on decision of 81st Authority Meeting dated 24th November 2020 - reg.

NPPA Notification No.S.O.4333(E), dated 3rd December, 2020

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

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

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

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

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NPPA fixes/revises Ceiling Price of 1 Formulation {Methylrosanilinium Chloride (Gentian Violet)} based on 81st Authority Meeting dated 24th November 2020 - reg.

NPPA Notification No.S.O.4334(E), dated 3rd December, 2020

In exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the item specified at Sr. No. 11 & 13 of the Order of the Government of India in the Ministry of Chemicals and Fertilizers, National Pharmaceutical Pricing Authority (NPPA) S.O. 1214(E), dated 25th March 2020, in so far as it relates to formulation packs mentioned in the table below, except in respect of things done or omitted to be done before such supersession, the NPPA hereby fixes the prices as specified in column (5) of the table herein below as ceiling price exclusive of Goods and Services Tax applicable, if any, in respect of the Scheduled formulation specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE

Sr. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
1.	Methylrosanilinium chloride (Gentian Violet)	Paint 1%	Per ml	0.08503

Note:

(a) All manufacturers of scheduled formulation, selling the branded or generic or both the versions of scheduled formulation 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 formulation downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

(b) All the existing manufacturers of above mentioned scheduled formulation having MRP lower than the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.

(c) 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.

(d) 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 Controllers and dealers.

(e) 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.

(f) 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.

(g) The manufacturers of above said scheduled formulation shall furnish quarterly return to the NPPA, in respect of production/ import and sale of scheduled formulation 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.

(h) 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.

(i) 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.

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

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

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NPPA fixes/revises Ceiling Price of 1 Formulation (Oral Poliomyelitis Vaccine) based on 81st Authority Meeting dated 24th November 2020 - reg.

NPPA Notification No.S.O.4335(E), dated 3rd December, 2020

1. Whereas, the Department of Pharmaceuticals (hereinafter referred as DOP) has amended Schedule I of the Drugs Price Control Order (hereinafter referred as DPCO) 2013 vide S.O. 701(E) dated 10.03.2016 based on revised National List of Essential Medicine (hereinafter referred as NLEM) 2015;

2. And whereas on amendment of the list of scheduled formulations, paragraph 17 of the DPCO 2013 requires fixation of the ceiling prices of formulations (i.e. medicines) added in the Schedule I to be fixed as per the provisions of the DPCO, 2013 within a period of sixty days from the date of amendment;

3. And whereas the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) initiated the process of the ceiling price fixation in March 2016. In this connection, NPPA vide its various Office Memorandums (OMs) had uploaded list of the scheduled formulations for which reference market based data required for price fixation was not available. Copies of the aforesaid OMs were also sent to Drugs Manufacturers Associations requesting

for submission of market based data and whereas NPPA had also suggested the Department of Pharmaceuticals to amend DPCO 2013 so as to facilitate consideration of the State Institutional Procurement Price for such scheduled formulations where market based data are not available to facilitate ceiling price fixation;

4. And whereas on the basis of inputs from the manufacturer and official data collection agency viz AIOCD AWACS in respect of certain scheduled formulations where market based prices could be traced, NPPA has fixed the ceiling prices of such scheduled formulations. NPPA has so far fixed the ceiling prices of 879 formulations on the basis of available data. However, even after a number of attempts made to obtain the relevant and reliable market based data, NPPA has not been able to fix the ceiling prices of remaining scheduled formulation for the want of requisite market data;

5. And whereas, it is obligatory on the part of the NPPA to revise the ceiling prices of all the drugs notified under the Schedule I of DPCO, 2013 so as to ensure the benefit of fair and reasonable ceiling prices to the consumers of such essential medicines to protect public interest, and thus there is a necessity to adopt alternative methods of price fixation;

6. And whereas, based on the communication of DOP dated 05.02.2019, NPPA had taken extra efforts to collect the institutional data. Letters were issued to Director General Health Services (DGHS), Central Drug Procurement Agencies; State Drug Procurement Agencies, State Drug Controllers (SDCs), Central/State Government Hospitals and private Hospitals, etc in order to obtain the data from the required Institutions.

7. And now, in exercise of the powers conferred by paragraphs 19 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No. S. O. 1214(E) dated 25.03.2020 (at Sl. No. 10), the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the prices as specified in column (5) of the table herein below as ceiling price exclusive of Goods and Services Tax applicable, if any, in respect of the Scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

TABLE

Sr. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
1.	Oral Poliomyelitis vaccine		1 ML	102.24

Note:

(a) All manufacturers of scheduled formulations, 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.

(b) All the existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table plus Goods and Services Tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.

(c) 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.

(d) 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.

(e) 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.

(f) 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.

(g) 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.

(h) 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.

(i) 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.

PN/213/81/2020/F
F.No.8(81)/2020/D.P./NPPA-Div.II

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

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GOVERNMENT PRESS RELEASE

Ministry of Commerce & Industry and Ministry of AYUSH decide to set up an AYUSH Export Promotion Council

Ministry of Commerce & Industry and Ministry of Ayush Press Release dated 6th December 2020

The Ministry of Commerce and Industry and the Ministry of AYUSH have decided to work together to set up an Export Promotion Council to boost AYUSH exports. This decision was taken recently in a joint review of AYUSH Trade and Industry by Shri Piyush Goyal, Minister of Commerce and Industry and Shri Shripad Naik, Minister of AYUSH.

It was also decided in the review that the entire AYUSH sector will work together to achieve price and quality competitiveness to boost AYUSH exports. The review was held through video conference on 4 December 2020, which was attended by nearly 50 industry and trade leaders from the AYUSH Sector. More than 2000 stakeholders of the AYUSH Sector also attended the e-event through live streaming on virtual platforms.

Secretary, AYUSH initiated the discussions with a presentation on the action taken on the recommendations of the previous meeting by the Ministry of AYUSH. He also briefed about the various other initiatives taken by the Ministry of AYUSH to mitigate the COVID-19 situation and to promote AYUSH industry. He spoke about the emerging opportunities for promotion of AYUSH sector and listed a few hurdles that deserved attention.

In the open forum that followed, officials from Ministry of Commerce and Industry, RIS, BIS and Invest India and AYUSH industry representatives shared their thoughts. The efforts put in by the Ministry of AYUSH to take AYUSH-based solutions to the public in the wake of COVID-19 came in praise from all. Shri Shripad Naik highlighted the growing global interest in AYUSH-based solutions for disease resistance and treatment during the difficult times of the Covid-19 pandemic.

He stated that Trade and Commerce in the AYUSH Sector needed to upscale quickly in order to meet the growing demands from India and abroad, and to serve the larger number of people who are now looking up to these systems for maintaining their health. He also recollected various steps taken by the Ministry during the pandemic to add protection to the people from the dreaded Corona virus.

He told the participants that the AYUSH immunity protocols and the National Clinical Management

Protocol for Covid-19 for Ayurveda and Yoga were timely interventions which provided relief to large sections of the population. The emerging evidence of a correlation between the low Covid-19 mortality rates and largescale adoption of AYUSH prophylactic solutions by the population is significant for the public health practice in the country.

Shri Piyush Goyal, praised the frontline role played by the AYUSH Sector in the fight against Covid-19. The protection offered by the AYUSH systems to the common people during the pandemic time neutralised the scepticism that many people had about the efficacy of the medicines and products offered by these systems. The spurt in exports of AYUSH products in the recent months is a direct reflection of their growing popularity in many countries.

The standardisation of the HS codes related to export will be considered on priority as a step to promote exports. He called upon the AYUSH Ministry to work in coordination with the Commerce and Finance Ministries to achieve this early. The Commerce Minister also advised the industry leaders to work simultaneously on the quality and pricing of their products, so that they become increasingly competitive in the global market.

He supported the concept of an AYUSH Export Promotion Council and said that the Commerce Ministry would be happy to support the same. The continued support of Commerce Ministry would be available to the AYUSH Sector on all matters of trade promotion, and special meetings with the functionaries of the Ministry would be arranged as and when required, to discuss any important issue. Evolving appropriate standards which could win international recognition was another advice from the Commerce Minister.

He also assured that AYUSH will figure appropriately in the "Brand India" activities being presently undertaken. He underlined the need for the industry and the Government to work together in various aspects of branding and promotion. The following are the action points that emerged from the meeting:

(1): Ministry of AYUSH and Ministry of Commerce and Industry will work together for establishing an AYUSH Export Promotion Council (AEPC). The proposed AEPC can be housed at Ministry of AYUSH.

(2): Standardisation of HS code for AYUSH will be expedited.

(3): Ministry of AYUSH will work in collaboration with Bureau of Indian standards to develop international standards for AYUSH products as well as services.

(4): Ministry of AYUSH and AYUSH industry will identify best practices/success stories and promote them amongst the public.

(5): AYUSH industry will work on ensuring quality and standards of AYUSH products as well as to become price-competitive.

(6): AYUSH will figure in the Brand India activities.

Source: PIB, MoC&I and MoA Press Release, 06.12.2020

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CBIC notifies New Exchange Rates w.e.f. 4th December 2020 - reg.

Notification No.110/2020-Customs (N.T.), dated 03rd December, 2020

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.108/2020-Customs(N.T.), dated 19th November, 2020 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, shall, **with effect from 4th December, 2020**, be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods.

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	55.90	53.55
2.	Bahraini Dinar	202.15	189.75
3.	Canadian Dollar	58.15	56.10
4.	Chinese Yuan	11.45	11.10
5.	Danish Kroner	12.25	11.80
6.	EURO	91.10	87.90
7.	Hong Kong Dollar	9.70	9.35
8.	Kuwaiti Dinar	250.50	234.85
9.	New Zealand Dollar	53.50	51.20
10.	Norwegian Kroner	8.55	8.25
11.	Pound Sterling	100.55	97.15
12.	Qatari Riyal	20.95	19.65
13.	Saudi Arabian Riyal	20.30	19.10
14.	Singapore Dollar	56.15	54.25
15.	South African Rand	5.00	4.65
16.	Swedish Kroner	8.90	8.55
17.	Swiss Franc	84.25	80.95
18.	Turkish Lira	9.70	9.10
19.	UAE Dirham	20.75	19.50
20.	US Dollar	74.70	73.00

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
1.	Japanese Yen	72.05	69.35
2.	Korean Won	6.95	6.50

F.No. 468/01/2020-Cus.V

Bullo Mamu, Under Secretary, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

In Lok Sabha & In Rajya Sabha

In Lok Sabha

Sale of Drugs at Higher Price

Lok Sabha Unstarred Question No: 1416

Shrimati Gitaben Vajesingbhai Rathva:

Shri Parbatbhai Savabhai Patel:

Shri Naranbhai Bhikhabhai Kachhadiya:

Shri Jaswantsinh Sumanbhai Bhabhor:

Shri Shantanu Thakur:

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state;

(a): whether the Government has any information regarding Pharma companies which are selling medicines at prices higher than the price fixed by the National Pharmaceutical Pricing Authority (NPPA);

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

(c): whether the NPPA has taken any action or issued notices against such companies; and

(d): if so, the outcome thereof?

Answered on 20th September 2020

A. (a): Yes, Sir. The National Pharmaceutical Pricing Authority (NPPA) monitors the prices of both scheduled and non-scheduled formulations on regular basis to check overcharging by pharmaceutical companies. Whenever companies are found to be overcharging consumer in the sale of medicine, the NPPA issues notices to the companies asking them to deposit the overcharged amount along with applicable interest under provisions of the Drugs (Prices Control) Order (DPCO) read with section 7A of the Essential Commodities Act, 1955.

(b): The NPPA does not maintain state-wise record of overcharging by pharmaceutical companies. However, the detailed list of overcharging cases where demand notices have been issued is available on the NPPA's website **www.nppaindia.nic.in.**

(c): Yes, Sir.

(d): Since inception of the NPPA till March, 2020, NPPA has issued 2086 demand notices to pharmaceutical companies for overcharging consumers on the sale of formulations at prices above the ceiling price notified by NPPA. Demand Notices have been issued for total amount of Rs.6411.28 crore. An amount of Rs.965.81 crore has been recovered from the Pharma Companies. An amount of Rs.4081.93 crore is under litigation. The detailed list of overcharging cases where demand notices have been issued is available on the NPPA's website **www.nppaindia.nic.in.**

Minister in the Ministry of Chemicals and Fertilizers (Shri D V Sadananda Gowda)

Research and Development of New Drugs

Lok Sabha Unstarred Question No:1457

Shri Manoj Kishorbhai Kotak:

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state;

(a): whether the Government has launched any programme or policy for Research and Development of new drugs/vaccines for treatment of newly emerging diseases across the country;

(b): if so, the details thereof;

(c): Whether the Government has constituted any inter-department related Committee for pharmaceuticals Research and Development and if so, the details thereof; and

(d): the details of the steps taken for the benefit of common people of the country?

Answered on 20th September 2020

A. (a) & (b): The Department has set up seven National Institutes of Pharmaceutical Education and Research (NIPERs) at Mohali (Punjab), Ahmedabad (Gujarat), Hajipur (Bihar), Hyderabad (Telangana), Guwahati (Assam), Kolkata (West Bengal) and Raebareli (Uttar Pradesh) to nurture and promote quality and excellence in pharmaceutical education and research in India. These are institutes of national importance, which besides imparting master's and doctorate education, conduct high end research in various specializations of pharmaceuticals.

Further, the Department of Biotechnology is implementing the National Biopharma Mission (NBM) through Biotechnology Research Assistance Council (BIRAC). This PAN-India program is focused on making India a hub for development of novel, affordable and effective vaccines, biotherapeutics and medical devices for combating public health concerns. The Department of Biotechnology is also supporting the implementation of the Ind-CEPI Mission entitled "Epidemic preparedness through rapid vaccine development: Support of Indian vaccine development aligned with the global initiative of the Coalition for Epidemic Preparedness Innovations (CEPI)" which aim to support vaccine development for diseases of epidemic potential in India. The Mission was approved for implementation in March, 2019 for a period of five years and is part of a broader Initiative called the Atal Jai Anusandhan Biotech Mission - Undertaking Nationally Relevant Technology Innovation (UNaTI).

(c) & (d): The Department has set up an Inter- Departmental Committee (IDC) in January, 2019 to periodically review and coordinate research work undertaken by various governmental organization under different Central Ministries/Departments in a collaborative, synchronized and synergized way for optimum utilization of funds and to ensure no overlapping and duplication of efforts and resources occur. Further, the Department has recently set up a High level inter-departmental Committee including eminent industry leaders/experts to frame a Policy on R&D and Innovation including Academia-industry linkage in Pharmaceuticals & Medical Devices.

Further, the National Biopharma Mission (NBM) under the Department of Biotechnology is supporting the development of candidate vaccines for Cholera, Influenza, Dengue, Chikungunya, Pneumococcal disease and COVID-19, for establishing shared facilities for vaccine development, funding of Technology Transfer Offices, supporting the development of TRC for chikungunya and dengue and the establishment of Clinical Trial Networks, Field sites for conducting epidemiology studies and preparing for conduct of population-based vaccine trials, Clinical trial consortium of hospitals across the country for specialities of Oncology, Rheumatology, Ophthalmology and Diabetology, Trainings and workshops are organised for enhancing skill development and capacity building activities.

Minister In the Ministry of Chemicals and Fertilizers (Shri D V Sadananda Gowda)

Setting up of NIPER

Lok Sabha Unstarred Question No. 1566

Dr Vishnu Prasad M K:

Q.Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state;

(a): whether the Government has set up any National Level Institute of Pharmaceutical Education and Research (NIPER) in various States for the establishment of pharmaceutical units and focusing on the pharmaceutical sector;

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

(c): whether the Government has received any proposal for setting up of NIPER in Tamil Nadu and if so, the details thereof; and

(d): the time by which approval is likely to be accorded?

Answered on 20th September 2020

A. (a) & (b): Yes Sir. The Government has established seven National Institutes of Pharmaceutical Education and Research (NIPERs) at Mohali (Punjab), Ahmadabad (Gujarat), Hajipur (Bihar), Hyderabad (Telangana), Guwahati (Assam), Kolkata (West Bengal) and Raebareli (Uttar Pradesh) to nurture and promote quality and excellence in Pharmaceutical Education and Research in India.

(c): A proposal for setting up of NIPER at Madurai, Tamil Nadu was approved in principle by the Central Government. Accordingly, a consolidated proposal seeking funds for the period 2017-18 to 2019-20 for setting up and equipping the existing NIPERs and four newly proposed NIPERs at Madurai (Tamil Nadu) and in the states of Chhattisgarh, Rajasthan and Maharashtra was placed for consideration of the Expenditure Finance Committee (EFC) in the Ministry of Finance on 26.03.2018. While the EFC approved continuation of the existing NIPERs, but it recommended for deferment of setting up of the proposed four new NIPERs at Tamil Nadu, Maharashtra, Rajasthan and Chhattisgarh.

(d): The consolidated EFC proposal for the period 2020-21 to 2024-25 was again sent to the Ministry of Finance in June, 2020 for strengthening and equipping the existing NIPERs and setting up of new NIPERs in the states of Tamil Nadu, Maharashtra,

Chhattisgarh, Rajasthan and Karnataka. However, the Ministry of Finance has returned back the proposal referring to their general guidelines which prescribe that the continuing schemes be appraised after 15th Finance Commission's recommendations are accepted and resource position of public exchequer is clear.

Minister In the Ministry of Chemicals and Fertilizers (Shri D V Sadananda Gowda)

Life Saving Drugs

Lok Sabha Unstarred Question No:1585

Shri Chandra Prakash Joshi:

Shri Sangamlal Kadedin Gupta:

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state;

(a): the numbers of life saving drugs whose prices have been decreased recently by the Government;

(b): the details of the decrease in prices in terms of percentage;

(c): whether the Government proposes to decrease the prices of more life saving drugs in the near future;

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

(e): the current status of the availability of generic medicines in the country?

Answered on 20th September 2020

A. (a) & (b): "Life Saving drugs" are not defined in the Drugs (Prices Control) Order, 2013 (DPCO, 2013). The National Pharmaceutical Pricing Authority (NPPA) fixes the ceiling prices of scheduled formulations as adopted from National List of Essential Medicines (NLEM) and included as Schedule - I of the DPCO, 2013.

The details of medicines under price control are as below:

(i): The NPPA has fixed the ceiling prices of 530 scheduled formulations under NLEM, 2011. The details of reduction in prices of scheduled formulations effected under the DPCO, 2013 as compared to the highest price prevailed prior to the price fixation is as below:

% reduction with respect to Maximum Price	No. of drugs
0<= 5%	80
5<=10%	50
10<=15%	57
15<=20%	43
20<=25%	65
25<=30%	49
30<=35%	26
35<=40%	34
Above 40%	126
	530

(ii): Further, Schedule - I of the DPCO, 2013 was amended by adopting NLEM, 2015. The NPPA has notified the ceiling prices of 871 scheduled formulations under NLEM, 2015 including ceiling price of 5 medicines fixed recently in March, 2020. The details of reduction in prices of scheduled formulations effected under the DPCO, 2013 as compared to the highest price prevailed prior to the price fixation is as below:

% reduction with respect to Maximum Price	No. of formulations
0<= 5%*	241
5<=10%	138
10<=15%	99
15<=20%	100
20<=25%	92
25<=30%	69
30<=35%	46
35<=40%	26
Above 40%	60
Total formulations in NLEM, 2015	871

(iii): The NPPA has also fixed the retail price of 1373 new drugs under the DPCO, 2013 till date.

(iv): The NPPA fixed prices of 106 Anti-diabetic and Cardiovascular drugs under Para 19 of the DPCO, 2013 in public interest.

(v): The NPPA has fixed ceiling price of Cardiac Stents being scheduled formulation under the DPCO, 2013 resulting in price reduction for Coronary Stents which worked out up to 85% for Bare Metal Stents and 74% for Drug Eluting Stents.

(vi): The NPPA has fixed ceiling price of Orthopaedic Knee Implants under Para 19 of the DPCO, 2013 in Public interest resulting in price reduction for Orthopaedic Knee Implants which worked out up to 69%.

(vii): The NPPA capped the Trade Margin of non-scheduled formulations of 42 Anti-cancer medicines under "Trade Margin Rationalization" approach as a Pilot for proof of concept, wherein

price of more than 500 brands of medicines were reduced up to 90%.

(c) & (d): The fixation of the ceiling prices by the NPPA is an on-going process. As and when the formulations are included in the National List of Essential Medicines (NLEM), their prices are fixed by the NPPA.

(e): The NPPA played a crucial role in ensuring the availability of essential drugs generic or branded at reasonable prices before and during the COVID-19 pandemic. Timely and effective steps were taken to ensure availability of drugs during the lockdown period throughout the country. Shortages of drugs reported were resolved in coordination with the State Drug Controllers, ensuring availability of medicines across the country. The office of Drug Controller General of India (DCGI) is also monitoring the availability of critical drugs.

Further, with an objective of making quality generic medicines available at affordable prices to all, the Department of Pharmaceuticals has launched Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP). Under this scheme, dedicated outlets known as Pradhan Mantri Bhartiya Janaushadhi Kendras (PMBJKs) are opened to provide generic medicines at cheaper price to the citizens. The product basket of PMBJP comprises 1250 medicines and 204 surgicals and consumables covering all 37 major therapeutic groups such as Anti-infectives, Anti-allergic, Anti-diabetics, Cardiovascular, Anti-cancers, Gastrointestinal medicines, Neutraceuticals, etc. Presently, 825 medicines and 122 surgical and consumables are available for sale at PMBJKs.

Minister in the Ministry of Chemicals and Fertilizers (Shri D V Sadananda Gowda)

In Rajya Sabha

Shifting of base to India by MNCs

Rajya Sabha Question No.704

Shri Sanjay Raut:

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

(a): whether it is a fact that a number of multinational companies of United States and other foreign companies have decided to shift their base from China to India during the last one year;

(b): if so, the details thereof and how much foreign investment has been received, so far, in the country, State-wise;

(c): how much new employment will be generated from such multinational companies in the country; and

(d): the details of steps taken or proposed to be taken by Government for bringing more manufacturing industry in the country to boost economy?

Answered on 18th September 2020

A. (a) to (c): Several multinational companies have evinced their interest to shift their base into India across different States in sectors such as Electronics, Retail, e-Commerce, Automotive, Food Processing, Textiles etc. However, due to sensitivity of information maintained by the companies, the reasons for relocation of operations are not explicitly spelt out. It has been seen that FDI inflows usually helps in augmenting domestic capital and promote employment opportunities across sectors. The FDI inflow from USA and other countries in the year 2019-20 had been USD 74.39 billion and for (April–July), 2020-21 (P) has been USD 16.26 billion.

(d): With a view to support and facilitate investments into India, the Government is working hard to institutionalize more investor friendly reforms. The Government has constituted an Empowered Group of Secretaries (EGoS) to provide support and facilitation to investors for investing in India and to boost growth in key sectors of the economy. EGoS shall identify potential investors/organizations, make recommendations to the Ministry/Department to promote investment, facilitate handholding of investors, examine and suggest ways to attract more investment in Greenfield projects. Project Development Cells (PDCs) are being set up in Ministries/Departments to fast track investments with coordination between Central Government Ministries and State Governments and thereby grow the pipeline of investment projects in India. The entire focus of the Government is to create an investment-friendly and business conducive ecosystem to drive investment growth in India. Several steps like Production Investment Schemes, GIS mapping of available land banks, issuance of Quality Control Orders to cut down cheap imports and many such measures have been put into place to attract further investment into the country.

Answer the Minister of Commerce & Industry (Shri Piyush Goyal)

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Moving away from China for APIs cannot happen overnight

India to move away from China for pharmaceutical supplies will not happen overnight. It will take some time. At the end of the day, all of us will have some dependency on China or any other country for some raw materials and products. However, we can see some shift in the supply chains moving to India in the next 5-10 years, said *Priyanka Chigurupati,* Executive Director, Granules India, in an email to *Nandita Vijay.*

Excerpts:

Do you envisage in the long-term Indian Pharma to counter the China capability with the Government announcing Productivity Linked Initiative (PLI) scheme and *Atmanirbhar?*

For India to compete or reduce its dependency on China, Pharma companies with expertise in process efficiencies are the backbone. This, accompanied by scale should be the focus to achieve economics-of-scale. Chinese API companies have an inherent advantage because the support from the Government in the form of financial incentives, infrastructure and regulatory policies. While the Government of India has been proactive with its PLI and Atmanirbhar, a few tweaks would be helpful.

It is appreciable that the Government has made some effort towards providing incentives for the API sector to become self-reliant. It is also listening to industry opinions and introducing new policies.

How enabling are Bulk Drug parks to speed up manufacture in Telangana and how does the company plan to capitalize such parks to its advantage?

The new bulk drug parks scheme to be established at various locations across the country and PLI scheme to promote domestic manufacturing of critical APIs/KSMs/ drug intermediates is a welcome move. Some of the key considerations for companies to consider setting up units in bulk drug park which would enable manufacturing of APIs to be done on a large scale would be the land cost which is generally expensive, common effluent discharge/ treatment facility, availability of utilities like power and piped steam, speedy approvals from various regulatory stakeholders and various other incentives provided by the Central and State Governments.

In terms of regulations, we want you to elaborate on where does India need to strengthen for approval of APIs and formulations? What more support is envisaged in further improving the regulatory environment to facilitate speedy approvals? When would India be as good as international regulatory offices of US FDA and UK MHRA or EMA?

India has strong regulatory systems, but the adherence and enforcement of those regulations should be done in order to strengthen the approval for APIs and formulations. The manpower also has to be beefed up at DCGI and skill enhancement of the reviewers should be carried out to be on par with the reviewers of the US FDA. More importantly, adherence to timelines is very important. Streamlining the filing process and increasing the transparency would help in obtaining speedy product approvals.

What are your views on the need for Pharmaceuticals to be disassociated from the Ministry of Chemicals and Fertilizers and become a standalone Ministry? Please elaborate what are the advantages and disadvantages?

The multiple regulatory mechanism very often slows down the growth of these sectors. The Government has taken cognizance of the issue from the fact that it created a separate Department of Pharmaceuticals (DoP) in July 2008 for regulating all the issues, including pricing, of these two sectors. The creation of DoP was the first step in the right direction, but a dedicated Ministry for Pharmaceuticals and Medical Devices would be the last answer to several issues confronting these sectors.

Currently, regulatory issues of these sectors are decided by different Ministries and Agencies. While all the administrative and pricing related policies of these sectors are decided by the Ministry of Chemicals and Fertilizers, all the issues related to quality of the drugs produced and

marketed in the country are decided by the Union Health Ministry. Policies related to investment and IPR as well as that of exports are decided by the Ministry of Commerce and Industry.

In the area of pricing, would you agree that India needs an accommodative Pricing Policy which is now dominated by DPCO 2013, NLEM as API costs shoot up?

As API prices surge, the Pharma industry is requesting the Government to bring in some time-bound amendments in the DPCO 2013. To prevent the shortage of essential medicines in the domestic market, various industry bodies have requested the DoP to consider the recommendations about relaxing the provision of para 13 (2) of the DPCO 2013. So, all those manufacturers who are selling essential medicines below the ceiling prices can also follow the ceiling price and not have to discontinue the product.

For any product, when the price of the API used in it rises, the cost increases while the profit margin decreases. As per DPCO 2013, a limited increase in the MRP is permitted on an annual basis. If this increase of MRP does not absorb the increased cost of the API, the manufacturer suffers. The Government must develop a mechanism to ensure that the profit margins, which are already low, are not further eroded. This is even more relevant in the case of low-value products where the unit price is below Rs.4. The profits margin is in paisa and that gets further eroded. This justifies the demand of the industry to remove drugs with low unit price, out of price control.

In its representation to the DoP, various associations have also suggested that a provision of price fixation of the new drug is added to clause 6 of Para 15 of DPCO 2013. As per the Para 15 (2) of DPCO 2013, every manufacturer of the new drug needs to file for price approval application in Form 1. And, Para 15 (6) prohibits from selling any new drug at a price higher than price already fixed by the Government.

In the short-term, dependence on China for APIs has been a concern for industry and the ongoing COVID-19 is also seen to impact its supply. In such a scenario how is Granules India looking at Indian market opportunity?

Granules India has transformed from an API manufacturer to formulations/finished dosage manufacturer and is vertically backward integrated in its APIs for most of the core molecules/high volume products it manufactures. Most of the APIs we manufactured is for our captive consumption before being sold in the open market. We do depend on China for some KSMs and other intermediates. We cannot reduce our dependency overnight. We are working on a few differentiated technologies for a limited number of products to potentially backward integrate into in the medium-term. For the short-term, we have qualified alternate sources for our major products and are in discussions with other partners for a few of the remaining products.

Source: Pharmabiz, 03.12.2020

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BOOK REVIEW

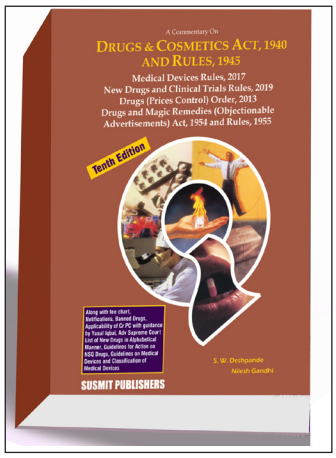
10th edition of Commentary on Drugs and Cosmetics Act, 1940 released

Authored by:

Shri S W Deshpande, Former Joint Commissioner, FDA, Maharashtra

and

Shri Nilesh Gandhi, Former Assistant Commissioner, FDA, Maharashtra



M/s Susmit Publishers, Mumbai have recently published 10th edition of Commentary on Drugs and Cosmetics Act, 1940 and Rules, 1945 together with Medical Devices Rules, 2017, New Drugs and Clinical Trials Rules, 2019, Drugs (Prices Control) Order, 2013, Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 authored by Shri S W Deshpande, Former Joint Commissioner, FDA, Maharashtra, Shri Nilesh Gandhi, Former Assistant Commissioner, FDA, Maharashtra.

The 10th edition is updated and includes all amendments to Drugs and Cosmetics Rules, Drugs (Prices Control) Order, 2013 and Medical Devices Rules, 2017. The unique feature of 10th edition is explanation of each Section with the help of legislative background, High Court and Supreme Court decisions. Unlike other commentaries, instead of only giving citation, this book includes facts, rival contentions, observations of the Court and final decision of the Court so as to enable the readers to understand the judgement and its impact on interpretation.

The authors have drawn on their rich experience in regulatory agency and as consultants and have accordingly designed the Commentary and have also included useful information such as chart of fees, Central Government's directions under section 33P for taking action on not of standard quality drugs, list of New drug, classification of Medical Devices, important notification etc.

The book will be useful to the professionals in industry, regulatory officers, distribution network and academicians. The 10th edition contains 1738 pages and is priced at Rs.3000/-.

For further enquiries please contact: SUSMIT PUBLISHERS, 022-26403277/09969272923 or Email: susmitpublishers@gmail.com

Source: Email from Mr Sudhir Deshpande, 07.12.2020

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Study finds metformin reduced COVID-19 death risks in women

University of Minnesota Medical School and United Health Group researchers found that metformin was associated with significantly reduced COVID-19 death risks in women in one of the world's largest observational studies of COVID-19 patients. Metformin is an established, generic medication for managing blood sugar levels in patients with type 2 diabetes. It also reduces inflammation proteins like TNF-alpha that appear to make COVID-19 worse.

The study, published in The Lancet Healthy Longevity, is a retrospective cohort analysis based on de-identified patient data from United Health Group. The team analyzed about 6,000 individuals with type 2 diabetes or obesity who were hospitalized with COVID-19 and assessed whether or not metformin use was associated with decreased mortality. They found an association that women with diabetes or obesity, who were hospitalized for COVID-19 disease and who had filled a 90-day metformin prescription before hospitalization, had a 21% to 24% reduced likelihood of mortality compared to similar women not taking the medication. There was no significant reduction in mortality among men.

"Observational studies like this cannot be conclusive, but contribute to growing bodies of evidence. Seeing a bigger association with protection in women over men may point towards inflammation reduction as a key way that metformin reduces risk from COVID-19. However, more research is needed," said Principal Investigator Carolyn Bramante, MD, MPH, who is an Assistant Professor in the Department of Medicine at the University of Minnesota Medical School. "A large database covering different geographic areas is rarely available. We were fortunate to have the opportunity to do this research alongside United Health Group."

"While effective therapies to mitigate the harm of the SARS-CoV-2 virus are being developed, it is important that we also look to, and evaluate commonly used medications with good safety profiles for their potential to combat the virus," said Deneen Vojta, MD, Executive Vice President, Enterprise Research and Development, United Health Group.

The results provide new directions for research against COVID-19. In collaboration with Christopher Tignanelli, MD, Assistant Professor in the Department of Surgery at the University of Minnesota Medical School, Bramante submitted an investigational new drug application to the Food and Drug Administration for use of metformin for COVID-19 treatment and prevention.

The FDA approved this application. Bramante and Tignanelli received a donation from the Parsemus Foundation to conduct a multi-site prospective, randomized pilot study in collaboration with the Executive Director of Clinical Research for United Health Group R&D, Ken Cohen, MD. This pilot trial will begin enrolling the week of December 8 and will lead into a larger trial that is fully powered for important clinical outcomes if additional funding becomes available. These collaborators are still seeking this funding.

Source: University of Minnesota Medical School, EurekAlert, 03.12.2020 (Excerpts)

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3 COVID-19 vaccine candidates under active consideration of drug regulator: Health Ministry

Three COVID-19 vaccines candidates, developed by Bharat Biotech, Serum Institute of India and Pzer, are under active consideration of India's drug regulator and there is hope that early licensure is possible for all or any of them, the Union Health Ministry said on Tuesday, (08.12.2020). Over the last four days, the Indian arm of US pharmaceutical giant Pzer, Pune based Serum Institute of India and Hyderabad-based pharmaceutical firm Bharat Biotech have applied to the Drugs Controller General of India (DCGI) seeking emergency use authorisation for their potential COVID-19 vaccines.

At a press briefing, NITI Aayog member (Health) V K Paul said the COVID-19 situation in India has stabilised with active cases showing a "clear-cut declining trend" even though the pandemic situation in many other countries is becoming quite serious. The concern and anxiety that arose following an increase in daily cases of infection in Delhi has also settled now, he said. Asked what

steps would be followed by the DCGI in the absence of a water-tight emergency use authorisation law for granting licence to vaccine makers, Union Health Secretary Rajesh Bhushan said not all countries' regulatory framework or rules and acts mention emergency Use authorisation. "So, the fact that this phrase is not used in the national regulatory framework of any country does not mean that specic country does not have an enabling provision to accord an approval which is early and which is distinct from a regular market approval.

COVID vaccines in India: 6 candidates in different trial stages, 3 may get licensed in 'next few weeks'

"India's regulatory framework has a specic provision for grant of emergency use authorisation. Although this phrase is not used," he said. The New Drugs and Clinical Trials Rules, 2019, clearly species that under specic special situations, relaxation, abbreviation, omission, or deferment of data including local Clinical Trial data may be considered for approval. "This is our law. Similarly other countries also have their legislations," Bhushan said.

Giving a bird's-eye view of the Indian landscape of COVID-19 vaccines, Bhushan mentioned that eight vaccines are at different stages of development. One is Covishield, which is being manufactured by Serum Institute of India in collaboration with AstraZeneca. Phase two and three Clinical Trials of this vaccine is underway and the firm has applied form emergency use authorisation.

Another is Covaxin, which is being indigenously developed by Bharat Biotech in collaboration with Indian Council of Medical Research (ICMR) and is presently in phase three of Clinical Trials. It has also applied to the DCGI seeking emergency use authorisation. The third one is ZyCOV-D, being developed by Cadila Healthcare Ltd in Ahmedabad in collaboration with Central Government's Department of Biotechnology and is in phase two of the trials. The fourth vaccine candidate is Sputnik V which is being manufactured by Dr Reddy's Lab, Hyderabad, in collaboration with Russia's Gamaleya National Centre and according to their mutual agreement.

The phase two trial in India is over and phase three will begin next week. The fifth one is NVX-CoV2373, which is being developed by Serum Institute of India in collaboration with Novavax and its phase three Clinical Trial is under consideration with the drug regulator. The sixth vaccine candidate is Recombinant Protein Antigen based vaccine, to be manufactured by Biological E Ltd, Hyderabad, in collaboration with MIT, USA. Its pre-clinical animal studies have concluded and phase one and two human Clinical Trials have started.

Another one is HGCO 19 being manufactured by Genova in Pune in collaboration with HDT, USA. Its pre-clinical animal studies are over and phase one and two Clinical Trials is set to start. The eighth vaccine is being developed by Bharat Biotech International Ltd in collaboration with Thomas Jeerson University, USA and it is at the pre-clinical stages. "Another vaccine, which is in initial stages, is the one being developed by Aurbindo Pharma. So there are a total of nine vaccines out of which six are in Clinical Trials and three are in pre-clinical stage," Bhushan said.

"There are multiple vaccine candidates in different stages of development and some may get licensed in the next few weeks. But we cannot foretell at this moment because licensure or market authorization is the domain of the national regulator." Most of the vaccines are of two or three doses to be administered three to four weeks apart. Significant to note that even after vaccination, COVID precautions must be taken and this has been advised by WHO also, Bhushan said, adding, "Vaccination does not mean people become carefree." About cold chain infrastructure augmentation, the Health Secretary said presently the system consists of 85,634 equipment for storage of vaccine at about 28,947 cold chain points across the country.

"Data on frontline healthcare workers being is uploaded on Co-WIN software in preparation of COVID-19 vaccination. The current cold chain is capable of storing the first lot of three crore COVID-19 vaccines for healthcare, frontline workers," he said. He told the press conference that while 2.38 lakh Auxiliary Nurse Midwives (ANMs) provide vaccination under universal

immunisation programme, only 1.54 lakh such health workers will be used for COVID-19 inoculation. "National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) has recommended that around one crore health workers should be given priority in the vaccination drive," Bhushan added

Source: The Economic Times, 09.12.2020

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CSIR to decide on human Clinical Trials of Molnupiravir — a drug that blocks SARS-CoV-2 in 24 hours

By taking the drug orally, treatment can be initiated early for preventing the condition of the patient from becoming severe

A decision on conducting human Clinical Trials with a new promising antiviral drug, Molnupiravir, taken at the strategic group meeting of the Council of Scientific and Industrial Research (CSIR) on Monday (07.12.2020) evening. A study published in Nature Microbiology, shows how this repurposed drug suppresses SARS-CoV2 transmission within 24 hours.

Dr Shekhar Mande, Director General CSIR told The Indian Express that this is an exciting development. "Researchers in the US have shown how the transmission is blocked in ferrets. It is like any other anti-flu drug and was on our list of drugs to go into Clinical Trials. We will take it up soon. A meeting will be held to decide," Dr Mande said.

The study, published by researchers at the Institute for Biomedical Sciences, Georgia State University, claims that a new antiviral drug has been designed which successfully suppresses the SARS-CoV-2 virus and inhibits transmission within 24 hours. According to the researchers, this is the first oral antiviral drug to quickly block SARS-CoV 2. Molnupiravir is being developed by the Biotechnology firm Ridgeback Biotherapeutics in collaboration with Pharmaceutical firm Merck. By taking the drug orally, treatment can be initiated early for preventing the condition of the patient from becoming severe.

Dr Mande explained that the drug is basically an inhibitor of RNA in cells and does not allow it to make copies of the virus. "Other drugs also do something similar but it is exciting to see that transmission being blocked in ferrets."

There is a basket of drugs which are under consideration. There are several on the priority list — for instance, the drug umifenovir which is mainly used for treatment of influenza has potential to be used against Covid-19 and is undergoing Clinical Trials, Dr Mande said.

Source: Anuradha Mascarenhas, The Indian Express, 08.12.2020

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Pfizer seeks emergency approval for Covid vaccine in India

Pfizer Inc has applied for emergency use authorisation of its Coronavirus Vaccine in India, reports said on Sunday, 06.12.2020. With this, Pfizer India has become the first pharmaceutical firm to seek from the Drugs Controller General of India (DCGI) an emergency use authorisation for its vaccine in the country, after its parent company secured such clearance in the UK and Bahrain. The firm, in its application submitted to the drug regulator, has sought permission to import the vaccine for sale and distribution in the country, besides waiver of ClinicalTtrials on Indian population in accordance with the special provisions under the New Drugs and Clinical Trials Rules, 2019, official sources said.

According to Emergency Use Authorisation (EUA) for its COVID-19 vaccine in India. The firm has submitted the EUA application in Form CT-18 for grant of permission to import and market Pfizer-BioNTech's COVID-19 mRNA vaccine BNT162b2 in the country. The UK recently became the first country to approve the Pfizer/BioNTech vaccine against COVID-19, with the UK regulator Medicines and Healthcare products Regulatory Agency (MHRA) granting a temporary authorisation for its emergency use. The British regulator said the jab, which claims to offer up to 95% protection against COVID-19, is safe for roll-out.

Bahrain also announced that it has granted an EUA for the two-dose vaccine made by Pfizer and its German partner BioNTech. The Pharma company has already applied to the US FDA seeking EUA for the vaccine. Pfizer told it remains committed to engaging with the Government of India and explore opportunities to make this vaccine available for use in the country. "During this pandemic phase, Pfizer will supply this vaccine only through Government contracts based on agreements with respective Government authorities and following regulatory authorisation or approval," the Global Pharma major said in a statement.

Five vaccines are in advanced phases of Clinical Trials in India with the Serum Institute of India conducting phase-3 trial of the Oxford-Astrazeneca COVID-19 vaccine, while the indigenously developed vaccine by Bharat Biotech in collaboration with ICMR has already started the phase-3 Clinical Trial.

Drug firm Zydus Cadila has received the approval from the DCGI to start the phase-3 Clinical Trials of the indigenously-developed Anti-Coronavirus vaccine Dr Reddy's Laboratories and the Russian Direct Investment Fund (RDIF) have announced that they commenced adaptive phase 2 and 3 Clinical Trials for COVID-19 vaccine Sputnik V in India, Also, Biological E Ltd has started early phase 1 and 2 human trials of its COVID-19 vaccine candidate. *(with inputs from agencies).*

Source: Wion Web Team, 07.12.2020

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Aurobindo Pharma expects to commercialise vaccine facility by April-May

- *The Hyderabad-based drug major is investing around ₹275 crore on the facility which would be utilised to produce vaccines.*
- *Aurobindo Pharma is also planning to collaborate with other companies who may be successful in developing the COVID-19 medication sooner than it.*

Aurobindo Pharma expects to commercialise its vaccine manufacturing facility in Hyderabad by April-May next year, according to a top company official. The Hyderabad-based drug major is investing around ₹275 crore on the facility which would be utilised to produce vaccines for the treatment of various viral diseases including COVID-19.

Besides developing its own vaccine for the infectious disease and also separately tying up with CSIR for development of a vaccine, Aurobindo Pharma is planning to collaborate with other companies who may be successful in developing the medication sooner than it.

"We have taken a three-pronged approach. One in terms of our own vaccine, one in terms of tie-up with CSIR Labs, which in fact, there are three different products on three different platforms by three institutes," Aurobindo Pharma Managing Director N Govindarajan said in an analyst call.

Besides, the company is exploring collaboration with the potential partners who will be getting ready with the product sooner than its product or even CSIR's product, he added. So, this is the three-pronged strategy, Govindarajan noted.

Elaborating further he said: "Our product is slightly delayed. But having said that, CSIR's products are progressing well, and our manufacturing facility, we are still targeting to complete it by March-April timeline and start the qualification by April. We can start commercialising it by the April-May timeline, which is the plan."

The Hyderabad-based facility would have a capacity to produce around 450 million vaccine doses, Govindarajan said. "The objective was that we would be able to utilise a facility along with our partner whoever is getting ready earlier than whatever efforts we are investing on. So that is the reason we went ahead and created the capacity," he noted. He added that the company is going to undertake a multi-pronged approach when it comes to tying up with partners going ahead. "We shall be doing the manufacturing, taking the bulk from them and over a period we can even do the bulk and then do the finished dosage and we will also be taking certain markets for distribution as well," Govindarajan said.

Aurobindo Pharma is developing the vaccine for SARS-COV-2 (COVID-19) through its wholly-owned US subsidiary Auro Vaccines, he added. The SARS-COV-2 vaccine candidate is based on the company's proprietary replication-competent, attenuated, recombinant vesicular stomatitis (VSV, VesiculoVax) vaccine delivery platform. Replying to a separate query on capex, Govindarajan said: "On the capital allocation front, we have been mentioning this in the past as well that we will not be looking at any large ticket acquisition for the next couple of years. Our current year capex should be around USD 180 million to USD 200 million."

Last month, the company inked a pact to divest Natrol, a wholly-owned unit of its US-based subsidiary, to private equity firm New Mountain Capital for USD 550 million (around ₹4,048 crore). Aurobindo Pharma had acquired Natrol in December 2014.

(This story has been published from a wire agency feed without modifications to the text. Only the headline has been changed).

Source: PTI, Mint-E-Paper, 29.11.2020 (Excerpts)

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Government receives 215 applications for bulk drug PLI and 28 for Medical devices

In a bid to encourage manufacturing of bulk drugs and medical devices in the country, the Narendra Modi Government on Tuesday (01.12.2020) has received "a very positive response" for the two Production Linked Incentive Scheme.

Confirming CNBC-TV18's newsbreak, Department of Pharmaceuticals in a press statement during the day said, "PLI scheme for bulk drugs and PLI scheme for medical devices have shown a very positive response from the pharmaceutical as well as the medical device industry." "The industry has shown a very good response to these schemes whereby 215 applications made by 83 pharmaceutical manufacturers have been received under the PLI scheme for bulk drugs.

Similarly, 28 applications made by 23 medical device manufacturers have been received under the PLI scheme for medical devices. The closing date of applications was 30.11.2020. IFCI Ltd is the Project Management Agency (PMA) for implementation of both the schemes."

Government sources privy to the developments told CNBC-TV18, "Some of the key manufacturers who have submitted their applications includes Alembic Pharmaceuticals Ltd, Aurobindo Pharma Ltd, Bajaj Healthcare Ltd, Brooks Laboratories Pvt Ltd, Cadila Pharmaceuticals Ltd, Dr Reddy's Laboratories Ltd, Lupin Ltd, IPCA Laboratories Ltd, Sun Pharmaceutical Industries Ltd, Surya Life Sciences Ltd and Vinati Organics Ltd."

Similarly, for the PLI scheme for manufacturing of medical devices has excited 23 companies with a total of 28 applications, Government confirmed. "The key applicants under medical device PLI scheme are Wipro, GE Healthcare Pvt Ltd, Siemens Healthcare Pvt Ltd, Helix Pvt Ltd, Skanray Technologies Pvt Ltd, NIPRO India Corporation Pvt Ltd etc.," Government sources told.

When it comes to the future process, well as stated by the Government, only 136 applications out of the 215, received for bulk drugs and APIs will be given the PLI benefits and 28 applications will be shortlisted for the PLI benefits under medical devices. "Since in case of medical devices only 28 applications have come in, it is not necessary that all 28 applications received will get the clearance," Government sources said.

The final scrutiny as per the process is that the appraisal of applications under PLI schemes begins shortly. IFCI Ltd is the Project Management Agency which will do the appraisal of the applications and the scrutiny and the final approvals for PLI benefits will be given by Empowered Committee chaired by CEO Niti Aayog.

The final approvals for bulk drug and API PLI scheme will be given in 90 days by the Government and for the medical devices PLI, will be given in 60 days. Looking at the increasing imperative of drug security, support to domestic production capability in bulk drugs would ensure higher resilience of the Indian Pharmaceutical industry to external shocks. The PLI scheme for medical devices will help meet the objective of product diversification and production of innovative and high value medical devices in India.

These initiatives have the potential to contribute significantly to achieving higher objective of affordable healthcare in the country and globally on a sustained basis. The PLI schemes for bulk drugs and for Government on March 20, 2020. The initial Guidelines for implementation of both the schemes which were initially issued on July 27, 2020 were amended based on the feedback received from the industry. These revised Guidelines were issued on October 29, 2020. Both the schemes have shown a very encouraging response from the Pharmaceutical as well as the medical device industry, Government said. To watch out for is who all make it for the final stage availing the PLI benefits announced by the Government.

Source: Timsy Jaipuria, cnbctv18.com, 02.12.2020 (Excerpts)

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India stockpiles syringes for COVID-19 immunisation

As India is gearing up to immunise over 30 crore Indians by July with vaccines, efforts are on to stockpile syringes required for the mass immunisation plans. Hindustan Syringes & Medical Devices Ltd (HMD), one of the largest

manufacturers of disposable syringes in the world, is readying to supply 177.6 million Auto Disabled (AD) syringes to the Indian

Government by March 2021, said Rajiv Nath, Managing Director of the firm.

"The front runner COVID-19 vaccines being launched in India would need a 0.5ml AD syringe for intramuscular drug delivery, we are informed. In addition to the annual procurement of 300-350 million of these syringes by the Indian Government for the UIP (Universal Immunisation Program), additional orders have been placed on us by the Ministry of Health and Family Welfare (MoH&FW)," he said.

The estimated demand in India would be around 900 million of different kinds of syringes for just one shot of vaccine, considering 60-70 percent of the country is going to be vaccinated. The number would amplify to 1.8 billion if the vaccine India chooses needs two shots. The MoH&FW is also in discussion with two more suppliers to place additional orders or are seeking to prepone deliveries of already placed orders with them.

"We have requested the Government to provide us clarity on various kinds of syringes required for the vaccine candidates under development as some of these would be by intra dermal delivery (via skin) or intra nasal delivery (via nose) or possibly oral delivery (via mouth). Each type would require a matching specialized syringe type. We need early intimation for boosting the capacities further.

Syringe production is not like production of PPE kits which can be easily ramped up. It requires precision engineered multi cavity molds, equipment and automation that have a lead time of nine months to a year from reputed suppliers in Europe & Japan," said Nath. Last year, India had exported nearly 1.07 billion syringes worth over Rs.250 crore, but imported Rs.423 crore worth of syringes. Currently over 50 percent of the AD syringes used in immunisation come in from China.

The Government should increase import duty on syringes from 7.5 percent to 15 percent to enable expansion of supply base and profitable growth of quality certified production of all components and products in India, he said.

He said HMD has also shipped over 100 million pieces of Auto Disable syringes to, an alliance of over 180 countries under the World Health Organisaton (WHO), and to fight the pandemic and ensure global equitable access to COVID-19 vaccines. The Covax facility has ordered 140 million AD syringes from HMD to be supplied between August and December 2020. The WHO and UNICEF have recommended that auto-disable syringes should be used for administering vaccines-particularly in mass immunisation programs.

In anticipation of the unprecedented spike in demand, HMD has ordered multi-cavity molds, high speed assembly and packaging lines and expects to achieve 800 million capacity per annum in the first quarter and 1,000 million by end of second quarter of 2021, up from the current capacity of 700 million of these specialised 0.5 ml AD syringes, said Nath. "We plan to allocate 50 percent of the total 0.5 ML AD syringes produced for the Government and 50 percent for export to UNICEF as we have got a global responsibility too," he added.

Source: P B Jayakumar, Business Today, 02.12.2020

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Government rolls out 'Mission COVID Suraksha' to help bolster vaccine Development

Earlier this month, the Government had announced a package of Rs.900 crore for vaccines

The Government has launched 'Mission Covid Suraksha' to help accelerate the development of approximately 5-6 vaccine candidates and ensure that these are brought closer to licensure and introduction in the market, the Department of Biotechnology said. The mission envisages vaccine development with end-to-end focus from preclinical through clinical development and manufacturing and regulatory facilitation, the DBT said. Earlier this month, the Government had announced a package of Rs.900 crore for vaccines. "Government of India (GoI) announced the third stimulus package of Rs.900 crore for the Mission Covid Suraksha - the Indian Covid-19 Vaccine Development Mission. This grant will be provided to the Department of Biotechnology (DBT) for Research and Development of Indian Covid-19 vaccines.

"This will help accelerate development of approximately five six vaccine candidates and ensure that these are brought closer to licensure and introduction in the market for consideration of regulatory authorities for introduction in public health systems to combat further spread of Covid infection," the DBT said.

Earlier, the DBT had announced programmes for vaccine development and other solutions, but this mission will be dedicated purely for development of vaccines, a DBT official said.

A total of 10 vaccine candidates have been supported by the DBT so far in both academia and industry. As on date, five vaccine candidates are in human trials, including the Russian Vaccine Sputnik-V, with at least three more in advanced stages of pre-clinical to enter human trials shortly. The important objectives of the fund will be to accelerate preclinical and clinical development, licensure of Covid-19 vaccine candidates that are currently in clinical stages or ready to enter clinical stage of development.

Its aim is to also establish Clinical Trial sites and strengthen the existing immunoassay laboratories, central laboratories and suitable facilities for animal studies, production facilities and other test facilities to support Covid-19 vaccine development, the DBT said. "The other important objective will be supporting development of common harmonised protocols, training, data management systems, regulatory submissions, internal and external quality management systems and accreditations," it added.

Capabilities for process development, cell line development and manufacturing of (Good Manufacturing Practices) batches for animal toxicology studies and Clinical Trials will also be supported under the mission. A key element will be development of a suitable target product profile so that vaccines being introduced through the mission have preferred characteristics applicable for India.

Source: PTI, Business Today, 27.11.2020

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COVID-19: Zydus Cadila gets DCGI nod for Phase-III Clinical Trials

Ahmedabad based Zydus Cadila Pharmaceuticals has announced that the company has received an approval from the Drugs Controller General of India (DCGI) to begin the phase-III Clinical Trials with its biological therapy Pegylated Interferon alpha-2b (PegiHep) in Covid-19 patients.

PegiHep is an approved drug and is being re-purposed for the treatment of Covid-19. According to sources, the trials will be conducted on 250 patients across 25 centres in India during this month. The Ahmedabad-based healthcare major had completed the phase-2 clinical trial last month.

The second phase trials indicated that this biological drug had a beneficial impact on the patient suffering from moderate Covid-19 disease by reducing their viral load. According to sources, a single dose therapy will improve compliance and make it highly affordable for patients.

Apart from this, Zydus has also completed the phase-II human Clinical Trials of its vaccine candidate-ZyCov-D for Covid-19 and its results are currently analysed.

Source: AIR News, 05.12.2020 (Excerpts)

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Centre to revoke Notification to allow export of Oseltamivir phosphate and Zanamivir; to be included in Schedule H1 of D&C Act

The Union Health Ministry may revoke Notification dated February 17, 2017 to allow export of drugs oseltamivir phosphate and zanamivir and these drugs will be included under Schedule H1 of the Drugs and Cosmetics (D&C) Rules, 1945 based on Drugs Technical Advisory Board (DTAB) and Drugs Consultative Committee (DCC) recommendations.

Oseltamivir and Zanamivir, two extensively used clinically effective anti-influenza drugs, are viral sialidase (also known as neuraminidase) inhibitors that prevent the release of progeny virions and thereby limit the spread of infection. Schedule H1 list contains third and fourth generation antibiotics, select habit forming drugs and anti-TB medicines. This special category mandates the chemists to not only sell it against a prescription but preserve details like name and address of the prescriber, name of the patient, name of the drug and the quantity supplied for three years.

The Drugs Controller General of India (DCGI) had earlier issued the Gazette Notification stating that oseltamivir has been removed from the Schedule X list and manufacturers therefore have to take an NOC from the Government. The

pharmaceutical companies that already had the permission to manufacture the drugs had to apply again for the requisite permissions for consistent supply of medicines.

DTAB and DCC were apprised that the Union Health Ministry had published the Gazette Notification vide GSR 144(E) dated February 17, 2017 under the D&C Act, 1940. The Gazette Notification GSR 144(E) inter-alia mandates that: "... no person shall manufacture for sale or distribution or sale or stock or exhibit or offer for sale or distribute any preparation containing the drug "Oseltamivir Phosphate" and "Zanamivir" except in the following manner: "(b) the conditions specified in the D&C Rules, 1945 in respect of the drugs specified under Schedule H1 to that Rules shall apply to the drugs "Oseltamivir Phosphate" and "Zanamivir" or any preparation based thereon.

Provided that the Drugs Controller General India (DCGI) may allow export of the drug "Oseltamivir Phosphate" and "Zanamivir" or any preparation based thereon for reasons to be recorded in writing and in consultation with the Central Government. Thus, permission by the Central Government is required to be given each time for the export of these drugs as per the above Notification. DCC in its 58th meeting held on July 14, 2020 deliberated the matter and recommended revoking the Notification GSR 144(E) dated February 17, 2017 by considering the aspect in the current context.

However, the DTAB also recommended that simultaneously, these drugs should be notified under Schedule H1 of the Drugs and Cosmetics Rules, 1945 for the regulation of their sale in the country. The DTAB after detailed deliberation recommended for revocation of the GSR 144(E) dated February 17, 2017 and inclusion of these drugs in Schedule H1 of the D&C Rules, 1945.

Source: Shardul Nautiyal, Pharmabiz, 03.12.2020

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Health Ministry to amend NDCT Rules-2019 for compassionate use of any new unapproved drug in country

The Union Health Ministry is planning to amend the New Drugs and Clinical Trials (NDCT) Rules, 2019 for compassionate use of any new unapproved drug based on Drugs Technical Advisory Board (DTAB) recommendations. DTAB considered the draft Notification regarding the same dated June 05, 2020 and after detailed deliberation recommended to amend the NDCT Rules, 2019 to include the provisions for compassionate use of unapproved new drugs.

The Central Government, in consultation with the DTAB, had issued a draft Gazette Notification on June 5, 2020, about making an amendment in NDCT Rules, 2019 for compassionate use of any new unapproved drug. It had also invited suggestions, objections on the draft Guidelines from the industry. DTAB was apprised that representation of Cure SMA Foundation of India had been received to frame the Rules and Guidelines for compassionate use of unapproved drugs in India.

In the representation, it was mentioned that the medical treatment of patients with chronic, life-threatening or seriously disabling rare diseases can be very disappointing both for the suffering patients, their families and physicians in cases where patients cannot be treated satisfactorily with currently authorized medicines. Market authorization of new pharmaceuticals in developing countries like India can take several years during which valuable time is lost from the patient's perspective. Further, it was mentioned in the representation that the way to tackle this problem was to allow patients with chronic, life-threatening or seriously disabling rare diseases to obtain the medicines under "compassionate use" for new pharmaceuticals under clinical development for which phase-II/III studies provide an acceptable safety profile in Clinical Trials.

It was also suggested to develop a framework for compassionate use of unapproved new drugs. As per the draft Gazette Notification, it is proposed that in Chapter XI, after rule 96, the following shall be inserted`- "96A: Application for import of unapproved new drug for Compassionate use for the treatment of patients by hospitals or and medical institution, 96B: Grant of Licence for import of new drug for compassionate use, 96C: Conditions of Licence, 96CA: Suspension or cancellation of license to import new drug for the purpose of compassionate use, 96D: Application for the permission to manufacture new drug for Compassionate use, 96E: Grant of the permission to manufacture new drug for Compassionate use, 96F: Condition of permission, 96G: Inspection of manufacturing site of new drug for the purpose of compassionate use, 96H: Suspension or cancellation of permission to manufacture new drug for the purpose of compassionate use and 96I: Licence to manufacture new drug for compassionate use under the Drugs and Cosmetics Rules, 1945".

It will come into force on the date of final publication in the Official Gazette in the NDCT Rules, 2019.

Source: Shardul Nautiyal, Pharmabiz, 04.12.2020

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Brazil joins PIC/S, high time India joins league to bolster its Global Pharma Status

With a developing country like Brazil joining the Pharmaceutical Inspection Co-operation Scheme (PIC/S), it is high time India also be part of the league. This is all the more imperative since India's neighbours like Pakistan, Bangladesh and China are already part of the same. PIC/S is a non-binding, informal cooperative arrangement between regulatory authorities. It is open to any regulatory authority having a comparable GMP inspection system. Currently, PIC/S comprises 53 participating regulatory authorities including Europe, Africa, America, Asia and Australasia. From January 1, 2021, Brazil will be 54th country. Other countries that are currently in the PIC/S application process include Armenia, Bulgaria, and Saudi Arabia.

Last year PIC/S came out with recommendations on how to demonstrate effectiveness of Pharmaceutical Quality System (PQS) in relation to risk based change management. It provided a practical guidance for GMP inspectors when seeking to evaluate the effectiveness of a company's PQS in relation to risk-based change management. Further it conveyed all steps related to management process, proposal, assessment, planning, implementation, review and effectiveness. In the wake of the COVID-19 pandemic, India's tag as the pharmacy of the world will be strengthened joining the PIC/S.

According to Kaushik Desai, Pharma Consultant, India is known to be the Pharmacy of the World. If we have to further grow and compete globally, Indian regulatory authority needs to make a serious move to join PIC/S. This is also a long pending wish list of the pharmaceutical industry. "The revised Schedule M of Drugs & Cosmetics Act is on the lines of WHO GMP Guidelines. Hence, it should not be much of an issue to join PIC/S once implemented and contribute in surpassing export targets," he added.

Speaking to Pharmabiz, Dinesh Dua, Chairman, Pharmexcil, said "Brazil joining PIC/S is a huge development. India is deeply engaged in this exercise as well. Our country wants to become a member of PIC/S because there is a major advantage. Although having said that inspite of the mutual recognition of 50 odd countries, some of these nations still want their own inspections which defeats the very purpose of PIC/S. However, getting a PIC/S approval is a great heads-up and our country needs to definitely go for it." Now India will need a year to come up to the PIC/S benchmark. The DCGI department led by Dr V G Somani is working towards this and is pushing the entire CDSCO to gear up and be in line for the PIC/S assessment, said Dua.

Noting that it is good news for Indian exporters, Dr Viranchi Shah, Sr Vice President, IDMA, said "We have over 650 sites that are EU-GMP certified and almost 600 plus US FDA approved. Both type of sites qualify as PIC/s approved sites. We also have large numbers of sites that are GMP certified from PIC/s nations. Brazil market will now become accessible to all these companies. Of course it also depends on MRA (Mutual Recognition Agreement) between Brazil and other PIC/s nations. According to Jatish N Sheth, Director Srushti Pharma and Member Steering Committee, Karnataka Drugs and Pharmaceutical Manufacturers Association, PIC/S enables mutual recognition. Now PIC/S mandate is to ensure total GMP compliance which Indian Pharma is already adhering to. Now with the new Schedule M coming into the picture, its preparation too was to make India set for PIC/S compliance.

Source: Nandita Vijay, Pharmabiz, 04.12.2020

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Ayush Ministry to develop Nisarg Gram campus in Pune for Naturopathy

The Union Ministry of Ayush has recently announced that the upcoming new campus of the National Institute of Naturopathy (NIN), Pune will be called Nisarg Gram. NIN, Pune, an autonomous body under the Union Ministry of Ayush is the inheritor of a unique Gandhian heritage, having been developed out of a Nature Cure institution of which the Mahatma was one of the founders. The Union Ministry of Ayush is taking all possible efforts to ensure that this campus is empowered to carry forward NIN's unique legacy into the future.

To start with, the new institute's curricula will be prepared in light of National Education Policy, 2020. The curricula will be rationalised to bring about qualitative, pedagogical understanding of naturopathy and allied disciplines at the Under-Graduate (UG) and Post-Graduate (PG) levels. Moreover, bachelors and masters courses in Naturopathy and allied disciplines will be the focal

programmes at Nisarg Gram. NIN is analysing the courses currently offered in Naturopathy in India and abroad with the objective of overhauling the curriculum with inputs from modern scientific advances on the one side, and Gandhian thought relating to health on the other.

The proposed Doctoral programmes in Naturopathy at Nisarg Gram will be the first of its kind and will further strengthen the Naturopathy and Yoga education in the country. With students, teachers and patients all staying in the same campus, the pedagogy will see elements of the Gurukul model being introduced into medical teaching, said the statement. These courses will be in consonance with the current healthcare demands and will conform to modern scientific standards.

The institution will place emphasis on the symbiotic relationship between research and teaching and the need to foster this relationship with respect to Naturopathy, it further added.

Source: Pharmabiz, 05.12.2020

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Centre to amend MDR-2017 to include provision to allow import of medical devices having lesser shelf-life

The Union Health Ministry will soon amend Medical Device Rules (MDR)-2017 to include the provision for allowing the import of medical devices having lesser shelf-life period but before the date of expiry in exceptional cases based on industry representations. Representations were received from the associations with the request to provide relaxation of residual shelf life requirements for medical devices and IVDs citing the reason that medical device industry is facing challenges in getting dispatches from overseas manufacturing sites, getting international cargo transportation and clearing the imported devices at port offices due to COVID-19 pandemic across the globe.

In the due course, the medical devices/In-vitro Diagnostics (IVD) are losing the shelf life and getting below the threshold limits of residual shelf-life. Drugs Technical Advisory Board (DTAB) was apprised of the matter that, as per the provision of Rule 47 of MDR- 2017, the requirement of residual shelf-life on the date of import is as follows: any medical device, whose total shelf life claim is less than 90 days, shall not be allowed to be imported if it has less than 40% residual shelf-life on the date of import; any medical device, whose total shelf life claim is between 90 days and one year, shall not be allowed to be imported if it has less than 50% residual shelf-life on the date of import; any medical device, whose total shelf life claim is more than one year, shall not be allowed to be if it has less than 60% residual shelf-life on the date of import.

In view of the concerns highlighted by the associations, considering the short shelf life of IVD and logistic issues faced by the industry in the supply of medical device and IVD kits/reagents, it was proposed that Rule 47 of Medical Device Rule, 2017 may be amended to include the following provisions. In the Medical Devices Rules, 2017, in Rule 47, after the third provision, the following proviso shall be inserted namely,- "Provided also that in exceptional cases the Central Licensing Authority may, for reasons to be recorded in writing, may allow, the import of any medical device having lesser Shelf-life period, but before the date of expiry as declared on the container of the medical device".

DTAB deliberated the proposal and recommended for the amendment of the MDR-2017 to include the provision for allowing the import of medical devices having lesser shelf-life period but before the date of expiry in exceptional cases.

Source: Shardul Nautiyal, Pharmabiz, 04.12.2020

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IPC to sensitize manufacturers about movement of information between stakeholders about SAEs

In order to foster the habit of reporting Serious Adverse Events (SAEs) related to medical devices, the Indian Pharmacopoeia Commission (IPC) on behalf of the Materiovigilance Programme of India (MvPI) has circulated a notice on programme communication of MvPI to sensitize manufacturers about the movement of information between the key stakeholders. This is also aimed to ensure continuous transfer of data, information and knowledge related to known or unknown, serious and non-serious, frequent or rare Serious Adverse Events.

The notice on programme communication of MvPI also specifies about committees constituted by the Union Health Ministry to give proper direction for efficient functioning of the programme. After several horrific cases of malfunctioning of medical devices, like babies being burnt to death due to short circuits in incubators or hip

implants causing blood poisoning, the Union Health Ministry launched Materiovigilance Programme of India on July 6, 2015 at IPC Ghaziabad in an effort to ensure safety of medical devices.

In addition to protection of Health and Safety of patients, Materiovigilance program reduces the likelihood of recurrence of the harmful incidents elsewhere thereby improving quality of health products. IPC has been keenly working on the development of resource material and reporting tools as the National Coordination Centre (NCC) for MvPI. Other reporting tools and reference documents for manufacturers available on IPC website are an updated Medical Devices Adverse Event Reporting (MDAER) Form (version 1.1), a Field Safety Corrective Action (FSCA) form, a reference manual for medical devices and a handbook for MvPI.

MvPI is administered and monitored by the Steering Committee to supervise and give proper direction to the programme and a working group has been constituted to approve major technical issues related to establishment and implementation of programme and giving technical inputs to Central Drugs Standard Control Organisation (CDSCO) for regulatory intervention of medical devices.

The notice stipulates use the 'Medical Device Adverse Event (MDAE) reporting form' which is available at **www.ipc.gov.in** to report any adverse event. Research Associates from Medical Device Adverse Event Monitoring Centres (MDMCs) after filling the MDAE form would submit it to the National Collaboration Centre (NCC)-MvPI (**mvpi@sctimst.ac.in**). NCC-PvPI helpline 1800-180-3024 (Toll free) also provides assistance in medical device adverse event reporting.

Adverse events related to medical devices can be reported by downloading the MDAE form available at **www.ipc.gov.in** and duly filled scanned form can be sent via e-mail on **mvpi@sctimst.ac.in** and copy to **mvpi.ipcindia@gmail.com**. MvPI which was launched in 2015 to ensure safety of medical devices is currently being coordinated by the IPC at Ghaziabad. IPC functions as the NCC for MvPI and Sree Chitra Tirunal Institute of Medical Sciences and Technology (SCTIMST) in Thiruvananthapuram acts as its collaborating centre. Technical support is being provided by the National Health System Resource Centre (NHSRC) in New Delhi.

Under MvPI Clinician, Biomedical Engineers, Clinical Engineers, Hospital Technology Managers, Pharmacists, Nurses, Technicians can report medical device SAEs. Medical device manufacturers/CDSCO notified medical device manufacturers/medical device importer traders can also report adverse events specific for their product to NCC-MvPI at SCTIMST, Thiruvananthapuram.

The key objectives of MvPI are to create a nation - wide system for patient safety monitoring, analyse the benefit-risk ratio of medical devices, to generate evidence based information on safety of medical devices, to support CDSCO in the decision-making process on use of medical devices, to communicate the safety information on use of medical devices to various stakeholders to minimise the risk, to emerge as a national centre of excellence for Materiovigilance activities, to collaborate with other healthcare organisations for the exchange of information and data management.

Source: Shardul Nautiyal, Pharmabiz, 05.12.2020

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INTERNATIONAL NEWS

EU's drug regulator wants longer approval process for Pfizer vaccine

Europe's drug regulator, the European Medicines Agency (EMA) has opposed to UK's fast-track approval of Pfizer's Coronavirus vaccine candidate, citing that a longer approval procedure based on more evidence and more checks was "more appropriate."

The UK became the first EU country to green-light a vaccine shot, a move that has been seen by many as an attempt by the country's Prime Minister, Boris Johnson to salvage his reputation for his handling of the pandemic.

On Tuesday (01.12.2020), US company Pfizer and the German partner BioNTech applied for conditional market authorisation for their Covid-19 vaccine with EMA, which now has to assess the application. One day earlier, American pharmaceutical company also announced it would submit its vaccine candidate for approval by EMA and the United States Food and Drug Administration (FDA).

EMA said on Tuesday (01.12.2020) it would decide by December 29 whether to provisionally authorise the vaccine from US drug maker Pfizer and its German partner BioNTech, as the safety and effectiveness of the vaccine jab first need to be assessed by the agency before they hit the bloc's markets, with the Commission President stressing that "transparency here is crucial and of utmost importance."

During the parliament's plenary session in late October, the Commission's Chief Ursula von der Leyen had told MEPs that the first European Citizens could be vaccinated by the end of 2020 and urged member-states to start preparing for vaccinations, which she labelled as Europe's "ticket out" of the Coronavirus pandemic.

While one of the Commission's priorities is securing vaccines for its citizens, another priority is "to make sure that everyone has access to the vaccines, everywhere in the world," von der Leyen has stressed.

The EU Executive arm has also warned Hungary against damaging trust on the safety and efficacy of vaccines, after Budapest announced it would import and use Russia's "Sputnik V" vaccine. The Kremlin-backed vaccine is not included in the EU's vaccine portfolio, as it has faced acute criticism over its fast-track approval that skipped the third phase of trials. According to the Union's legislation, and in particular the Regulation on the conduct of Clinical Trials with and supply of medicinal products for human use containing or consisting of genetically modified organisms intended to treat or prevent Coronavirus disease (COVID-19), "no medicinal product may be placed on the market in the Union or in a Member State unless a marketing authorization has been granted by the competent authorities" under the relevant directives or regulations.

However, some exceptions are foreseen, "in situations characterised by an urgent need to administer a medicinal product to address the specific needs of a patient, for compassionate use or in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation that could cause harm."

Source: Zoe Didili, New Europe, 05.12.2020

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UK medicines regulator gives approval for first UK COVID-19 vaccine

The first COVID-19 vaccine for the UK, developed by Pfizer/BioNTech, has been given approval for use following a thorough review carried out by the Medicines and Healthcare products Regulatory Agency (MHRA). The decision by the UK regulatory authority was made with advice from the Commission on Human Medicines (CHM), the Government's Independent Expert Scientific Advisory Body. A dedicated team of MHRA scientists and clinicians carried out a rigorous, scientific and detailed review of all the available data, starting in October 2020.

This was done using a regulatory process known as a 'rolling review'. A 'rolling review' can be used to complete the assessment of a promising medicine or vaccine during a public health emergency in the shortest time possible. This is done as the packages of data become available from ongoing studies on a staggered basis. The MHRA expert scientists and clinicians reviewed data from the laboratory pre-clinical studies, Clinical Trials, manufacturing and quality controls, product sampling and testing of the final vaccine and also considered the conditions for its safe supply and distribution. The National Institute for Biological Standards and Control, part of the agency, has been and will continue doing, independent laboratory testing so that every batch of the vaccine meets the expected standards of safety and quality.

MHRA Chief Executive, Dr June Raine said: "We have carried out a rigorous scientific assessment of all the available evidence of quality, safety and effectiveness. The public's safety has always been at the forefront of our minds - safety is our watchword. "I'm really pleased to say that the UK is now one step closer to providing a safe and effective vaccine to help in the fight against COVID-19 - a virus that has affected each and every one of us in some way - and in helping to save lives. "We are globally recognised for requiring high standards of safety, quality and effectiveness for any vaccine. Our expert scientists and clinicians worked tirelessly, around the clock, carefully, scientifically, robustly and rigorously poring over hundreds of pages and tables of data, methodically reviewing the data. "Vaccines are the most effective way to prevent infectious diseases. They save millions of lives worldwide."

The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks. The decision to approve the supply of this vaccine was taken under Regulation 174 of the Human Medicine Regulations 2012, which enables rapid

temporary regulatory approvals to address significant public health issues such as a pandemic. The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health and Social Care. The Commission on Human Medicines (CHM) advises Ministers on the safety, efficacy and quality of medicinal products. The CHM is an advisory non-departmental public body, sponsored by the Department of Health and Social Care.

Source: World Pharma News, 02.12.2020 (Excerpts)

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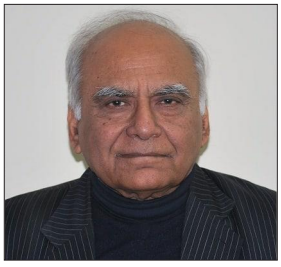
FEATURE

Indian Pharma: Driving excellence in quality and patient Centricity

Dr N K Ganguly, former Director-General, Indian Council of Medical Research (ICMR), outlines measures to enhance India Pharma Inc's expertise in manufacturing and exporting high-quality generics, and cement its position as the 'Pharmacy of the World'



The Indian Pharma industry has recorded tremendous growth over the decades, more so during the pandemic. The Indian Pharma sector has continued to be one of the key stakeholders in the Pharma supply chain, providing access to affordable and quality medicines. Even at a time when COVID-19 posed several challenges to manufacturing and transport, the Indian Pharma industry was driven to meet domestic and export needs while ensuring the safety and quality of medicines.

Companies toiled relentlessly to ramp-up production and ease out disruptions to ensure uninterrupted supply of medicines. Considering the production capacity that the country enjoys, several countries across the world export from India. The US imports close to one-third of generics used, from India. This is due to the availability of a high volume of quality drugs at cost-efficient prices compared to other manufacturing hubs in the world.

While volume is certainly key, quality is of equal importance and cannot be comprised with as patient-centricity is one of the key tenets of the Pharma ecosystem. This is the main reason why the US FDA established stringent Guidelines which ensure that quality manufacturing standards for products are maintained by every Pharma company. Considering India's expertise in manufacturing and exporting high-quality generics, diligent adherence to the US FDA Guidelines is evident.

A recent study published by the Centre for Drug Evaluation and Research (CDER) and the US FDA concluded the high standards of Indian drugs. The study, conducted between February to November 2019, assesses the quality of imported drugs from outside the US. The sample size included 252 difficult-to-make drug products, of which 36 percent of sampled products and nine percent of finished dosages were from India.

Researchers stated these products met the US market standards for dosage unit uniformity and dissolution, indicating acceptability for use by patients regardless of manufacturer or region.

What could this mean for the Indian Pharma industry?

It is evident that the stringent regulations set forth by the US FDA and Indian companies' compliance of the same imply that the quality of drugs is assured. Furthermore, the lure of Indian generics in the international community is undeniable. While Trump's recent call to 'Buy American' – a means for the American Pharma industry to move towards self-reliance prompted countries across the world to delve into the larger implications this move would have on the global Pharma ecosystem, such a shift is easier said than done. The high costs incurred in manufacturing drugs in the US coupled with the low-profit margins the companies would face, given the drug prices in the country,

would make importing drugs from countries like India an attractive option.

Having said that, there is scope to further strengthen the Indian regulatory system. The Indian Pharma sector must become more stringent when it comes to the quality of drugs and the manufacturing process. The Indian drug regulatory system is complex. To meet the global standards of manufacturing and quality assurance, the institution of a regulatory authority independent of bureaucracy is imperative. This will ensure transparency in the entire manufacturing ecosystem. Providing impetus to Pharma companies which, over the course of COVID, have forayed into new drug discovery is also essential. Driving innovation through a single window, fast-track approvals without compromising on quality will be crucial, going forward.

To surmise, the Guidelines set out by the US FDA, along with the industry's commitment to provide high-quality, affordable generics to the country and the world are evidenced by both the CDER study and India's position as the leader in the generics space, specifically in the exports market. However, there is further scope in the regulatory ecosystem to be further strengthened. Companies complying with the guidelines following safe manufacturing practices which in turn ensure the export of high-quality, safe and efficacious therapeutics should be incentivised. In doing so, India will certainly cement its position as the 'Pharmacy of the World'.

Source: Express Pharma, 04.12.2020 (Excerpts)

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Pharma deserves the Nobel Peace Prize for the COVID vaccines

Daniel Henninger

File Photo Reuters

This is the moment to put into nomination the obvious recipient for 2021's Nobel Peace Prize: the Scientists at the pharmaceutical companies whose vaccines are about to rescue the world from the catastrophe of SARS-CoV-2. Who else was going to save us from Covid-19? The answer, we've learned across nine long months, is no one.

When the virus threat became clear last March, the political authorities naturally turned for guidance to specialists in the discipline known as public health, and specifically to professional epidemiologists who had worked with previous viruses, such as AIDS or Ebola. In a fortnight, epidemiology was effectively given unprecedented authority over the daily lives of the world's citizens.

In turn, these specialists took as Guidance the Global pandemic their profession understood—the Spanish flu outbreak from 1918 to 1920. Based on the evidence from this 100-year-old pandemic, their advice to the world's political leadership was: Send your national populations home, and keep them there. And so they did.

Once they'd done that, once most of the world's factories, schools, offices, business and churches had been emptied and once most of the world was staying home, political leadership turned to the representatives of science and asked, "Now what do we do?"

And the answer the scientist-advisers gave—an answer that will be remembered by every sentient man, woman and schoolchild the world over—was: "Wait for a vaccine." That was it. Other than go home and minimize human contact, epidemiologists and public-health officials had no Plan B, C or D for living with this Coronavirus pandemic.

Whether go-home-and-stay-home was the most balanced strategy conceivable inside the reality of this complex virus is, as usual, a matter that likely will never be resolved. In the event, the pandemic policies enacted effectively divided the US and much of the world's

population into two crude categories: people who get a paycheck deposited in their bank account no matter what, and those who don't.

Those who don't have been hammered without mercy by the Coronavirus. They may not have died or contracted Covid, but many have been wiped out—personally and financially. Next time epidemiology's daily briefers should include a metric for lost sense of purpose. By now, the "vaccine" has been invoked so often that it exists in the public mind almost as an abstraction, as if eventually it would show up one day, like manna from heaven. With the vaccines finally arriving, the originators of the vaccines themselves appear in the news as distant corporate entities with names like Moderna, Pfizer, BioNTech, AstraZeneca, Johnson & Johnson.

But the story of how these new vaccines came to us so fast would make a thrilling documentary. The accomplishments of these private-sector teams of scientists is a culmination of progress across decades, not least the identification of messenger RNA 60 years ago. Today, biological science has so many moving parts that it takes multidisciplinary teams to produce products like the vaccines heading this month to the Food and Drug Administration for emergency approval.

Yes, much remains to be learned about the demographic efficacy and durability of these vaccines. But as the world confronts the burden of this winter's resurgence of the virus, we should also recognize the political rescue these private-sector scientists have sent us.

People have been remarkably good at holding up their side of the social-consent bargain with public authorities through the pandemic, but that is breaking down. After nearly a year of chaotic handling of the crisis by US states and European Governments—not least the spectacle of public officials personally violating their own directives—we are on the edge of tipping into widespread civil disobedience.

The vaccines are arriving, by one notable example, just as the belligerent New York Gov Andrew Cuomo is wearing out his welcome. President Trump has largely disappeared into his postelection challenges, but officials of the Trump administration, notably Vice-President Mike Pence and the head of Operation Warp Speed, Moncef Slaoui—whose expertise grew from three decades with GlaxoSmithKline—deserve more credit than they are receiving for the vaccines' imminent deliverance from Covid-19. Recognizing that their task was more like D-Day than business as usual, they created a Public-Private Partnership that actually worked, in large part by busting through the bureaucratic sludge that normally slows anything. Presumptive President-elect Joe Biden should complete this good game plan, rather than reawaken the bureaucracies with a national mask mandate.

The chances of a Nobel Peace Prize being given to anyone inside the for-profit sector are about zero. This year's went to the United Nations's World Food Programme. In the US, the pharmaceutical industry, or "Big Pharma," is most of the time a punching bag for Democratic and Republican politicians.

Reality check: The intellectual, technical and organizational firepower of thousands of men and women employed by Pharma is what made these savior vaccines happen in 10 months rather than years. They won't ask for anyone's gratitude, but they deserve it.

(This story has been published from a wire agency feed without modifications to the text).

Source: The Wall Street Journal, Reuters/Live Mint, 04.12.2020

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