PRICE
PER COPY
25/-

LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2018-20
RNI REGN. NO. 18921/1970
REGN NO. MCW/95/2018-20

IDMA BULLETIN

VOL. NO. 51 | ISSUE NO. 15 (PAGES: 36) | 15 TO 21 APRIL 2020 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

★ **IDMA Representation on Urgent Need for providing flexibility in Environment Control Guidelines for API Industry** (Page No. 5)

★ **Request to extend last date for filing Provident Fund Payments and Returns to 30 June 2020: IDMA Representation to PF Commissioner** (Page No. 6)

★ **How an anti-malarial drug has become a tool of India's diplomacy** (Page No. 19)

★ **India pharma faces acute manpower shortage due to lockdown** (Page No. 29)

SIGNET CHEMICAL CORPORATION PVT. LTD.

34 years of history.

25 global principals.
400+ products.

850+ customers.
1,250 manufacturing locations.

1st recall name.

is now

SIGNET EXCIPIENTS PVT. LTD.

Still the same. With a sharper name.

Over 3 decades of setting, meeting and breaching our own benchmarks in the excipients distribution industry have taught us a thing or two.

Like **FOCUS**. And while we have always focused on our core expertise that has made us today the dominant player in the high quality pharma excipients industry, we are now focusing on our name. By making it more focused.

Signet

The Complete Excipients Company

A Publication of
Indian Drug Manufacturers' Association
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

Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
₹ 1000/- *(for IDMA members)*
₹ 2000/- *(for Government Research/Educational Institutions)*
₹ 4000/- *(for non-members)* **US$ 400** *(Overseas)*
Please send your payment in favour of
Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 51 **Issue No. 15** **15 to 21 April 2020**

IDMA ACTIVITIES:
Urgent need for providing flexibility in Environment Control Guidelines for API (Bulk Drug) industry - IDMA Representation 5
Request to extend last date for filing Provident Fund Payments and Returns to 30 June 2020: IDMA Representation to PF Commissioner 6

DPIIT MATTERS:
Review of FDI policy for curbing opportunistic takeovers/acquisitions of Indian companies due to COVID-19 pandemic 7

GOVERNMENT COMMUNICATIONS:
COVID-19 - Information for General Public 8

CDSCO MATTERS:
Consolidated Revised Guidelines on the Measures to be taken by CDSCO - reg. 8
Submission of Notarized/Apostilled Documents for Import and Registration of Drugs in view of COVID-19 - reg. 9
To monitor and ensure the availability and supply of Paracetamol, API and its formulation in domestic market in wake of COVID-19 - Reg 9

CBIC MATTERS:
CBIC notifies New Exchange Rates w.e.f. 17th April 2020 - reg. 11

NPPA MATTERS:
NPPA fixes Ceiling Price of 1 scheduled formulation under Drugs (Prices Control) Order, 2013 - reg. 12
NPPA fixes/revises Ceiling Prices of 2 scheduled formulations under Drugs (Prices Control) Order, 2013 – reg. 13

DGFT MATTERS:
Manner of Continuation of MEIS for shipments on or after 01.04.2020 and Introduction of the RoDTEP Scheme - reg. 14
Track and Trace for Export of Pharma Packs extended till 1st October 2020 - reg. 15
Amendment in Export Policy of formulations made from Paracetamol (including FDCs) - reg. 15

NEW DEVELOPMENTS:
Researchers use 3d Printed Coatings to create Personalized Drug Release Profiles .. 16
Experimental schizophrenia drug could reduce long-neglected symptoms 17

NATIONAL NEWS:
How an anti-malarial drug has become a tool of India's diplomacy 19
To continue to provide medicines to patients, says Pharma Industry post government move 20
Azithromycin, paracetamol, other APIs see upto 190% price jump as China resumes production 21
Covid-19 disrupts pharmaceuticals value chain 22
DCGI directs state DCs to ensure availability of critical drugs to manage situation arising out of COVID-19 23
Maharashtra FDA issues product licenses to 64 companies to produce HCQ to tide over its growing demand 25
ICMR grants permission to set up two more advanced COVID-19 diagnostic centres in Hyderabad 25
NPPA develops IT platform to monitor availability of HCQ and azithromycin 26
DST invites research proposals for developing antiviral nano coating for PPE 26
Only 10% Pharma Wholesale business in Maharashtra due to curtailed workforce and logistics challenges 27
Ayush Ministry issues suggestive self-care guidelines for preventive healthcare measures 27
One each for import and export: How over-dependence on China and US Markets blocks Indian Pharma's Growth 28
India pharma faces acute manpower shortage due to lockdown 29
ICMR to study if BCG vaccine helps prevent Coronavirus 30

INTERNATIONAL NEWS:
Designing peptide inhibitors for possible COVID-19 treatments 30
NIH to launch Public-Private Partnership to speed COVID-19 vaccine and treatment options 31

IDMA Publications Rate Card 10
IDMA Bulletin Advt. Tariff Card 33
Advertisements ..... 2, 4, 34, 35 & 36

Urgent need for providing flexibility in Environment Control Guidelines for API (Bulk Drug) industry - IDMA Representation

The Association has made the following representation on 17th March 2020 to Hon'ble Shri Prakash Javadekarji, Minister for Environment, Forest & Climate Change, Indira Paryavaran Bhawan, New Delhi with copies to Dr Vinod K Paul, Member, NITI Aayog, New Delhi, Dr P D Vaghela, IAS, Secretary, Department of Pharmaceuticals, Shri C K Mishra, Secretary, Ministry of Environment, Forest & Climate Change, Shri Ravi Shankar Prasad, Chairman, Central Pollution Control Board and Shri Hardik Shah, Deputy Secretary, Prime Minister's office on the above subject:

"Greetings from Indian Drug Manufacturers' Association.

We have in the past on many occasions highlighted the necessity to make the current pollution control regulations more flexible for API industry to encourage greater production while still complying with effluent standards.

In view of the COVID 19 pandemic resulting in disruption in supplies from China, these measures become all the more necessary. We once again highlight the major concerns of the API manufacturers as under:

1. Need to consider API & intermediate manufacture as a group and "Consents" to be given in this general category instead of individual products, as in other advanced countries.
2. Although, need for EC has been rightly dispensed with by MoEF&CC for expansion up to 50% when there is no increase in overall pollution load, the subsequent procedure of obtaining "no increase in pollution load certificate" at State level takes anywhere between 4 to 6 months. Hence, need to put a cap of 30 days on clearance time else to be considered deemed approved.
3. Example is of recent spurt in demand from India and other countries for Paracetamol and Hydroxychloroquine, **which has necessitated overnight increase in production** to meet the same as a humanitarian gesture. In such cases even 30 days' time for granting permission will be too long and just a declaration of "no increase in pollution load" from the API manufacturer is the way forward.
4. **All old cases of "violation" of Consent Terms need to be compounded** and closed so that API manufacturers can concentrate all their energy to meet the crying need of increased demand. Most so called "violations" have been for exceeding production quantities beyond the Consent, or manufacturing 'non-consented' products; in both cases without any change in effluent quality or quantity. In many cases even after giving forced "closures" as punishment, parallel criminal cases were also filed on the Directors which are still continuing.
5. A few EC cases have been held up for long time as the units are considered "violator" because of exceeding production within given pollution load by developing useful bye products and optimising the washings for reducing per unit pollution load. Such units are being insisted to go for Public Hearings, even though located in designated Industrial Estates (which were established prior to 2006) and are proposed to go for Zero Liquid discharge. EC for such units is requested to be cleared on fast track basis without insisting for public hearing.

We once again request you to urgently look into above reasonable suggestions, positive action on which will go a long way to give much needed fillip to the Indian API industry to take on the challenges before the country. Thanking you with warm regards".

● ● ●

Request to extend last date for filing Provident Fund Payments and Returns to 30 June 2020: IDMA Representation to PF Commissioner

The Association has made the following representation on 10th April 2020 to The Regional Provident Fund Commissioner, Bhavishay Naidhi Bhavan, Bandra (East), Mumbai with copies to Shri Sunil Barthwal, IAS, Central Provident Fund Commissioner, EPFO Head Office, Shri Santosh Kumar Gangwar, Minister of State (Independent Charge), The Ministry of Labour & Employment and Dr Pramod Kumar Misra, The Principal Secretary, The Prime Minister's Office, New Delhi on the above subject:

"Greetings from Indian Drug Manufacturers' Association.

We refer to our submission as below* about inability of our Member-companies to comply with statutory Guidelines and Timelines due to the nation-wide lockdown in force till 15 April 2020. It is possible that Government may decide to prolong the lockdown to bring the Covid-19 pandemic under control.

We request you to extend the timeline for filing Provident Fund Payments and Returns from 15 April 2020 to 30 June 2020 in line with extensions provided by Central Government for compliances of Direct and Indirect Taxes.

We also request you to kindly issue necessary circular providing this extension.

Your reply in acknowledgment of our request as above will be highly appreciated. Thanking You".

*(*Not reproduced here, as the same was already published in IDMA Bulletin Issue dated 30th March 2020).*

● ● ●

Review of FDI Policy for curbing opportunistic takeovers/ acquisitions of Indian companies due to COVID-19 pandemic

DPIIT Press Note No. 3(2020 Series), dated 17th April 2020

The Government of India has reviewed the extant FDI policy for curbing opportunistic takeovers/ acquisitions of Indian companies due to the current COVID-19 pandemic and amended para 3.1.1 of extant FDI policy as contained in Consolidated FDI Policy, 2017 as under:

1. Present Position:

Para 3.1.1: A non-resident entity can invest in India, subject to the FDI Policy except in those sectors/ activities which are prohibited. However, a citizen of Bangladesh or an entity incorporated in Bangladesh can invest only under the Government route. Further, a citizen of Pakistan or an entity incorporated in Pakistan can invest, only under the Government route, in sectors/activities other than defence, space, atomic energy and sectors/activities prohibited for foreign investment.

2. Revised Position:

Para 3.1.1: 3.1.1(a) A non-resident entity can invest in India, subject to the FDI Policy except in those sectors/activities which are prohibited. However, an entity of a country, which shares land border with India or where the beneficial owner of an investment into India is situated in or is a citizen of any such country, can invest only under the Government route. Further, a citizen of Pakistan or an entity incorporated in Pakistan can invest, only under the Government route, in sectors/activities other than defence, space, atomic energy and sectors/activities prohibited for foreign investment.

3.1.1(b) In the event of the transfer of ownership of any existing or future FDI in an entity in India, directly or indirectly, resulting in the beneficial ownership falling within the restriction/purview of the para 3.1.1(a), such subsequent change in beneficial ownership will also require Government approval.

3. The above decision will take effect from the date of FEMA notification:

File No. 5(5)/2020-FDI-Policy

Manmeet Kaur Nanda,
Joint Secretary,
Ministry of Commerce & Industry,
Department for Promotion of Industry and Internal Trade,
FDI Policy Section,
New Delhi.

● ● ●

GOVERNMENT COMMUNICATIONS

COVID-19 - Information for General Public

Public Notice dated 16th April 2020

The Ministry of Health and Family Welfare along with its various stakeholders, partner Ministries and agencies is working round the clock to ensure the safety of every Indian in the wake of spread of COVID-19. Important updates- Availability and use of necessary medicines in the country:

1. As per the clinical management protocol, Hydroxichloroquene (HCQ) in combination with Azithromycin is to be considered as an off - label indication only in patients with severe disease and requiring ICU management, under close medical supervision and monitoring of its side effects,
2. Similarly, as per the protocol for prophylaxis, the HCQ has been prescribed only for Asymptomatic Healthcare Workers and Asymptomatic Household contacts and laboratory confirmed cases, on the advice/prescription of medical practitioner.
3. India is one of the largest suppliers of Active Pharmaceutical Ingredients and formulations globally, hence there is no reason for panic.
4. The Ministry of Health & Family Welfare has already ensured more than adequate supply of Hydroxychloroquine (HCQ) tablets for all patients, health workers and household contacts of confirmed cases.
5. HCQ is a prescription medicine and its sale is allowed on prescription only.
6. The guidelines issued by the Ministry of Health and Family Welfare states that "Hydroxychloroquine (HCQ) should be utilized as per prescription and is not advised for patients with cardiac irregularities or those suffering from cardiac disease which can be harmful."
7. DO NOT acquire or take any medicine without prescription as it may have adverse effects on your health.
8. Govt. of India is ensuring that there is no hoarding of medicines and that all essential drugs are available at all medical stores/ pharmacies throughout the country.
9. Illegal sale or dispensing of Hydroxychloroquine will lead of legal action under the Drugs & Cosmetics Act, 1940.

There is absolutely NO NEED TO PANIC.

Source: PIB, MoHFW, 16.04.2020

● ● ●

CDSCO MATTERS

Consolidated Revised Guidelines on the Measures to be taken by CDSCO - reg.

DCG(I) Office Memorandum Ref. F.No. A.32029/01/2020-D, dated 16th April 2020

1. All Zones/sub-zones/port offices/laboratories of CDSCO.
2. All officers at CDSCO(HQ).
3. Office of DCGI/PPS to DGHS/PS to JS(R).
4 CDSCO website/Guard file

Attention is invited to the Order No. 40-3/2020-DM-1(A), dated the 15th April, 2020 whereby the Ministry of Home Affairs have issued consolidated revised guidelines on the measures to be taken by the Ministries/Departments of Government of India, State/UT Governments and State/UT Authorities for containment of COVID-19 in the country.

Vide para 3 of the said order, the Ministry of Home Affairs have, inter-alia, allowed select additional permitted activities as enumerated in para 5 to 20 of the said order. As per para 18, Ministries/Departments under the Government of India and their Autonomous/Subordinate

offices will continue to function with effect from 20th April, 2020 as detailed below :

(i) Defence, Central Armed Police Forces, Health & Family Welfare, Disaster management and Early Warning Agencies (IMD, INCOIS, SASE and National Centre of Seismology, CWC), National Informatics Centre (NIC), Food Corporation of India (FCI), NCC, Nehru Yuva Kendras (NYKs) and Customs to function without any restriction.

(ii) Other Ministries and Departments, and offices under their control, are to function with 100% attendance of Deputy Secretary and levels above that. Remaining officers and staff to attend upto 33% as per requirement.

As CDSCO and all its Field offices, including the laboratories are functioning under the M/o Health & Family Welfare, the undersigned has been directed to convey that the above guidelines of the Ministry of Home Affairs, Government of India be scrupulously followed. Absence from duty of regular staff beyond 20.4.2020 shall be regulated in terms of CCS (Leave) Rules, 1972. The contractual staff not attending office after 20.4.2020 shall not be paid remuneration for the days of absence. Till further orders, all Field offices shall submit a weekly statement of attendance of staff in their offices on every Friday.

Arun Sharma, Director(A), Directorate General of Health Services, Central Drugs Standard Control Organisation, New Delhi.

● ● ●

Submission of Notarized/Apostilled Documents for Import and Registration of Drugs in view of COVID-19 - reg.

DCG(I) Notice Ref.File No. Import/Misc./101/2020-DC, dated 15th April 2020

To

All Stakeholders through CDSCO website.

This office have received representation about difficulties in submission of notary, apostilled and embassy attestation of regulatory documents such as Power of Attorney, Manufacturing Licence, GMP Certificate, COPP certificate etc. due to COVID-19 pandamic.

The matter has been examined carefully in view of situation due to COVID-19 outbreak and it has been decided that the applicant may submit applications for import registration as per the provisions of Drugs and Cosmetics Act, 1940 & Rules made thereunder along with self attested documents and an undertaking that they will submit the notarized/ apostilled documents obtaining the same from the concerned authority after normalization of the situation in light of COVID-19.

Such applications, as and when received, will be processed and, if found satisfactory, import registration may be issued with the condition that the firm shall submit notarized/ apostilled documents obtaining the same from the concerned authority after normalization of situation in light of COVID-19.

Dr V G Somani, Drugs Controller General (I), Directorate General of Health Services, Central Drugs Standard Control Organisation, Import & Registration Division, FDA Bhawan, New Delhi.

● ● ●

To monitor & ensure the availability and supply of Paracetamol, API and its formulation in domestic market in wake of COVID-19 - reg.

File No. DCGI/Misc/2020(102), dated 16th April 2020

This office has received a letter vide no. 37001/2020/Div III/NPPA dated 15.04.2020 from National Pharmaceutical Pricing Authority (NPPA), Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers regarding recommendation for release for exports of Paracetamol API / Formulations and this office has been requested to

ensure that manufacturers continue to supply the quantity of Paracetamol API /Tablets as usual to domestic market and to continuously monitor the availability of stock of Paracetamol in domestic market (Copy enclosed*).

In view of above, you are requested to give necessary instruction to the manufacturers of Paracetamol API / Formulations under your jurisdiction to continue to manufacture Paracetamol API / Formulations as usual to domestic market in public interest. You are also requested to monitor the availability, supply chain and address the issues regarding logistics, if any to ensure the availability of domestic stock of said drug in wake of COVID-19.

Action taken in this regard may be communicated to undersigned from time to time on enforcecell.divcdsco.nic.in and dci@nic.in.

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

*(*Not reproduced here)*

● ● ●

CBIC notifies New Exchange Rates w.e.f. 17th April 2020 - reg.

Notification No.39/2020-Customs (N.T.), dated 16th April, 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.37/2020-Customs(N.T.), dated 1st April, 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 17th April, 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	49.30	47.10
2.	Bahraini Dinar	206.20	200.90
3.	Canadian Dollar	55.30	53.45
4.	Chinese Yuan	11.00	10.70
5.	Danish Kroner	11.40	11.00
6.	EURO	85.00	81.95
7.	Hong Kong Dollar	10.10	9.75
8.	Kuwaiti Dinar	254.65	238.80
9.	New Zealand Dollar	46.95	44.75
10.	Norwegian Kroner	7.40	7.15
11.	Pound Sterling	97.40	94.05
12.	Qatari Riyal	21.75	20.45
13.	Saudi Arabian Riyal	21.10	19.80
14.	Singapore Dollar	54.60	52.80
15.	South African Rand	4.25	3.95
16.	Swedish Kroner	7.75	7.50
17.	Swiss Franc	80.85	77.80
18.	Turkish Lira	11.45	10.75
19.	UAE Dirham	21.60	20.25
20.	US Dollar	77.65	75.95

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Export Goods)
1.	Japanese Yen	72.40	69.80
2.	Korean Won	6.45	6.05

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

Pramod Kumar, Director, Central Board of Indirect Taxes and Customs, Ministry of Finance, Department of Revenue, New Delhi.

● ● ●

NPPA fixes Ceiling Price of 1 Scheduled Formulation under Drugs (Prices Control) Order, 2013 - reg.

NPPA Notification No.S.O.1241(E), dated 03rd April, 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, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the price 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 (₹)
(1)	(2)	(3)	(4)	(5)
1.	Human Normal Immunoglobulin	Solution for infusion 16.5%	1 ml	379.83

Note:

(a) All manufacturers of scheduled formulation, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

(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/206/74/2020/F
F. No. 8(74)/2020/D.P./NPPA-Div-II

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

● ● ●

NPPA fixes/revises Ceiling Prices of 2 Scheduled Formulations under Drugs (Prices Control) Order, 2013 – reg.

NPPA Notification No.S.O.1242(E), dated 03rd April, 2020

In implementation of directions given in line with review orders issued by the Department of Pharmaceuticals (DOP) vide order(s) specified in column (6) of the table herein below passed by the Department of Pharmaceuticals under para 31 of Drugs (Prices Control) Order, 2013 and 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 Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) specified in the Column (7) of the table regarding formulation specified as mentioned in the table in so far as it relates to formulation pack mentioned in the table below, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby fixes/revises the price 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(s) 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 (₹)	Review Order number and date	Existing SO number and date
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.	Paclitaxel	Injection 100mg/ 16.7ml	1 ML	205.04	31015/33/2016-PI.I dated 19.09.2016	1213(E) dated 25.03.2020 (at Sl. No. 613)
2.	Paclitaxel	Injection 30mg/ 5ml	1 ML	205.04	31015/33/2016-PI.I dated 19.09.2016	1213(E) dated 25.03.2020 (at Sl. No. 614)

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 prices of such formulations 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/206/74/2020/F
F. No. 8(74)/2020/D.P./NPPA-Div-II

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

● ● ●

DGFT MATTERS

Manner of Continuation of MEIS for shipments on or after 01.04.2020 and Introduction of the RoDTEP Scheme - reg.

DGFT Trade Notice No.03/2020-21, dated 15th April, 2020

To,
EPCs/FIEO,
Members of Trade and Industry,
All Regional Authorities (RAs) of DGFT,
All Customs Authorities.

1. With approval of the RoDTEP scheme by Cabinet on 13th March 2020, to replace the ongoing MEIS scheme as publicized vide PIB Press Note dated 13th March 2020, this Directorate had been receiving queries from the members of the trade, as to in what manner benefits under MEIS will be available under the FTP beyond 31.03.20, the then envisaged end date of the FTP 2015-20, which has since been extended till 31.03.2021.

2. It is clarified, without prejudice and subject to changes that may be deemed necessary in public interest from time to time, that:

a) Benefits under MEIS for any item/tariff line / HS Code currently listed in Appendix 3B, Table 2 (MEIS Schedule) will be available only up to 31.12.2020;

b) Prior to 31.12.2020, as and when an item/tariff line/HS code is notified to be covered under RoDTEP Scheme, it would at the same time be removed from coverage under MEIS;

c) Detailed operational framework for the Scheme for Remission of Duties and Taxes on Exported Products (RoDTEP) will be notified separately in consultation with Department of Revenue, Ministry of Finance.

3. This is issued with the approval of the competent authority.

01/61/180/288/AM20/PC-3

Dr Praveen Kumar, Deputy Director General of Foreign Trade, Directorate General of Foreign Trade, Ministry of Commerce and Industry, Department of Commerce, Udyog Bhawan, New Delhi.

● ● ●

Track and Trace for Export of Pharma Packs extended till 1st October 2020 - reg.

DGFT Public Notice No.66/2015-2020, dated 30th March, 2020

1. In exercise of the powers conferred under Paragraph 2.04 of the Foreign Trade Policy, 2015-20, as amended from time to time, the Director General of Foreign Trade hereby amends Para 2.90A of Handbook of Procedure- 2015-20, as notified vide Public Notice No. 43/2015-20 dated 05.12.2017 read with Public Notice No. 52 / 2015-20 dated 05.01.2016, Public Notice No. 05/2015-20 dated 09.05.2018, Public Notice No. 43/2015 2020 dated 01.11.2018 and Public Notice No. 16/2015-2020 dated 04.07.2019 on laying down the procedure for implementation of the Track and Trace system for export consignments of drug formulations.

2. In Para 2.90 A (vi) and (vii) of Handbook of Procedure - 2015-20 (as amended vide Public Notice No. 16/2015-2020 dated 04.07.2019), "01.04.2020" may be substituted by **"01.10.2020".**

Effect of this Public Notice:

The date for implementation of Track and Trace system for export of drug formulations with respect to maintaining the Parent-Child relationship in packaging levels and its uploading on Central Portal has been extended upto **01.10.2020** for both SSI and non SSI manufactured drugs.

F.No.01/91/180/648/AM 09/EC (Vol.11)

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

● ● ●

Amendment in Export Policy of formulations made from Paracetamol (including FDCs) - reg.

DGFT Notification No. 03/2015-2020, dated 17th April, 2020

1. In exercise of powers conferred by Section 3 of the Foreign Trade (Development & Regulation) Act, 1992 (No. 22 of 1992), as amended, read with Para 1.02 and 2.01 of the Foreign Trade Policy, 2015-20, the Central Government hereby makes following amendment in the Chapter 30 of the Schedule 2 of the ITCHS Export Policy amending the Notification No. 50/2015-20 dated 03.03.2020 related to export Policy of APIs and formulations made from Paracetamol:

Sr. No	ITC HS Codes	Description	Present Policy	Revised Policy
156 M	30049099	Formulations made of Paracetamol (including FDCs)	Restricted	Free

2. Effect of this Notification:

The Notification No. 50/2015-20 dated 03.03.2020 is further amended to the extent that the formulations made from Paracetamol (including FDCs) under any ITCHS Code, including the ITCHS Code mentioned above, are made "Free" for export, with immediate effect. However, Paracetamol APIs will remain restricted for export.

File No. 01/91/180/24/AM20/EC

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

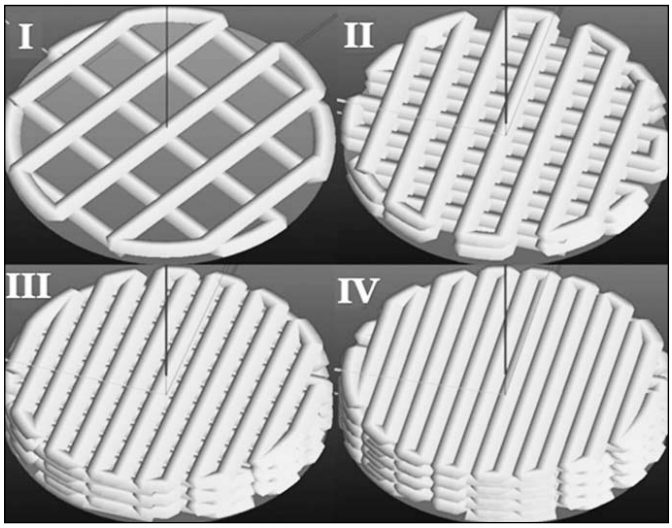
● ● ●

Researchers use 3d Printed Coatings to create Personalized Drug Release Profiles

A group of researchers from Greece and Italy have explored the use of 3D printing as a coating technology for customizing the release rate of drugs for patient-specific delivery.

Using semi-solid extrusion 3D printing technology to partially coat the tablet, the researchers set about tuning the release of two Active Pharmaceutical Ingredients (APIs) within the tablet. The team were able to customize the selected APIs release profile by modifying various parameters of the 3D printing coating process using experimental design techniques.

By tuning these parameters, the researchers have been able to achieve different dissolution profiles for the tablets, thus customizing their release rate. As such, this process can be tuned according to a specific patient's needs, according to the researchers: "The feasibility of the proposed technology was shown by modifying the geometry of the coating and acquiring knowledge on which of these parameters and/or their interactions affect the release profile of the APIs and thus achieving personalized drug release rates according to the patient's needs," explain the authors.



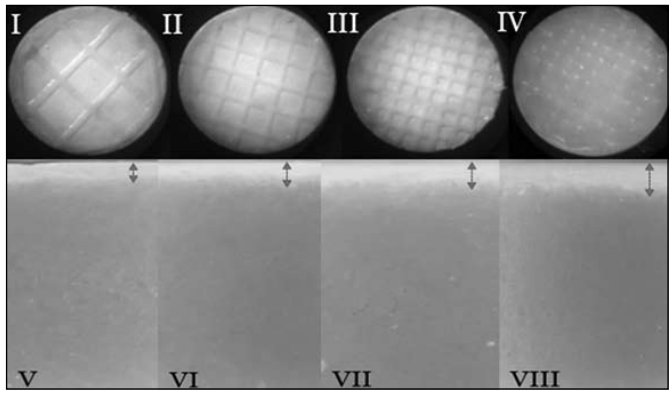
CAD drawings of coating. Image via International Journal of Pharmaceutics.

The advantages of 3D printed pharmaceuticals:

The authors of the study first set out describing the advantages of using 3D printing in the production of pharmaceuticals. They explain that 3D printing's ability to produce multiple versions of a drug for variant populations in short run batches is challenging the traditional manufacturing technologies. This is exemplified by the FDA approval of Spritam, the first 3D printed pill to receive such a certification in 2015.

Spritam, produced by Aprecia Pharmaceuticals, is used to treat seizures in people with epilepsy. Aprecia 3D printed the pill using its ZipDose process, a method that involves the use of print fluids to bind layers of API-containing powder together into porous structures or tablets. The porosity of the tablets is the main advantage of Aprecia's ZipDose 3D printed pill technology, as they are more porous than those made using conventional methods. This then means that they dissolve, and act, much faster when taken with a sip of water.

However, the researchers also explain that the literature and research on the use of 3D printing for the coating or partial coating of solid dosage forms is limited, while the materials used consist of a specific range of polymers. Additionally, the researchers found that no publications demonstrated the use of glycerides for the coating of tablets with 3D printing. Glycerides are emulsifiers, meaning they help to blend oil and water. As such, they are often used as food additives to improve texture and stability, prevent oil from separating, and extend shelf life.



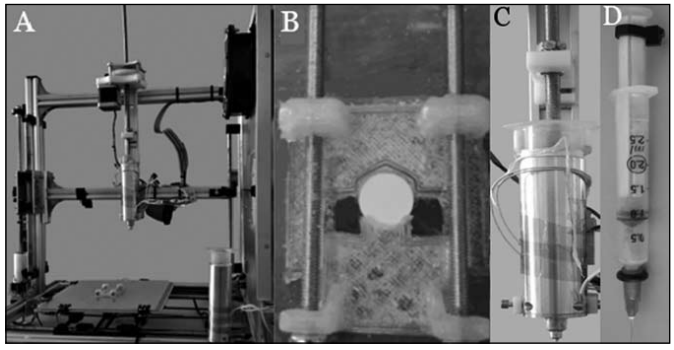
Examples of partially coated tablets with 3D printing at four levels. Image via International Journal of Pharmaceutics.

Tablet coating using 3D printing:

Identifying this gap in research, the aim of the team's study was to demonstrate the feasibility of employing 3D printing to partially coat tablets with glycerides, where the release of two API's would be precisely regulated

by controlling the coating characteristics only, without modifying the core formulation. Such a process would benefit the production of tablets with tailored release profiles, as it eliminates the need for complex equipment and processes, and thus accelerates the time production to patient.

As such, this process does not use 3D printing to produce the tablets, instead they were produced using conventional manufacturing processes. 3D printing was only used to partially coat the tablet in order to demonstrate an alternative application of the technology, and how it can be leveraged to alter the API release profile of already commercially available dosage forms according to the desired therapeutic effect.



The semi-solids 3D printer used to create the tablet coatings. Image via International Journal of Pharmaceutics

The tablet coating process was carried out using a lab scale 3D printer for semisolids, designed and constructed at the Department of Mechanical Engineering, University of Parma, Italy. A support structure was 3D printed and attached to the printing bed in order to keep the tablets at the same position while the coating was printed. The coating was partially applied to the tablets through material extrusion using a heated syringe filled with glyceride.

Subsequently, the dissolution profiles were recorded and analysed in order to identify the effect of the selected coating parameters on the API release of the two selected drugs. The researchers found that different dissolution profiles could be achieved for both the API by tuning three coating parameters, namely the surface coverage, number of the applied layers and the number of the coating sides. Concluding the research, the authors state that: "3D printing technology can be successfully used in addressing the challenging demands for designing dosage forms with release profiles customized to each patient's unique needs and/or production at the point of need."

The paper, "Partial tablet coating by 3D printing" is written by Eleni Tsintavi and Dimitrios M. Rekkas of the Department of Pharmacy, National & Kapodistrian University of Athens, and Ruggero Bettini of the Food & Drug Department, University of Parma. It is published in the 'International Journal of Pharmaceutics'

Source: Anas Essop, 3dprintingindustry, 15.04. 2020

● ● ●

Experimental schizophrenia drug could reduce long-neglected symptoms

For the first time in decades, researchers may have a new way to tweak brain signals to treat psychosis and other symptoms of schizophrenia. Results from a 245-person clinical trial hint that a compound called SEP-363856, which seems to act on neural receptors involved in dopamine signaling, might address a broader range of schizophrenia symptoms than currently available drugs do—and with fewer side effects.

"If these results are confirmed, this will be big, big news," says Jeffrey Lieberman, a psychiatrist at Columbia University. The drug's developer, Sunovion Pharmaceuticals Inc., identified it through an unusual screening process not guided by the brain circuits and receptors already implicated in the disease, Lieberman says. "It was a big gamble on their part. This study suggests that it may pay off."

The biological basis of schizophrenia remains a puzzle, but researchers have linked patients' hallucinations and delusions to an excess of the chemical messenger dopamine. To inhibit dopamine signaling, existing antipsychotic drugs bind to a type of dopamine receptor on neurons called D2. These drugs help control abnormal perceptions and thoughts—the "positive" symptoms of schizophrenia. But they don't do much to address either cognitive impairments

or the "negative" symptoms, including lack of motivation, dulled emotion, and social withdrawal. "Those negative symptoms are often the most devastating," says Diana Perkins, a psychiatrist at the University of North Carolina, Chapel Hill. "A person can become, at the most extreme, robotlike."

The first generation of antipsychotic drugs that emerged in the 1950s sometimes actually worsened these negative symptoms, Perkins says. And tamping down on dopamine signaling can lead to side effects including tremors and other involuntary movements. A second generation of D2-targeting drugs has reduced the risk of some of these side effects, but many cause weight gain and other metabolic problems.

Sunovion started its drug search wanting to avoid D2 receptors. "It was a bit of an antitarget approach," says Kenneth Koblan, the company's chief scientific officer. "If [a compound] worked through the D2 system, we didn't want to work on it."

The researchers relied on a drug screening method, developed by PsychoGenics Inc., that used artificial intelligence to analyze the behavior of mice exposed to hundreds of candidate compounds. The researchers looked for a compound that mimicked the effects of D2-targeting drugs. One stage of the testing involved trying to reverse the effects phencyclidine, better known as PCP, which causes hyperactivity and other schizophrenialike behaviors.

SEP-363856 rose to the top of the heap. This compound didn't touch D2 receptors, the researchers found, but it activated two other types of neural receptors—known as TAAR1 and 5-HT1A—that help regulate the synthesis and release of dopamine. The mechanisms of the drug aren't fully clear, but the researchers suspect they've hit on a new way to tweak dopamine signaling.

The clinical trial tested SEP-363856's effects in people who were still early in the course of schizophrenia—none had been hospitalized for acute psychotic symptoms more than twice. During a flare-up of these symptoms, the participants, who ranged from 18 to 40 years old, spent 4 weeks in the hospital taking either SEP-363856 or an identical-looking placebo pill once a day.

Clinicians then evaluated a broad set of schizophrenia symptoms using a measure called the Positive and Negative Syndrome Scale (PANSS), which gives scores ranging from 30 to 210, with a higher score representing worse symptoms. On average, participants scored roughly 100 on entering the study; after 4 weeks, the average score in the drug group had dropped by 17.2 points, versus 9.7 in the placebo group, the researchers report today in The New England Journal of Medicine.

"This is great news," says Romina Mizrahi, a psychiatrist at the University of Toronto. The trial didn't directly compare SEP-363856 to other drugs, but she notes that the reduction in PANSS scores is similar to results from some trials of now-approved antipsychotic drugs.

The group taking SEP-363856 also had a larger drop than the placebo group on another scale, one meant to measure negative symptoms like lack of pleasure and motivation. Though the study wasn't statistically designed to draw conclusions using this secondary measure, this early indication "is a big deal, and it's potentially a game changer," Perkins says. "If it's confirmed … that would mean a lot for many patients and their families."

Rates of side effects, including movement disorders, nausea, agitation, and drowsiness, were low in both groups. And although SEP-363856's long-term effects on metabolism aren't clear, the compound didn't cause major weight gain in either the 4-week trial or a 26-week extension that included 156 of the participants, all of whom got the experimental drug.

Sunovion isn't the only company looking to sidestep D2 receptors in treating schizophrenia. Karuna Therapeutics is studying xanomeline, a compound with a different neural target, which Eli Lilly developed in the 1990s and later abandoned after finding that many patients experienced side effects that include nausea and dizziness. (Karuna aims to reduce those effects by combining xanomeline with another drug.) The company announced positive results from a study involving 182 patients last year.

In September 2019, Sunovion launched a larger, phase III trial that will include more than 1000 people, designed to prove the drug's efficacy and win regulatory approval. Koblan says he can't estimate when the trial might yield results, citing COVID-19.

"I would be very comfortable answering that question if we weren't in the midst of a pandemic," he says.

Source: Kelly Servick, Brain & Behavior/Science, 15.04.2020

How an anti-malarial drug has become a tool of India's diplomacy

India, one of the largest producers of HCQ now used in coronavirus treatment, is exporting the drug to many countries.

Days after India banned the export of pharmaceuticals amid the coronavirus pandemic, it reversed its decision after US President Donald Trump last week demanded New Delhi ship anti-malarial drug hydroxychloroquine (HCQ) to the United States.

Foreign policy experts in India expressed shock at Trump's threat of retaliation against India - a close trade and security ally of the US. But New Delhi's decision to export HCQ seems to have changed the US President's tune immediately.

"Extraordinary times require even closer cooperation between friends. Thank you India and the Indian people for the decision on HCQ. Will not be forgotten! Thank you Prime Minister @NarendraModi for your strong leadership in helping not just India, but humanity, in this fight!" tweeted Trump.

Earlier, the US President, while speaking to reporters, had called Modi "terrific" and said the US will "remember" that India allowed what they had requested.

Modi was quick to respond, underlining the close ties between the two countries. "Fully agree with you President @realDonaldTrump. Times like these bring friends closer. The India-US partnership is stronger than ever. India shall do everything possible to help humanity's fight against COVID-19. We shall win this together," Modi tweeted.

'Game-changer' drug:

Trump, who has faced criticism for his handling of the COVID-19 crisis domestically, has called hydroxychloroquine a "game-changer" drug in the fight against coronavirus.

Global rush for HCQ forced India to put restrictions on its export and that of several other drugs on March 25. The only exceptions were on humanitarian grounds or for those who had made their advance payments in full. Used for treating rheumatoid arthritis and malaria, India is one of the largest producers of HCQ in the world and exports $50m worth of it every year. After the revocation of the ban, reports claimed that India has decided to export HCQ and other drugs used for treating COVID-19 patients to more than a dozen countries under two categories - humanitarian aid and commercial supply. India, dubbed "the pharmacy of the world", has drawn praise for the decision to export pharmaceuticals to some African and Latin American countries on humanitarian grounds.

Brazilian President Jair Bolsonaro and Israeli Prime Minister Benjamin Netanyahu thanked Modi after New Delhi decided to ship the medicines.

Several other countries, including the United Kingdom, expressed their gratitude, earning diplomatic goodwill for New Delhi.

Ever since the coronavirus outbreak worsened, Modi has been constantly reaching out to the heads of states to create solidarity in fighting the pandemic.

In mid-March, Modi proposed a coronavirus fund for the South Asian Association for Regional Cooperation (SAARC) countries, with New Delhi committing $10m. India will also send drugs to neighbouring countries such as Nepal, Bhutan, Sri Lanka, Afghanistan, Bangladesh, Maldives, Mauritius and Seychelles.

Will drug diplomacy work?

The jury is still out on whether these efforts will strengthen India's diplomatic position.

"In some terms, this decision has earned some goodwill. People are aware that unlike China which has a surplus of PPEs [personal protective equipment] or ventilators and the machinery to produce a lot of these things, India is making genuine sacrifices to show international solidarity and not to earn money," Kanwal Sibal, India's former foreign secretary, told.

According to Sibal, these gestures will help India earn goodwill but it still remains a much smaller part of the overall scenario of how developing countries are going to relate to each other after the coronavirus pandemic is brought under control.

"So, I don't think one should exaggerate the amount of goodwill but certainly India's diplomatic hand would be strengthened when it would seek a similar favour from some of the countries to which it is showing a degree of generosity," said Sibal.

Meanwhile, India's former ambassador to the US, Lalit Mansingh, said at this point, diplomacy should not be discussed in transactional terms.

"When a country makes an appeal for drugs in this kind of calamity, humanity remains the foremost priority in the decision making. It is not about taking advantage of a particular country in a crisis. Right now, it's the humanitarian sentiment that is uppermost," Mansingh told.

He claimed that India has not deviated from its policy to help those in need, especially in the pharma sector. "As a fact, India has a policy of helping like it did in the case of HIV/AIDS. Drugs made in India helped millions of lives in Africa," he said.

Pharma industry hit by pandemic:

India is the largest producer of generic drugs and has, over the years, made the cost of treatment much cheaper for people all over the world.

According to Global Business Reports, "The generic drugs industry continues to strengthen itself as a key pillar of India's burgeoning economy. As the largest provider of generics in the world, the sector contributes to 40 percent of the United States' generic demand with Indian companies receiving 304 Abbreviated New Drug Application approvals from the US Food and Drug Administration in 2017. Moreover, the industry exports to almost every nation, and has significant footprints in all the highly-regulated developed markets." India is home to the third-largest pharmaceutical industry in the world in terms of volume and 10th-largest in terms of value.

The total size of the industry, including drugs and medical devices, is approximately $43bn of which it exports $20bn worth of drugs. The pharmaceutical sector currently contributes about 1.72 percent to India's gross domestic product (GDP).

India exports pharma products to more than 200 countries, including heavily regulated markets in the US, Western Europe, Japan and Australia.However, with businesses across the globe taking a major hit because of the pandemic, Indian pharma sector, too, is not untouched by the crisis.

The spectre of coronavirus has exposed the chinks in India's pharmaceutical sector which is struggling to ramp up production due to its overreliance on China for active pharmaceutical ingredients (API) and other bulk drugs which are key ingredients of the finished formulations.

"Last year, the country imported roughly 50,000 crore rupees ($6.5bn) worth of API and other intermediaries that go into production of finished formulations," said Dr Saktivel Selvaraj of the Public Health Foundation of India.

"About 31,740 crore rupees ($4.1bn) [worth of API] were from China alone, accounting for two-thirds of API imports."

A large section of these APIs are imported from the Hubei province of China, which is believed to be the origin of the new coronavirus and a manufacturing hub of API and other bulk drugs.

Over the years, India's dependency on China has increased substantially since Indian pharma companies found it cheaper to import than to manufacture the key ingredients.

Meanwhile, domestic drug manufacturers have claimed that if the government did not intervene soon, the consumer would start feeling the pinch of the shortage of API, as many essential drugs could disappear from shelves in the next few weeks.

Manav Grover, managing director of Cosway Pharmaceutical, which manufactures more than 200 drugs, including painkillers, antibiotics and other medicines, said the company's stocks are depleted and the cost of raw materials has skyrocketed in the last few weeks, especially after imports from China were stopped due to the spread of the coronavirus.

According to him, the end consumer will start to feel the heat of this shortage very soon.

"Suppliers are hoarding raw materials and have increased the price manifold. The situation is really bad, there is so much black-marketing. Even those raw materials which were easily available are being hoarded by traders," Grover told Al Jazeera.

"Just like masks and hand sanitisers, raw materials too are not easy to find. For instance, we used to get HCQ for 20,000 rupees ($261) a kg but the rate is now 85,000 rupees ($1,111) a kg. So, production of one HCQ tablet cost the manufacturer five rupees ($0.06) earlier, it costs 35 rupees ($0.45) now."

Source: Akash Bisht, Aljazeera News, 16.04.2020

● ● ●

To continue to provide medicines to patients, says Pharma Industry post government move

The pharma industry welcomed the government decision to allow manufacturing units to remain operational amid the lockdown.

These units include pharmaceuticals, drugs, medical devices, medical oxygen, their packaging material, raw material and intermediates.

The government has also allowed pharmaceutical and medical research labs, and institutions to carry out COVID-19 related research.

"We laud the government's decision. The pharmaceutical industry is covered under essential services and manufacturing has been operational. We will continue to operate and with these guidelines, the supply of medicines will continue," Indian Pharmaceutical Alliance Secretary General Sudarshan Jain said.

IPA is committed to provide quality medicines to patients in India and globally, he added. In similar vein, Indian Drug Manufacturers'' Association Executive Director Ashok K Madan said: "Pharmaceutical industry and its ancillary industries have been notified as essential Industry. It has helped our efforts to manufacture the life saving medicines".

There have been some problems of absence of work force and on average around 35 to 45 per cent of workers are attending. Production levels consequently are down to around 45 to 50 per cent, he added.

"We are facing major problems at the ports with regard to imports and export consignments. Curfew passes at ports are now to be issued by Port authorities. Orders have already been issued by MHA for movements of trucks with drivers licence being accepted along with one cleaner help," Madan said.IDMA hopes things to improve and assure the nation of continuous efforts to provide essential medicines, he added.

Source: PTI, Outlookindia, 15.04.2020

● ● ●

Azithromycin, paracetamol, other APIs see upto 190% price jump as China resumes production

With China, the world's leading manufacturer of raw materials for drugs, resuming production after a four-month Covid-19 lockdown, the prices of active pharmaceutical ingredients or APIs of four top-selling drugs have shot up sharply.

According to data ThePrint collated from Indian pharma companies, antibiotics azithromycin and ornidazole, anti-inflammatory drug nimesulide and antipyretic drug paracetamol have seen their prices jump between 60 and 190 per cent.

Nimesulide price has spiked from Rs 450 per kg in January to Rs 1,300 — a jump of 189 per cent. Azithromycin price has gone up 96 per cent from Rs 7,650 to Rs 10,500 per kg, while paracetamol is dearer by 62 per cent — from Rs 262 to Rs 450 per kg.

The price hike poses a challenge for Indian pharma companies as these APIs are used to manufacture drugs that are under price control, meaning the firms are only allowed an annual price hike of 10 per cent.

"There was a gap in API production in China as the production units were shut due to an outbreak there from January to March. Now they have opened up with bulk orders in hand," said Arjun Juneja, chief operating officer, Mankind Pharma.

Medicinal drugs (Representational image) | Pixabay

"Also, due to Covid-19 the global demand for medicine is higher than usual which has pushed China to increase the prices even more," said Juneja, who manufactures formulations using all the four APIs named above. Another industry official who works for a Mumbai-based pharmaceutical firm said on condition of anonymity, "The hike can also be credited to the increase in price of dollar while additional cost of landing charges such as freight cost has also gone up."

Other APIs in red zone:

Several other APIs, including tinidazole, amoxicillin, ceftriaxone, ofloxacin, amikacin and cloxacillin, have seen a price jump from 20 to 40 per cent in the period between January and April. The jump has been moderate — between 12 and 20 per cent — for APIs such as tetracycline, gentamicin, norfloxacin, doxycycline and tramadol.

"It is a worrying trend. These raw materials are for important drugs, especially paracetamol and azithromycin. All these drugs are under price control, hence manufacturers are not allowed to increase the retail price of the medicine," said Sandeep Arora, chief executive officer at Bengaluru-based Ultra Pharmaceuticals.

What are APIs?

APIs, also known as bulk drugs, are chemical compounds that are the most important raw material to produce a finished medicine.

In medicine, API produces the intended effects to cure the disease. For instance, paracetamol is the API for crocin, and it gives relief from body ache and fever.

Every medicine is made up of two main ingredients — the chemically active APIs and chemically inactive, excipients, which is a substance that delivers the effect of APIs to one's system.

Indian drug makers import around 70 per cent of their total bulk drug requirements from China. In the 2018-19 fiscal, the government had informed the Lok Sabha that the country's drug makers had imported bulk drugs and intermediates worth $ 2.4 billion from China.

With a lockdown in China from January due to the Covid-19 outbreak, API supplies to produce drugs for treating HIV, cancer, epilepsy, malaria as well as commonly-used antibiotics and vitamin pills, was hit.

(This report has been updated to correctly reflect that Ultra Pharmaceuticals is based in Baddi and not Bengaluru).

Source: Himani Chandna, The Print, 16.04.2020

● ● ●

Covid-19 disrupts pharmaceuticals value chain

THE pharmaceutical manufacturers have said their raw material stocks are fast depleting due to import restrictions from suppliers as a result of the outbreak of Covid-19.

Industry expert and Pharmaceutical Society of Zimbabwe immediate past president, Mr Sikhumbuzo Mpofu, said that the Covid-19 outbreak was going to have a huge impact on the country's pharmaceutical industries, which are largely dependent on China and India for raw materials as the two Asian countries are still grappling to contain the pandemic.

"The impact of the Covid-19 outbreak is huge given that the biggest manufacturer of Active Pharmaceutical Ingredients (APIs) is China which was the epicentre of the outbreak of the pandemic," said Mr Mpofu.

He said although the pandemic seems to be under control in China, the whole supply chain has been disrupted.

Mr Mpofu said with India having reduced exports of a number of products, the country's pharmaceutical manufacturers are likely to face challenges in producing some of the medication due to insufficient raw materials.

He said the situation is being worsened by shortage of foreign currency to import from other countries. "India has already started reducing exports in certain products as announced in a circular by their ministry of trade a couple of weeks ago and us being a country that is constrained in terms of resources, we cannot afford to buy raw materials to cushion us

"In the short to medium term we are definitely going to see challenges in certain lines of medicines," said Mr Mpofu.

According to international media reports about 90 percent of the core components of widely-used antibiotics like amoxicillin, doxycycline, and penicillin are manufactured in China whose industry was disrupted by Covid-19 lockdown.

After the manufacture of the pharmaceutical ingredients in China, they are exported mainly to India, the world's leading supplier of generic drugs.

Some companies in India have already reported supply chain problems, according to a letter to customers released by AmerisourceBergen on March 31.

South Africa has put a ban on the exportation of all Covid-19 material, which further compounds the situation.

"To make matters worse, South Africa has put an embargo on exporting Covid-19 materials. This means we can't import gloves and face masks from South Africa, which items are needed on a daily basis by citizens as they fight the spread of Covid-19," said Mr Mpofu.

He also said the situation would also be worsened by the fact that the manufacturing industry was facing capacity utilisation challenges and depressed uptake of its products. Meanwhile, Musimboti Traditional Science and Technology Institute (MTSTI) managing director Mr Morgan Zimunya said registered herbal medicine practitioners should ride on the falling consumer demand of conventional medicines to aggressively market their traditional remedies.

"The low uptake of conventional medicines is an opportunity for players involved in the production of traditional medicines to market their products. "Many people are not aware of the healing powers of traditional medicine.

"They only know modern pills administered at hospitals and pharmacies yet traditional medicines are equally effective and cheaper," he said.

Source: Dumisani Nsingo, The Chronicle, 16.04.2020

● ● ●

DCGI directs state DCs to ensure availability of critical drugs to manage situation arising out of COVID-19

To manage the situation arising out of COVID-19 pandemic, the Drugs Controller General of India (DCGI) has directed state and Union Territory drugs controllers (DCs) to take steps to ensure availability of sufficient quantity of critical drugs in the domestic retail markets besides ensuring that the products conform to the prescribed specifications.

The Union health ministry on April 16, 2020 has come out with a list of 55 drugs for ICU management of COVID-19 patients admitted to hospitals. Hydroxychloroquine (200mg) and azithromycin (500mg) tablets have already been recommended for patients requiring ICU management, asymptomatic healthcare workers and asymptomatic household contacts of positive cases.

The list of 55 drugs contains vasopressors—injection noradrenaline Img/ml, injection vasopressin 5mg/ml, injection dobutamine Img/ml, injection adrenile 1 mg/ml, and injection atropine sulphate 1 mg/ml. The list also contains arrhythmia drugs/emergency cardiac drugs such as injection amiodarone 150mg, injection enalaprilat 1.25mg, and injection labetalol 5mg/ml (10ml).

The list also has analgesia sedatives/muscle ralaxants--injection midazolam l0mg, vecuronium 4mg/ml, injection suxamethonium 50mg/ml, and injection fentanyl 50mcg/ml. Antibiotics/antimicrobial agents found place in the list are injection amoxcillin/clavulinic acid (500mg/125mg), injection ceftriaxone 1gm, injection meropenam 1gm, injection targocid 400mg, injection vancomycin 500 mg, injection ciprofloxacin 500mg, injection levofloxacin 500mg, injection cefotaxime 1gm, injection artesunate 120mg, injection linezolid 600mg, injection clindamycin 600mg, and injection metronidazole 500mg.

Besides this, the list has nebulisation products—salbutamol respiratory solution 5mg, salbutamol/pratropium solution 5mg/500mcg, formetrol/budesonide (20mcg/0.5mg). The list also contains anti-epileptic drugs—diazepam 5mg/ml (2ml), injection sodium valproate 100mg/ml, and injection levetiracetam 500mg. There are IV fluids in the list which includes normal saline, ringer's lactate, dextrose normal saline, and mannitol 20% (500ml).

Other drugs in the list are lignocaine 2% injection (30ml), chlorhexidine mouth wash, chlorhexidine skin preparation, betadine skin preparation, heparin 5000 IU/ml injection (5ml), injection enoxaprin 0.6ml, injection tranexamic acid 0mg/ml, injection frusemide 10mg/ml (2ml), injection hydrocortisone acetate 100mg/1ml, injection potassium chloride 15% (10ml), injection sodium bicarbonate 7.5%, regular insulin (100U/ml), paracetamol 500mg tablet, levocetrizine 5mg tablet, pantoprazole 40mg tablet, prednisolone 5mg tablet, cetrizine 10mg tablet, oseltamivir 75mg tablet, amlodipine 5mg tablet, and atenolol 50mg tablet.

In addition, the ministry has also provided a general list containing essential drugs that are projected to be required in the country during next three-month. The list includes non-steroidal anti-inflammatory agents, antibacterial agents, anti-fungal drugs, drugs affecting blood, cardiovascular drugs, dermatological drugs, antiallergic medicine/medicine for anaphylaxis, respiratory tract drugs, anticonvulsants/antiepileptics, antianxiety medications, hormonal products, anesthetic/analgesic agents etc.

DCGI in a letter asked state and Union territory drug controllers to monitor stockpiling of drugs including sanitizers and keep strict vigil on any possible shortages of the drugs caused by disruption to global supplies.

The stake and UT drugs control authorities were also instructed to maintain checks on availability of drugs for use in the treatment of COVID-19 disease in consultation with relevant stakeholders, develop a pandemic communication strategy with dealers, distributors and pharmacies to help determine available quantities of medical supplies used in slowing the spread of the virus.

The DCGI further asked them to ensure that the drug formulations are available at affordable prices in the market and prevent black-marketing, illegal hoarding and artificial shortages as well as ensure that retailers/wholesalers continue to adhere to normal ordering patterns and avoid stockpiling of medications. Stockpiling of medications can result in reduced volume of medicines in supply chains, which could compromise the ability of the healthcare system to respond to a crisis.

Accordingly DCGI has directed to chemists and druggists associations to ask their members to ensure availability of the drugs with assured quality at affordable price and to supplement the efforts of the government for management of the situation arising due to COVID-19 in the country.

Following the DCGI direction, All India Organisation of Chemists and Druggists (AIOCD), a representative body of 8.5 lakh chemists in the country, has appealed to its members to ensure availability of drugs included in both the lists for effective management of situation arising out of coronavirus pandemic.

The list of essential drugs required for 3 months period for the whole country includes non-steroidal anti-inflammatory agents—paracetamol (500mg), paracetamol syrup (oral liquid 125mg /5ml), Ibuprofen (400mg & 200mg), diclofenac sodium (50mg).

It includes antibacterial agents-- albendazole (400mg), amoxycillin capsule (500mg & 250mg), amoxycillin syrup (125mg/5ml), ampicillin capsule (500mg), ampicillin injection (500mg), azithromycin (oral suspension 200mg/5ml), capsule doxycycline (100mg), amoxicillin + clavulanic acid (injection 1.2 gm & capsule 500mg+125mg & powder for oral suspension 125mg+31.25/5ml), cefoperazone sulbactum (injection 1.5 gm), meropenam (injection 1gm), pipercillin + tazobactum (injection 4gm), ceftriaxone (injection 1gm/vial), cephalexin (tab/cap 250 mg), azithromycin (tablet 500mg), ofloxacin (tablet 200mg), metronidazole (tab 400mg), cotrimoxazole (trimethoprim + sulphamethoxazole (tablet 80+400mg), cefixime (powder for oral suspension 100mg/5ml).

It also has anti-fungal drugs -- clotrimazole (Pessary 500mg), fluconazole (tablet 150 mg) while list of antiviral drug comprises of acyclovir (tablet 400 mg).

Cardiovascular drugs are also in the list viz. acetyl salisylic acid (tablet 75mg), amlodipine (tablet 5 mg), enalapril (tablet 5mg), furosemide (tablet 40mg), MethylDopa (tablet 250mg), hydralazine (powder for injection 20mg/ampoule), atenolol (tablet 50mg), glyceral trinitrate (tab 500mcg), atropine (injection 1mg/ml 1 ml/ampoule), epinephrine (adrenaline) (injection 1 mg/ml & 1 ml/ampoule). The list contains dermatological drugs-- povidine iodine (10%, 200 ml bottle), miconazole (oint 2%), silver sulfadiazine, cream 1% (tube, 50 g), omeprazole (tab 20mg), domperidone (tab 10mg), ondansteron (tab 4mg), antacid(Al hydroxide +mg hydroxide), dicyclomine (tab 10mg).

It further has antiallergic medicine/medicine for anaphylaxis—cetrizine hydrochloride (tab 10mg), pheniramine maleate (injection 22.75 mg/ml), hydrocortisone, powder for injection 100 mg (as sodium succinate), prednisolone (tablet 5 mg).

The list has respiratory tract drugs-- salbutamol (tab 4mg), salbutabol inhaler (100mcg/dose), beclomethasone inhaler (100mcg/dose), etofylline+ theophylline (tab 84.3+25.3mg).

Anticonvulsants/antiepileptics which are also in the list are carbamazepine, tablets (scored) 200 mg, sodium valproate 9tab 200mg), phenytoin sodium (injection 50 mg/ml), diazepam, injection 5 mg/ml [controlled substance] (2ml ampoule), magnesium sulfate, injection 500 mg/ml (10 ml/ampoule).

There is a list of hormones, other endocrine medicines and contraceptives which include Injection Intermediate-acting insulin (100 IU/ml [cold chain] 10 ml/vial), injection soluble insulin (100 IU/ml [cold chain] 10 ml/vial), metformin (tab 500mg), glimepride (tab 2mg), thyroxine (50 mcg).

Apart from this, drugs affecting blood are also in the list viz. folic acid (5mg tablet), heparin sodium (injection 5 000 IU/ml vial 5 ml) and list of oxytocics has misoprostol (tab 200 mcg), oxytocin (injection 10 IU/ml [cold chain] ampoule). Antianxiety medications are also in the list viz. biperiden, tablets 2 mg, diazepam, tablets 5 mg [controlled substance], fluoxetine, tablets 20 mg, haloperidol, injection 5 mg/ml (1 ml/ampoule), haloperidol, tablets 5 mg. List of antidiarrheoal agents comprises of ORS (oral rehydration salts) powder (10 x 200), zinc sulfate, dispersible tabs 20 mg (10x1000).

The list has solutions correcting water, electrolytes and acid-based disturbances comprises of Ringer's lactate, injectable solution, with giving set and needle (500 ml bag), glucose 5%, injectable solution, with giving set and needle (500 ml bag), sodium chloride (0.9% isotonic). List of vitamins and minerals includes ferrous sulfate + folic acid, tablets 200 mg + 0.4 mg, vitamin B complex, calcium + Vit D3 (tablet (500 mg + 250 IU), ascorbic acid, tablets 250 mg.

The list has anesthetic/analgesic agents including nitrous oxide (inhalation), oxygen (inhalation) morphine 10mg/ml, ketamine, injection 50 mg/ml, lidocaine, injection 1% (20ml), thiopentone sodium S, T (injection 1 g powder), lignocaine hydrochloride (topical forms, 2-5%).

Besides this, there are miscellaneous products such as activated charcoal (oral, tab 250mg), specific antisnake venom, calcium gluconate (injection 100mg/ml, 10/ml/amp), anti rabies vaccine,a rabies seru (injection 5000IU/2ml) and eye/ear drop –ciprofloxacin.

Source: Laxmi Yadav, Pharmabiz, 18.04.2020

● ● ●

Maharashtra FDA issues product licenses to 64 companies to produce HCQ to tide over its growing demand

The Maharashtra Food and Drug Administration (FDA) has issued product licenses to 64 manufacturers in the state to produce hydoxychloroquine (HCQ) in the past one month to tide over its growing demand domestically and globally for the treatment of COVID-19. HCQ is being used by several countries as a preventive measure against COVID-19.

Through easing export restrictions on the HCQ drug, the Indian government has taken the lead in supplying HCQ to over 20 countries including the US. According to industry sources, the country has the availability of 12 crore tablets and its major manufacturer IPCA has planned to supply 10 crore tablets in the month of April itself for the domestic requirement first. It has also been learnt that there are 15 lakh tablets in the retail supply chain.

To discourage its irrational use, HCQ which is widely prescribed for auto immune disorders has also been brought under Schedule H1 by the Government. Panic buying of HCQ was reported under the assumption that its consumption can prevent COVID-19 even as health experts have cautioned that it can be taken only against physician prescription. The demand for HCQ has increased approximately 30 per cent in India so far in view of the COVID-19 pandemic. The demand for the drug is increasing day by day due to rise in positive cases of COVID-19 in the country.

Indian Council of Medical Research (ICMR) has recommended the use of HCQ for treating healthcare workers handling suspected or confirmed coronavirus cases and also the asymptomatic household contacts of the lab-confirmed cases.

Currently India manufactures 40 metric tonnes of hydroxychloroquine API per month which amounts to a production of 200 million tablets of 200mg. Domestic manufacturers such as Ipca Laboratories and Zydus Cadila are ramping up production from the current 50 to 70 metric tonnes per month. 100 million tablets out of 350 million tablets are sufficient to manage 7 million patients in the country keeping 250 million tablets aside, sources stated. Both Ipca and Zydus have received orders to produce the drug for the USA market in the wake of outbreak of COVID-19 pandemic. Zydus Cadila is the largest player in the US market with 32 per cent market share by volume.

A couple of days back India had exported 29 million dosages of the drug to US following US President Donald Trump's appeal.

Source: Shardul Nautiyal, Pharmabiz, 18.04.2020

● ● ●

ICMR grants permission to set up two more advanced COVID-19 diagnostic centres in Hyderabad

Adding to the existing 7 COVID-19 testing centres in Hyderabad, the Indian Council for Medical Research (ICMR) has granted permission for setting up 2 more most advanced COVID-19 diagnostic centres, which are expected to come up in the next two weeks time. According to sources from the health department, at present there are only 7 diagnostic centres which are conducting tests on the samples of corona infected patients. However, as these centres are not able to meet the growing demand for coronavirus tests in the state, the state government had urged the central government to grant permission for conducting COVID-19 tests in Hyderabad.

"At present we are having a capacity of conducting 2,000 to 2,500 coronavirus tests in the existing 7 diagnostic laboratories. However, as there is a growing demand for more and more tests to be conducted among the public, we have urged the central government to permit two more COVID-19 diagnostic centres in Hyderabad. Very soon one diagnostic centre will be set up at the labour department and the other will be set up at the forensic department. If these two centres come into being, Telangana will be having a capacity of conducting 5,000 tests per day," informed a senior official from the health department.

Currently, coronavirus tests are being conducted at Osmania Medical College, Gandhi Hospital, Government MGM Hospital in Warangal, Centre for Cellular and Molecular Biology, Fever Hospital, Institute of Preventive Medicine and Nizam's Institute of Medical Sciences.

However, as all these centres are having limited resources and can conduct coronavirus infection tests to only a limited number of patients, the state government had urged the central government to grant permission to two more coronavirus diagnostic laboratories in the state. Based on the request, the ICMR authorities have issued permission to set up two more coronavirus diagnostic laboratories, which are expected to come into being in the next few days.

Source: A Raju, Pharmabiz, 18.04.2020

● ● ●

NPPA develops IT platform to monitor availability of HCQ and azithromycin

The Drugs Controller General of India (DCGI) has directed all state licensing authorities (SLAs) to ensure registration of all drug distribution stakeholders in prescribed format of National Pharmaceutical Pricing Authority (NPPA)'s online platform circulated from the DCGI office to collect information on hydroxychloroquine (HCQ) and azithromycin tablets to monitor their availability.

As per a DCGI circular to all SLAs and drug sale license holders in the country, NPPA is developing an IT platform to monitor availability of HCQ and azithromycin tablets at all distribution channels - C&F agents or depot, distributors, wholesalers and retailers. It will be a very simple platform to upload the information. Before uploading the data, all are requested to first register themselves in the DCGI prescribed format to create master data through the following link immediately at https://tinyurl.com/wavqapo.

Drugs control officers are requested to forward the message to all concerned groups in respective states/ districts, as per DCGI.

NPPA had also earlier directed merchant importers, stockists, manufacturers of active pharmaceutical ingredients (APIs) and formulations to submit data of 58 APIs to prevent illegal hoarding and black marketing in the country.

The drug pricing regulator's directive had come in the wake of outbreak of coronavirus (COVID-19) in China which has affected availability of key APIs and Key Starting Materials (KSMs) in India.

NPPA took this decision in pursuance of the powers laid down under Para 29 of Drugs Price Control Order (DPCO)-2013, which stipulates that all importers of APIs, manufacturers of formulations and APIs and stockists are directed to submit the information in the prescribed Form-A for merchant importers and Form-B for indigenous manufacturers or stockists duly signed by the authorised person along with soft copy in excel format at manjesh.porwal@gov.in or dir-me.nppa@nic.in.

NPPA had also urged all SLAs to ensure compliance of this order and an indicative list of importers has also been shared for ready reference.

Indian Drug Manufacturers' Association (IDMA), Indian Pharmaceutical Alliance (IP Alliance), Organisation of Pharmaceuticals Producers of India (OPPI), Bulk Drug Manufacturers Association (BDMA), Federation of Indian Chambers of Commerce and Industry (FICCI), Confederation of Indian Industry (CII) and Federation of Pharma Entrepreneurs (FOPE) were also asked to disseminate information related to it and also ensure compliance of this order.

Source: Shardul Nautiyal, Pharmabiz, 17.04.2020

● ● ●

DST invites research proposals for developing antiviral nano coating for PPE

The Department of Science and Technology (DST) has invited short-term research grant special call for developing nano coating COVID-19 and new nano-based material for use in personal protective equipment (PPE), which can be transferred to a partnering industry or start-ups for scale up.

The purpose will be for the development of antiviral nano-coatings for materials to be used on appropriate material for producing anti-COVID-19 triple layer medical masks and N-95 respirator or better masks in large quantities and components of PPE for safeguarding the health of all health care workers against COVID-19.

Such nano coatings could contribute immensely in the emerging health care requirements in India's fight against the COVID-19 pandemic. The project duration should be maximum up to 1-year with a maximum budget limit of Rs. 25-30 lakhs.

The industry contribution could be in the form of manpower and its Central Technical Committee (CTC), or partly for testing of nano coating to meet the European Union (EU) or US standards for exporting the developed product.

The coating will be used on masks, other protection gear used by healthcare workers. This call is for bringing academic groups and industrial groups together to submit proposals to DST's Nano Mission. Interested groups can forward their applications to the Science and Engineering Research Board (SERB).

The proposals will be initially screened for the competence of PI, suitability and scope prior to peer-review. All items developed and transferred to industry should meet the International standards or BSI standards for ensuring quality of the nano coating based product produced. Projects concerning other pathogens will not be considered in this call. The last date for submission of proposals is April 30, 2020.

Source: Neethikrishna, Pharmabiz, 17.04.2020

● ● ●

Only 10% Pharma Wholesale business in Maharashtra due to curtailed workforce and logistics challenges

There is only 10% wholesale business happening in Maharashtra due to curtailed workforce in the wake of COVID-19 leading to negatively affecting the drug retail supply chain in the state. Besides this, there is an inventory available for drugs in the chronic segment and other emergency drugs for 40 days only, according to reliable trade sources.

Wholesalers have cautioned that if the workforce and logistic issues are not resolved soon, there are likely shortages of medicines for chronic segments such as cardio vascular (heart) and diabetes drugs soon. Even the medicines with general physicians are likely to go out of stock.

Therefore they have voiced their concern that ease of transport of medicines just like milk and other household provisions should be given priority. The vehicles transporting medicines should be allowed to operate without hindrances through a robust administrative protocol.

"Those who are engaged in healthcare be it doctors, nurses, ward boys, those engaged in logistic/supply chain of medicine should be given special passes and special arrangements may be made for their plying from their home to work and back," the wholesalers associations further explained. This comes in the backdrop of Indian pharmaceutical market (IPM) growing 8.9% year on year to Rs. 11,856 crore, propelled by robust sales of cardiac care, respiratory and anti-diabetes medication, according to market sources.

There are also reports that hydroxychloroquine (HCQ) has been bought by people for prophylactic use due to panic buying which again has led to its reported shortages in the market. India is the world's largest manufacturer of HCQ, which is used for treatment of rheumatoid arthritis, malaria and lupus and can be taken only against a doctor's prescription.

This is amid the assurance given by National Pharmaceutical Pricing Authority (NPPA) that there is enough stock of HCQ in the country and its demand, availability and production is monitored on a daily basis. India has manufacturing capacity of 10 crore tablets per month. Last year, 2.4 crore HCQ tablets were sold in the domestic market. Moreover, pharmaceutical companies in the state have also been facing issues in terms of manufacturing due to manpower resource crunch and in terms transporting goods to C&F Agents, according to industry sources.

The Indian pharmaceutical industry earlier this week said there is enough stock of HCQ in the country and drug firms are ready to ramp up the production to meet domestic as well as export requirements. In order to boost domestic production and indigenous manufacturing, leading stockists have recommended that Indian Government has to come out with friendly labour policies, offer estate or economic zones, infrastructure and single window clearances through simplification of licensing and approvals.

Companies like IPCA, Zydus Cadila, Mangalam Drugs and Vital Laboratories are the major manufacturers of HCQ in the country. India currently has an annual installed capacity of around 40 tonnes of active pharmaceutical ingredients (APIs) of HCQ. With this capacity, it can make around 200 million tablets of 200 mg, which can be ramped up.

Source: Shardul Nautiyal, Pharmabiz, 16.04.2020

● ● ●

Ayush Ministry issues suggestive self-care guidelines for preventive healthcare measures

With an aim to guide the people to stay fit and gain immunity towards any kind of viral attacks in these times of widely spreading COVID-19 viral pandemic in India, the Ministry of Ayush, Government of India has issued a few

suggestive self-care guidelines for preventive healthcare of the people.

According to an advisory released by the Ayush ministry, it has stressed more focus on taking more liquids, citrus juices and other nutritious foods to boost the immune system of an individual. "To contain the spread of deadly corona virus, people must follow the guidelines issued by the Ayush ministry. Individuals must take all the necessary safety precautions like regular washing of hands and covering their face with masks. In addition to this, they should also concentrate on taking liquids and nutritious foods to boost their immune system so that the respiratory health is strengthened to sustain any viral attacks," advised Dr Surya Prakash, Additional Director of Ayurveda, government of Telangana.

As per the advisory, the ministry has recommended that it will be good to take preventive measures which boosts immunity as there is no medicine for COVID-19 viral disease, which is spreading alike a wild fire across the globe causing deaths to lakhs of people. During his recent address to the Nation, Prime Minister Narendra Modi has also mentioned in his 7 point appeal to the nation advising the people to follow the guidelines laid down by the ministry of Ayush to help everyone build their immunity and fight against the pandemic.The Aysuh experts said that these guidelines are based on the measures, recommended by eminent Vaidyas (Ayush doctors) from across the country as they may possibly boost an individual's immunity against corona virus infection. The recommendations of the ministry are supported by ayurvedic literature and scientific publications.

The key recommendations as per the ministry's guidelines include drinking warm water throughout the day and practicing yogasana, pranayama and meditation daily for at least 30 minutes. The ministry also advised having chyawanprash (sugar free for diabetic patients) in the morning and golden milk (milk with turmeric) daily.

The Ayush preventive measure also recommended taking herbal tea or decoction made from tulsi (basil), dalchini (cinnamon), kalimirchi (black pepper, shunti (dry ginger) and munakka (raisin) once or twice a day with jaggery or fresh lemon juice in it for better taste.

Ayush guidelines also suggested oil therapies such as oil therapies and application of sesame oil or coconut oil or ghee in both the nostrils. It also suggested steam inhalation with fresh mint (pudina) leaves or ajwain (caraway seeds) which can be practiced once a day to help during dry cough and sore throat. Lavang (clove) powder mixed with natural sugar or honey can be taken 2-3 times a day in case of cough or throat irritation. However all these measure are only suggested as preventive measures to keep away people from getting infection and does not claim to provide any treatment for COVID-19.

Source: A Raju, Pharmabiz, 16.04.2020

● ● ●

One each for import and export: How over-dependence on China and US Markets blocks Indian Pharma's Growth

Why the Government must work to reduce excessive dependence of Indian pharma industry on China and US

At a time when even China struggles to ramp up production of critical medical equipment such as ventilators, Indian pharma industry has secured adequate supplies of vital drugs, including hydroxychloroquine – not just for India but for most of our friends and strategic allies.That this is an opportunity to emerge as a major manufacturing country is well regarded but ensuring the same would require us to identify key challenges and find potential solutions.This was discussed at length in the High Level Advisory Group (HLAG) report that highlighted some of the challenges faced by the sector while suggesting possible recommendations.

It is important that we revisit them:

First, the challenges. On top of the list is India's excessive dependence on China for sourcing active pharmaceutical ingredients (APIs).

India's import of APIs grew at CAGR 11 per cent between 2004 and 2016 of which 60 per cent of imports by volume (70 per cent by value) were from China alone. The cost differential between Indian and Chinese manufactured APIs is estimated to be 25-30 per cent.

The disruption and lack of availability of raw materials had exposed the problems associated with this overdependence over the last few months. Consequently, we need to recognise that this price difference between Indian and Chinese APIs must be moderated to adequate supply of APIs from domestic sources. Another problem has been increasing competition from China in generics and biologics. Add to that excessive regulation and frequent changes being made by the Central Drug Standards and

Control Organisation (CDSCO) and Foods and Drugs Administration of the state (state FDA).

A regulatory overhaul is needed urgently to ensure that our pharmaceutical sector, which has proved its mettle can indeed flourish.Multiple regulatory agencies across central government departments and state governments stifle innovation and impose additional regulatory compliances that increases the operational costs for our firms.

HLAG here proposes a central FDA-like institution, which would be in contrast with the current structure of NPPA, DGCI etc, which have many overlaps and consequently slow the decision-making process. The other challenge has been excessive dependence on the US and generics as India's pharmaceutical industry has about 35 per cent of its export revenues coming from North America, mainly the US.

Consolidation in US markets, greater competition and pricing pressures have indeed dampened export value. Indeed, just as overdependence on one market for import of inputs is dangerous, similarly overdependence on select markets for exports are also problematic.

Indeed, that Indian pharmaceutical Industry has survived, flourished and made its mark at one of the most challenging times is encouraging. However, government regulations over the last seven decades have done little compared to other countries to facilitate their growth. An industry that rises to the occasion on its entrepreneurial spirit rather than government support must be respected, appreciated and complemented.

Source: Karan Bhasin, Swarajya, 16.04.2020

● ● ●

India pharma faces acute manpower shortage due to lockdown

The country-wide lockdown imposed by the Central government to contain the spread of COVID-19 pandemic in the country has hit the manpower requirements of the Indian pharma industry. Pharma companies across India are working with just 30-35 per cent strength since employees who had left for different cities are unable to return to the plants because of the lockdown.

As a result of this, the plants are unable to function to their full capacity. This comes at a time when global markets are looking at India for supply of drugs like anti-virals and hydroxycholoroquine (HCQ), according to a panel of experts at a webinar hosted by Messe Muenchen India and organised by IPMMA in association with Indian Analytical Instruments Association.

The panel, comprising Paresh Chawla, MD, Alpa Laboratories and chairman, IDMA, MP state board; Dr Viranchi Shah, director, Saga Laboratories and chairman, IDMA Gujarat state board; and Shirish Belapure, senior technical advisor, Indian Pharma Alliance deliberated on the topic 'COVID-19 pandemic: Time to Collaborate, Cooperate and Innovate to face the Challenges in the Pharma Industry'. The webinar was moderated by Kaushik Desai, advisor, Indian Pharma Machinery Manufacturers Association. Dr Shah said that the pharma sector was facing challenging times with disruptions in the supply chain and deceleration in pharmaceutical manufacturing. This has come about because only 30-35 per cent of the workforce is reporting for duty. This pandemic has not spared anyone in terms of scale and challenges encountered, he said.

However, Indian pharma's robust processes will help it face any challenge, he added.Shah said only employees living in close proximity with the plant have been able to return to work. This is the time to maximize the available manpower and ensure that right safety mechanisms are put in place. These include temperature mapping, masks, gloves and sanitisers. "In addition, we need to handle those coming to work with compassion to improve productivity since the rampant spread of the pandemic has given rise to fear in people," he added.

According to Belapure, pharma manufacturing is essential to avoid drug shortages in the face of the pandemic. "We have not faced a problem since there is adequate inventory. But going forward, we need to take measures to offset the shortages," he said.

"Companies need to focus on risk mitigation and create emergency plans. Even 20 percent absenteeism of workforce is a big issue," said Belapure.

Chawla noted that the world was looking at India for drugs with considerable demand for HCQ coming from the US, Malaysia and other countries. "The US FDA has given permission to Lupin, Dr Reddys and IPCA to export to the US. This is the positive side of the pandemic. The industry recorded 8.9 percent growth in March. We are geared up to manufacturing, innovation and collaboration," Chawla.

However, Chawla noted that there is a need to adopt design thinking concepts, go digital and automate processes to overcome shortage of labour. "Hence supply chain management and staff motivation are the need of the hour," he added.

Concluding the session, the three speakers noted that while the current situation is far from getting normal, the Indian pharma industry along with Government and Associations has to cooperate, collaborate and innovate to offset the shortage of manpower and other areas in order to ensure availability of medicines to the needy patients.

Source: Nandita Vijay, Pharmabiz, 18.04.2020

● ● ●

ICMR to study if BCG vaccine helps prevent Coronavirus

The Indian Council of Medical Research (ICMR) will start a new trial next week to study the efficacy of BCG vaccine in preventing Covid-19, with the results expected to help the government decide if the vaccine can be recommended to frontline healthcare workers taking care of patients.

"The ICMR will begin a study next week. Till we have definitive results from this, we won't recommend it even for health workers," Dr R R Ganga khedkar, head of epidemiology and communicable disease at ICMR, said.

The possible effects of BCG vaccine in boosting antiviral immunity has been the subject of considerable comment, with some studies pointing to higher fatalities in European nations that have discontinued vaccination. Bacille Calmette-Guérin (BCG) is a vaccine primarily used against tuberculosis.

'No proof for official position, can give partial protection'

One dose is recommended for healthy babies as close to the time of birth as possible.

The trial on BCG vaccine will be one of a few lines of treatment and prevention being pursued around the world, with work continuing on antivirals like remdesivir, found useful against Ebola, and plasma or immune therapies besides research on an anti-Covid-19 vaccine.

"We do not have evidence to take an official position on the BCG vaccine in Covid-19. It cannot even stop TB but it can only protect from severity. It probably stops meningitis-—so it is partial protection.

There are some studies that show that it is an immunomodulator," Dr Gangakhedkar said Explaining its usage and efficacy, he said the vaccine is given at birth and is effective for 15 years.

There are studies about re-vaccination with BCG but even that is till adolescence or 15 years of age. However, there is no evidence or studies about the utility of re-vaccination after 15 years of age.

Source: Sushmi Dey, The Times of India, 18.04.2020

● ● ●

INTERNATIONAL NEWS

Designing peptide inhibitors for possible COVID-19 treatments

Scientists across the globe are rushing to find inhibitors of SARS-CoV-2, the new coronavirus behind the COVID-19 pandemic. Some are using computer simulations to identify promising compounds before conducting actual experiments in the lab. Now, researchers reporting in ACS Nano have used computer modeling to assess four peptides that mimic the virus-binding domain of the human protein that allows SARS-CoV-2 to enter cells.

To infect cells, SARS-CoV-2 uses its spike protein to attach to the ACE2 receptor, a protein on the surfaces of certain human cells. This attachment lets the virus fuse with the host cell membrane and gain entry. Many researchers have been trying to find compounds that block key regions of the spike protein, preventing the virus from infecting cells. Yanxiao Han and Petr Král wanted to use computer modeling to design compounds that mimic the spike protein's natural target, ACE2. To do so, the researchers examined the recently published X-ray crystal structure of the receptor-binding domain of SARS-CoV-2 when it is bound to ACE2. They identified 15 amino acids from ACE2 that interact directly with the viral protein. Then, the researchers designed four inhibitors that contain most or all of these amino acids, with additional sequences that they thought would stabilize the structures. Through computer simulations, the team studied how the inhibitors might attach to the spike protein in the body and the energies needed for binding. One of the compounds showed a particularly good fit with the viral protein. The peptide still needs to be tested in the lab and in patients, but being able to narrow down drug candidates on the computer could help expedite this process, the team says.

Source: World Pharma News, 16.04.2020 (Excerpts)

● ● ●

NIH to launch Public-Private Partnership to speed COVID-19 vaccine and treatment options

The National Institutes of Health and the Foundation for the NIH (FNIH) are bringing together more than a dozen leading biopharmaceutical companies, the Health and Human Services Office of the Assistant Secretary for Preparedness and Response, the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration and the European Medicines Agency to develop an international strategy for a coordinated research response to the COVID-19 pandemic. The planned Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership will develop a collaborative framework for prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes and/or leveraging assets among all partners to rapidly respond to the COVID-19 and future pandemics. This is part of the whole-of-government, whole-of-America response the Administration has led to beat COVID-19.

"We need to bring the full power of the biomedical research enterprise to bear on this crisis," said NIH Director Francis S. Collins, M.D., Ph.D. "Now is the time to come together with unassailable objectivity to swiftly advance the development of the most promising vaccine and therapeutic candidates that can help end the COVID-19 global pandemic."Coordinated by the FNIH, ACTIV government and industry partners will provide infrastructure, subject matter expertise and/or funding (both new and in-kind) to identify, prioritize and facilitate the entry of some of the most promising candidates into clinical trials. Industry partners also will make available certain prioritized compounds, some of which have already cleared various phases of development, and associated data to support research related to COVID-19. The partnership is being developed with input from a steering committee managed by the FNIH which includes leaders from NIH, FDA and the research and development organizations of the companies.

"COVID-19 is the most significant global health challenge of our lifetime, and it will take all of us working together as a global community to put an end to this pandemic," said Paul Stoffels, M.D., Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson. "We will need to harness the best ideas from multiple stakeholders, including governments, regulatory authorities, academia, NGOs and industry to stop COVID-19. At Johnson & Johnson, we are committed to working closely with FNIH, IMI and are part of other important consortia to speed solutions to stop this pandemic."

"Battling the COVID-19 pandemic is far too great a challenge for any one company or institution to solve alone," said Mikael Dolsten, M.D., Ph.D., Chief Scientific Officer and President, Worldwide Research, Development and Medical, Pfizer. "We are seeing an unprecedented level of collaboration across the innovation ecosystem to address this global health crisis, and this potentially powerful NIH initiative may allow us to further accelerate the delivery of much needed therapies to patients around the world."

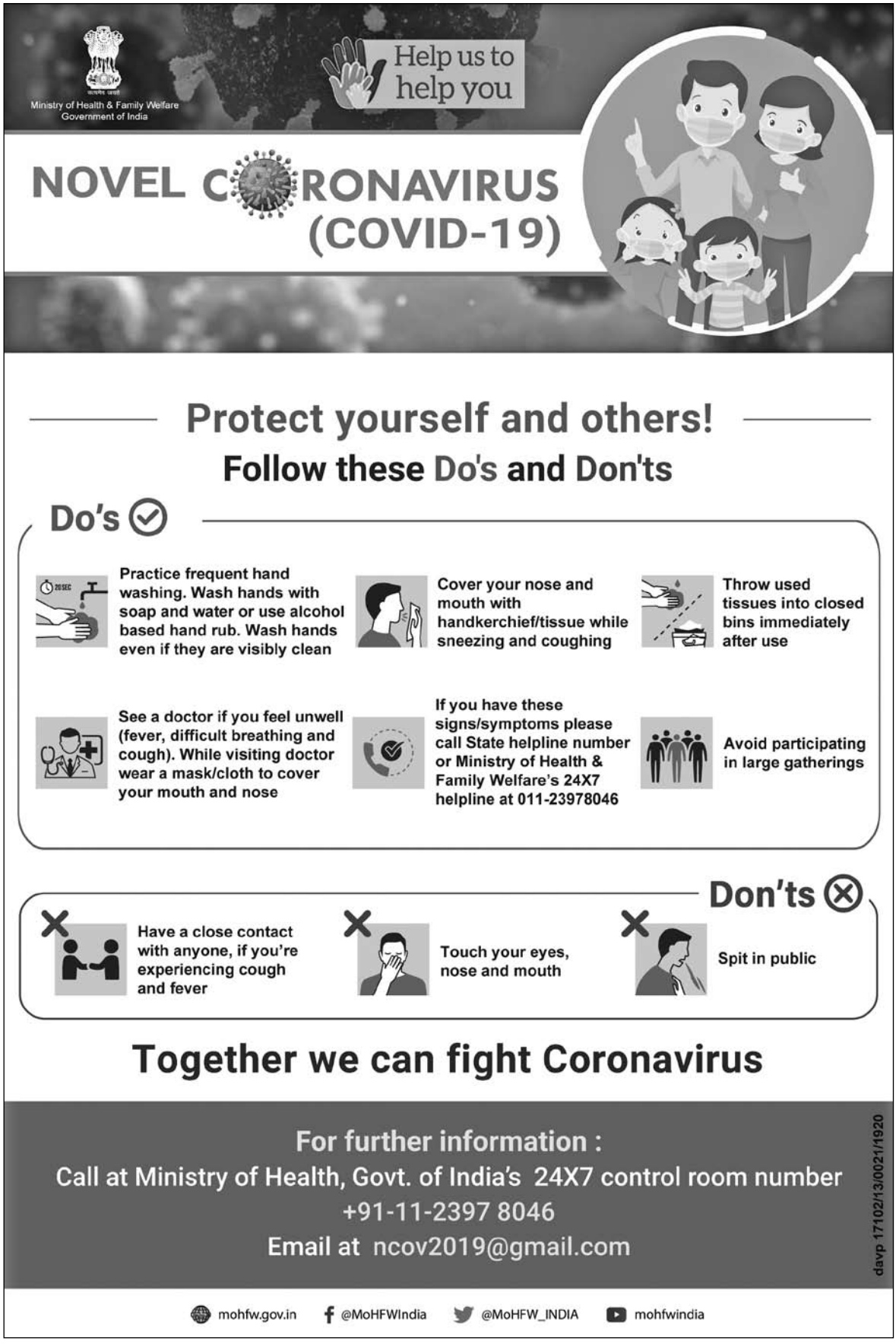
The research community is currently striving to sift through more than 100 potential preventives and therapeutics for COVID-19. ACTIV will aim to provide guidance which can be used to prioritize the plethora of vaccine and therapeutic candidates in development and connect clinical trial networks to test new and repurposed candidates quickly and efficiently."Using the most advanced clinical trial methods to rapidly test multiple interventions will help get the answers we need as soon as possible to expedite potential prevention and treatment approaches to fight COVID-19," said FDA Commissioner Stephen M. Hahn, M.D. "Collaboration is a critical ingredient for success and the FDA will continue to use every tool possible under our Coronavirus Treatment Acceleration Program(link is external) to speed the development of safe and effective medical countermeasures."

ACTIV will have four fast-track focus areas, each of which will be led by a highly motivated working group of senior scientists representing government, industry and academia:

- Standardize and share preclinical evaluation methods in an open forum that allows for comparison and validation
- Prioritize and accelerate clinical evaluation of therapeutic candidates with near-term potential
- Maximize clinical trial capacity and effectiveness
- Advance vaccine development

"This powerful public-private partnership will focus and expedite R&D activities required to combat COVID-19," says Maria C. Freire, Ph.D., President and Executive Director, FNIH. "Working in lock-step, the public and private sectors will maximize the chances of success and provide a roadmap to pre-emptively manage future threats."

Source: World Pharma News, 17.04.2020 (Excerpts)


Ministry of Health & Family Welfare
Government of India
Help us to help you
NOVEL CORONAVIRUS (COVID-19)
Protect yourself and others!
Follow these Do's and Don'ts
Do's
Practice frequent hand washing. Wash hands with soap and water or use alcohol based hand rub. Wash hands even if they are visibly clean
Cover your nose and mouth with handkerchief/tissue while sneezing and coughing
Throw used tissues into closed bins immediately after use
See a doctor if you feel unwell (fever, difficult breathing and cough). While visiting doctor wear a mask/cloth to cover your mouth and nose
If you have these signs/symptoms please call State helpline number or Ministry of Health & Family Welfare's 24X7 helpline at 011-23978046
Avoid participating in large gatherings
Don'ts
Have a close contact with anyone, if you're experiencing cough and fever
Touch your eyes, nose and mouth
Spit in public
Together we can fight Coronavirus
For further information :
Call at Ministry of Health, Govt. of India's 24X7 control room number
+91-11-2397 8046
Email at ncov2019@gmail.com
davp 17102/13/0021/1920
mohfw.gov.in
@MoHFWIndia
@MoHFW_INDIA
mohfwindia

IDMA BULLETIN

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

ADVERTISEMENT TARIFF

(Effective from 01.11.2017)

Magazine Size: 21.5 cm x 27.5 cm / Print Area: 18.5 cm x 23.5 cm

Position		Rate per Insertion ₹	
		B/W	Colour
Full Page (18 cm wd x 23.5 cm ht)	:	9,000	12,500
Half Page (18 cm wd x 11.5 cm ht) (Horizontal)		5,000	8,500
Half Page (8.5 cm x 23.5 cm) (Vertical)	:	5,000	8,500
Quarter Page (8.5 cm wd x 11.5 cm ht)	:	2,500	6,000
Strips Advts (4 cm ht x 18 cm wd)	:	2,500	-
Inside Cover Pages	:	-	18,000
Back Cover	:		25,000
Centre Spread (double spread) Print area (40cm wd x 27cm ht)	:	25,000	30,000

Terms and Conditions:

- All payments by **Cheque/ Demand Draft/RTGS** in advance only to be made in favour of **"Indian Drug Manufacturers' Association", Payable at Mumbai**

  Please see the NEFT/RTGS details:

  ACCOUNT NAME : *Indian Drug Manufacturers' Association,*

  RTGS to BANK: *CITIBANK N.A.,* ***BANK Account number :*** *0036274115.*

  IFSC Code: CITI 0100000,BRANCH: *FORT BRANCH, MUMBAI — 400 001.*
- GST will be charged extra, as applicable. *(Current Rate is @5%*)
- SPECIAL DISCOUNTS for Series Advertisements
- For colour advertisements, positives to be supplied otherwise processing charges to be paid.
- **Advertisement material must reach us 7 days before the date of publication.**
- Positioning of the Advt other than Cover Positions will be at our discretion.
- Only Colour Advts will be entertained on Cover Positions.

Classified Advertisements

- Upto 80 words — ₹2,000/-
- 50% extra for Advt Box Number
- 50% extra for indent/layout spacing, bold captions, etc.
- ₹50/- extra for voucher copy
- Series discount not applicable for classifieds

For further details such as series discounts etc, please contact:
Mr T R Gopalakrishnan — Cell: +98190 35076 (Email: admin@idmaindia.com)/
Mr *C* K S Chettiar— Cell: +98206 29907 (Email: mail_idma@idmaindia.com)
PUBLICATIONS DIVISION

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai 400 018. Tel: 022-2494 4624/2497 4308 Fax: 022-2495 0723
Website: **www.idma-assn.org www.indiandrugsonline.org**


व्यं राष्ट्रे जागृयाम
Rising to the Hon'ble Prime Minister's call..
SETU
A VOLUNTARY INITIATIVE OF IRTS OFFICERS
Are you a pharma manufacturer or distributor?
Are you a medical equipment supplier?
Looking to send medicines/ PPEs/ Ventilators/ Raw materials across the country?
Avail Parcel Services of Indian Railways!
Contact the Sr DCM and Sr DOM of the Railway Division nearest to you.
Dedicated Helpline
888 826 1234
@IRTS_SETU
Any station to any station
Time Tabled

LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2018-20
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2018-20
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 21.04.2020

Edited, Printed and Published by **Dr.Gopakumar G. Nair** on behalf of **Indian Drug Manufacturers' Association**, Printed at **Ebenezer Printing House**, Unit No. 5 & 11, 2nd Floor, Hind Services Industries, Veer Savarkar Marg, Dadar (West), Mumbai 400 028 and Published from 102-B, Poonam Chambers, "A" Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai 400 018. Editor: **Dr.Gopakumar G. Nair.**