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. 20 (PAGES: 40) | 22 TO 30 MAY 2020 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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. 20** **22 to 30 May 2020**

IDMA PUBLICATIONS RATE CARD

Sr. No.	Name of Publications	Cost in ₹
1.	**IDMA BULLETIN (Annual Subscription – 48 Issues)** *(Published on 7th, 14th, 21st and 30th of every month)*	
	• Members	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
2.	**INDIAN DRUGS (Annual Subscription – 12 Issues)** *(Published on 28th of every month)*	
	• Members	1000/- p.a
	• Students	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
3.	**IDMA APA Forum**	
	• Annual Membership	500/-
	• Life Membership	5000/-
4.	**TECHNICAL MONOGRAPHS**	
	NO. 1: STABILITY TESTING OF EXISTING DRUG SUBSTANCES AND PRODUCTS	400/-
	NO. 2: PRIMARY & SECONDARY CHEMICAL REFERENCE SUBSTANCES	400/-
	NO. 3: INVESTIGATION OF OUT OF SPECIFICATION (OOS) TEST RESULTS	400/-
	NO. 4: PHARMACEUTICAL PREFORMULATION ANALYTICAL STUDIES	400/-
	NO. 5: ENVIRONMENTAL MONITORING IN CLEANROOMS	400/-
	NO. 6: CORRECTIVE/PREVENTIVE ACTIONS (CAPA) GUIDELINE	400/-
	NO. 7: DATA INTEGRITY GOVERNANCE	400/-
5	**TECHNICAL DOCUMENT** QUALITY 4.0 DIGITAL TECHNOLOGY OF THE FUTURE	500/-
6.	**IDMA MEMBERSHIP DIRECTORY**	1,500/-
7.	**IDMA ANNUAL PUBLICATION**	1,500/-

Kindly note:

- *Mailing of IDMA Bulletin and Indian Drugs by Post will commence prospectively only after receipt of payment.*
- *All payments may be made in advance by Cheque / DD / RTGS / NEFT only in favour of:* ***"Indian Drug Manufacturers' Association".***
- For **RTGS / NEFT**: Account Name***: Indian Drug Manufacturers' Association, Bank****: CITIBANK N.A, **Bank Account Number:****0036274115, **IFSC Code****: CITI0100000, **Branch****: Fort Branch, Mumbai – 400 001.*
- Courier charges for Publications under Serial Nos. 3 to 7 will be extra as applicable.
- Please intimate us details through email immediately after making the remittance through RTGS/NEFT, so as to enable us to do the needful promptly.
- GST will be charged extra, as applicable.

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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

NGOs ask Government to revoke all three patents granted to Remdesivir as it lacks novelty and innovation

NGOs, working in the health sector, have demanded to the Government to revoke all the three patents granted to drug Remdesivir, which is being considered as a potential treatment for COVID-19 disease and could be an effective treatment. Remdesivir is patented and manufactured by American biopharmaceutical company Gilead Sciences Inc. Remdesivir is not approved as yet and is an investigational drug undergoing Clinical Trials.

In a letter to the Secretary, Department of Promotion of Industry and Internal Trade (DPIIT), Ministry of Commerce & Industry, the NGOs pointed out that the drug Remdesivir has been granted three patents in India viz IN 275967 (7068/DELNP/2010), IN 319927 (1328/CHENP/2013) and IN332280 (201727012821); and all these patents have been granted against the provisions of the Patents Act.

These three patents fail to satisfy the patentability criteria set out in the Indian Patents Act viz novelty and inventive step. Thus, there is a failure from the part of the Patent Office in the actual implementation of the provisions of the Patents Act and its Guidelines for the Examination of Inventions in the Field of Pharmaceuticals.

The NGOs stated that the first patent i.e. IN275967 contains Markush claims, which does not satisfy the inventive steps and goes against the Guidelines for granting Markush claims under the Guidelines for the Examination of Claims on Pharmaceutical Inventions. The patent claims chemical structures without evidence of their antiviral activity. Markush claims granted are vague and too broad leading to structural possibilities not contemplated by the patent specification.

The second patent i.e. IN 319927 the structure of Remdesivir is already disclosed in the Patent IN275967 and therefore has no novelty. The IN'927 claims new use, which is per se prohibited by the Act. The IN'927 patent claims nucleoside analogs that are well known to exhibit antiviral properties. For decades chemists have been developing nucleoside and its nucleoside phosphonate analogues with different modifications. The modification with nucleoside analogues having 1'-CN and 2'-OH modifications were indeed known in the context of viral or tumor suppression. Further, developing a phosphoramidate prodrug is very obvious from the existing prior art and therefore not satisfies the inventive step criteria under the Patents Act, 1970.

Regarding the third patent IN332280, we would like to bring your attention to the communication of the Cancer Patient Aid Association (CPAA), which clearly shows the illegality in the grant of the patent. We reiterate and rely on their arguments against IN'280, the NGOs, CAMD-India and Third World Network (India), in the letter to the DPIIT Secretary said.

Source: Pharmabiz, 18.05.2020

● ● ●

High-level panel to reform drug regulatory system as Modi Government works to fast-track approvals

The panel, which meets today to discuss the details of reforming the system, comprises entrepreneurs Adar Poonawalla and Pankaj Patel and senior health officials among others. The Narendra Modi government has constituted a high-level committee to "simplify and expedite" the drug approval process in India, ThePrint has learnt, as the country continues to fight the Covid-19 pandemic.Comprising top drug and vaccine entrepreneurs of India and senior bureaucrats, the committee was set up by the Ministry of Health and Family Welfare as an urgent measure to reform the drug regulatory system in India.

"The issue of reforms in the drug regulatory system has been engaging the attention of the government of India for quite some time now," said the health ministry order

titled 'Constitution of a committee for reforming the Drug Regulatory System in India'. It was issued on 11 May. The committee will revamp the Central Drugs Standard Control Organization (CDSCO), an arm of the health ministry that heads the regulatory system of drugs and medical devices in India.

While the order, accessed by ThePrint, applauds the latest moves taken by the CDSCO following the pandemic — including the fast-track access to testing kits, vaccines, therapeutics, preventive treatments and diagnostics — it stresses the need for "comprehensive changes" to make the system more effective.

Committee to chalk out plan:

On the committee are billionaire entrepreneurs Adar Poonawalla, CEO of Serum Institute of India, and Zydus Cadila's Pankaj Patel, along with top officials from the Department of Pharmaceuticals, Indian Council of Medical Research (ICMR), Department of Biotechnology (DBT) and All India Institute of Medical Sciences (AIIMS). The committee will be chaired by Rajesh Bhushan, Officer on Special Duty, Ministry of Health, while Joint Drug Controller of India Dr Eswara Reddy will assist the committee that will work on adopting global standards for drug and medical device regulation amid the ongoing pandemic. The committee first met on 19 May for a formal introduction and setting the agenda. Its second meeting for more elaborate discussions is scheduled to take place shortly.

How the committee will work:

The Ministry had ordered the committee to study previous reports by various committees on the working of the CDSCO, on clinical trials, and on whether the current qualification criteria for the department head — the Drugs Controller General of India — needs to be revised and also address recommendations suggested by these committees that were not unimplemented. "The committee will submit its report within a period of one month from the date of its formation," the 11 May Ministry order said.

The Ministry noted in the order that the "requisite procedural changes" which have been carried out by CDSCO "have worked quite well", but added: "However, it is felt that comprehensive changes in the drug regulatory regime should be carried out to reflect global best practices as well as domestic requirements and to streamline the CDSCO to make it more effective." "…It has, therefore, been decided to constitute a committee for studying the current drug regulatory system and to submit recommendations for reforming the system to bring it in line with global standards and to deliver more efficiently," it further stated.

Source: Himani Chandna, ThePrint, 22.05.2020

● ● ●

IDMA ACTIVITIES

IDMA Members donate essential Vitamins to Maharashtra Police Force

IDMA received an appeal from Shri Krishna Prakash, IPS, Special Inspector General of Police (Admn), Maharashtra State to provide Vitamin D3 tablets for Maharashtra Police Force. They requested for supply of 2 Lakh 50 Thousand strips of Vitamin D3 tablets or any other equivalent tablets and later also requested for similar quantity of Vitamin C tablets. As you are aware, our Police Forces have been on the field for more than two months without any weekly off and holiday for protecting us 24/7 from this pandemic. They have been serving the society selflessly despite the severe summer. We requested Members for the contribution of these essential Vitamins to be supplied directly to the Police HQ at Mumbai. Our Members responded whole-heartedly and we thank them all. We gratefully acknowledge contribution of medicines by the following Members:

- **Abbott Healthcare Ltd**
- **Alkem Ltd**
- **Bharat Parenterals Ltd**
- **Blue Cross Laboratories Pvt Ltd**
- **Cipla Ltd**
- **Emil Pharmaceutical Industries Pvt Ltd**
- **Fermenta Biotech Ltd**
- **Indchemie Health Specialities Pvt. Ltd.**
- **Intas Pharmaceuticals Ltd**
- **Magpie Labs Pvt Ltd**
- **Sun Pharmaceutical Industries Ltd**
- **Umedica Laboratories**
- **USV Ltd**
- **Wallace Pharmaceuticals Ltd**
- **Zuventus Healthcare Ltd**

The Medicines are still being sent as Members have informed us that they are procuring the same from units in various other States and also being specially manufactured.

Amendments to EIA Notification, 2006 – reg.

Gazette Notification No. S.O.1562(E), dated 21st May, 2020

Whereas, the Central Government in the erstwhile Ministry of Environment and Forests, in exercise of its powers under sub-section (1) and clause (v) of sub-section (2) of section (3) of the Environment (Protection) Act, 1986 has published the Environment Impact Assessment Notification, 2006 (hereinafter referred to as the EIA Notification, 2006) vide number S.O.1533 (E), dated the 14th September, 2006, mandating prior Environmental Clearance from the Central Government in the Ministry of Environment and Forests for matters falling under Category 'A' in the Schedule and at State level the State Environment Impact Assessment Authority for matters falling under Category 'B' in the said Schedule;

And whereas, the State Environment Impact Assessment Authority and State Level Expert Appraisal Committees shall be constituted by the Central Government under sub-section (3) of section 3 of the Environment (Protection) Act, 1986 for a fixed term of three years;

And whereas, the Ministry of Environment, Forest and Climate Change is in the receipt of representations for extension of tenure of the State Environment Impact Assessment Authority and State Level Expert Appraisal Committees, beyond three years in certain situation like pandemic COVID 19, for uninterrupted dealing the matters under Category “B” proposals;

And whereas, the Central Government deems it necessary to extend the tenure of the existing State Environment Impact Assessment Authority and State Level Expert Appraisal Committees, in exceptional circumstances;

Now, therefore, in exercise of the powers conferred by sub-section (1) and clause (v) of sub-section (2) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986), read with sub-rule (4) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government after having dispensed with the requirement of notice under clause (a) of sub-rule (3) of the rule 5 of the said rules, in public interest, hereby makes the following further amendments in the EIA Notification, 2006, namely:-

In the said notification;

(i) in paragraph 3, in sub-paragraph (6), the following proviso shall be inserted, namely:-

“Provided that wherever considered necessary and expedient, the Central Government may extend the term for a further period not exceeding six months.”

(ii) in paragraph 5, for sub-paragraph (c), the following sub-paragraph shall be substituted, namely:-

“(c) The Expert Appraisal Committee and State Level Expert Appraisal Committee shall be reconstituted after every three years:

Provided that wherever considered necessary and expedient, the Central Government may extend the term for a further period not exceeding six months.”

(iii) in the APPENDIX VI, in item 7, the following proviso shall be inserted, namely:-

“Provided that wherever considered necessary and expedient, the Central Government may extend the term of such member for a further period not exceeding six months.”

F. No. J-11013/30/2007-IA.II(I)

Geeta Menon, Joint Secretary, Ministry of Environment, Forest and Climate Change, New Delhi.

● ● ●

Anti-dumping Duty on Sodium Citrate imposed – reg.

Notification No. 08/2020-Customs (ADD), dated 19th May, 2020

Whereas, the designated authority, *vide* notification No.7/21/2019-DGTR, dated the 25th October, 2019, published in the Gazette of India, Extraordinary, Part I, Section 1, had initiated a review in the matter of

continuation of anti-dumping duty on imports of "Sodium citrate" (hereinafter referred to as the subject goods) falling under tariff item 2918 15 20 of the First Schedule to the Customs Tariff Act, 1975 (51 of 1975) (hereinafter referred to as the Customs Tariff Act), originating in or exported from China PR (hereinafter referred to as the subject country), imposed *vide* notification of the Government of India, in the Ministry of Finance (Department of Revenue) No. 19/2015-Customs (ADD), dated the 20th May 2015, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R. 409(E), dated the 20th May 2015;

And whereas, in the matter of review of anti-dumping duty on import of the subject goods, originating in or exported from the subject country, the designated authority in its final findings, published *vide* notification No. 7/21/2019-DGTR, dated the 30th April, 2020, in the Gazette of India, Extraordinary, Part I, Section 1, has come to the conclusion that:

i) there is continued dumping of the subject goods from subject country and the imports are likely to enter the Indian market at dumped prices in the event of expiry of duty;

ii) the domestic industry has suffered continued injury on account of dumped imports from the subject country;

iii) the information on record shows likelihood of continuation of dumping and injury in case the Anti-dumping duty in force is allowed to cease at this stage;

iv) there is sufficient evidence to indicate that revocation of the Anti-dumping duty at this stage will lead to continuation of dumping and injury to the Domestic Industry;

and has recommended continuation of definitive anti-dumping duty, as modified therein, on the subject goods, originating in or exported from the subject country;

Now, therefore, in exercise of the powers conferred by sub-sections (1) and (5) of section 9A of the Customs Tariff Act, read with rules 18 and 23 of the Customs Tariff (Identification, Assessment and Collection of Anti-dumping Duty on Dumped Articles and for Determination of Injury) Rules, 1995, the Central Government, after considering the aforesaid final findings of the designated authority hereby imposes on the subject goods, the description of which is specified in column (3) of the Table below, falling under tariff item of the First Schedule to the Customs Tariff Act as specified in the corresponding entry in column (2), originating in the countries as specified in the corresponding entry in column (4), exported from the countries as specified in the corresponding entry in column (5), produced by the producers as specified in the corresponding entry in column (6) and imported into India, an anti-dumping duty at the rate equal to the amount as specified in the corresponding entry in column (7), in the currency as specified in the corresponding entry in column (9) and as per unit of measurement as specified in the corresponding entry in column (8) of the said Table, namely:

Table

Sr. No	Tariff item	Description of Goods	Country of origin	Country of exports	Producer	Amount	Unit of measurement	Currency
1	2	3	4	5	6	7	8	9
1	2918 15 20	Sodium Citrate	China PR	Any country including China PR	Jiangsu Guoxin Union Energy Co. Ltd.	96.05	MT	US$
2	-do-	-do-	China PR	Any country including China PR	Any other producer other than serial no.1	152.78	MT	US$
3	-do-	-do-	Any country other than China PR	China PR	Any	152.78	MT	US$

Note:

1. *The description of the goods in the Table above includes Tri Sodium Citrate, Tri Sodium Citrate dihydrate, Sodium Citrate dihydrate, Tribasic Sodium Citrate, Sodium Citrate Tribasic Dihydrate, Sodium Citrate Dibasic Sesquihydrate and Sodium Citrate Monobasic Bioxtra.*

2. *The anti-dumping duty imposed under this notification shall be effective for a period of five years (unless revoked, superseded or amended earlier) from the date of publication of this notification in the Official Gazette and shall be paid in Indian currency.*

   Explanation: For the purposes of this notification, rate of exchange applicable for the purposes of calculation of such anti-dumping duty shall be the rate which is specified in the notification of the Government of India, in the Ministry of Finance (Department of Revenue), issued from time to time, in exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and the relevant date for the determination of the rate of exchange shall be the date of presentation of the bill of entry under section 46 of the said Customs Act.

F. No. 354/78/2015-TRU (Pt-I)

Gaurav Singh, Deputy Secretary, Department of Revenue, Ministry of Finance, New Delhi.

● ● ●

DGFT MATTERS

Issuance of Preferential Certificate of Origin for India's exports to Thailand and Vietnam under ASEAN-India FTA - reg.

DGFT Trade Notice No.12/2020-2021, dated 22nd May, 2020

To,
1. All Exporters/Members of Trade,
2. All Designated Agencies under FTAs/PTAs.

1. Trade Notice 01/2020-2021 dated 07.04.2020 was issued in view of the movement restrictions in place due to COVID-19 pandemic in India wherein, the designated agencies were enabled to issue digitally signed electronic Certificates of Origin.

2. Further to this, various representations have been received from exporters expressing difficulties in obtaining preferential access in Thailand and Vietnam based on the digitally signed electronic Certificates of Origin.

3. In view of above, the earlier procedure of issuing physical copy of Certificate of Origin (CoO) by the designated agencies for exports to Thailand to Vietnam under ASEAN-India FTA is being restored. The CoO applications under ASEAN-India FTA for exports to Thailand and Vietnam should now be submitted manually by the exporters to the offices of the designated issuing agencies i.e. EIA, MPEDA and Textile Committee.

4. The e-platform (coo.dgft.gov.in) will not accept CoO applications submitted for exports destined to Thailand and Vietnam. However, the e-platform shall continue to accept and process CoO applications for export to other countries under ASEAN-India FTA.

5. These agencies (EIA, MPEDA and Textile Committee) will henceforth issue the Certificate of Origin in physical paper format as was being done before issuance of Trade Notice 01/2020-21 dated 07.04.2020 for Thailand and Vietnam, till further Notice.

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

File No.01/02/82/AM-19/EDI

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

● ● ●

Promotion of WHO Online Courses amongst RCI Certified Professionals/Personnel and other Teaching and Non-Teaching Staff to combat with COVID-19 outbreak in India - reg.

Ref. File No. 7-16/RCI-2016, dated 20th May, 2020

To
The Directors of National Institutes of DEPwD & Heads of the RCI Approved Institutions/University Departments;
(As per list attached).

As you are all aware, World Health Organization (WHO) has declared the COVID-19 outbreak as a global pandemic since the virus has been spreading rapidly across the world. On account of it, not just our country, but the world as a whole is passing through unprecedented times. The numbers of persons infected with the corona virus is increasing day-by-day and several precious lives are being lost. While many ongoing clinical trials evaluating potential treatments are underway, however, no specific vaccines or treatments for COVID-19 have so far been formulated.

Government is doing its best to combat this situation. In view of the above there is an urgent need to create awareness amongst the masses to prevent the spread and to slow down the transmission of this virus. Each one of us must, therefore, become a COVID WARRIOR in the fight against this global pandemic. The responsibility becomes more important for rehabilitation personnel who can come up as a sensitized and trained second line level front line workers, in times of need, and post pandemic when the world will need to be healed, from the trauma, with rehabilitative care.

As you might be aware, WHO has developed several free Online courses on COVID-19 to mitigate the spread of corona virus and to prepare people to work in such circumstances. These courses may be accessed by clicking this link **http://openwho.org/courses.**

In light of above, it was felt that it would be the civic and a critical responsibility of all RCI's approved Institutions and certified Rehabilitation Professionals/Personnel to educate and orient themselves by undergoing these online free courses which would enable them to take precautionary measures to safeguard themselves and to curb the further spread of this virus amongst the general public.

To encourage and motivate the professionals as well as personnel for taking the said courses in preparedness of this pandemic, the Council has decided to award 5 CRE points (additional 10 CRE Points for Visually Impaired professionals) for minimum 1 hour of each online course offered free by the WHO. This will also help in accumulating CRE Points for the renewal of registration with the Council, subject to the submission of Certificate of Participation Record of Achievements issued by WHO. There would be an overall ceiling of 50 CRE points for each professional/ personnel. Details of the shortlisted courses with content, duration, CRE weightage points, Certification by WHO are enclosed herewith.

All the recognised Training Institutes/University Departments, National Institutes, CRCs of DEPWD are also advised to encourage their faculty members, non-teaching and other support staff to undergo these courses to educate and orient themselves about COVID-19 and to ensureures are taken while dealing with persons with disabilities. The active participation of institutions and other stake holders will be appreciated by the Council giving additional reward points during the assessment of their courses due for extension.

Given the above need of the hour, you are all requested to announce this initiative of the RCI prominently on your organization/ university websites and give wide publicity among the stakeholders about the courses and their benefits. The numbers of personnel who have taken these courses may be advised to RCI by June 30, 2020.

Shakuntala D Gamlin, Secretary, DEPwD & Chairperson, RCI, Ministry of Social Justice & Empowerment Department of Empowerment of Persons with Disabilities (Divyangjan), New Delhi.

● ● ●

CBIC notifies Extension of last date of export by six months due to COVID-19 pandemic - reg.

Notification No.24/2020-Customs, dated 21st May, 2020

In exercise of the powers conferred by sub-section (1) of section 25 of the Customs Act, 1962 (52 of 1962), the Central Government being satisfied that it is necessary in the public interest so to do, hereby makes the following amendments in each of the notifications of the Government of India in the Ministry of Finance (Department of Revenue), specified in column (2) of the Table below, which shall be amended or further amended, as the case may be, in the manner specified in the corresponding entry in column (3) of the said Table, namely:-

TABLE

Sr. No.	Notification number and date	Amendments
(1)	(2)	(3)
1.	40/2015-Customs, dated the 21st July, 2015 [G.S.R.568(E), dated the 21st July,2015]	In the said notification,- (1) in the Table, after serial number 4 and the entries relating thereto, the following serial number and entries shall be inserted, namely:- "5. International Gemological Institute (India) Pvt. Ltd, Bandra Kurla Complex, Mumbai."; (b) in condition (x), the following proviso shall be inserted, namely:- "Provided that for the cases where the last date of re-export falls between the 1st February, 2020 and the 31st July, 2020, the last date stands extended by six months;".
2.	56/2000-Customs dated the 5th May, 2000 [G.S.R.399(E), dated the 5th May, 2000]	In the said notification, after the second proviso, the following proviso shall be inserted, namely:- "Provided also that for the cases where the last date of exports falls between the 1st February, 2020 and the 31st July, 2020, the last date of exports stands extended by six months.".
3.	57/2000-Customs dated the 8th May, 2000 [G.S.R.413(E), dated the 8th May, 2000]	In the said notification, after the second proviso the following proviso shall be inserted, namely:- "Provided also that for the cases where the last date of exports falls between the 1st February, 2020 and the 31st July, 2020, the last date of exports stands extended by six months.".

F.No.DGEP/EOU/08/2020

Gopal Krishna Jha, Director (Drawback), Central Board of Indirect Taxes and Customs, Ministry of Finance, New Delhi.

Note:

(1) The Principal Notification No.40/2015-Customs, dated the 21st July, 2015 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.568(E), dated the 21st July, 2015 and was last amended by Notification No.61/2017-Customs, dated the 30th June, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.739(E), dated the 30th June, 2017.

(2) The Principal Notification No.56/2000-Customs, dated the 5th May, 2000 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (i) vide number G.S.R. 399 (E), dated the 5th May, 2000 and was last amended by Notification No.90/2017-Customs, dated 27th November, 2017, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (i) vide number G.S.R. 1450 (E), dated the 27th November, 2017.

(3) The Principal Notification No.57/2000-Customs, dated the 8th May, 2000 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.413(E), dated the 8th May, 2000 and was last amended by Notification No.28/2019-Customs, dated 2nd September, 2019, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (i) vide number G.S.R.624(E), dated the 2nd September, 2019.

● ● ●

COMPANIES LAW AMENDMENTS

Schedule VII of the Companies Act, 2013 (18 of 2013) amended - reg.

Corporate Affairs Notification No.S.O.GSR 313(E), dated 26th May, 2020

1. In exercise of the powers conferred by sub-section (1) of section 467 of the Companies Act, 2013 (18 of 2013), the Central Government hereby makes the following further amendment to Schedule VII of the said Act, namely:-

In Schedule VII, item (viii), after the words "Prime Minister's National Relief Fund", the words "or Prime Minister's Citizen Assistance and Relief in Emergency Situations Fund (PM CARES Fund)" shall be inserted.

2. This notification shall be deemed to have come into force on 28th March, 2020.

F.No.13/18/2019-CSR

Gyaneshwar Kumar Singh, Joint Secretary, Ministry of Corporate Affairs, New Delhi.

Note : *The Schedule VII was brought into force with effect from the 1st April, 2014 and was amended (effective from the 1st April, 2014) vide Notification Number G.S.R.130(E), dated the 27th February, 2014, Corrigenda number G.S.R.261(E), dated the 31st March, 2014, Notification Number G.S.R.568(E), dated the 6th August, 2014, Notification Number G.S.R.741(E), dated the 24th October, 2014, Notification Number G.S.R.390(E), dated the 30th May, 2019, Notification Number G.S.R.776(E), dated the 11th October, 2019 and Corrigenda Number G.S.R.859(E), dated the 19th November, 2019.*

● ● ●

MSME Minister Gadkari bats for technology upgradation and attracting foreign investment to combat post COVID scenario

Ministry of MSME Press Release dated 20th May 2020

Union Minister for MSMEs and Road Transport & Highways Shri Nitin Gadkari has called upon the MSME sector to consider technology upgradation and to look for foreign investment to forge ahead in the post-COVID scenario. He said, the relief package announced by the Prime Minister for MSME sector should be utilised by the medium and small scale industry to jump back into action. Addressing the members of Confederation of Faridabad Industries Association and Materials Recycling Association of India in two separate video conferences from Nagpur today, the Minister said, this package will energize the local indigenous industry with new life.

Shri Gadkari said, the stimulus package announced by the Finance Minister will prove substantially helpful for MSME sector. He informed that by this 31st March, nearly 6 lakh MSMEs were restructured, and this number will be added by another 25 lakh by 31st December this year. The Fund of Funds worth Rs 10 thousand crore will be strengthened to Rs 50 thousand crore by adding other funds.

The Minister also spoke about linking MSME liquidity to equity market. He said, the government will support those MSME units which have good rating by sharing 7.5% in their stock market strength. He said, orders have been issued to clear all MSME dues with 45 days. Shri Gadkari said, he has requested the big industry as well to do the same. He informed that Ministry's Samadhan portal has helped payment Release of nearly Rs 40 thousand crore to MSMEs. He also said, there are plans to bring in a scheme of providing loans to such units on the basis of their supply order to the big industries.

The Minister was very upbeat over the change of definition of the MSME sector. Raising of investment limit in this sector will give great boost to the industry, which will now get easy finance from banks. The sector was demanding this revision for long, he said. Similarly, easing of global tendering norm is a remarkable step, he said.

Shri Gadkari urged the industry representatives to join together and consider forming industrial clusters around the proposed Delhi-Mumbai green expressway, where land prices are low. He said, he is open to all such proposals, and will help the industry in this direction.

Source: PIB, Ministry of MSME, 20.05.2020

● ● ●

Japanese Companies invited to invest in Indian Pharmaceutical and Medical Devices industry

India has taken several initiatives offering huge Opportunity to the investors: Pharma Secretary Dr P D Vaghela

MoC&F Press Release dated 22nd May 2020

A webinar on 'Medical Devices and API sector: Challenges & Emerging Opportunities' was held on 22nd May, 2020 at 11.30 am for business and trade collaboration between India and Japan in the post COVID-19 scenario. The webinar was organized by the Embassy of India, Tokyo in partnership with the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India.

Mr. Sanjay Kumar Verma, Ambassador of India to Japan shared his valuable thoughts on the golden opportunity for India and Japan to further boost their relationship in the context of the ongoing COVID-19 crisis. Dr P D Vaghela, Secretary, Pharmaceuticals presented the sectoral view and the investment opportunities in the pharmaceutical and medical device industry in India. He also presented

various initiatives taken by the Government of India to promote trade and business in the country. Mr. Navdeep Rinwa, Joint Secretary, Pharmaceuticals explained the Department's schemes to promote manufacturing of bulk drugs and medical devices viz. Production Linked Incentive schemes and Promotion of Bulk Drug/Medical Devices Parks and requested the delegates to avail benefits of the schemes.

Representatives of Japan Pharmaceutical Traders Association and Japan Federation of Medical Devices Associations deliberated on the Post COVID-19 challenges & opportunities for Pharmaceutical & Medical Device sectors and its impact on the global supply chain and suggested that cooperation between the two countries can contribute to stabilize the supply-chain of especially APIs and Medical Devices. Representative of JETRO Chennai also shared insights on challenges and emerging opportunities in API sector and Medical Devices.

Ms. Mona K C Khandhar, Minister (Economic & Commerce), EoI, Tokyo mentioned about the resilience and strength of the Indian economy and detailed on the stimulus & reform packages announced by the Government of India to address the COVID-19 crisis and to improve the investment environment. The advantages of Indian economy, FDI ecosystem & Japan specific facilitation were also mentioned.

Representatives of Japanese subsidiaries Nipro India Corp and Eisai Pharmaceuticals India Pvt Ltd shared a detailed presentation and their experience about 'Make in India' program.

Representatives of major Indian Pharmaceutical and Medical Device Associations presented the future growth opportunities and way forward for Pharmaceutical and Medical Device industry in India.

Representatives of State Governments of Gujarat, Telangana, Himachal Pradesh and Goa offered finer details of the investment opportunities in their respective States including package for incentives and taxation benefits, ease of doing business initiatives, land availability, infrastructural facilities, regulatory framework and invited Japanese companies for investing in their respective States.

Representatives of Andhra Pradesh MedTech Zone, Wockhardt, Sun Pharma, Panacea Biotec and other large number of Japanese companies also participated in the webinar as part of G2B and B2B networking.

Source: RCJ/RKM, PIB, MoC&F Press Release, 22.05.2020

● ● ●

Prices of N-95 Masks are getting reduced by the Importers/ Manufacturers/Suppliers of N-95 Masks after an Advisory issued by NPPA

MoC&F Press Release dated 25th May 2020

The Government has notified N-95 Masks as an essential commodity under Essential Commodities Act, 1955 by the Government vide Notification dated 13th March 2020. Thus, hoarding, black-marketing of the essential commodity is punishable offence under the Act. To keep check on the hoarding, black-marketing of the essential commodity, NPPA in exercise of the powers conferred under National Disaster Management Act, 2005 had directed all States/ UT Governments to ensure sufficient availability of surgical and protective Masks, Hand Sanitizers and Gloves at prices not exceeding the Maximum Retail Price printed on the pack size vide Orders dated 13th March 2020.

Grievances have been received regarding hoarding, black-marketing and differential higher pricing of N-95 Masks in the country. In this context, NPPA has directed State Drug Controllers/Food & Drug Administrations of all State/UT Governments to take appropriate actions. As reported, raids have been conducted by few SDCs/FDAs and appropriate action is being taken against the hoarders and black-marketers of the essential commodity. A PIL has also been filed before Hon'ble High Court of Bombay on

the plea of bringing price cap on the N-95 Masks by the Government.

The Government is striving to ensure uninterrupted supply of N-95 Masks in adequate quantity in the country. For this, the Government is procuring largest chunk of the N-95 Masks directly from the manufacturers/ importers/suppliers at bulk rates. To address the issue of higher prices of the N-95 Masks, NPPA intervened to bring down the prices. In this regard, in order to ensure availability of N-95 Masks at affordable prices in the country, NPPA issued an Advisory on 21st May 2020 to all the manufacturers/importers/suppliers of the N-95 Masks to maintain parity in prices for non-Government procurements and to make available the same at reasonable prices. Further, NPPA submitted before Hon'ble High Court of Bombay on the plea of bringing price cap on the N-95 Masks that looking to the mismatch in the demand-supply of N-95 Masks in the country, NPPA advised manufacturers/importers/ suppliers to bring down the prices voluntarily.

Meanwhile NPPA denies the news item appeared in the Times of India today alleging that NPPA approvingly cited a price that is more than three times the government procurement rate for the masks. The Government procurement rate quoted in the news clipping is fallacious, deceptive and misleading.

After issuing such an Advisory, major manufacturers/ importers of N-95 Masks have reduced their prices significantly up to 47% leading to availability of N-95 Masks in the country at affordable prices. As reported by the other manufacturers/importers of N-95 Masks, it is expected that other manufacturers/importers will follow the advice of the Government and roll down the prices in the larger public interest.

Source: PIB, MoC&F Press Release, 25.05.2020

● ● ●

Cabinet approves additional funding of up to Rupees three lakh crore through introduction of Emergency Credit Line Guarantee Scheme (ECLGS)

100% credit guarantee coverage by National Credit Guarantee Trustee Company Limited (NCGTC) to Member Lending Institutions (MLIs)

Guaranteed Emergency Credit Line (GECL) facility to eligible Micro, Small and Medium Enterprise (MSME) borrowers, including interested MUDRA borrowers

Union Cabinet Press Release dated 20th May 2020

The Union Cabinet, chaired by the Prime Minister Shri Narendra Modi, has given the following approvals:

- To enable additional funding of up to Rs. three lakh crore to eligible MSMEs and interested MUDRA borrowers by way of "Emergency Credit Line Guarantee Scheme."
- Under the Scheme, 100% guarantee coverage to be provided by National Credit Guarantee Trustee Company Limited (NCGTC) for additional funding of up to Rs. three lakh crore to eligible MSMEs and interested MUDRA. borrowers, in the form of a Guaranteed Emergency Credit Line (GECL) facility.

For this purpose, corpus of Rs. 41,600 crore shall be provided by Government of India spread over the current and the next three financial years.

The Cabinet also approved that the Scheme would be applicable to all loans sanctioned under GECL Facility during the period from the date of announcement of the Scheme to 31.10.2020, or till an amount of Rs 3,00,000 crore is sanctioned under the GECL, whichever is earlier.

Details:

The Emergency Credit Line Guarantee Scheme (ECLGS) has been formulated as a specific response to the unprecedented situation caused by COVID-19 and the consequent lockdown, which has severely impacted manufacturing and other activities in the MSME sector. The Scheme aims at mitigating the economic distress being faced by MSMEs by providing them additional funding of up to Rs. 3 lakh crore in the form of a fully guaranteed emergency credit line. The main objective of the Scheme is to provide an incentive to Member Lending Institutions (MLIs), i.e., Banks, Financial Institutions (FIs) and Non-Banking Financial Companies (NBFCs) to increase access to, and enable availability of additional funding facility to MSME borrowers, in view of the economic distress caused by the COVID-19 crisis, by providing them 100 per cent guarantee for any losses suffered by them due to non-repayment of the GECL funding by borrowers.

The salient features of the Scheme include:

i. All MSME borrower accounts with outstanding credit of up to Rs. 25 crore as on 29.02.2020 which were less than or equal to 60 days past due as on that date, i.e., regular, SMA 0 and SMA 1 accounts, and with an annual turnover of up to Rs. 100 crore would be eligible for GECL funding under the Scheme.

ii. The amount of GECL funding to eligible MSME borrowers either in the form of additional working capital term loans (in case of banks and FIs), or additional term loans (in case of NBFCs) would be up to 20% of their entire outstanding credit up to Rs. 25 crore as on 29th February, 2020.

iii. The entire funding provided under GECL shall be provided with a 100% credit guarantee by NCGTC to MLIs under ECLGS.

iv. Tenor of loan under Scheme shall be four years with moratorium period of one year on the principal amount.

v. No Guarantee Fee shall be charged by NCGTC from the Member Lending Institutions (MLIs) under the Scheme.

vi. Interest rates under the Scheme shall be capped at 9.25% for banks and FIs, and at 14% for NBFCs.

Implementation schedule:

The Scheme would be applicable to all loans sanctioned under GECL during the period from the date of announcement of the Scheme to 31.10.2020, or till an amount of Rs three lakh crore is sanctioned under the GECL, whichever is earlier.

Impact:

The Scheme has been formulated as a specific response to the unprecedented situation caused by COVID-19 and the consequent lockdown, which has severely impacted manufacturing and other activities in the MSME sector. In view of the critical role of the MSME sector in the economy and in providing employment, the proposed Scheme is expected to provide much needed relief to the sector by incentivizing MLIs to provide additional credit of up to Rs.3 lakh crore to the sector at low cost, thereby enabling MSMEs to meet their operational liabilities and restart their businesses. By supporting MSMEs to continue functioning during the current unprecedented situation, the Scheme is also expected to have a positive impact on the economy and support its revival.

Source: VRR/KSH, PIB, Cabinet Press Release, 20.05.2020

● ● ●

Brief on Initiatives taken by CDSCO for streamlining the Regulatory Process

CDSCO Communication dated 22nd May, 2020

I. Clarification on manufacturing of new drug by a manufacturer in their own multiple manufacturing sites:

Clarification was issued on 30.08.2019 regarding manufacturing of new drug by a manufacturer in their own multiple manufacturing sites, wherein CMC data generated by a manufacturer in one of its manufacturing facility may be utilized by the same manufacturer for manufacturing of same product in its additional manufacturing sites with certain provision that manufacturer shall establishes the similarity by way of technology transfer between the proposed additional manufacturing sites and the approved manufacturing site.

II. Clarification on renewal of registration of Ethics Committee:

CDSCO has issued a notice on 18.10.2019 regarding renewal of registration of Ethics Committee whereby it was clarified that if the application for renewal of registration is received by the Central Licencing Authority ninety days prior to the date of expiry, the registration shall continue to be in force until an order is passed by the said authority on such case.

III. Modalities on drugs meant for dual use:

CDSCO laid down the modalities on drugs meant for dual use on 18.10.2019, granting one time dual use NOC for importing such products for their end use (other than medicinal use) for one year which may be further relaxed with certain provisions.

IV. Setting of Public Relations Office at all Zonal and Sub-Zonal offices of CDSCO:

Public Relations Office (PRO) was setup at all Zonal and Sub-Zonal offices of CDSCO on 12.12.2019 in order to make regulatory guidance more accessible, for Single Window disposal of grievances, to provide information regarding regulatory requirements for development & commercialisation of products, provide clarification on Act and Rules and to handhold by guiding investors in various phases of business life cycle as per the existing focus on “Invest India/ make in India”.

V. Clarification on submission/processing of applications for manufacturing/import of new drugs for test and analysis, CT or BA/BE study:

Notices issued on 18-02-2020 and 20-02-2020 giving detailed clarification regarding submission/ processing of applications for grant of permission to manufacturing/import of new drugs for test and analysis, CT or BA/BE study.

VI. Fast track processing of applications for grant of permission to manufacture trial batches of new drug or investigational new drug for test and analysis CT or BA/BE study:

Notice No. PG/298/Import/TL/2019-DCGI issued dated 20-02-2020 issued to all States/UT Drug Controllers requesting to consider processing of applications for grant of licence to manufacture new drugs for the purpose of test, analysis, CT or BA/BE study within 07 working days and similar directions were also issued to all officers of CDSCO (HQ)/Zonal/ Sub-zonal office.

VII. Clarification on requirement of process validation report for permission to conduct clinical trial/ BA-BE studies:

Notice issued on 21-02-2020 clarifying that process validation as required for commercial batches may not be required for Phase I, Phase II studies. However, the proof of process standardization may be required. Further, for the phase III clinical trial batches the requirements of process validation though may not be required as per commercial batches, however, it will vary depending on the complexity of the product (biological, high tech etc).

VIII. Streamlining the timeline for processing the application for BA/BE permission and import licence for export:

Notice issued dated 21-02-2020 clarifying that process of applications for BA/BE permission and

import licence for export will be done within 15 working days of receipt of such application.

IX. Procedure laid down for pre-submission meeting:

Notice No. 12-01/19-DC(PT-195) issued on 21.02.2020 confirming that as and when application for a pre-submission meeting is received, meetings are conducted and guidance about the requirements of law and procedure for licence or permission of manufacturing process, clinical trial and other requirements are provided by CDSCO in writing to the applicant, in accordance with the New Drugs and Clinical Trials Rules, 2019.

X. Clarification on requirement of sub-acute toxicity study report for injectable products for BA/BE study in human for export:

Notice No. 12-01/19-DC(PT-195) issued on 21.02.2020 clarifying that sub-acute toxicity data for innovator products are neither required nor asked for conduct of BA/BE study in human for export.

XI. Clarification on fixing of limit of impurities in the specification of INDs:

Notice issued dated 21.02.2020 clarifying that Indian Pharmacopoeia (IP) prescribes the general limits for impurities. However, the applicant when submit scientific justifications in support of limits of impurities for Investigational New Drugs beyond that specified in IP, the same are considered and accepted.

XII. Simultaneous processing and approval of applications for conduct of Clinical trial/BA-BE permission:

Notice No. 12-01/19-DC(PT-195) issued dated 21.02.2020 clarifying that, in general, applications for grant of permission to conduct clinical trial/BA-BE study as part of requirements for grant of permission to manufacture or import of new drugs are processed in accordance with the New Drugs and Clinical Trials Rules, 2019, and if found satisfactory, permission to conduct BA/BE study and clinical trial are granted simultaneously, subject to condition that CT should be conducted after submission of BA/BE study result.

XIII. Consideration of stability data generated during development stage for grant of WHO-GMP and COPP:

Notice No.12-01/19-DC(PT-195) issued on 21.02.2020 clarifying that if the stability data is generated during development stage as per the WHO guidelines, no further stability data on the commercial batches are required before grant of WHO-GMP and COPP.

XIV. Clarification on sequence of approval process of new drugs and Fixed Dose Combinations (FDC) containing that particular new drug:

Notice issued dated 21.02.2020 clarifying that there is no such requirement that approval process of new drug and FDC containing that particular new drug are sequential. As per the requirements of Paragraph 4 of Second Schedule of the New Drugs and Clinical Trials Rules, 2019, the first group of Fixed Dose Combinations (FDCs) includes those in which one or more of the active ingredients are a new drug. For such Fixed Dose Combinations (FDCs) to be approved for marketing data to be submitted will be similar to data required for any new drug (including clinical trials). However, such issues are examined as case-by case basis depending of nature of the products, indication, etc in consultation with the SEC to ensure safety and efficacy of the FDC.

XV. Clarification on requirement of stability study data for CT & BA/BE study in human for export:

Notice No. 12-01/19-DC(PT-195) issued on 21.02.2020 clarifying that as per the provisions of the Second Schedule of the New Drugs and Clinical Trials Rules, 2019 when the application is for clinical trials only, the stability data supporting the stability of the investigational new product in the intended container-closure system for the duration of the clinical trial are required. However, depending on the product development one month stability data may be accepted for issuance of the BE NOC for export. While conducting the BE study, the firm shall submit the updated stability data to ensure the stability of the product throughout the BE study.

XVI. Submission and processing of application Registration Certificate and import License in parallel with New Drug application:

Notice issued on 26.02.2020 deciding that, applicant can submit application for Registration Certificate and import License in parallel with New Drug application and the same will be processed simultaneously.

XVII. Clarification on requirement of CMC documents for approval of additional indication of an already approved drug product:

Notice issued dated 13-03-2020 clarifying that requirements of data and information for permission

to import or manufacture of a drug already approved which is now proposed to be clinically tried or marketed with certain new claims are specified in paragraph (3) of Clause 1 of Second Schedule of New Drugs and Clinical Trials Rules, 2019.

XVIII. Guideline for approval of synthetically manufactured drug which has been previously approved as r-DNA derived drug:

Notice issued dated 13.03.2020 clarifying that for approval of synthetically manufactured peptide drug which has been previously approved as r-DNA derived drug, the applicant is required to submit application as a subsequent new drug.

XIX. Timeline for testing of new drugs:

Notice issued dated 13-03-2020 specifying timelines for testing of all categories of new drugs for their approval to the Central Government Laboratories.

Source: CDSCO, 22.05.2020

● ● ●

NPPA MATTERS

NPPA issues directions to manufacturers/importers/suppliers of N-95 Masks to maintain parity in prices for non-government procurements and at reasonable prices - reg.

NPPA OM Ref. File No. 37007/2020/Div.III/NPPA, dated 21st May, 2020

To

1. *All the Manufacturers/Importers/Suppliers for necessary action;*
2. *Medical Devices Industry Associations (AIMED, MTal, CII, FICCI, PWMAI) for wider dissemination among Member companies concerned.*

1. This refers to the grievances being received regarding hoarding, black-marketing and differential higher pricing of N-95 Masks in the country. In this context, it is hereby informed that N-95 Mask has been notified as an essential commodity under Essential Commodities Act, 1955 by the Government vide Notification dated 13th March 2020. Further, hoarding, black-marketing of the essential commodity is punishable offence under the Act. Further, this Office in exercise of the powers conferred under National Disaster Management Act, 2005 had directed all States/UT Governments to ensure sufficient availability of surgical and protective Masks, Hand Sanitizers and Gloves at prices not exceeding the Maximum Retail Price printed on the pack size vide Orders dated 13th March 2020.

2. In the prevailing situation due to COVID-19, a mismatch is noted between the demand and supply of N-95 Masks in the country. As per Guidance issued by the Ministry of Health & Family Welfare and World Health Organization (WHO) for management of COVID-19, it has been stated that Medical Masks are primarily meant for use of frontline health care workers.

3. In the wake of the prevailing situation due to COVID-19, the Government is striving to ensure uninterrupted supply of N-95 Masks in adequate quantity primarily for the health care workers. For this, the Government is procuring largest chunk of the N-95 Masks directly from the manufacturers/ importers/suppliers at bulk rates and ex-factory prices. However, it has been noticed that other procurers (non-government entities) are getting N-95 Masks at differential prices.

4. Thus, in order to ensure availability of N-95 Masks at affordable prices in the country, NPPA hereby directs manufacturers/importers/suppliers of the N-95 Masks to maintain parity in prices for non-government procurements and to make available the same at reasonable prices.

5. Any instance of hoarding, black-marketing and higher pricing of N-95 Masks reported will be viewed seriously and action shall be initiated by the Government under the Essential Commodities Act, 1955.

Alok Ranjan, Assistant Director (M&E), National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

● ● ●

Quality Standards of Indian Medicinal Plants

(Volume 17)

Volume 17 of Quality Standards of Indian Medicinal Plants, Indian Council of Medical Research, New Delhi,

2019, ISSN: 0972-7213,

360 pages,

Price in land Rs.2100/ Foreign USD 91

Continuing the work on providing authentic scientific and technical information on quality standards for Indian medicinal plants ICMR has brought about this 17th volume. It provides standards for 31 botanicals not covered in the earlier volumes. Some of the botanicals which are becoming very popular in terms of usage as an herbal product or supplement or herbs used in cosmetics are covered in this volume. For example mango, plaksa (Ficus variety), shigru (moringa), pippali stem and roots, vijaysar (pterocorpus), sugar cane roots and stem and cumin skeels. Important information on methods for isolation of markers, drying and storage of raw materials, pesticide residues testing are covered in appendices.

Researchers, suppliers, traders and industry would be highly benefited by the contents of this book. Reproduction of colored photographs of the raw herb, TLC profiles and chromatograms add high utility index for this book. These can be adopted to develop in house specifications that meet international quality requirements. The book should be highly useful to these stakeholders.

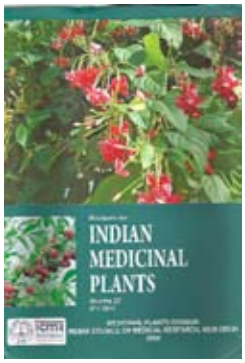
ICMR's medicinal plants division needs to be complimented for bringing out these volumes at regular intervals providing high quality data based information. It may be appropriate to bring out a separate volume in this series that provides standard procedures for DNA based identity authentication and providing DNA barcode data of plants for which such data is available. Some of the international buyers of medicinal plants and their powders are demanding authenticity certificates based on DNA barcode testing and a reference book that provides this information would be very valuable.

(Reviewed by Dr D B A Narayana)

● ● ●

Reviews on Indian Medicinal Plants

(Volume 21 & Volume 22)



Volume 21 (Piq-Pre), of Reviews on Indian Medicinal Plants,

Indian Council of Medical Research, New Delhi, 2019, ISSN: 0972-7957,

350 pages, Price in land Rs.2900/ Foreign USD 120

Volume 22 (Pri - Qui), of Reviews on Indian Medicinal Plants, Indian

Council of Medical Research, New Delhi, 2020, ISSN: 0972-7957,

935 Pages, Price in land Rs.2200/

Foreign USD 92

ICMR has brought out volume 21 of Reviews on Indian Medicinal Plants in December 2019 followed by Volume 22 in February 2020. Volume 22 covers Quisqualis Linn. At this rate ICMR would soon complete providing reviews of Indian Medicinal Plants with name starting with Z.

Any scientist would be satisfied and perhaps excited to see the exhaustive review of published data on the Indian Medicinal Plants provided in these volumes. The extent of information provided, reviewed and relevant information classified and tabulated to separately cover *in vitro*, *in vivo* and other studies make the publication exhaustive and appreciative. Scientists who prepare review papers on medicinal plants can adopt the structure and methodology as well as coverage on such reviews which we do not see often. Readers would be happy when they read for example the review on dadima (Punica) in Volume 22 occupies more than 130 pages with relevant references to each of the data quoted.

Volume 21 covers 60 plants and volume 22 covers 30 plants. Highly useful, quick search information is provided in appendices for those who are searching for chemical constituents or pharmacological activity or regional and other names.

Stakeholders intending to undertake focused research, those involved in developing phytopharmaceuticals from Indian medicinal plants, pharmacopoeial organizations and regulators would find these reviews highly relevant and useful. Publishing these books using art paper makes the book very heavy and ICMR may explore using light weight papers like sunlit bond or rice papers in future editions to make them more user friendly.

ICMR needs to also consider bringing out crisp patient information leaflets for selected Indian medicinal plants that can provide authentic data based information on safety, efficacy, and indications for usage, directions and doses in future. This would assist in evidence based and data based usage of Indian medicinal plants by physicians and support mainstreaming of Indian plants having medicinal value, as ICMR has already collated scientific information on them.

(Reviewed by Dr D B A Narayana)

DBT invites research proposals on cancer immunology & immunotherapy

The Department of Biotechnology (DBT) has invited research proposals from the eligible researchers and clinicians who have fresh perspectives and ingenious ideas to identify problems in the area of cancer immunology & immunotherapy.

The DBT has now called Letters of Intent (LoI) for setting up of Virtual Network Centers (VNCs) for a period of five years.

The goal of this call is to create a centralized platform for sharing concepts and resources bringing in the complimentary expertise of the individual Principal Investigators (PIs) from different organizational settings and partnering scientific institutions to work together to develop and actualize a cancer research agenda.

The major purpose of this programme is to connect competence in basic biology/clinical research/technology development.

Under this, the researchers have to study the unraveling the immunosuppressive microenvironment in cancer and development of strategies to overcome them and for the identification and characterization of newer regulatory pathways for an effective immune response.

It also includes top down approach for identifying the value of repurposed drugs to act as checkpoint inhibitors, including phase 2 clinical trial.

Another area of research is understanding the development of novel vectors for CAR-T cell therapies, development of bispecific monoclonal antibodies and Bispecific T cell engagers (BiTEs) for cancer immunotherapy, In vivo priming and maturation of dendritic cells for boosting immune response and NK cell based immunotherapy including amplification of NK cell numbers for therapeutic use.

Other area include metronomic chemotherapy to boost immunotherapeutic effects, model pre-clinical systems for rapid translation of cellular therapies into clinical trials, overcoming constraints in cellular immunotherapy in solid tumors and understanding of the T and B cell physiology, subsets and use for cancer therapy. A team of clinical researchers/basic scientists/pharmacologists/ health care experts are eligible for the proposals. Last date of submitting applications is 10th June 2020.

Source: Neethikrishna, Pharmabiz, 16.05.2020

● ● ●

NPPA not to bring PPE kits under price control citing its non-inclusion in NLEM by Health Ministry

The national drug pricing regulator National Pharmaceutical Pricing Authority (NPPA) has refused to bring Personal Protective Equipment (PPE) kits under price control citing that only scheduled medical devices which are included in National List of Essential Medicines (NLEM)-2015 prescribed by the Union Health Ministry are brought under price control.

In a letter addressed to the All India Drug and License Holders Foundation (AIDLHF), the NPPA stated that it fixes ceiling prices or brings under price control only scheduled medical devices which are included in National List of Essential Medicines (NLEM)-2015 prescribed by the ministry. Further, it stated that it also needs to be included in Schedule-1 of Drugs Price Control Order (DPCO)-2013, as per DPCO Rules for the purpose of price control.

As of today, only surgical masks have been brought under price control by the Centre. As per Health Ministry guidelines, components of PPE are goggles, face-shield, mask (both surgical and N95 mask), gloves, coverall/ gowns (with or without aprons), head cover and shoe cover.

This comes soon after Prime Minister Narendra Modi in his recent speech on Lockdown 4 said that today we are in a situation to produce 2 lakh PPE and 2 lakh N-95 masks daily turning the COVID-19 pandemic crisis into an opportunity while announcing the Rs. 20 lakh crore economic package to revive Indian economy badly impacted due to COVID-19. Prime Minister announced a package worth Rs. 20 lakh crore under 'Atmanirbhar Bharat Abhiyan' to deal with the current economic crisis.

Reports of unapproved PPE kits being sold at exorbitant costs ranging from Rs. 900 to Rs. 1,500 in the open market due to lack of effective price control policy and standards

had earlier prompted health activists and experts to suggest to the government to bring PPE kits under price control to curb unethical marketing.

A PPE kit usually costs not more than Rs. 330. Cases of overcharging were also detected in Maharashtra and Uttarakhand wherein PPE kits were sold at three times its current cost to government and private healthcare institutions.

As a major step towards indigenization and ensuring compliance to quality, government has kick-started indigenous manufacturing of PPE kits in the wake of rising cases of COVID-19 globally and in India. As per official estimates, around 107 PPE manufacturers have been identified who have raised their daily production to about 1.87 lakh PPE kits. The total projected demand of PPE kits till June, 2020 is estimated to be 2.01 crore.

Department of Pharmaceuticals (DoP) Secretary Dr P D Vaghela has also stated that out of the total 2.49 crore N-95 masks ordered, 1.49 crore of these masks have been ordered from domestic manufacturers. The total projected demand of N-95 masks till June, 2020 has been estimated to be 2.72 crore. As of now, about 49.12 lakh N 95 masks have been received and additional domestic supply in the next two months would be more than 1.40 crore. Union Health Minister Dr. Harsh Vardhan also informed that 29.06 lakh PPEs and 62.77 lakh N-95 masks have been distributed among the States/UTs/Central Institutions. India imported 1.70 lakh PPEs from China and 2 lakh PPEs from Singapore.

Association of Indian Medical Devices Industry (AiMeD) has however has cautioned the Central Government about the harmful effects of duty free imports while considering government's decision to import ventilators, face masks, surgical masks, PPE kits and COVID-19 test kits in view of the immediate requirement due to COVID-19 crisis.

According to Rajiv Nath, forum coordinator of AiMeD, "Government of India needs to take policy decisions towards ending 80 to 90% import dependence and an ever increasing import bill of over Rs. 38,837 crore, and expedite steps for patient's protection, stronger quality and safety regulations and judicious price controls to make medical devices and quality treatment accessible and affordable."

To regulate the production of PPEs among Indian manufacturers in line with the specifications of the World Health Organisation (WHO) and the Union Health Ministry, Government has also issued a notification on April 6, 2020, which stipulated a Unique Certification Code (UCC-COVID-19) to be applied to PPE garments and fabric which pass the laboratory tests laid down by the eight notified government testing labs in the country. The Code will record the type of garment, its test procedure and date of test. Another directive was that in the case of coveralls, the manufacturer will print in indelible ink or in a tamper-proof sticker details such as name of producer, code, test standard, batch number and order details.

Source: Shardul Nautiyal, Pharmabiz, 15.05.2020

● ● ●

DCGI directs state DCs to assess production & availability of hand sanitizers to allow export

In a bid to examine feasibility of allowing export of hand sanitizers, the Drugs Controller General of India (DCGI) has directed all state and Union territory drugs controllers to assess the present situation of production and sufficiency of availability in domestic market and excess production, if any, of handrub.

The drugs controllers in states and Union Territories have been asked to provide manufacturing details of hand sanitizers such as name and address of manufacturer, average production capacity per month (litre), average actual monthly production in April 2020 (litre), whether the domestic supply request is fulfilled by the firm, whether the manufacturers have adequate supply and easy availability of raw materials like ethanol, isopropanol alcohol (IPA) etc for manufacturing purpose, if excess is available after fulfillment of domestic request and how much quantity (litre).

Besides furnishing manufacturing details of handrubs, the state and Union Territory drugs regulators have also been asked to inform that whether there is sufficient availability of hand sanitizers in their state/Union territory and whether hand sanitizer is being produced in excess quantity than demand required for domestic market in India by the firms.

They have been directed to submit above information to DCGI by May 15, 2020 at noon. Based on the details provided by state and Union territory drugs regulators on availability of hand sanitizers in their region, the DCGI will examine feasibility of permitting its export.

The DCGI has urged all zonal/sub zonal offices of Central Drugs Standard Control Organisation (CDSCO) to coordinate with state and Union Territory drugs control authorities in the matter.

Confirming the letter, Dr H G Koshia, Commissioner, Gujarat Food and Drug Control Administration (FDCA) said "We have received DCGI letter seeking details about production of hand sanitizers an its surplus stock in the state. Before this, we have been regularly taking stock of availability of hand sanitizers in the state and accordingly updating the DCGI about this. There is enough number of hand sanitizer manufacturers in the state. There were 5 lakh units of sanitizers available in the state since the outbreak of COVID-19 which have now gone up to 37 lakh units."

"We have issued 1,264 product licences to manufacture sanitizers in the state. As of now there are 334 licenced manufacturers of hand sanitizers in the state. Initially IPA was used in hand sanitizers but due to short supply and black marketing of IPA, we have allowed firms having licence to manufacture IPA based sanitizers to produce ethanol based sanitizers. Product licences have been issued to big companies like Asian Paints, Marico, Nivea India to manufacture hand sanitizers in the state," he added.

Earlier pharma Micro, Small and Medium Enterprises (MSMEs) manufacturing hand sanitizers have urged Directorate General of Foreign Trade (DGFT) to lift restriction on export of ethanol-based hand sanitizers in the wake of surplus production of ethyl alcohol in the country.

Ethanol, an active ingredient in the production of hand sanitizers, is manufactured by sugar mills in India.

The hand sanitizer industry is expected to require 8-10 million litres of ethanol per month at full capacity utilization. Currently, India has an ethanol production capacity of 3.5 billion litres/year, as per official records.

Hence the stock of ethanol available for domestic use is way more than the requirement.

With a sharp rise in number of manufacturers of hand sanitizers due to speedy clearance of product manufacturing licence, there is abundant supply of sanitizers in the domestic market. Lifting restriction on export of ethanol based sanitizers will benefit pharma MSMEs, sugarcane producers, sugar mills and distilleries sitting on excess ethanol, said Amit Chawla, Vice President of Laghu Udyog Bharati Indore unit.

There is no shortfall of hand sanitizer made of ethanol with the impurity of isopropyl alcohol (IPA) making it unfit for drinking. Due to stoppage of alcohol sale for 40 days in the lockdown, the distilleries due to continuous process remained working. Now they are full of alcohol and molasses are under maturing condition. Its high time the government allows export of ethanol based hand sanitizers so that excess supply of ethanol will be consumed, said Nipun Jain, Chairman of Small & Medium Pharma Manufacturers Association (SMPMA).

DGFT on March 24, 2020 imposed restriction on export of all sanitizers made of both ethanol and IPA to meet rising demand in the country due to coronavirus pandemic.

Source: Laxmi Yadav, Pharmabiz, 15.05.2020

● ● ●

Covid-19 lockdown: After April shock, drug sales improve in May

Till May 15, the overall inventory was 39 days, compared to 43 days in first half of the previous month

Drug inventory in the market shrank in the first two weeks of May, indicating that sales had picked up after a dull and lockdown-hit April.

At an industry level, the inventory (which is calculated in terms of number of days of stock lying with trade) reduced marginally, but some therapy areas have seen a sharp fall. Industry insiders say this is the result of pent up demand in these therapy areas like gynaecology, oncology, ophthalmology, vitamins, and vaccines.

Data from the market research firm AIOCD AWACS shows that till May 15 the overall inventory in the Indian pharma market (IPM) was 39 days, compared to 43 days in the first half of April. The IPM as such has dipped by about 5 per cent on a month-on-month basis.However, some therapy areas have seen a sharp fall in inventory, indicating a faster offtake. For example, gynaecological drugs have seen a fall from 58 days of inventory lying with traders to 46 days in May so far. Similarly, for vaccines, the inventory has reduced to 39 days from 62 days in mid-April, indicating that catch-up immunisation has started.

"Gradually, the out-patient departments (OPDs) have opened and many paediatricians have started

TAKING STOCK

Therapy Area	Inventory days April*	May*
Vaccines	62	39
Gynaecology	58	46
Opthalmology	51	44
Oncology	53	45
Pain/analgesics	53	43
Derma	59	47
Vitamins	43	35
Anti-infectives	70	64
Diabetic	26	25
Indian pharma market	43	39

*First 15 days of the months Source: AIOCD AWACS

catch-up vaccinations for children who missed out on their scheduled shots," said a senior official of a multinational pharma player.

On the whole, the industry feels two factors have played a role in improving the offtake and reducing trade inventory — one is that the supply chain in pharmaceuticals has more or less stabilised, and secondly, with lockdown curbs easing and OPDs opening, some demand has grown at the consumer end as well.

"April was hit by the lockdown and also the supply chain was affected. With the supply chain stabilising now in May, we can see that trade inventories are going down. This is indeed a good sign," said a spokesperson for Glenmark.

At end of March, and in the first half of April, the supply chain was hit — be it in terms from drugs reaching from the plant to the distributor and then from the distributor to the retailer. On top of that, there was panic buying by consumers for chronic medicines like diabetes and cardiac ailments, which also created a shortage-like situation.

April did not see much panic buying and logistics stabilised during this period. However, some firms highlighted that on a year-on-year basis, the numbers don't look good yet.

Pranabh Mody, President of J B Chemicals, said if we compare with last May, the market has come down quite a bit. "Labour issues too persist, but are slowly improving," he said.

Pharma industry insiders claimed that historically, May is usually a weak-sales month. "It is not the flu season and usually only sales of anti-fungal drugs (dermatology category) are high. This year, however, with people staying indoors, the sales of anti-fungals have been hit," said a senior official of a Mumbai-based company that sells some leading dermatology topical brands in the market.

Source: Sohini Das, Business Standard, 20.05.2020

● ● ●

Zydus delivers first batch of antibody test kits to ICMR

The first batch of 30,000 COVID KAVACH ELISA Tests manufactured by Zydus Diagnostics, has been supplied to Indian Council of Medical Research (ICMR), free of cost. These test kits have been manufactured in technology transfer with ICMR-NIV of Pune for surveillance purposes.Robust antibody tests are critical for surveillance and understanding the proportion of population exposed to SARS-COV-2 infection.

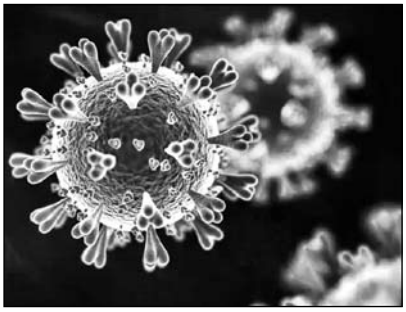
ICMR-NIV, Pune has successfully developed an indigenous IgG ELISA test for antibody detection for COVID-19. The test was validated at two sites in Mumbai and has been found to have high sensitivity and specificity. In addition, the test will have the advantage of testing 90 samples together in a single run of 2.5 hours. Moreover, ELISA based testing is easily possible even at district level. After development at ICMR-NIV, Pune, technology has been commercialised by Zydus Cadila for mass scale production. The test kits then manufactured at Zydus Cadila were validated by NIV and were found to have high sensitivity & specificity.

The test named as 'COVID KAVACH ELISA' have been manufactured in just four days of receiving all necessary materials from ICMR – NIV, Pune. Speaking on the development, Chairman, Mr. Pankaj R. Patel, said, "This reaffirms our commitment to do everything that we can to help the nation fight this healthcare challenge. We believe that the need of the hour is to be prepared in every way that we can with the latest diagnostic technologies and that is why we are providing the initial supplies at no costs."

Source: ETHealthWorld, 22.05.2020

● ● ●

Ayurvedic drug 'Fifatrol' finds mention in compendium to tackle coronavirus



Fifatrol as an immunity-boosting ayurvedic drug has found a mention among around 200 technologies and research activities evaluated by experts in a recently released compendium for combating coronavirus. Compiled by the state-run National Research Development Corporation, the 'Compendium of Indian Technologies for Combating COVID-19 (Tracing, Testing &Treating)' provides the status of 200 indigenously developed technologies and ongoing research activities and efforts taken by the government to combat the deadly viral infection.

Health experts have suggested that boosting the body's immune system may help minimise the effects and hasten the recovery from the disease, the compendium stated.

"Prime Minister Narendra Modi, too, recently highlighted the benefits of ayurveda and urged people to have a look at AYUSH Ministry's protocol to stay fit, saying good health is the harbinger of happiness.

"Fifatrol acts as an immunity enhancer which is a multi-drug combination of ayurvedic classical medicines and herbs. Researchers have suggested that Fifatrol acts as a natural antibiotic and fights infection, flu and ache," it stated.

Elaborating the salient features of the drug, the compendium stated that Fifatrol is a natural formulation providing fast relief from nasal congestion, sore throat, body ache and headache.

"It is enriched with scientifically validated botanical extracts and micro-nutrients. It is a rational combination of vital phytoconstituents, immunomodulators and antioxidants which justifies its beneficial effect for the treatment of viral upper respiratory infections," it said.

Fifatrol, developed by the AIMIL Pharma, is a formulation of well-known immunity enhancer herbs like 'Guduchi', 'Sanjeevini Ghanvati', 'Daruharidra', 'Apamarga', 'Chirayata', 'Karanja', 'Kutaki', Tulsi, 'Godanti' (Bhasam), 'Mrtyunjaya Rasa', 'Tribhuvana Kriti Rasa' and 'Sanjivani Vati'.

The drug offers improved immune system in top notch form to fight off viral, bacterial and other infections; normalises raised body temperature, fastens recovery and eases the associated symptoms like flu, cold and congestion, the compendium stated.

The Prime Minister had urged AYUSH practitioners to pitch in to tackle the coronavirus pandemic. He has also been exhorting the citizens to fall back on traditional home remedies to boost their immunity amid the outbreak.

Source: PTI, Healthworld, 12.05.2020

● ● ●

CDSCO observes lower supply of 15 drugs used for COVID-19 treatment

The Central Drugs Standard Control Organisation (CDSCO) has issued a letter to all drug manufacturers associations intimating about the lower supply of 15 essential drugs for the treatment of novel coronavirus (COVID-19). The DCGI has also requested all pharma associations to take up the matter of less production and potential shortage with concerned manufacturers to ensure adequate supply and availability of these essential drugs.

The list of these drugs was prepared by the NPPA on May 18, 2020, from the data provided by the CDSCO office on May 15, 2020, which, in turn, was supplied by Drug Controllers after examining the availability of all medicines in their respective States/Union Territories.

Then, the NPPA requested the CDSCO office to ensure adequate production, supply and availability of these 15 drugs in the country by coordinating with the manufacturers and suppliers of these medicines.

The drugs which were found in lower supply are:

1) Thiopentone Sodium Injection
2) Vasopressin Injection
3) Enalaprilat Injection
4) Clotrimazole Pessary
5) Targocid Injection
6) Biperiden Tablets
7) Activated Charcoal tablets
8) Linezolid Injection
9) Salbutamol Pratropium inhaler
10) Beclomethasone inhaler

11) Formoterol 20mcg + Budesonide 0.5 mg inhaler capsules

12) Oxygen inhalation

13) Morphine 1mg/ ml injection

14) Lidocaine injection

15) Hydralazine injection

Speaking on concerns about the lower supply of these drugs, Mahesh Doshi, President, Indian Drug Manufacturers' Association (IDMA) said, "We have checked with our IDMA member companies and realised that there is no shortage of these medicines in the market. However, due to the nationwide lockdown to prevent the spread of Coronavirus in the country, Pharma manufacturers across the country faced operational difficulties in production. The majority of issues were related to manpower, logistics and low availability of raw materials, all these could be the reasons for the lower supply of these medicines in the market."

He further informed that IDMA has communicated and requested all its members to ensure the availability of these medicines in the market. He also said that the companies have also been assured that if they face any of the problems mentioned above, the association will initiate necessary steps towards their resolution.

Sudarshan Jain, Secretary-General, Indian Pharmaceutical Alliance (IPA) said, "We have checked with the IPA members who are involved in manufacturing these essential medicines and found that we are maintaining the supply as against the pre-COVID-19 situation. Nevertheless, we have communicated to our member companies about the lower supply of 15 essential drugs in the market as well as the need to ensure the availability of these drugs in the market. Similarly, we have also updated the DCGI about ensuring the availability of these 15 essential drugs in the market from our member companies."

Source: Usha Sharma, Express Pharma, 21.05.2020

● ● ●

Why India saw only 4 Pharma products launched in April, its lowest count ever

The Pharma industry has seen a fall of about 99% in new product launches since April 2019, when 349 products were launched

The Coronavirus crisis and subsequent lockdown has impacted every industry in India, including the one industry needed to fight the pandemic — pharmaceuticals.

According to data by IQVIA, an advanced analytics and health research company, only four new products were launched in April by pharmaceutical companies in India — the lowest ever. The four products launched include two in dermatology, one immunomodulator and one in the respiratory category.

In comparison, the pharma industry launched 349 brands last April, posting a fall of about 99 percent to this year, according to data accessed by ThePrint. In March this year, 26 brands were launched as opposed to the 280 that were launched in the same month last year. On average, about 150 new products are launched per month while last year's lowest month was in November, when 195 products were launched.

The current low production is due to a host of factors brought on by the pandemic — lockdown restrictions causing shortage of labour, delay in transporting raw material and finished goods, social distancing measures complicating processes, and significantly, a dip in sales.

Drop in sales and production:

Chemists across the country have started feeling the pinch from the dropping sales of medicines across categories. "Sales have dropped to half. At present, we have reached just 60 per cent of the routine sales for May target," said Rajiv Singhal, Secretary General, All India Organisation of Chemists and Druggists (AIOCD) — a body representing 8.5 lakh chemists across India.

But it isn't just sales that have dipped; domestic pharmaceutical companies are struggling to maintain the flow of their regular products by operating at just 40 to 50 per cent of their total capacity. Larger research-driven drug makers, both Indian and foreign companies, are operating at between 50 to 70 per cent.

What is impeding them is a shortage of labour at manufacturing sites and ancillary units, key raw materials being stuck at ports, and a delay in transportation of raw materials and finished products to and from the market.

"From unloading the raw material from trucks to filling the production lines, packaging the products and again loading on to trucks, a manufacturing site requires hundreds of labourers. They are unavailable due to a variety of reasons," Mr Daara Patel, Secretary General, Indian Drug Manufacturers' Association (IDMA) told. IDMA is the country's largest pharma lobby with over 1,000 pharma companies as its members,

including Torrent Pharmaceuticals, Lupin, Cipla, Sun Pharma and Jubilant Life Sciences.

Half-a-dozen pharma companies — three large and three medium sized — ThePrint reached, cited similar reasons for manpower shortage. However, they didn't wish to be quoted considering they are working with the government to solve the issue. Among the issues being faced with labour, apart from them going back to their native hometowns, are movement restrictions while traveling to work or not allowed to leave by their village or community heads while some labourers are worried about contracting Covid-19 at factories, according to all the six drugmakers.

However, the restricted production may not lead to shortage of drugs at a retail level for at least next one month. "There may be a very short duration of anxiety at chemist outlets (due to a delay in delivery to stock of medicines), but, by and large, as of now, we don't see shortages of medicines for the next 45 days," Mr Patel said. Some pharmaceutical companies are, in fact, thankful for the dip in sales.

"Our production capacity is just half of the usual. Thankfully, sales have dipped across the market. Very few prescriptions are being handed over and hospital OPDs (outpatient departments) have just resumed. If demand from the market remained normal, we could have feared the shortage of drugs," said an industry official running a medium scale Mumbai-based pharmaceutical company.

Foreign drug makers face similar issues:

Organisation of Pharmaceutical Producers of India (OPPI), a lobby of foreign-based drug makers which represents Pharma giants such as Novartis, Pfizer, AstraZeneca and Abbott, said their "members are operating at 50 to 60 percent of their installed capacities, an improvement from the last few weeks".

However, they have also reached out to the Government to avoid any product shortages. The challenges remain the same as those faced by domestic drug makers. "We have requested support from the government to address the challenges of low attendance of workmen in manufacturing facilities due to fear and logistical issues faced by them and poor supplies from ancillary units to Pharma manufacturing facilities which hovers around 40 per cent currently," said K G Ananthakrishnan, Director General, OPPI. They have also asked for priority clearance of imported raw material (Active Pharmaceutical Ingredients or APIs) and improved operations of courier services within the country while finished formulation stuck at ports or airports also remain areas of concern.

"Printing and labelling on finished products also remains an issue as it mostly depends on ancillary units which are facing shortage of workers along with shortage of papers, ink and other products. Proper labelling is a legal requirement. No good can be dispatched without proper packaging," said an official from a listed pharmaceutical company. Another drugmaker who has a plant in Palghar, Maharashtra, said, "Only one driver and one loader are allowed to travel in trucks bringing raw material or taking finished products to market.

"It becomes difficult for one person to load (or unload) the entire truck and for other to drive day and night alone for thousands of kilometres. No food outlets are opened on highways. Also, with shortage of staff on manufacturing sites, labour who unload (or load) the truck is missing. It took days at our unit waiting for people to come and take products inside the unit. Everything is being delayed."

However, the overall situation is relatively better than last month when on 11 April, the Department of Pharmaceuticals, an apex authority under the Ministry of Chemicals and Fertilizers, intervened. "Our department told the Home Ministry that the industry was operating at just 20-30 per cent of capacity and requested for immediate measures such as acknowledgment among essential services and relaxation in movement of staff and goods," said a Senior Official from DoP. "We are working with the industry closely and trying to resolve the present situation."

Source: Himani Chandna, The Print, 21.05.2020

● ● ●

India extends anti-dumping duty on Chinese sodium citrate used by Pharma industry

After a thorough investigation, the Directorate General of Trade Remedies (DGTR) on April 30 recommended to extend the anti-dumping duty on imports of sodium citrate from China for another five years. The government has extended duty protection on sodium citrate -- a key pharmaceutical ingredient – imported from China for another five years after an investigation found that there has been continued dumping of the Chinese product in India hampering the domestic industry, the Finance Ministry said.

"There is continued dumping of the subject goods from subject country and the imports are likely to enter the Indian market at dumped prices in the event of expiry of duty," an order issued by the ministry said on Tuesday, 19.05.2020. The duty protection, which was imposed by the department of revenue on May 20, 2015 was to expire on Tuesday, 19.05.2020.

Dumping, an unfair trade practice that entails export of a product at a price lower than its normal value, is countered by a punitive anti-dumping duty. A safeguard duty is also imposed to check an unexpected import surge that poses a threat the domestic industry.

After a thorough investigation, the Directorate General of Trade Remedies (DGTR) on April 30 recommended to extend the anti-dumping duty on imports of sodium citrate from China for another five years. The DGTR, earlier known as the Directorate General of Anti-dumping and Allied Duties, is an integrated single window agency for providing comprehensive and swift trade defence mechanism in India.

On May 11, HT reported that India may extend anti-dumping duties and safeguards on more than two dozen Chinese goods ranging from sodium citrate to solar cells amid concern that a flood of imports would kill domestic manufacturers who will lose duty protection soon against such products in the current calendar year. Anti-dumping duty against 25 Chinese products would expire in 2020.

Chinese imports under review include sodium citrate, USB flash drives, calculators, hot-rolled flat products of stainless steel, Vitamin C and E, nylon tyre cord, measuring tapes, compact fluorescent lamps (CFLs), flax fabrics, caustic soda, float glass, tableware, kitchenware, plastic processing machinery and solar cells.

Sodium citrate is a key chemical compound that comes in the form of monosodium citrate, disodium citrate and tri sodium citrate. It is mainly used as an expectorant and a urine alkanizer. It is also used as a pharmaceutical aid and as a food additive in dairy industries for manufacturing of cheese and beverages. It is a water treatment chemical and is used as a laboratory reagent. It is also used as an acidity regulator in drinks and as an emulsifier for oils when making cheese. Sodium Citrate is also used as an antioxidant in food.

Source: Rajeev Jayaswal & (Edited by Sabir Hussain), Hindustan Times, 20.05.2020 (Excerpts)

● ● ●

Potential Oxford vaccine fails to prevent Coronavirus spread in monkeys, but protects from Pneumonia

This vaccine is among the eight that are ahead in terms of being tested in humans for efficacy

A high-profile potential vaccine for COVID-19 being tested by researchers at Oxord University failed to protect vaccinated monkeys from being infected by the virus. However, the test animals appeared to be protected from pneumonia.

The vaccine candidate, ChAdOx1 nCoV-19, being tested is a weakened form a common cold virus (adenovirus) that affects chimpanzees but has been neutered to prevent replication in humans.

Reports of the candidate vaccine's performance in monkeys (rhesus macaque) have prompted researchers to test the vaccine's potency in humans. Its promise has also led to Indian vaccine manufacturer, the Pune-based Serum Institute announcing plans to manufacture a four to five million doses by end-May in India. It is one of seven global institutions that will manufacture the vaccine being developed by the Oxford Vaccine Group.

However, detailed results of the trials in monkeys available on pre-print server *bioRxiv* suggest that, based on these results, the vaccine may not be the panacea to protecting people from being infected and passing on the infection to others. The research paper is yet to be peer-reviewed.

Rajesh Gokhle, Faculty, National Institute of Immunology and former head of the CSIR-Insitute of Genomics and Integrative Biology, who has read the paper, said that in an "ideal" world, no company would continue testing the vaccine in humans based on the available data in monkeys.

"We have presence of the virus in the upper respiratory tract (of the animals). It is possible that these can come down again to the lower respiratory tract (and cause pneumonia). Ideally, if you've been inoculated with the vaccine, you should be able to substantially clear out the virus," he told.

The researchers, in their paper acknowledge the presence of virus in the upper respiratory tract. "Despite this marked difference in virus replication in the lungs, reduction in viral shedding from the nose was not observed," they note. They explain it as being possibly due to the unusually high amount of the virus that the monkeys were exposed to. Unusual, in that human beings were unlikely to be ordinarily exposed to those quantities of the virus.

The researchers, led by Sarah Gilbert of The Jenner Institute, University of Oxford and Vincent Munster of the National Institutes of Health, United States, argue that the presence of virus was significantly reduced in BAL fluid (collected from the lungs) and lung tissue of vaccinated animals than in the animals that were not vaccinated. Moreover, virus specific neutralising antibodies were detected in those macaques vaccinated and no such antibodies were seen in those that didn't get the vaccine.

For their analysis they vaccinated six monkeys with the candidate vaccine and 3 were given a 'control' vaccine called ChAdOx1 GFP. Based on these results 1,110 people are taking part in human trial, half receiving the vaccine and the other half (the control group) receiving a meningitis vaccine. The dose of the vaccine was half that of what is being used for humans right now. This vaccine is among the eight that are ahead in terms of being tested in humans for efficacy.

Source: Jacob Koshy, The Hindu, 18.05.2020

● ● ●

Covid-19: Govt panel considers measures to hasten drug approval process

With the Covid-19 pandemic getting the Indian drug regulatory system working in a faster gear, a Government panel on Friday, 22.05.2020 considered all the measures taken for faster approval process and use these to overhaul the drug regulatory system, three sources in the know told.

"The discussions revolved around what all measures the CDSCO (Central Drugs Standards Control Organization) took to make the whole system faster, and how we can apply these to normal times because a lot of industry officials had expressed satisfaction at the speed of the approval process," one of the sources said.

Among the measures that were discussed in the meeting was how the CDSCO's manpower can be efficiently utilised to make the approval faster, while another measure under discussion was on giving clearances to clinical trials faster, a second official said. While the discussions were on the broader contours, a few more meetings are likely, with a report expected to be tabled in front of the Health Ministry in June, the second official said. The committee, chaired by Health Ministry's officer on special duty Rajesh Bhushan, was constituted by the Ministry through an order on 11 May.

"The issue of reforms in the Drug Regulatory System has been engaging the attention of the Government of India for quite some time now. Although requisite procedural changes have been carried out during the current Covid-19 pandemic and have worked quite well, it is felt that comprehensive changes in the drug regulatory regime should be carried out to reflect global best practices as well as domestic requirements and to streamline Central Drugs Standard Control Organization to make it more effective," the Health Ministry order said, a copy of which was seen by *Mint*.

Apart from Health Ministry, the panel comprised of bureaucrats from the Department of Pharmaceuticals (DoP) and Department of Biotechnology, as well as experts from Indian Pharmacopoeia Commission, Indian Council of Medical Research and All India Institute of Medical Sciences in Delhi.Representatives from industry bodies, Indian Pharmaceutical Alliance and Indian Vaccine Manufacturers' Association, are also part of the panel.

The Health Ministry's meeting comes on the back of Prime Minister Narendra Modi expressing concern in a meeting earlier this month that the India's regulatory system for new drugs and vaccines needed to be faster, while having the highest quality and ethical standards.

Source: Leroy Leo, LiveMint, 23.05.2020

● ● ●

Panel formed to suggest reforms in Drug Regulatory System

A high-level committee of experts has been formed by the Government to recommend reforms in India's drug regulatory system so that approval processes can be fast-tracked.

Faced with the ominous threat of the Coronavirus infection, a number of steps such as fast-tracking the approval process for drugs, research and vaccine development were taken. A Health Ministry official said the aim of the panel is to identify and formalise these measures. According to a recent Health Ministry order, the committee will study the current drug regulatory system and submit recommendations for reforms to bring the system in line with global standards and make it more efficient. "The issue of reforms in the Drug Regulatory System has been engaging the attention of the Government for quite some time now.

"Although requisite procedural changes have been carried out during the COVID-19 pandemic and have worked quite well, it is felt that comprehensive changes in the drug regulatory regime should be carried out to reflect global best practices as well as domestic requirements, and to streamline Central Drugs Standard Control Organization (CDSCO) to make it more effective," the order issued on May 11 stated.

The committee chaired by Rajesh Bhushan, the OSD to the Union Health Minister, comprises top drug and vaccine entrepreneurs of India along with officers nominated from the Department of Pharmaceuticals, Department of Biotechnology, Indian Pharmacopoeia Commission, Indian Pharmaceutical Alliance, ICMR along with public health expert from AIIMS.

The order stated, "While nominating a member, the ministries/departments/institutions should keep in mind that the officer being nominated should have a flexible approach and willing to consider far-reaching reforms with an open mind." India's Joint Drug Controller Dr Eswara Reddy will assist the committee in their work on adopting global best practices.

The committee, which has met twice till now, will submit its report within one month from the date of its formation. The committee has been asked by the ministry to also study earlier reports given by the department-related Parliamentary Standing Committee on clinical trials and working of the CDSCO and address the unimplemented recommendations of the previous panels.

Source: Press Trust of India, NDTV, 24.05.2020

● ● ●

INTERNATIONAL NEWS

Trump administration signs up new company to make COVID-19 drugs in US

U.S. President Donald Trump's administration awarded a contract worth up to $812 million for a new U.S. company to manufacture drugs and drug ingredients to fight COVID-19 on American soil, aiming to end dependence on other countries.

The administration has been looking to build up the ability to produce drugs and their raw materials in the United States after the global pandemic exposed the industry's dependence on China and India for its supply chain.

"For far too long, we've relied on foreign manufacturing and supply chains for our most important medicines and Active Pharmaceutical Ingredients while placing America's health, safety, and national security at grave risk," Peter Navarro, Director of the White House Office of Trade and Manufacturing Policy, said in a statement. Navarro for months has been advocating that Trump issue an executive order to require federal agencies to buy U.S. made medical supplies and pharmaceuticals.

The U.S Department of Health and Human Services said it had awarded a four-year, $354 million contract to privately-held Phlow Corp to make COVID-19 drugs, other essential drugs and their ingredients. The contract - which is for generic drugs, not more complicated products like vaccines - can be extended to a total of $812 million over 10 years.

Phlow, which was incorporated in January, said the contract will help it contribute to a national stockpile of pharmaceutical ingredients for essential medicines.

The company is run by Eric Edwards, who previously founded the drug company Kaleo Pharmaceuticals with his twin brother. He said in an interview that Phlow initially reached out to the U.S. health department last November,

to tell them that they were working to build U.S. drug manufacturing capacity.

After COVID-19 hit, Edwards said Phlow focused on drugs for the virus and reached out to Navarro's office and government agencies.

"We said, 'You're going to have a problem.' The supply chain was already vulnerable, with all of these drug shortages before COVID-19," he said.

The company submitted a proposal on drug manufacturing in response to an open request from the Biomedical Advanced Research and Development Authority, one of the HHS agencies overseeing COVID-19 vaccine and drug development, he said.

Phlow has already started making pharmaceutical ingredients and finished dosage forms for over a dozen medicines to treat hospitalized patients with COVID-19 related illnesses, including medicines for pain management, sedation for ventilators, blood pressure support for critical patients and antibiotics.

All pharmaceutical products will be made in the United States, according to Phlow's website. The company said it is working to build advanced manufacturing capability in Virginia, as well as sterile manufacturing facilities for injectables.

It has partnered with generic drug manufacturer Civica Rx, chemical company Ampac Fine Chemicals and Virginia Commonwealth University's Medicines for All Institute. It said it has already delivered over 1.6 million doses of five essential generic medicines to treat COVID-19 patients to the U.S. Strategic National Stockpile. Edwards' previous company Kaleo was criticized for high prices, including a $4,500 price tag on Evzio, its device to treat painkiller overdoses. Kaleo lowered the price for federal and state government agencies as well as patients without government or commercial insurance

A Phlow spokesman said Edwards never had any control over drug pricing during his tenure at Kaleo and is committed to providing low-cost generic drugs.

(Reporting by Michael Erman in New York, and Ankur Banerjee and Saumya Sibi Joseph in Bengaluru; Editing by Saumyadeb Chakrabarty, Nick Zieminski and David Gregorio)

Source: Michael Erman & Ankur Banerjee, Reuters, 22.05.2020 (Excerpts)

● ● ●

Will established generics firms take Trump's cue and bring drug manufacturing to the U.S.?

The COVID-19 pandemic is reshaping the global supply chain, and the Trump administration has a message for established generics drugmakers: Bring your manufacturing on shore, or we will find new companies that do.

That's how Bernstein analyst Ronny Gal summarizes the two recent contracts the U.S. government signed to bring drug manufacturing to American soil. But will companies follow?

The HHS' Biomedical Advanced Research and Development Authority just inked a $354 million four-year deal with a company called Phlow to make generic medicine and active pharmaceutical ingredients in Virginia. The Department of Defense awarded a $138 million grant to ApiJect to expand U.S. production capability for prefilled syringes, following a $450 million deal the company won from the HHS.

After the Trump administration's $354 million deal with Phlow aimed at making drugs and APIs in the U.S., Bernstein analyst Ronny Gal suspects large, established generics makers will also move to bring drug manufacturing on shore. (Getty/Viperfzk)

Both deals fall in the injectables category and involve significant investments to upgrade facilities and purchase future products. They both tap relatively new companies, which appear to be using innovative manufacturing technologies, Gal noted in a report to clients.

Where does that leave traditional generic players such as Teva, Novartis' Sandoz and Mylan? They may choose to join in, Gal projects.

The Association for Accessible Medicines recently rolled out a blueprint (PDF) for improving the security of the U.S. pharma supply chain. It's about identifying a list

of essential medicines that should be made in the U.S., creating a network of friendly and reliable manufacturers and several financial incentives including HHS grants to support facility construction.

But Gal noted that the administration's language and actions suggest it wants more drastic approaches to fulfill President Donald Trump's "America First" economic promises.

"For far too long, we've relied on foreign manufacturing and supply chains for our most important medicines and Active Pharmaceutical Ingredients while placing America's health, safety, and national security at grave risk," Peter Navarro, Director of the White House Office of Trade and Manufacturing Policy, said in a statement about the Phlow deal.

"The COVID-19 pandemic has reminded us how health threats or other sources of instability can threaten America's medical supply chains, potentially endangering Americans' health," HHS Secretary Alex Azar said in his statement.

Currently, China and India are the world's largest suppliers of APIs. But the public health emergency has renewed concerns of reliance on such outside supplies. The virus has halted manufacturing activities around the world and spurred at least one export ban as India scrambled to preserve pharma output for its own use.

The COVID-19 crisis presents an opportunity for generics companies to get a break from pricing pressures and even investigations of dubious marketing behavior. "Even in the longer term, we don't rule out the possibility that customers may be willing to consider higher prices for more reliable supply," SVB Leerink analyst Ami Fadia wrote in an investor note in April.

But now, traditional generic players will face new competitors with new facilities, novel technologies and cozy relationships with the buyer—the U.S. Government.

Gal suspects traditional companies will join in. "These are sizable capital investments, and companies with existing infrastructure have no reason to hold back," he said.

This is particularly true for those that established U.S. facilities not long ago. Amneal Pharmaceuticals, for example, is the largest U.S.based player with API capacity, Gal noted. In December, the company took a 65.1% majority stake in AvKARE, a generic supplier primarily focused on serving the DoD and the Department of Veterans Affairs. Other companies could use the money to upgrade existing onshore facilities if they get aggressive, Gal argued. Mylan has its Morgantown, West Virginia, site; Teva has a campus in Irvine, California; and Pfizer's Hospira has facilities in North Carolina. They may not have much choice, anyway. Navarro recently proposed a "Buy American" executive order, which would soon require federal agencies to purchase U.S.-made medical products.

Meanwhile, Sen. Tom Cotton, an Arkansas Republican, and Rep. Mike Gallagher, a Republican from Wisconsin, recently introduced the Protecting Our Pharmaceutical Supply Chain from China Act, which calls for a complete cutoff from purchases of APIs and finished.

Source: Angus Liu, FiercePharma, 21.05.2020 (Excerpts)

● ● ●

FEATURE

India's tryst with destiny

Sundeep V Bambolkar, Joint Managing Director, Indoco Remedies outlines several measures that the Indian Government must implement to revive the economy and fast-track its growth

Working from home for over seven weeks now has been an experience in itself. While addressing a town hall video meeting of 75 persons, a thought actually crossed my mind — What about the scenario post-COVID-19? Press reports, articles appearing in global magazines are all hinting at a recession, hitherto not experienced globally for the last nine decades. We need to be mentally and physically prepared to absorb the aftershocks of this dastardly pandemic that is likely to leave indelible scars on our minds for the rest of our lives. The Coronavirus outbreak has significantly harmed the global population and caused substantial disruption to the economic activity in many countries including the US. There is a lurking danger of a large number of businesses drying up and eventually shutting down unless substantial liquidity is infused. This shut down would damage the economy to no end.

It is during such unprecedented times that we look back into history to seek advice and explore solutions that seem obvious but not easy to implement. When a catastrophe of such magnitude strikes the world, only Governments of nations possess the financial power to protect its citizens in general, and the lower economic strata of its population in particular.

This is when the Keynesian theory comes into play. John Maynard Keynes, a British Economist promulgated this theory in the year 1936. Keynesian economics is a theory that says the Government should increase demand to boost growth. Keynes believed that consumer demand is the primary driving force in an economy.

Considering the current situation the Indian economy is facing, one of the topmost challenging priorities the government is facing is food security for the migrant labour, who have lost their jobs and are struggling to get back to their villages. India, fortunately, has enough food stock to feed its poor population and that should not be a problem in the short term. However, for the medium term, the Government must speedily commence a plethora of construction activity viz highways, bridges, expressways, airports and seaports to name a few.

This will ensure steady and guaranteed employment and income for construction labourers particularly those below the poverty line. It will also boost demand for cement, iron and steel besides providing sustainable employment to engineers, architects and consultants. Large construction and infrastructure companies such as L&T, HCC to name only a few could be awarded huge contracts thus triggering both employment and demand.

The private sector has been a major driving force and a huge contributor to the Government exchequer for the Indian economy, ever since the economy was subjected to bold reforms in 1991. Next year we will celebrate the 30th Anniversary of this initiative. The size of our GDP in 1991 was $266 billion; which subsequently rose to ~$3 trillion by March 2020. In 1991, agriculture accounted for nearly 30 percent of the GDP. By fiscal 2019 agriculture had contracted to 17 percent on an enhanced GDP base. Gigantic steps were taken by the Finance Ministry and the RBI in the expansion of the banking sector – in enlarging both private banks and NBFCs – played a major role in the expansion and speedy growth of the industrial, manufacturing and services sector in the last twenty-nine years.

Sadly, the banking and the NBFC sector has suffered due to some setbacks in recent times. It is therefore imperative that the banking sector starts getting its act together and restarts incremental lending operations at least to companies with a proven track record to enable industrial and economic activity to flourish. This, in turn, will ensure that employment is sustained and quantum scale up in production becomes a predictable economic output than a one-off peak in performance. The RBI has drastically lowered the reverse repo rate currently to 3.75 percent, thus disincentivising commercial banks from parking money with the RBI. This move should act as a catalyst to force banks towards sanctioning and disbursement of incremental working capital limits for the manufacturing and services sectors that will be looking forward to this financial liquidity immediately.

Unprecedented times demand extraordinary measures. It is high time the Government of India incentivises the private sector to fuel the economy. If the migrant labour issue needs a long term solution, we need to think of total out-of-the-box measures. The Prime Minister along with his team of advisors needs to take some very bold decisions. Firstly land acquisition for construction of infrastructure projects needs to be up to lightning speed. Industrial Development Corporations need to be set up in the most backward areas in case they have not already been established and private sector needs to be sanctioned capital subsidy along with 100 percent exemption of income-tax, GST for new industrial undertakings. The Income Tax exemption and GST benefits should be for a minimum of 10 years.

A case in point is the Pharma industry. The Government of India has acknowledged its over-dependence on China for Key Starting Material (KSM) used in the manufacturing of Active Pharmaceutical Ingredients (APIs). The Government has now announced that it will invest 25 percent of the capital in the project. One of the conditions is the total project investment should exceed Rs 500 crores. Thus

the Government has clearly demonstrated that when the country is pushed to the wall, it is willing to make extremely quick decisions.

Another investment area where India can do well immediately is Foreign Direct Investment (FDI). The Government needs to encourage FDI in Greenfield projects pertaining to electronics, smartphones, computers and allied industries.

However, this FDI will not just happen. This has to be simultaneously accompanied by labour reforms, quick land allotment for the proposed industrial undertaking and other infrastructure required. We must realise quickly that billions of dollars' worth of FDI money can make its way to India if we move extremely fast to sanction all the approvals required for setting up of industrial enterprises.

Greenfield projects of huge scale, with an investment of around $250 million to $500 million each, can totally change the dynamics of the Indian economy. Growth in India's industrial and service sector would boost economic activity. This would bring buoyancy to the stock markets and bring in large funds flowing into India. Corporates would naturally reward shareholders and employees besides pumping in more money into expansion plan. This, in turn, would give more employment to every stratum of the Indian population. Only if this cycle is kept in motion, can we have an impressive growth in GDP as is being envisaged by many experts recently.

The country's need for renewable energy also needs to be looked at very urgently considering the huge expansion, the industrial sector will undertake.

All in all, the Prime Minister and his cabinet colleagues along with the advisory team, have a task cut out for themselves. The success of this entire initiative will certainly depend upon excellent execution. It is the absolute need of the hour for India and its tryst with destiny.

Source: Express Pharma, 25.05.2020

● ● ●

Explained: The Covid-19 resolution at the World Health Assembly

While the resolution has been endorsed at the WHA, it remains to be seen how the probe will be carried out and to what degree of independence

The 73rd session of the World Health Assembly (WHA) took place virtually from May 18-19. During the session, countries including India, Japan, Indonesia, New Zealand, UK and Canada accepted a resolution asking for an "impartial, independent and comprehensive evaluation" of the World Health Organization's (WHO) response to the pandemic as well as the identification of the "zoonotic" source of the coronavirus. The origin of the virus is currently believed to be a wet market in Wuhan, China. According to a Reuters report, 116 of the 194 member states were in favour of the resolution.

What is the World Health Assembly (WHA)?

The WHA is the decision making body of the WHO and the Assembly, which is held annually in Geneva, Switzerland, is attended by member states. During the Assembly, the WHO's 194 member states discuss health agendas set by the body's Executive Board, set new goals and assign tasks to fulfill these goals. Australia's Foreign Minister Marise Payne Monday hailed the global support into a comprehensive investigation into the Covid-19 response.

Germany's Chancellor Angela Merkel, meanwhile, said "no country can solve this problem alone" and backed the WHO's efforts to combat the outbreak. Merkel added that countries should "work to improve procedures" and the WHO should ensure its funding is sustainable.

Apart from this, the Assembly also addressed a global vaccine action plan with the "Immunisation Agenda 2030" that aims to ensure immunisation for all age groups to prevent the spread of preventable diseases and sustaining vaccine supplies.

What is the WHA draft resolution?

On Tuesday, 19.05.2020 the resolution brought forward by the European Union (EU) and moved by Australia on behalf of more than 100 countries including India, Australia and Japan, was endorsed at the Assembly.

While it does not mention China, the draft says the Director General of the WHO, Tedros Adhanom Ghebreyesus should continue "to work closely with the World Organisation for Animal Health (OIE), the Food

and Agriculture Organization of the United Nations (FAO) and countries, as part of the One-Health Approach to identify the zoonotic source of the virus and the route of introduction to the human population, including the possible role of intermediate hosts, including through efforts such as scientific and collaborative field missions, which will enable targeted interventions and a research agenda to reduce the risk of similar events as well as to provide guidance on how to prevent SARS-COV2 infection in animals and humans and prevent the establishment of new zoonotic reservoirs, as well as to reduce further risks of emergence and transmission of zoonotic diseases."

Further, the resolution states, "Initiate, at the earliest appropriate moment, and in consultation with Member States, (1) a stepwise process of impartial, independent and comprehensive evaluation, including using existing mechanisms, (2) as appropriate, to review experience gained and lessons learned from the WHO-coordinated international health response to COVID-19."

Why is the resolution important?

Since the pandemic, there has been increasing pressure on China, which so far has opposed suggestions for inquiry into the origins of the virus. Meanwhile, the US has repeatedly blamed the WHO and claims the organisation failed to obtain timely information and share it in a transparent fashion. The US has said that the pandemic "had spun out of control" in great part due to a costly "failure" by the WHO. On Tuesday, 19.05.2020 US President Donald Trump threatened to permanently cut funding to the WHO. Last month, Trump halted funding to the organization after he said it had "missed the call" on the pandemic. Trump said at the time the body's response was "China-centric" and suggested that the WHO had gone along with Beijing's efforts to under-represent the severity of the outbreak. At present, the US is the WHO's biggest contributor and makes up over 14.67 per cent of the total funding, at $553.1 million. On Monday, 18.05.2020 night Trump posted on Twitter a letter* he had addressed to Ghebreyesus. In the letter, Trump accused the WHO of being "curiously" insistent on praising China and for its "alleged transparency".

"Even now, China continues to undermine the International Health Regulations by refusing to share accurate and timely data, viral samples and isolates..." Trump wrote.

So, what does this mean for China?

While the resolution has been endorsed at the WHA, it remains to be seen how the probe will be carried out and to what degree of independence. Significantly, the timeline of the probe is also not clear. So far, China has opposed demands calling for an international investigation into the virus.

On Monday, China's premier Xi Jinping announced a $2 billion donation to the United Nations, which is over twice the amount the US contributed before Trump cut off funding. It also offered to set up hospitals and health infrastructure in Africa. Speaking at the opening ceremony of the WHA, Xi said China "supports" the idea of a comprehensive review of the global response towards Covid-19 after it was brought under control. The Trump administration sees China's announcement as a way to escape scrutiny over its alleged role in delaying providing information about the disease outbreak.

Source: The Indian Express, 21.05.2020 (Excerpts)

*(*Not reproduced here)*

● ● ●

For India to be the Setu for Aarogya world, it must unleash bold internal reforms

- *The healthcare management presents today a policy muddle, lying uncomfortably between various ministries in the Union government.*
- *There is a loud talk of India emerging as a global health player in the wake of the pandemic.*
- *Down by over 20 percent since February 19, about 15 of the 20 top gainers on the BSE 500 Index are Pharmaceutical companies.*

We are at an important cross road. This big crisis carries with it both a message, and an opportunity. When this crisis first hit us neither did we produce a single PPE kit nor N95 masks. Now we have reached a stage where we produce 2.5 lakh PPE kits and 2.5 lakh N95 masks a day. The definition of self-reliance is changing in the world," said Prime Minister Narendra Modi during his May 12 address to the nation.

Alluding to the role he believes India will play as a global health caregiver, Modi said, "When we end open defecation, it impacts the world. Our fight against TB, polio also impacts the world. When we send out medicines that we produce here it impacts the world."

There is a loud talk of India emerging as a global health player in the wake of the pandemic. Global experts buy the pitch that India can make healthcare the engine of its post-pandemic growth. The excitement is palpable with the stock market endorsing the sentiment. Down by over 20 percent since February 19, about 15 of the 20 top gainers on the BSE 500 Index are Pharmaceutical companies.

Cashing in on the sentiment, the government has set in motion—under the Department for Promotion of Industry and Internal Trade (DPIIT)—a fast track mechanism to clear applications of global pharmaceutical companies likely to move out of China and set up base in India.

All this is fine to create excitement around the self-reliance pitch bordering on integration and not isolation. But all such moves can come to naught if India does not mount urgent domestic reforms in the holistic healthcare policy framework.

India – Global Healthcare Leader?

Any talk of being a leader is fine but the ground situation presents a policy conundrum that is bound to force India to be a laggard in the foreseeable future. It is not lamenting the dismal official healthcare spend as a percent of the GDP; it is far more complex and only a nuanced reading shall mitigate the challenge and potentially help India achieve global scale and speed.

The healthcare management presents today a policy muddle. It lies uncomfortably between various ministries in the Union Government. These are the Ministry of Health & Family Welfare, Ministry of Chemicals, Petrochemicals and Fertilizers, Ministry of Science and Bio-Technology, and Ministry of Consumer Affairs. The role of the Commerce Ministry is already well articulated.

The Union Health Ministry is, so to say, the parent Ministry and hosts a Union Minister and a Minister of State. Given the constitutional mandate, each state government hosts its own health minister. In terms of a regulator, there is the Central Drugs Standard Control Organization (CDSCO), under Directorate General of Health Services, Union Ministry of Health & Family Welfare. Headquartered at New Delhi, CDSCO, has six zonal offices, four sub zonal offices, and thirteen Port offices across the country.

CDSCP is also to ensure the safety, efficacy and quality of the medical product manufactured, imported and distributed in the country.

Plethora of Regulators:

Under the Drugs and Cosmetics Act, CDSCO is also responsible for the approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organization.

Let us move now to the Ministry of Chemicals, Petrochemicals and Fertilizers, which rightly or wrongly administers independently a key component of the healthcare management in the country. The ministry overviews three departments namely—Department of Chemicals and Petrochemicals, Department of Fertilizers and Department of Pharmaceuticals.

Headed by a Secretary level officer, the Department of Pharmaceuticals (DoP) has been set up with the objective of giving greater focus and thrust on the development of the pharmaceutical sector in the country and to regulate various complex issues related to pricing and availability of medicines at affordable prices, Research & Development, protection of Intellectual Property Rights and international Commitments related to the pharmaceutical sector.

Within its ambit, there is also an independent regulator namely—the National Pharmaceutical Pricing Authority (NPPA). Its key role is to fix and revise the prices of controlled bulk drugs and formulations and to enforce prices and availability of the medicines in the country, under the Drugs (Prices Control) Order, 1995. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels.

DoP – In Need of a New Identity:

Under DoP, additionally resides the faculty to build and develop medical devices, a window for pharmaceutical industry promotion, manufacturing of strategic pharmaceutical products under the central public sector enterprises. Jan Aaushdi (a citizen-centric initiative offering affordable medicines) and nurturing quality and excellence in pharmaceutical education and research.

In essence, all of them are key pillars of what is being touted as India's leverage in building a global healthcare business. But on the ground they reside in non-descript departments oddly tagged inside a ministry which on the

face of it has nothing to do with health as a key focus area.

Strangely, this study also throws up the duality of regulators—one in Health Ministry and the other in the Chemicals and Fertilizers Ministry. This is highly avoidable, especially, since there is another regulator knocking on the doors when it comes to taking an integrated view of the health sector.

The Food Standards Safety Authority of India (FSSAI), popularly known as the food regulator, has some discreet play in the health sector as well. The key remit of the food regulator is to set standards on safe and nutritious food. Most importantly, labeling, a key aspect of the food business, comes under its jurisdiction. Given the play on immunity and nutrition, a key focus of the healthcare business, FSSAI has significant levers under its belt.

Moving away from food, when we talk of the most important piece of drug and vaccine management, there is another Ministry that has a role play. The idea is not to grudge them the role but to look at complex duplicity and parallelism often leading to bureaucratic hurdles that have the potential to stymie the India growth story in the sector.

The Department of Bio-technology, led by a Secretary level official, under the administrative control of the Ministry of Science and technology, the mandate is to launch a major, well-directed effort backed by significant investment for the generation of biotech products, processes and technologies to enhance efficiency, productivity. All this makes great sense with COVID-19 a reality that we are destined to live with for some time in the short and medium-term.

An Umbrella Health Ministry?

With the stated goal of building India as a global healthcare leader, it is imperative that there is a singular cogent policy framework to tap into the huge potential. As has been demonstrated in COVID times, there is a need to diversify the search for resident expertise (textile ministry pushing the medical textiles agenda).

However, it is time to build consensus around creating an umbrella organization. With turfs pretty dear to politicians and their favoured set of bureaucrats, there is a need to set up an urgent empowered Group of Ministers (GoM) tasked with offering the mechanism to set up the new umbrella ministry/body. There, however, is need to learn from past mistakes. The empowered GoM on pharmaceuticals under Sharad Pawar during the UPA era did not achieve what was expected of it. May be one to be set up under NDA will deliver the magic and actually make India the Setu for an Aarogya world?

(Rakesh Khar is senior editor, Special Projects, Network 18. He writes at the intersection of politics and economy).

Source: Rakesh Khar, Economy/cnbctv18.com (Excerpts)

● ● ●

● ● ●

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 30.05.2020

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.**