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# IDMA BULLETIN

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## Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

## HIGHLIGHTS


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# IDMA BULLETIN

**Vol. No. 51** **Issue No. 27** **15 to 21 July 2020**

## IDMA ACTIVITIES:



## CBDT MATTERS:



## CDSCO MATTERS:



## CBIC MATTERS:



## NEW DEVELOPMENTS:



## NATIONAL NEWS:



## FEATURE:

# IDMA request to MoEF&CC for amendment *re.* applicability for environmental clearance to manufacture Intermediates of APIs – reg.

***The Association has made the following representation on 17th July 2020 to Shri Rameshwar Prasad Gupta, IAS, Secretary, Ministry of Environment, Forest & Climate Change with copies to Dr P D Vaghela, IAS, Secretary, Department of Pharmaceuticals and Dr (Ms.) Preeti Sudan, IAS, Secretary, Ministry of Health & Family Welfare, New Delhi on the above subject:***

**"Greetings from Indian Drug Manufacturers' Association.**

The Ministry of Environment, Forest and Climate Change deemed it necessary to expedite Environmental Clearances (EC) to projects or expansions in respect of Bulk Drugs (APIs) and Intermediates. As part of a comprehensive policy to handle the Novel Corona Virus (COVID-19) outbreak, drug availability, production and self-reliance to reduce the impact of the Novel Corona Virus (COVID-19) has been the focus of the Government of India. The Ministry vide Notification No.S.O.1223(E) dated 27th March 2020 (attached)* deemed it necessary to expedite all projects or expansions in respect of bulk drugs for addressing ailments such as Novel Corona Virus (COVID-19) and categorized them as 'B2'.

**Intermediates** are also separately produced and sold to others for final conversion to APIs. It is thus pertinent that the Notification should also include intermediates, in addition to APIs. We would like to bring to your notice that, although the Government of India's intent was to include both Active Pharmaceutical Ingredients (APIs) and Intermediates, may be through oversight, the italic para in the Notification has restricted the 'B2' categorization, **only to APIs and does not include intermediates.** As a result, State Expert Appraisal Committees (SEAC) are rejecting applications for prior environmental clearance under category B2, wherein intermediates, are listed in the application form.

We are reproducing the Section 5 (f) of Ministry of Environment & Forest Notification No.S.O.1533(E), dated 14.09.2006 for your kind reference. This Category states 'bulk drugs and intermediates'.

| (1) | (2) | (3) | (4) | (5) |
|---|---|---|---|---|
| 5(f) | Synthetic organic chemicals industry (dyes & dye intermediates; bulk drugs and intermediates excluding drug formulations; synthetic rubbers; basic organic chemicals, other synthetic organic chemicals and chemical intermediates) | Located outside the notified industrial area/ estate. | Located in a notified industrial area/ estate. | General as well as specific condition shall apply." |

In light of the above facts, amendment of the said Notification is warranted to include APIs & Intermediates under the 'B2' category, to expedite prior environmental clearance.

**Following is the italic para of the said Notification:**

***"All proposals for projects or activities in respect of Active Pharmaceutical Ingredients (API), received up to the 30th September 2020, shall be appraised, as Category 'B2' projects, provided that any subsequent amendment or expansion or change in product mix, after the 30th September 2020, shall be considered as per the provisions in force at that time."***

**We humbly submit that the above stated para of the Draft Notification be amended, as below:**

*"All proposals for projects or activities in respect of Active Pharmaceutical Ingredients (API)/**Key starting materials (KSM)/and its intermediates**, received up to the 30th September 2020, shall be appraised, as Category*

*'B2' projects, provided that any subsequent amendment or expansion or change in product mix, after the 30th September 2020, shall be considered as per the provisions in force at that time."*

Sir, we submit, that the situation is still not normalized and support for API & Intermediates is needed for the country to become self-reliant. Also, the revised EIA Guidelines are not yet notified; in the interim period it is but natural that this Notification is continued to be operative so that the API sector continues to be considered as B2 Category. We therefore request that the validity of the said notification may kindly be extended till March 31st 2021.

We humbly request the above is considered on an URGENT basis and in line with the Government's intent to make India self-reliant in the manufacture of intermediates and APIs and ensure availability of medicines to Indian patients. Thanking you with warm regards".

(**Published in IDMA Bulletin dated 21 April 2020)*

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# IDMA Representation to DoP on Unfair Tender condition/ Fall Clause of seeking Lowest Rates than quoted to any other Institution – reg.

***The Association has submitted the following representation on 13th July 2020 to Dr P D Vaghela, IAS, Secretary, Department of Pharmaceuticals, New Delhi on the above subject:***

**"Greetings from Indian Drug Manufacturers' Association.**

With reference to the above subject, we had submitted our request to the Secretary, Department of Health, Ministry of Health & Family Welfare on 30th July 2018 (Copy attached)*. We received a letter dated 18.10.2018 in reply from Shri Somnath Basu, Assistant Drugs Controller (India), CDSCO, Public Grievance Cell requesting us to direct our representation to NITI Aayog (Copy attached)*.

Accordingly, we made a representation to Member (Health), NITI Aayog and also submitted the copy of the same in your esteemed office.

Manual for Procurement of Goods 2017 issued by Government of India, Ministry of Finance, Department of Expenditure provides exceptions to the said rule of Fall Clause and clearly excludes "Sale of goods such as drugs, which have expiry date" from the provisions of the said fall clause (Relevant Page Nos. 117 & 118 of the manual are attached for your ready reference)*. In spite of this, the condition of Fall Clause continues to be included in the tenders pan India.

We were informed that a meeting was held on the above subject on 6th January 2020 under your esteemed Chairmanship wherein Ministry of Health, Department of Expenditure, DPIIT were represented.

It was decided in the meeting that Department of Expenditure will be issuing necessary instructions to all the procuring agencies to strictly follow the guidelines of Manual for Procurement of Goods 2017 and remove the Price Fall Clause from their tender of procurement of drugs.

Sir, so far we have not received any further communication in the matter. We request your kind help so that an advisory be issued by Department of Expenditure to all the procuring agencies with a copy to IDMA for information. Thanking you and with regards".

*(*Not reproduced here)*

● ● ●

# REPURPOSING OR SECONDARY USE OF KNOWN DRUGS

***Dr Gopakumar G Nair,*** *Editor, Indian Drugs*

*Dear Reader,*

*Repurposing of drugs was most often a strategic approach, though by "serendipity" in few instances.*

*Early practice of pharmacovigilance in USA, led to near 'serendipitous' addition to market value for many "first use" drugs. Glaxo-Welcome's Bupropion brand "Wellbutrin" was first approved for treatment of depression. While "Wellbutrin" received an average response in the anti-depression segment, pharmacovigilance reports to FDA was perplexing. Patients gave conflicting response. While a few wanted to change to another drug, many others wanted to continue the use of the prescribed drug even after being advised to stop. The reason when investigated, was that the patients felt the urge to discontinue smoking, which was acceptable to some, while not to others. When this finding was received by the FDA from multiple specialists, Glaxo-Welcome was asked to conduct a full study on a priority basis. Consequently, FDA granted a fast track approval for use of Bupropion for smoking cessation. Antidepressant "Wellbutrin" opened up new pathway for smokers to "kick the Butts" through its second use "Avatar", in form of "Zyban" for smoking cessation and become the first global breakthrough drug of choice for this second use. Pharmacovigilance helps in developing a road map for secondary use.*

*There are many more Repurposed drugs which have been strengthening the therapeutic armoury over the years. An outstanding example is Zidovudine (azidothymidine or AZT)) which was initially investigated in 1964 as an anticancer medication, but failed. Just like Zyban, AZT was reborn in its new incarnation globally for the treatment of HIV/AIDS. Another typical example for repurposing is Erlotinib (TARCEVA) which was originally approved for non-small-cell lung cancer, turned out as global blockbuster for the treatment of pancreatic cancer and other therapeutic indications.*

*Aspirin has been in use for hundreds of years to treat inflammation, in its earliest incarnation from the extract of willow bark. Synthetic Aspirin emerged as the most popular anti-inflammatory, analgesic and antipyretic of our times, once introduced by Bayer in 1990. After living its role for nearly 100 years, Aspirin got a new life with its revolutionary use in*

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

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

*cardiovascular and cerebrovascular disease. The "Aspirin story" is now becoming the trend in the new millennium as "Repurposing of drugs" is attracting attention like never before, for multiple reasons. Aspirin's successor Paracetamol has now emerged as a front-line treatment for near asymptomatic patients of COVID-19. Reportedly, ibuprofen is also being investigated. Closer home, HCQ (Hydroxychloroquine) emerged from the antimalarial family as a treatment for rheumatoid arthritis, lupus and other diseases in combination with methotrexate. HCQ has further proved effective in a combination with Nitazoxanide and even with Azithromycin in the latest repurposing for treatment of Sars-cov-2, popularly known as Covid-19.*

*Repurposing of the drugs have emerged as the most potent strategy to treat Covid-19. Task Force constituted by the Government's Principal Scientific Advisor, Dr K Vijay Raghavan for inter-disciplinary assessment of drug candidates (Repurposing) have identified nearly thirty molecules as potential candidates for the treatment of Covid-19. Remdesivir developed for treatment of Ebola is now emerging as a front-runner along with Tocilizumab and Favipiravir. Even well-known drugs like Famotidine, Lisinopril, Losartan, Ivermectin+Doxycycline, Dexamethasone, Interferon Beta, Lopinavir+ Ritonavir, Ribavirin, Darunavir and others are emerging useful against Covid-19, often in combinations. However, there is an emerging global conflict against cheaper options of well-known drugs used for years and proven to be safe in preference to costlier newly invented patented molecules. India needs to continue the repurposing exercise to exhaust all options in its armoury against treatment of Covid-19, at least till an effective vaccine option emerges. Even after vaccines enter the market, it is absolutely essential that continued research into new uses of known drugs must continue. Today, it may be for Covid-19, tomorrow for another emerging disease. The momentum gained through new initiative of repurposing must keep up beyond Covid-19. Many of the safe and effective drugs in the market could be evaluated for secondary indications as a need-based research strategy based on market needs. The roadmap for future research for the Indian pharma industry and academia should be in repurposing or second medical use. The options are enormous, the opportunity is there for grabbing. The need in the market place or treatment gaps are too strong to be ignored.*

*The current crisis has also created more awareness on the need for strong immunity building to prevent or avoid co-morbidities. Awareness on need for monitoring and maintaining general well-being has opened up opportunities of nutraceutical, herbal supplements, probiotics and food supplements. Herbal options are being clinically evaluated not only for immunity-building, but also for prophylactic and even therapeutic use. AQCH based on Cissampelos Pareira (Patha, velvet leaf, Hirtusa Abuta) is being clinically evaluated for the treatment of Covid-19. It is time that Indian Pharma researcher redirects attention to repurposing or newer use of known drugs. The patentability or non-patentability considerations should not deter these valuable frontiers for need-based research. New use of known drugs (not patentable in India under Section 3 (d) of Patents Act, 1970) is patentable in all developed countries. Even in India, a novel and inventive formulation developed distinctively and distinguishingly over the prior primary use dosage form, could be patented when developed for the secondary use. Let us jump into this new "Kurukshetra" domain to fight against emerging threat to health and well being using the weapons we already possess in our armoury with effective use of observations and reports received through the sales-force or though Pharmacovigilance.*

***Courtesy: Indian Drugs, Editorial, Vol. 57 (05) May 2020***

# CBDT notifies Income Tax (16th Amendment) Rules 2020 - reg.

**Gazette Notification No.G.S.R.429(E), dated 3rd July 2020**

In exercise of the powers conferred by sections 194A, 194J, 194K, 194LBA, 194N, 194-O, 197A and 200 read with section 295 of the Income-tax Act, 1961 (43 of 1961), the Central Board of Direct Taxes, hereby, makes the following rules further to amend the Income-tax Rules, 1962, namely:-

**1. Short title and commencement:**

(1) These rules may be called the Income-tax (16th Amendment) Rules, 2020.

(2) Save as otherwise provided in these rules, they shall come into force from the date of their publication in the Official Gazette.

**2. In the Income-tax Rules,** 1962 (hereinafter referred to as the principal rules), in rule 31A, in sub-rule (4), --

(a) in clause (viii), after the words "not deducted", the words "or deducted at lower rate" shall be inserted;

(b) for clause (ix) the following shall be substituted from the 1st day of July, 2020, namely:-

"(ix) furnish particulars of amount paid or credited on which tax was not deducted or deducted at lower rate in view of the notification issued under second proviso to section 194N or in view of the exemption provided in third proviso to section 194N or in view of the notification issued under fourth proviso to section 194N";

(c) after clause (ix), the following clauses shall be inserted, namely:--

"(x) furnish particulars of amount paid or credited on which tax was not deducted or deducted at lower rate in view of the notification issued under sub-section (5) of section 194A.

(xi) furnish particulars of amount paid or credited on which tax was not deducted under sub-section (2A) of section 194LBA.

(xii) furnish particulars of amount paid or credited on which tax was not deducted in view of clause (a) or clause (b) of sub-section (1D) of section 197A.

(xiii) furnish particulars of amount paid or credited on which tax was not deducted in view of the exemption provided to persons referred to in Board Circular No. 3 of 2002 dated 28th June 2002 or Board Circular No. 11 of 2002 dated 22nd November 2002 or Board Circular No. 18 of 2017 dated 29th May 2017."

**3. In the principal rules, in Appendix II,**

(I) in form 26Q –

(a) for the brackets, words, figures and letters

"[See sections 192A, 193, 194, 194A, 194B, 194BB, 194C, 194D, 194DA, 194EE, 194F, 194G, 194H, 194-I, 194J, 194LA, 194LBA, 194LBB, 194LBC, 194N and rule 31A]" the following brackets, words, figures and letters "[See sections 192A, 193, 194, 194A, 194B, 194BB, 194C, 194D, 194DA, 194EE, 194F, 194G, 194H, 194-I, 194J, 194K, 194LA, 194LBA, 194LBB, 194LBC, 194N, 194-O, 197A and rule 31A]" shall be substituted;

(b) for the "Annexure", the following "Annexure" shall be substituted, namely :-

(b) for the "Annexure", the following "Annexure" shall be substituted, namely :-

"[*ANNEXURE: DEDUCTEE/PAYEE WISE BREAK UP OF TDS*

***(Please use separate Annexure for each line-item in Table at Sl. No. 4 of main Form 26Q)***

*Details of amount paid/credited during the quarter ended……. (dd/mm/yyyy) and of tax deducted at source*

| | |
|---|---|
| *BSR Code of branch/Receipt Number of Form No. 24G* | |
| *Date on which challan deposited/Transfer voucher date (dd/mm/yyyy)* | |
| *Challan Serial Number / DDO Serial No. of Form No. 24G* | |
| *Amount as per Challan* | |
| *Total tax to be allocated among deductees/payees as in the vertical total of Col. 421* | |
| *Total interest to be allocated among the deductees/payees mentioned below* | |

| | |
|---|---|
| *Name of the Deductor/Payer* | |
| *TAN* | |

| ***Sl. No.*** | ***Deductee /payee reference number provided by the deductor/payer, if available*** | ***Deductee/ payee code (01-Company 02-Other than company)*** | ***PAN of the deductee/ payee*** | ***Name of the deductee/ payee*** | ***Section code (See Note 12)*** | ***Date of payment or credit (dd/mm/ yyyy)*** | ***Amount paid or credited*** | ***Amount of cash withdrawal in excess of Rs. 1 crore as referred to in section 194N (in cases not covered by the first proviso to section 194N)*** | ***Amount of cash withdrawal which is in excess of Rs. 20 lakhs but does not exceed Rs. 1 crore for cases covered by sub-clause (a) of clause (ii) of first proviso to section 194N*** | ***Amount of cash withdrawal which is in excess of Rs. 1 crore for cases covered by sub-clause (b) of clause (ii) of first proviso to section 194N*** | ***Total tax deducted*** | ***Total tax deposited*** | ***Date of deduction (dd/mm/yyyy)*** | ***Rate at which deducted*** | ***Reason for non-deduction/ lower deduction/ Higher Deduction/ Threshold/ Transporter etc. (See notes 1 to 11)*** | ***Number of the certificate under section 197 issued by the Assessing Officer for non-deduction/ lower deduction*** |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *[412]* | *[413]* | *[414]* | *[415]* | *[416]* | *[417]* | *[418]* | *[419]* | *[419A]* | *[419B]* | *[419C]* | *[420]* | *[421]* | *[422]* | *[423]* | *[424]* | *[425]* |
| *1* | | | | | | | | | | | | | | | | |
| *2* | | | | | | | | | | | | | | | | |
| *3* | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | |
| *Total* | | | | | | | | | | | | | | | | |

**Verification**

I, ..... , hereby certify that all the particulars furnished above are correct and complete.

Place: ……..

Date: ……..

……..

Signature of the person responsible for deducting tax at source

……..

*Name and designation of the person responsible for deducting tax at source*

***Notes:***

1. *Write "A" if "lower deduction" or "no deduction" is on account of a certificate under section 197.*
2. *Write "B" if no deduction is on account of declaration under section 197A other than the cases mentioned in sub-section (1F) of section 197A.*
3. *Write "C" if deduction is on higher rate on account of non-furnishing of PAN by the deductee/payee.*
4. *Write "D" if no deduction or lower deduction is on account of payment made to a person or class of person on accont of notification issued under sub-section (5) of section 194A.*
5. *Write "E" if no deduction is on account of payment being made to a person referred to in Board Circular no. 3 of 2002 dated 28th June, 2002 or Board Circular no. 11 of 2002 dated 22nd November, 2002 or Board Circular no. 18 of 2017 dated 28th May, 2017.*
6. *Write "Y" if no deduction is on account of payment below threshold limit specified in the Income-tax Act, 1961.*
7. *Write "T" if no deduction is on account of deductee/payee being transporter. PAN of deductee/payee is mandatory [section 194C (6)].*
8. *Write "Z" if no deduction or lower deduction is on account of payment being notified under section 197A (1F).*
9. *Write "M" if no deduction or lower deduction is on account of notification issued under second proviso to section 194N.**
10. *Write "N" if no deduction or lower deduction is on account of payment made to a person referred to in the third proviso to section 194N or on account of notification issued under the fourth proviso to section 194N.**
11. *Write "O" if no deduction is as per the provisions of sub-section (2A) of section 194LBA.*
12. *List of section codes is as under:*

| ***Section*** | ***Nature of Payment*** | ***Section Code*** |
|---|---|---|
| *192A* | *Payment of accumulated balance due to an employee* | *192A* |
| *193* | *Interest on securities* | *193* |
| *194* | *dividend* | *194* |
| *194A* | *Interest other than interest on securities* | *94A* |
| *194B* | *Winnings from lotteries and crossword puzzles* | *94B* |
| *194BB* | *Winnings from horse race* | *4BB* |
| *194C* | *Payment of contractors and sub-contractors* | *94C* |
| *194D* | *Insurance Commission* | *94D* |
| *194DA* | *Payment in respect of life insurance policy* | *4DA* |
| *194EE* | *Payments in respect of deposits under National Savings Schemes* | *4EE* |
| *194F* | *Payments on account of repurchase of Units by Mutual Funds or UTIs* | *94F* |
| *194G* | *Commission, prize etc., on sale of lottery tickets* | *94G* |
| *194H* | *Commission or Brokerage* | *94H* |
| *194-I(a)* | *Rent* | *4-IA* |
| *194-I (b)* | *Rent* | *4-IB* |

| | | |
|---|---|---|
| *194J(a)* | *Fees for Technical Services(not being professional services), royalty for sale, distribution or exhibition of cinematographic films and call centre (@2%)* | *94J-A* |
| *194J (b)* | *Fee for professional service or royalty etc. (@10%)* | *94J-B* |
| *194K* | *Income in respects of units.* | *94K* |
| *194LA* | *Payment of Compensation on acquisition of certain immovable property* | *4LA* |
| *194LBA(a)* | *Certain income in the form of interest from units of a business trust to a residential unit holder* | *4BA1* |
| *194LBA(b)* | *Certain income in the form of dividend from units of a business trust to a resident unit holder* | *4BA2* |
| *194LB* | *Income in respect of units of investment fund* | *LBB* |
| *194LBC* | *Income in respect of investment in securitization trust* | *LBC* |
| *194N* | *Payment of certain amounts in cash* | *94N* |
| *194N First proviso** | *Payment of certain amounts in cash to non-filers* | *94N-F* |
| *#194-O* | *Payment of certain sums by e-commerce operator to e-commerce participant* | *94O"* |

(II) in form 27Q --

(a) for the brackets, words, figures and letters

"[See sections 194E, 194LB, [194LBA, 194LBB, 194LBC], 194LC, 195, 196A, 196B, 196C, 196D, and rule 31A]"

the brackets, words, figures and letters

"[See section 194E, 194LB, [194LBA, 194LBB, 194LBC], 194LC, 194N, 195, 196A, 196B, 196C, 196D, 197A and rule 31A]" shall be substituted;

(b) for the "Annexure" the following "Annexure" shall be substituted, namely:--

"[ANNEXURE: DEDUCTEE WISE BREAK UP OF TDS]

*(Please use separate Annexure for each line item in Table at Sl. No. 04 of main Form 27Q)*

*Details of amount paid/credited during the quarter ended (dd/mm/yyyy) and of tax deducted at source*

*Name of the Deductor/Payer*

| | |
|---|---|
| TAN | |

| | |
|---|---|
| BSR Code of branch/Receipt Number of Form No. 24G | |
| Date on which challan deposited/Transfer voucher date (dd/mm/yyyy) | |
| Challan Serial Number/DDO Serial No. of Form No. 24G | |
| Amount as per Challan | |
| Total TDS to be allocated among deductees as in the vertical total of Col. 726 | |
| Total interest to be allocated among the deductees mentioned below | |

| *Sl. No.* | *Deductee reference number provided by the deductor, if available* | *Deductee code (01-Company 02-Other than company)* | [Permanent Account Number or Aadhaar Number] *of the deductee* [see *note 9*] | *Name of the deductee* | *Section code (See Note 8)* | *Date of payment or credit (dd/mm/yyyy)* | *Amount of cash withdrawal in excess of Rs. 1 core as referred to in section 194N (in cases not covered by the first proviso to section 194N)** | ***Amount of cash withdrawal which is in excess of Rs. 20 lakhs but does not exceed Rs. 1 crore for cases covered by sub-clause (a) of clause (ii) of first proviso to section 194N**** | ***Amount of cash withdrawal which is in excess of Rs. 1 crore for cases covered by sub-clause (b) of clause (ii) of first proviso to section 194N**** | *Amount paid or credited* | *Tax* | *Surcharge* | *Education Cess* | *Total tax deducted [722+ 723 + 724]* | *Total tax deposited* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| *[714]* | *[715]* | *[716]* | *[717]* | *[718]* | *[719]* | *[720]* | *[720A]* | *[720B]* | *[720C]* | *[721]* | *[722]* | *[723]* | *[724]* | *[725]* | *[726]* |
| 1 | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | |
| Total | | | | | | | | | | | | | | | |

| *Date of deduction (dd/mm/yyyy)* | *Rate at which deducted* | *Reason for non-deduction/ lower deduction/ grossing up/ Higher Deduction (See notes 1 to 3)* | *Number of the certificate issued by the Assessing Officer for non-deduction/ lower deduction* | *Whether the rate of TDS is as per IT Act (a) DTAA (b)* | *Nature of Remittance* | *Unique Acknowledgement of the corresponding Form No. 15CA, if available* | *Country to which remittance is made* | *Email ID of deductee* | *Contact number of deductee* | *Address of deductee in country of residence* | *Tax Identification Number/ Unique identification number of deductee* |
|---|---|---|---|---|---|---|---|---|---|---|---|
| *[727]* | *[728]* | *[729]* | *[730]* | *[731]* | *[732]* | *[733]* | *[734]* | *735* | *736* | *737* | *738* |
| 1 | | | | | | | | | | | |
| 2 | | | | | | | | | | | |
| 3 | | | | | | | | | | | |
| | | | | | | | | | | | |
| Total | | | | | | | | | | | |

**Verification**

I, ....., hereby certify that all the particulars furnished above are correct and complete.

..... .....

*Place:* .....

*Signature of the person responsible for deducting tax at source*

*Date:* .....

.. .....

*Name and designation of the person responsible for deducting tax at source*

Notes:

1. Write "A" if "lower deduction" or "no deduction" is on account of a certificate under section 197.
2. Write "C" if grossing up has been done.
3. Write "D" if deduction is on higher rate on account of non-furnishing of [Permanent Account Number or Aadhaar Number] by the deductee.
4. Write "O" if no deduction is in view of sub-section (2A) of section 194LBA.
5. Write "M" if no deduction or lower deduction is on account of notification issued under second provison to section 194N.*
6. Write "N" if no deduction or lower deduction is on account of payment made to a person referred to in the third proviso to section 194N or on account of notification issued under the fourth proviso to section 194N.*
7. Write "G" if no deduction is in view of clause (a) or clause (b) of sub-section (1D) of section 197A.
8. List of section codes is as under:

| *Section* | *Nature of Payment* | *Section Code* |
|---|---|---|
| 192A | Payment of accumulated balance due to an employee | 192A |
| 194E | Payments to non-resident Sportsmen/Sport Associations | 94E |
| 194LB | Income by way of interest from infrastructure debt fund | 4LB |
| 194LBA(a) | Income referred to in section 10(23FC)(a) from units of a business trust | LBA1 |
| 194LBA (b) | Income referred to in section 10(23FC)(b) from units of a business trust | LBA2 |
| 194LBA(c) | Income referred to in section 10(23FCA) from units of a business trust | LBA3 |
| 194LBB | Income in respect of units of investment fund | LBB |
| 194LBC | Income in respect of investment in securitisation trust | LBC] |
| 194LC | Income by way of interest from Indian company | 4LC |
| *194LD* | *Income by way of interest on certain bonds and Government securities.* | *4LD* |
| *194N* | *Payment of certain amounts in cash* | *94N* |
| *194N First Proviso** | *Payment of certain amount in cash to non-filers.* | *94N-F* |
| 195 | Other sums payable to a non-resident | 195 |
| 196A | Income in respect of units of Non-Residents | 96A |
| 196B | Payments in respect of Units to an Offshore Fund | 96B |
| 196C | Income from Foreign Currency Bonds or shares of Indian Company payable to Non-Resident | 96C |
| 196D | Income of foreign institutional investors from securities | 96D |

9. In case of deductees covered under rule 37BC, *Permanent Account Number or Aadhaar Number* NOT AVAILABLE" should be mentioned."

*in relation to section 194N, the changes shall come into effect from 1st July, 2020. #in relation to section 194-O, the changes shall come into effect from 1st October, 2020.

**F. No. 370142/11/2020-TPL** *Ankit Jain, Under Secretary, Tax Policy and Legislation Division, Central Board of Direct Taxes, DoR, MoF, New Delhi.*

***Note:*** *The Principal Rules were published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-section (ii) vide number S.O.969(E), dated the 26th March, 1962 and were last amended vide Notification Number G.S.R. 423(E), dated 30.06.2020*

# Ensuring sufficient availability of Methylprednisolone (IV) and low molecular weight Heparin (Enoxaparin and Dexamethasone drugs) – reg.

**DCG(I) Circular dated 10th July 2020**

*To*
*Drugs Manufacturing Associations;*

**1.** Methylprednisolone (IV) & low molecular weight heparin e.g. Enoxaparin and Dexamethasone drugs are included in revised treatment protocol. Further, as per the information of Ministry of Health & Family Welfare, Government of India, these drugs are being used for patients admitted in ICU and Hospitalisation due to Covid-19.

**2.** In this regard, this office has received communication from NPPA dated 01.07.2020 for measures to ensure the sufficient availability of these drugs in the country.

**3.** Accordingly, you are requested to ask your members to enhance the production and to ensure the sufficient availability of Methylprednisolone (IV) & low molecular weight Heparin e.g. Enoxaparin and Dexamethasone drugs in trade channels across the States/UTs to supplement the efforts of Government for management of the situation arising due to COVID-19 in the country. Further, you are also requested to provide the information on said drugs in Annexure-I on **dccdtab@cdsco.nic.in**, **enforcecell.div@cdsco.nic.in**, **dci@nic.in** and **vgsjdci@gmail.com** urgently on top priority. Your cooperation will be appreciated.

**File No.DCGI/Misc/2020(96)**

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

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**Annexure I**

**Name of Drug.....**

| Sr.No. | Name of Manufacturer/ Importer | Installed Capacity (units/ month) | Current production (units/month) | Current stock of formulations | Current stock of API (in MT) | Source of procurement of API (Manufactured Indigenous/ imported/ both) | Name of countries from where API is imported | Remarks |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
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# CBIC notifies New Exchange Rates w.e.f. 03rd July 2020 - reg.

**Notification No.55/2020-Customs (N.T.), dated 02nd July, 2020**

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.53/2020-Customs(N.T.), dated 18th June, 2020 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, shall, **with effect from 3rd July, 2020,** be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods. .

**SCHEDULE-I**

| Sr. No. | Foreign Currency | Rate of exchange of one unit of foreign currency equivalent to Indian Rupees | |
|---|---|---|---|
| (1) | (2) | (3) | |
| | | (a) | (b) |
| | | (For Imported Goods) | (For Exported Goods) |
| 1. | Australian Dollar | 53.45 | 51.15 |
| 2. | Bahraini Dinar | 206.70 | 193.70 |
| 3. | Canadian Dollar | 56.50 | 54.60 |
| 4. | Chinese Yuan | 10.85 | 10.55 |
| 5. | Danish Kroner | 11.60 | 11.20 |
| 6. | EURO | 86.60 | 83.55 |
| 7. | Hong Kong Dollar | 9.90 | 9.55 |
| 8. | Kuwaiti Dinar | 253.60 | 237.75 |
| 9. | New Zealand Dollar | 50.35 | 48.05 |
| 10. | Norwegian Kroner | 8.10 | 7.80 |
| 11. | Pound Sterling | 96.00 | 92.75 |
| 12. | Qatari Riyal | 21.25 | 19.95 |
| 13. | Saudi Arabian Riyal | 20.80 | 19.50 |
| 14. | Singapore Dollar | 55.10 | 53.30 |
| 15. | South African Rand | 4.60 | 4.30 |
| 16. | Swedish Kroner | 8.25 | 8.00 |
| 17. | Swiss Franc | 81.40 | 78.35 |
| 18. | Turkish Lira | 11.35 | 10.70 |
| 19. | UAE Dirham | 21.25 | 19.95 |
| 20. | US Dollar | 76.40 | 74.70 |

**SCHEDULE-II**

| Sr. No. | Foreign Currency | Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees | |
|---|---|---|---|
| | | (For Imported Goods) | (For Export Goods) |
| 1. | Japanese Yen | 71.60 | 69.00 |
| 2. | Korean Won | 6.50 | 6.10 |

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

*Radhakrishnan Ananth, Deputy Secretary, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.*

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## Drug linked to 45% lower risk of dying among COVID-19 patients on ventilators

Critically ill COVID-19 patients who received a single dose of a drug that calms an overreacting immune system were 45% less likely to die overall, and more likely to be out of the hospital or off a ventilator one month after treatment, compared with those who didn't receive the drug, according to a new study by a team from the University of Michigan.

The lower risk of death in patients who received intravenous tocilizumab happened despite the fact that they were also twice as likely to develop an additional infection, on top of the novel Coronavirus. The study is published in the peer-reviewed journal *Clinical Infectious Diseases* after being available as a preprint last month.

It suggests a benefit from timely and targeted efforts to calm the "cytokine storm" caused by the immune system's overreaction to the Coronavirus. Tocilizumab, originally designed for rheumatoid arthritis, has already been used to calm such storms in patients receiving advanced immunotherapy treatment for cancer.

The researchers base their conclusions on a thorough look back at data from 154 critically ill patients treated at Michigan Medicine, U-M's academic medical center, during the first six weeks of the pandemic's arrival in Michigan from early March to late April. The analysis looked at patients' records through late May. During that time, when little was known about what would help COVID-19 patients on ventilators, about half of the studied patients received tocilizumab and half did not.

Most received it within the 24-hour period surrounding their intubation. This created a natural opportunity for comparing the two groups' outcomes in an observational study, though clinical trials are still needed to truly see if the drug provides a benefit, the authors say.

**Promising result:**

Lead author Emily Somers, Ph.D., Sc.M., an epidemiologist who has studied both rheumatologic and immunologic diseases, says the research team went into their analysis uncertain whether they would find a benefit, a risk, or no clear effect associated with tocilizumab in the patients with life-threatening COVID-19. But they knew it was a critically important question that they were uniquely positioned to answer at that point in the pandemic.

"One role of epidemiology is to rigorously evaluate real-world data on treatment effects, especially when evidence from clinical trials is not available. We kept trying to prove ourselves wrong as signals of benefit emerged in the data, both because of the immediate implications of these data, and in part because of concern about the supply of the medication for other patients," she says. "But the difference in mortality despite the increase in secondary infection is quite pronounced, even after accounting for many other factors."

Somers is an Associate Professor in the U-M Medical School's Department of Internal Medicine and member of the U-M Institute for Healthcare Policy and Innovation. She co-leads the COVID-19 Rapid Response Registry, which is supported by the Michigan Institute for Clinical and Health Research.

The paper's co-first author is Gregory Eschenauer, Pharm.D., a clinical pharmacist at Michigan Medicine and clinical Associate Professor at the U-M College of Pharmacy. He and senior author Jason Pogue, Pharm.D., are members of the Michigan Medicine Antimicrobial Stewardship Program.

The ASP group developed treatment Guidelines provided to Michigan Medicine physicians in mid-March that identified tocilizumab as a potentially beneficial therapy for the most severely ill COVID-19 patients. Those Guidelines also pointed out its risks and the lack of evidence for its use in COVID-19, and recommended a dose of 8 milligrams per kilogram. This led some physicians to choose to use it, while others did not - setting the stage inadvertently for a natural comparison.

**More research needed:**

Pogue, Clinical Professor at the U-M College of Pharmacy and an infectious disease pharmacist at Michigan Medicine, notes that more robust data released in June from a large randomized controlled trial in the United Kingdom has led him to recommend the steroid dexamethasone as the first choice to treat critically ill COVID-19 patients.

"For a retrospective, single-center study, our data are robust. But at this time, due to the lack of randomized controlled trial data and the much higher cost, we recommend reserving tocilizumab for the treatment of select patients who decompensate while on or after

receiving dexamethasone or in patients where the risks of adverse events from steroid therapy outweigh the potential benefits" says Pogue.

"Further studies of tocilizumab, which is more targeted than dexamethasone in addressing the hyperinflammatory process, could include combining these agents or comparing them head-to-head," he adds. Pogue notes that a single dose of tocilizumab is roughly 100 times more expensive than a course of dexamethasone. He also notes that another drug that aims to treat cytokine storm by targeting the interleukin-6 (IL-6) receptor - one called sarilumab - appears to have failed to improve outcomes in a Clinical Trial in COVID-19 patients including those on ventilators.

Michigan Medicine had been participating in the sarilumab study at the time the patients in the current study were treated, but not all patients qualified because of the timing of their admission or issues around testing for COVID-19. The current study does not include any patients who received sarilumab.

If the evidence around IL-6 targeting bears out in further studies, the authors note that it will be important to select the dose and timing carefully, to address the cytokine storm without interfering with IL-6's other roles in activating the body's response to infections and its processes for repairing tissue.

**More about the study:**

The majority of the patients were transferred to U-M from Detroit-area hospitals after diagnosis with COVID-19, and those who received tocilizumab were less likely overall to have been transferred while already on a ventilator.

By the end of the 28-day period after patients went on a ventilator, 18% of those who received tocilizumab had died, compared with 36% of those who had not. When adjusted for health characteristics, this represents a 45% reduction in mortality. Of those still in the hospital at the end of the study period, 82% of the tocilizumab patients had come off the ventilator, compared with 53% of those who didn't receive the drug.

In all, 54% of the tocilizumab patients developed a secondary infection, mostly ventilator associated pneumonia; 26% of those who didn't receive tocilizumab developed such infections. Such "superinfections" usually reduce the chance of survival for COVID-19 patients.

Hydroxychloroquine was included in the treatment Guidelines for COVID-19 inpatients at Michigan Medicine for the first two and a half weeks of the study period, before being removed as evidence of its lack of benefit and risks emerged. In all, it was used in one-quarter of the patients who received tocilizumab and one-fifth of those who didn't.

Similar percentages of the two patient groups received steroids, though none received dexamethasone. The patients in the two groups were similar in most ways except for a slightly higher average age in the non-tocilizumab group, and lower rates of chronic obstructive pulmonary disease and chronic kidney disease among the tocilizumab patients.

*Source: World Pharma News, 13.07.2020 (Excerpts)*

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## New study supports Remdesivir as COVID-19 treatment

The news about Remdesivir, the investigational anti-viral drug that has shown early promise in the fight against COVID-19, keeps getting better. This week researchers at Vanderbilt University Medical Center (VUMC), the University of North Carolina at Chapel Hill and Gilead Sciences reported that Remdesivir potently inhibited SARS-CoV-2, the virus which causes COVID-19, in human lung cell cultures and that it improved lung function in mice infected with the virus.

These preclinical findings help explain the clinical effect the drug has had in treating COVID-19 patients. Remdesivir has been given to patients hospitalized with COVID-19 on a compassionate use basis since late January and through Clinical Trials since February. In April, a preliminary report from the multicenter Adaptive COVID-19 Treatment Trial (which included VUMC) suggested that patients who received the drug recovered more quickly.

"All of the results with remdesivir have been very encouraging, even more so than we would have hoped, but it is still investigational, so it was important to directly demonstrate its activity against SARS-CoV-2 in the lab and in an animal model of disease," said VUMC's Andrea Pruijssers, Ph.D.

Pruijssers, Research Assistant Professor of Pediatrics at VUMC and lead antiviral scientist in the laboratory of Mark Denison, MD, is the paper's co-corresponding author with Timothy Sheahan, Ph.D, Assistant Professor of Epidemiology at UNC-Chapel Hill. Denison, the E.C. Stahlman Professor

of Pediatrics at VUMC, directs the Division of Pediatric Infectious Diseases. He and Ralph Baric, Ph.D, the William R. Kenan, Jr Distinguished Professor of Epidemiology at UNC-Chapel Hill, and colleagues have been studying Remdesivir since 2014.

They were the first to perform detailed studies to demonstrate that the drug, which was developed by Gilead Sciences to combat hepatitis C and respiratory syncytial virus, and later the Ebola virus, also showed broad and highly potent activity against Coronaviruses in laboratory tests. The current findings, reported this week in the journal Cell Reports, provide "the first rigorous demonstration of potent inhibition of SARS-CoV-2 in continuous and primary human lung cultures." The study is also the first to suggest that Remdesivir can block the virus in a mouse model.

Ongoing clinical trials will determine precisely how much it benefits patients in different stages of COVID-19 disease. Meanwhile in the laboratory, Pruijssers said, "We also are focusing on how to use Remdesivir and other drugs in combinations to increase their effectiveness during COVID-19 and to be able to treat at different times of infection."

COVID-19, which to date has infected more then 12 million people and killed nearly 600,000 worldwide, is at least the third instance since 2003 in which a Coronavirus originally transmitted from bats has caused serious illness in humans.

Thus there is an urgent need to identify and evaluate broadly efficacious and robust therapies that can limit and prevent Coronavirus infections. "Broad-spectrum antiviral drugs, antibodies, and vaccines are needed to combat the current pandemic and those that will emerge in the future," the researchers said.

In addition to SARS-CoV-2, studies in the Denison and Baric labs have shown that Remdesivir is effective against a vast array of Coronaviruses, including other bat viruses that could emerge in the future in humans.

"We hope that will never happen, but just as we were working to characterize Remdesivir over the past six years to be ready for a virus like SARS-CoV-2, we are working and investing now to prepare for any future Coronavirus," Denison said. "We want Remdesivir and other drugs to be useful both now and in the future."

*(Others VUMC co-authors were Amelia George, MS, Maria Agostini, PhD, Laura Stevens, MS, James Chappell, MD, PhD, Xiaotao Lu, MS, and Tia Hughes, MS. The study was supported by National Institutes of Health grants AI142759, AI132178 and AI132178-03S1, AI081197 and AI007151, the Dolly Parton COVID-19 Research Fund and the Elizabeth B. Lamb Center for Pediatric Research at Vanderbilt)*

*Source: Vanderbilt University Medical Center, Science Daily, 09.07.2020*

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## Industry asks Government to take out minimum investment criteria from PLI scheme

The Guidelines for the Production Linked Incentive (PLI) scheme is yet to be released, however, industry stakeholders request the Government to take out the minimum investment criteria of Rs 20 crores from the scheme. The industry believes that such a modification in the scheme will benefit industry, patients and the nation at large. Stakeholders also propose time-bound ad-hoc schemes, until the PLI scheme starts flourishing.

Recently, the CII Northern Region Council had organised a webinar, which was also attended by Mansukh L Mandaviya, Minister of State, Chemicals and Fertilisers along with Pharma stakeholders. During the webinar, the industry had flagged the issues related to the minimum investment criteria of PLI scheme and their implications.

On behalf of the industry, B R Sikri, Chairman, FOPE, and Vice-President, BDMA suggested to the MoS, to take into consideration existing API manufacturers as well. In his presentation, Sikri had mentioned that the Government should consider all the API manufacturers and see if they have the capacity to manufacture 41 Key Starting Materials (KSM), API or intermediates which are mentioned in the Government announced PLI scheme. The MoS expressed his consensus on the given suggestion and assured the industry that the authority will look into the given suggestion.

Speaking about the Government's plans and industry's concerns, Navdeep Rinwa, Joint Secretary, Department of Pharmaceuticals informed, "The objective of PLI scheme is to make the Indian Pharma industry self-reliant. We also need to ensure that the objective of the PLI scheme is achieved even after the incentive period is over. We are yet to release the Guidelines but the department has not received any request from the industry about removing the minimum investment criteria from the scheme. The proposed set Guidelines are designed after having consultations with the industry stakeholders and understanding the requirements of long-term strategies".

**However, Yogin Majmudar, Chairman of Bulk Drug Committee, IDMA said, "Since the beginning of announced production linked incentive scheme, we have been pointing out to the committee involved in the formation of the said scheme Guidelines that the minimum investment criteria will not work in favour of the industry and will delay the aimed objective. Hence, time and again, on behalf of the industry as well as our members, we have raised concerns and highlighted that the objective of the much-awaited scheme is to make the Indian Pharma industry self-reliant by manufacturing Active Pharmaceutical Ingredients (API) within the country, not just creation of employment. However, I hope that the respective authorities are taking our request into consideration, as it will start showing positive outcomes immediately."**

An industry observer highlighted the need to relook the PLI scheme and said, "Surprisingly, there are no takers of fermentation-based products which are 14 in number because they need huge investments and there are very few fermentation-based Pharma companies in the country. They can be counted on the fingers. But in the chemical synthesis category, out of 27 products, 20-21 products can be manufactured by the industry. And large companies, as well as those with years of subject experience, have already shown interest in producing such items".

"This consideration of removing the minimum investment criteria can give a breather to the industry, patients as well as to the nation. And can also give a setback to China because nearly 75 percent of the products in the chemical synthesis category can be started soon, provided the Government takes a prompt decision in implementing the proposed suggestion," he added.

He emphasised that with a minimum Rs 20 crore investment embargo under the PLI scheme for chemical synthesis category also restricts other manufacturers who can make minimum investment considering they already have common surplus utilities available to them. They need to simply install a few reactors and make minor changes in the existing plant. Therefore, there is a need that the Government understands these points, discusses them with the industry and finalises accordingly.

Nipun Jain, Chairman, Small and Medium Pharma Manufacturers Association, informed, "We have written a letter to the Joint Secretary of DoP with our suggestion of removing the minimum investment limit of Rs 20 crore in the PLI scheme. In that letter, we have also mentioned that certain products can also be made with backward integration which will require less than Rs 20 crores investment. They are diclofenac sodium, ofloxacin, levofloxacin, ornidazole, atorvastatin and losartan".

He continued, "If DoP considers our request it will go in a long way to strengthen not only MSME sector of Pharma industry but also benefit the nation at large. It will also help in creating more employment."

An industry expert suggested that even if there is a requirement to expand the incentives, the Government should consider bringing ad-hoc schemes because it is a matter of national security. However, the Government can insert a clause mentioning about withdrawal details which can be removed once the PLI scheme is implemented successfully.

These days, the PMO and Niti Aayog are closely monitoring the API industry's activities and hopefully, the Department of Pharmaceuticals (DoP) will be discussing the matter with the higher authorities in the Government.

*Source: Express Pharma, 16.07.2020*

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## Indian Pharma Market registers 2.4% Growth in June 2020

The Indian Pharmaceutical Market (IPM) has registered a growth of 2.4% for the month of June 2020, due to significant revival in some therapies. The COVID crisis had impacted the IPM and the trend of negative growth in April–May 2020 comes to an end in June 2020 with growth of 2.4%. According to AIOCD AWACS report, the IPM has recorded sales of Rs.1,42,285 crore for Moving Annual Total (MAT) basis during June 2020.

Amongst the top 10 Corporates, Mankind exhibited the highest growth of 11.8 percent, followed by Torrent Pharma at 9.4 percent. Amongst the 11-25 ranked Corporates, Aristo exhibited highest growth of 18.2 percent followed by Pfizer at 11.3 percent. Amongst the 26-50 ranked Corporates, Boehringer Ingelheim registered the highest growth 29.6 percent followed by JB Chemicals at 16.8 percent. Amongst the 51-75 ranked Corporates, Danone registered the highest growth 29.6 percent and Eli Lilly at 19.7 percent. Amongst the 76-100 ranked Corporates, Llyod Hc exhibited the highest growth at 37 percent, followed by Unison at 14.9 percent.

Cardiac registered a monthly growth of 13.9% as compared to 3.9% in May 2020, anti-diabetic registered growth of 8.5% as compared to 1.1% in May 2020. Respiratory medicines has exhibited significant growth of 4.2% compared to -5.9% in May 2020. Post unlockdown 1, the struggle for anti-infectives -20.8% in May 20 has revived, but it is still showing negative growth of -9.7% and its associated therapy like gastro showed improvement growth of 0.4% as against -12.8% in May 2020. Vitamins have bounced back has shown growth of 5.7% as against -9.1% in May 20 and pain and analgesics are at -1.9% as against -17.2% in May 20.

The NLEM 2013 containing molecules market showed growth at 1.6 per cent, whereas the non NLEM market registered growth of 2.6 percent. Among the top brands, Mixtard has maintained the top position for the month of June 20. While Glycomet-GP has slipped to number 2 position, while Lantus has retained the position No.3.

*Source: Pharmabiz, 14.07.2020*

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## Bill Gates says Indian pharmaceutical industry is capable of producing COVID-19 vaccines for the world

***Microsoft co-founder and philanthropist Bill Gates has expressed confidence that India's pharmaceutical industry will be able to produce COVID-19 vaccines not only for itself, but also for the world.***

*India's pharmaceutical industry will be able to produce COVID-19 vaccines not just for the country but also for the entire world, Microsoft co-founder and philanthropist Bill Gates has said.*

A lot of "very important things have been done" in India and its pharmaceutical industry is doing work "to help make the Coronavirus vaccine building on other great capacities that they have used for other diseases," said Gates, who is also the Co-Chair and Trustee of Bill and Melinda Gates Foundation.

Appearing in a documentary 'COVID-19: India's War Against The Virus', which will premiere on Discovery Plus on July 16, Gates said India also faces a huge challenge in terms of the health crisis because of its large size and population density in urban centres.

Commenting on the strength of India's pharmaceutical industry, Gates said: "India has a lot of capacity there -- with the drug and vaccine companies that are huge suppliers to the entire world. You know, more vaccines are made in India than anywhere -- starting with Serum Institute, that's the largest."

"But (there are) also Bio E, Bharat (Biotech), many others. They are doing work to help make the Coronavirus vaccine, building on other great capacities that they have used for other diseases," he added.

Stating that India joined the Coalition for Epidemic Preparedness Innovations (CEPI), a group working worldwide to build vaccines platforms, Gates said, "I am excited that the Pharmaceutical industry there will be able to produce not just for India but also for the entire world. (This is) what we need to reduce the deaths and make sure we are immune, which is how we end the epidemic."

Gates said his foundation is also a "partner with the Government, particularly with the Department of Biotechnology, the Indian Council of Medical Research (ICMR) and the office of the Principal Scientific Advisor provide advice and help about getting these tools going".

Commenting on the deadly virus breaching India's borders in the documentary which was shot extensively during the period of lockdown, he said, "India is still at the beginning of this, but there's a lot of very important things have been done.

"It is a huge challenge with India because you've got a gigantic country. You've got your urban centers with a lot of density -- and so that -- drives the spread. You have people moving around."

However, he added: "Yet people are stepping up ... Looking at how we reduce the spread while trying not to reduce food availability, equipment that people need."

*Source: PTI, Money Control, 15.07.2020 (Excerpts)*

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## IPA re-elects Dr T V Narayana as National President for two more years

The Indian Pharmaceutical Association (IPA), headquartered in Mumbai, has unanimously re-elected Dr T V Narayana as the National President of the association for another one more term. The Central Executive Committee has accepted and agreed upon a recommendation by the Election Returning Officer of the IPA to allow other office-bearers to continue till 2022.

*Source: Pharmabiz, 16.07.2020 (Excerpts)*

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## Laghu Udyog Bharati asks Government to scrap reclassification of alcohol based hand sanitizer as disinfectants

The Laghu Udyog Bharati, all India organization for Micro and Small Industries, has urged the Department of Goods and Services Tax to restore the classification of the alcohol based hand sanitizer as medicaments under HSN 3004 attracting 12% GST and stop any action being initiated against sanitizer manufacturing units obtaining product licence from state Food and Drugs Administration in Form 25 and paying 12% GST.

The Laghu Udyog Bharati (Pharma Wing) has written to the department following GST intelligence officers' raid on manufacturing units of alcohol based hand sanitizer for tax evasion following reclassification of the product as disinfectant under HSN code 3808 attracting 18% GST. The Director General of GST Intelligence (DGGI) in its letter on June 10, 2020 has instructed the Principal Chief Commissioner/Chief Commissioner to check evasion of GST by alcohol based hand sanitizer manufacturers. The DGGI stated that there is misclassification of 'hand sanitizer' (alcohol based) and it is required to be classified as 'disinfectants' under HSN 3808 attracting 18% GST as against existing classification as 'medicaments' under HSN 3004 attracting 12% GST.

It said the misclassification has led to significant evasion of GST. Authorities have analysed data for 62 manufacturers with the help of online shopping platforms like Amazon, Flipkart, Snapdeal, Paytm, etc and have asked field offices to check if other manufacturers including distilleries and sugar mills have also misclassified the product.

Taking exception to reclassification of alcohol based hand sanitizers as disinfectants attracting 18% GST, Dr Rajesh Gupta, All India Head, Laghu Udyog Bharati (Pharma Wing) said "Alcohol based hand sanitizers have always been classified as medicinal preparation. Those wishing to manufacture alcohol based handrub are required to obtain drug licence under the Drugs and Cosmetics Act, 1940. After the introduction of the GST regime in the country, industries manufacturing this product under the drug licence began to pay GST at the rate of 12% as alcohol based hand sanitizers are classified as 'medicaments' under heading 3004 of the HSN classification."

However, it is unfortunate that the Department of Goods and Services has of late started classifying 'alcohol based

hand sanitizers' under HSN 3808 as 'disinfectants' in order to extract GST at the rate of 18% from the manufacturing industries. In fact the department has initiated raids and visits to such companies who charge 12% GST as per the licence obtained, Dr Gupta said.

Mostly, 'disinfectants' as a word is more applicable to products meant for use in animals, herbs, fungi and plant oriented products, which is different class then the 'alcohol based hand sanitizers' which are for human use and come under the 'medicinal products' category. Even if there is a change in the taxation policy with the introduction of the GST regime with effect from July 1, 2017 it cannot change the basic character of a product which is a medicinal preparation and remains as such, he pointed out.

In fact in this pandemic era where 'alcohol based hand sanitizers' are a must for protection and security of citizens, there should have been an attempt to lower the GST rates, thereby making the product more viable for all sections of the society. An immediate corrective step is needed by the Goods and Services Department to ensure that 'all alcohol based sanitizers' continue to be under heading 3004 of the HSN classification and further to stop any action being initiated against manufacturing units with drug licence under 'medicaments' who are paying 12% GST, he stated.

Amit Chawla, a hand sanitizer manufacturer and Vice President of Laghu Udyog Bharati Indore unit said, "The DGGI should have come with reclassification earlier when State Licensing Authorities have stepped up efforts to issue product licence to manufacturers of hand sanitizers to overcome its short supply. It would have helped manufacturers to collect 18% GST rather than 12% GST. MSMEs which are major manufacturers of sanitizer and already paid 12% GST are finding it very difficult to pay the 6% difference in GST antedated as per reclassification of the handrub. This could lead to financial hardship of MSMEs already facing monetary problems in the wake of COVID-19 induced lockdown."

*Source: Laxmi Yadav, Pharmabiz, 15.07.2020*

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## Government working to select locations for bulk drug, medical device parks

This is being done in order to encourage domestic production of critical APIs The Government on Monday, 13.07.2020 said it is finalising Guidelines for selection of locations of upcoming bulk drug and medical device parks in the country. "Department of Pharmaceuticals is finalising Guidelines, which will form the basis for objectively selecting locations of upcoming three bulk drugs parks and four medical devices parks in the country", Minister of Chemicals & Fertilisers D V Sadananda Gowda said.

Union Cabinet on March 12, 2020 had approved scheme for development of three bulk drug and four medical device parks, in which the Government will extend grants-in-aid to states with a maximum limit of Rs 1,000 crore per bulk drug park and Rs 100 crore per medical device parks, the Ministry of Chemicals & Fertilizers said in a statement.

This is being done in order to encourage domestic production of critical APIs (Active Pharmaceutical Ingredients)/KSM (Key Starting Material) and medical devices, it added. In addition, the Government has also announced, "a Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of key critical starting materials/drug intermediates & APIs and medical devices across the country," the statement said.

Total financial implications of these schemes would be about Rs 13,760 crore, it added. "The scheme for promotion of bulk drug park is expected to result in incremental production of bulk drugs worth about Rs 46,400 crore, while scheme for promotion of medical device park will lead to incremental production of medical devices worth about Rs 68,437 crore," the Ministry said.

These schemes will also result in significant generation of jobs, it added. Development of these parks will not only reduce the country's dependence on imports but will also be helpful in making India a major player in global Pharma exports, Gowda had earlier said.

*Source: PTI, Business Standard,13.07.2020*

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## IDMA to approach Government to lift cap on prices of drugs as cost of APIs imported from China increases manifold

The Indian Drug Manufacturers' Association (IDMA) is soon planning to submit a representation to the Central Government asking it to lift the cap on the prices of some of the formulations and finished drug products, as the import costs of various Active Pharmaceutical Ingredients (APIs) sourced from China have increased steeply owing to COVID-19 restrictions.

According to members of IDMA, China has imposed stricter pollution control regulations on the API manufacturers since the outbreak of the COVID-19 pandemic in that country. Because of which many smaller API manufacturers have shut their shops and a few of those who have withstood the restrictions have raised the prices of APIs being exported to India. This has directly impacted the Indian drug manufacturers as they are facing drug price pressure as the National Pharmaceutical Pricing Authority (NPPA) has put a cap on some of the essential medicines in India.

"The Pharma Industry in India is facing tough time at this juncture, as the cost of prices of APIs sourced from China has increased manifold. In view of this, the IDMA is planning to approach the NPPA to seek permission to increase prices of certain formulations," IDMA sources said.

As it is already known that the NPPA had recently lifted the price cap on the drug Heparin which is used for blood thinning, after many Pharma companies submitted their representations seeking upward revision of the price of the essential drug. Similarly the IDMA and other members of Pharma companies are planning to approach the NPPA to lift the cap on the prices of certain formulations and finished drug products and help the Pharma industry from facing losses.

Similar opinion was also expressed by Dr P V Appaji, former Director General of Pharmexcil. Various reasons such as the prevailing COVID-19 restrictions and the border stand-off between India and China have led to an uncertainty in the Pharma trade between the two nations. This has directly impacted the prices of drugs and medicines because of which the Pharma industry is facing increased pressure.

"India has been heavily depending on China for sourcing its APIs. In fact nearly 80 percent of India's API requirements are being fulfilled by China. With the outbreak of COVID-19 and due to border stand-off between the two countries, there has been a sense of uncertainty prevailing and this is impacting on the drug prices in the country," said Dr Appaji. It is expected that the prices of drugs and essential medicines may shoot up from 10 to 30 percent in the coming days, if the Government does not concede to the requests of the Pharma companies, which is going to impact heavily on the healthcare expenses of the public.

*Source: A Raju, Pharmabiz, 15.07.2020*

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## Pharma technology propels access to advanced medicines and drug delivery devices

Pharma Technology has accelerated the access to advanced medicines and drug delivery devices. The newer drugs ensuing from the use of technology include formulations that provide targeted delivery and also those that have reduced dosing frequency.

According to Sunil Chiplunkar, Vice President, Business Development, Group Pharma, it is Pharmaceutical Technology that has enabled development of products based on science. "Therefore practical application of science in pharmacy is pharmaceutical technology."

The traditional technological approaches allow the Pharma industry to develop the routine, reliable formulations including generics and branded medicines. However the trending technologies are personalized medicine and Artificial Intelligence (AI). The latter is the targeted therapy used for cancer care. The former is used in drug design, said Chiplunkar at a recently concluded webinar on Impact of Pharma Technology on healthcare organised by the RR College of Pharmacy and Group Pharmaceuticals.

Further pharmaceutical technology is also extensively used for the development of suitable and affordable Active Pharmaceutical Ingredients (APIs), excipients, and intermediates. Technology has also played a major role in the development of New Chemical Entities. Current focus is to make indigenous affordable technologies for the APIs and excipients. This will reduce Indian Pharma's dependence on imports mainly from China. There is also a trend of in-licensing technologies to create product differentiation advantage for marketing, he said.

Giving example of chlorine dioxide which is mainly used as a bleach, Chiplunkar said that here too technology has enabled the development of stabilized chlorine dioxide solution. This is a popular disinfectant that is effective even at low concentrations, because of its unique qualities. The stabilized chlorine dioxide is registered with the Environmental Protection Agency (EPA) as an excellent bactericide, fungicide, and antimicrobial agent, he said.

Moving on to the Madagascar pink periwinkle flowering plant, he said that with the adoption of technology researchers were able to prove and develop cytoblastin 10mg injection which is an anti-cancer medication used in the treatment of breast cancer. Another example is in

the case of pencillin which is a fungus mould that was developed using fermentation technology to become the mostly widely used antibiotic.

The present unpredictable black swan event, Coronavirus Disease (COVID-19) pandemic too has seen a slew of advancements using Pharma Technology. These include Remdesivir which is an RNA polymerase inhibitor from Gilead Pharma, an antiviral drug: Favipiravir, corticosteroid: Dexamethasone, immunosuppressant: Toclizumab, anti-malarial: Hydroxychloroquine, Convalescent Plasma Therapy (CPT) and vaccines. These developments have been significant, said Chiplunkar adding that hand sanitizers and mouth washes are some of the other examples to control and prevent the deadly virus, stated Chiplunkar.

*Source: Nandita Vijay, Pharmabiz, 15.07.2020*

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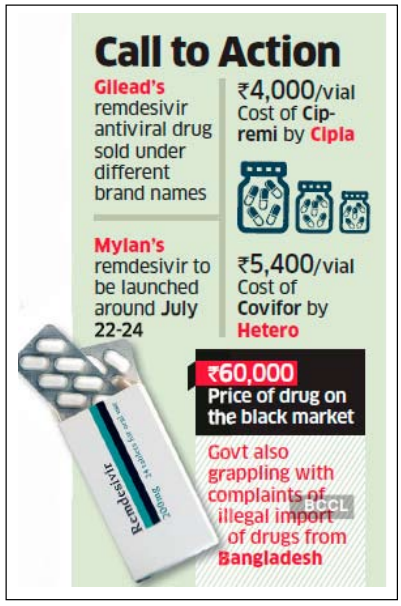
## Remdesivir makers told to ramp up production by Department of Pharmaceuticals

The Department of Pharmaceuticals (DoP) has asked the manufacturers of Remdesivir to ramp up the production of the antiviral, even as state authorities grapple with complaints of black marketing of the drug.

The Delhi state regulator, meanwhile, has written to the association of chemists warning of strict action including imprisonment against those hoarding and black marketing the drug prescribed for Covid-19 treatment.

The DoP Secretary on Friday, 10.07.2020 held a meeting with the drug's manufacturers after State Drug Controllers received several complaints of profiteering in pandemic. The Government had stepped in after they found the drug priced at 4,000-5,400 a vial being sold at as high as Rs.60,000.

"Though it is a prescription drug, complaints have been received of its black marketing. Making money out of tragedy is not done. However, it's a fluid situation and we have told the manufacturers that we will provide them all necessary assistance in case they want the Government's help to ramp up production," an official told.




US-based Gilead's Remdesivir, sold under the brand name Cipremi by Cipla and Covifor by Hetero, costs Rs.4,000 and Rs.5,400, respectively, in the Indian market. Mylan will launch Remdesivir around July 22-24.

Delhi's state regulator has written to chemists' association also about illegal imports of Covid-19 related drugs Remdesivir, favipiravir and tocilizumab from Bangladesh, with the letter by Atul Nasa, Head of Office, Controlling and Licensing Authority, warning of strict action against those dealing with such trade.

To clamp down on the alleged black marketing of Remdesivir drug, the Drugs Controller General of India has also asked State Drug Regulators and the National Pharmaceutical Pricing Authority (NPPA) to enforce the Maximum Retail Price of the experimental Covid-19 drug.

The action by Drug Controller General of India V G Somani came after it received a letter from Local Circles, a social media site dedicated for governance and community engagement, on the alleged black marketing.

In the letter dated July 6, Local Circles Chief Executive Officer Sachin Taparia appealed to Government organisations, including the Health Ministry, to check on the high price that the patients were being made to pay to procure the Covid-19 drug.

*Source: Teena Thacker, The Economic Times/Reuters, 14.07.2020*

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## DBT invites research proposals on BRICS STI Framework Programme response to COVID-19

The Department of Biotechnology (DBT) has invited call for proposals on BRICS STI Framework Programme

in response to COVID-19 pandemic coordinated call for BRICS multilateral Research and Development (R&D) projects 2020. The BRICS STI Framework Programme aims to support excellent research on priority areas which can best be addressed by a multinational approach.

The initiative should facilitate cooperation among the researchers and institutions in the consortia which consist of partners from at least three of the Brazil, Russia, India, China and South Africa (BRICS) countries. In response to the COVID-19 pandemic, the BRICS STI Framework Programme is launching a call for multilateral basic, applied and innovation research projects facilitating cooperation among the researchers and institutions in the consortia.

Under this call the researchers are focused on Research and Development of new technologies/tools for diagnosing COVID-19, Research and Development of COVID-19 vaccines and drugs, including repurposing of available drugs and genomic sequencing of SARS-CoV-2 and studies on the epidemiology and mathematical modelling of the COVID-19 pandemic. Another area of research includes AI, ICT and HPC oriented research for COVID-19 drugs design, vaccine development, treatment, clinical trials and public health infrastructures and systems and epidemiological studies and clinical trials to evaluate the overlap of SARS-CoV-2 and co-morbidities, especially tuberculosis.

Brazil has developed dynamic complex health systems. In the case of Russia, it views traditional systems of medicine as evidence based system of therapeutic approach. The Moscow Institute of Paediatrics and Paediatrics Surgery of the Health Ministry of Russia use Ayurveda for cerebral palsy, bronchial asthma and gastroenterology.

China's new round of medical and health reform aims at providing its people with safe, effective, convenient and affordable solutions. In South Africa, traditional medicine system is a preferred form of healthcare and also remains the most available and affordable form of therapy across the world. Government of India recognised not-for-profit, NGOs/VOs/Trusts)/Research foundations are eligible for the proposals. The last date for submitting the application is August 24, 2020.

*Source: Neethikrishna, Pharmabiz, 15.07.2020*

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## DoP soon to release Guidelines on Rs. 6,940 crore PLI scheme for domestic production of bulk drugs

The Department of Pharmaceuticals (DoP) is all set to release Guidelines on the Rs. 6,940 crore Production Linked Incentive (PLI) scheme for domestic production of 53 pharmaceutical products out of the key 41 bulk drugs based on the multi-stakeholder consultation involving pharmaceutical industry, bulk drugs industry and regulatory authorities.

"Guidelines for the PLI scheme are all set to be released anytime soon as the technical committee's final report along with industry recommendations has been submitted to the DoP. We are also taking ahead development of bulk drugs parks based on challenge method which implies that only states which guarantee maximum benefits to potential investors like good R&D facilities among others will be given chance to develop bulk drugs parks," DoP Secretary Dr P D Vaghela said.

The draft Guidelines on PLI scheme were prepared by a technical committee, headed by the Joint Drugs Controller of India Dr S Eswara Reddy, constituted by DoP on April 17, 2020 after detailed consultations with industry, experts and other relevant stakeholders. Major objective of the PLI scheme is to reduce import dependency and boost domestic production of bulk drugs. Currently, India imports nearly 68 percent of API, by value, from China. The import of APIs has risen at a CAGR of 8.3 percent from 2012 to 2019 and the bulk drug import reached a value of Rs. 249 billion in 2019.

Earlier, the DoP had discussed draft Guidelines for the Rs. 6,940 crore PLI scheme with representatives of the drug industry at a meet on June 13, 2020 to boost domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates (DIs)/Active Pharmaceutical Ingredients (APIs) in India.

As a part of the plan to boost domestic drug manufacturing, DoP also has plans to set up bulk drugs parks in the country based on its ongoing consultations with potential states in the country in the wake of over-dependence of poor quality Chinese imports. PLI scheme was first announced by the Union Cabinet in March. Key bulk drugs include penicillin-G, vitamin B1, prednisolone and diclofenac sodium among others. Out of the 53 identified pharmaceutical products, 26 are fermentation based bulk drugs and 27 are chemical

synthesis based bulk drugs. Rate of incentive will be 20% (of incremental sales value) for fermentation based bulk drugs and 10% for chemical synthesis based bulk drugs. A sum of Rs. 6,940 crore has been approved for the next 8 years.

Meanwhile, industry has welcomed PLI scheme and urged DoP to also revive existing API units which can produce chemical synthesis based bulk drugs to ensure that these API units don't turn into non-performing assets (NPAs). "Indian Drug Manufacturers' Association (IDMA) has recommended that in order to create domestic capacities, provision of minimum investment should be removed. This would allow existing 'brown field' units also to be able to take benefit under the PLI scheme by utilising spare capacity available with them or by changing product mix," suggested Ashok Kumar Madan, Executive Director, IDMA.

PLI scheme is expected to reduce manufacturing cost of bulk drugs in the country and dependency on other countries for bulk drugs. The scheme intends to boost domestic manufacturing of critical KSMs/drug intermediates and APIs by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce India's import dependence on other countries for critical KSMs/drug intermediates and APIs.

It will lead to expected incremental sales of Rs.46,400 crore and significant additional employment generation over 8 years. PLI scheme will be implemented by State Implementing Agencies (SIA) to be set up by the respective state Governments and target is to set up 3 mega bulk drug parks. The scheme will be implemented through a Project Management Agency (PMA) to be nominated by the DoP.

Common infrastructure facilities would be created with the financial assistance under the sub-scheme in 3 bulk drug parks. It is expected to reduce manufacturing cost and dependency on other countries of bulk drug in the country. India is significantly dependent on import of basic raw materials, viz., bulk drugs that are used to produce medicines. In some specific bulk drugs the import dependence is 80 to 100%.

While Maharashtra, Gujarat and Karnataka are the front-runners, the Centre has also plans to set up bulk drug parks at Himachal Pradesh, Visakhapatnam, Ahmedabad and Tamil Nadu to boost bulk drug production in the country.

*Source:Shardul Nautiyal, Pharmabiz, 13.07.2020*

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## Prices of medicines could go up as the cost of Chinese bulk drugs imports surges

There is an insignificant increase in the price of medicines as the cost of raw materials has increased abruptly. This move has suddenly fallen as there is an insignificant increase in the prices of Active Pharmaceutical Ingredients (APIs), which are mostly imported from China.

The Pharma industry had made several representations to the pricing regulator after the prices of the APIs of Heparin went up by over 200 percent in the last 2 years. The current crisis has perhaps added to the woes as supplies from China have been disrupted. India which imports various drugs and APIs for producing medicines to China constitutes about two-thirds of total imports of bulk drugs and drug intermediates. According to the Ministry of Commerce and Industry, the Indian Pharma industry has been growing consistently over the last few years. Pharma exports in FY19 were $19.13 billion, with a growth of 10.72 percent over the previous years.

During April 2019-January 2020, the exports stood at $17.32 billion, registering a growth of 11.53 percent over the corresponding period of the previous year. India also imported bulk drugs and drug intermediates worth $3,560.35 in FY19, of which 67.56 percent or $2,405.42 came from China, according to the Chemical Ministry. The Department of Pharmaceuticals (DoP) has constituted a committee under the Chairmanship of Eshwara Reddy, Joint Drugs Controller, Central Drugs Standard Control Organization (CDSCO), has written to the DGFT asking to restrict exports of 13 APIs and formulations.

Now the drug-makers in India are reaching out to the Government with the proposal to bring in law under which the price hikes could be made possible due to unforeseen factors. According to the data collated by the Bulk Drug Manufacturers' Association (BDMA), antibiotics, Azithromycin, and Ornidazole and anti-inflammatory drugs inside nimesulide and antipyretic drug paracetamol have seen their prices jump between 60 and 190 percent since January. According to the data collected by BDMA, the price of chemical compound 6APA used to manufacture antibiotics has swelled to Rs.1,875 per kg from Rs.400 per kg in February, which was an increase of more than 360 percent. However, as per the law that governs the pricing of medicines, Drug Pricing Control Order (DPCO) said that drug makers are not allowed to pass on the price hike to customers beyond 10 percent. "According to BDMA, it is not only the prices of drugs or APIs that are going up, the prices of other raw materials and intermediates have also

increased. It's high time for the Government to intervene and bring some law to accommodate such wild price fluctuations," says B R Sikri, Vice President of BDMA.

NPPA has the power under para 19 of Drug Price Control 2013 to fix sealing prices of any drug whether or not they fall under the National List of Essential Medicines (NLEM). It also allows the NPPA to increase or decrease the price of any drug irrespective of the annual Wholesale Price Index (WPI) of the year. Last year they used this power to increase the price of 21 drugs by 50 percent, and that was the first time NPPA invoked para 19 to raise prices of drugs. Recently on July 2, 2020, the NPPA has allowed Pharmaceutical Companies to take-time price increase on Heparin injections by 50 percent. This drug is used as a blood thinner and plays a very important role in the treatment of Covid-19. "The Government does not wish to be seen as the reason of raising medicine prices during the pandemic. They understand the reason behind the representations and we have presented all data related to Chinese prices going up", as said by an insider from the Industry reported by the Business Standards.

*Source: TPT Bureau, The Policy Times, 14.07.2020*

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## CDSCO extends deadline till October 31, 2020 for allowing import of drugs with residual shelf life less than 60%

The Central Drugs Standard Control Organisation (CDSCO) has extended the deadline till October 31, 2020 for allowing import of drugs with residual shelf life less than 60% following representations from importers on delay in clearances at port offices due to shortage of staff in the wake of COVID-19 pandemic. The CDSCO's move has brought cheers to the drug industry which stated that this will ensure availability of drugs to patients in a timely manner. Earlier on April 17, 2020 CDSCO had granted importers permission to import medicines having residual shelf life under 60% on the condition that they give an undertaking that the drug would be consumed before the expiry date in the light of the pandemic situation.

The CDSCO's move came after representations of industry associations that clearance of consignments at port offices has taken a hit due to COVID-19 outbreak and several drugs are losing their shelf life and getting below the threshold of 60 percent. As per Rule 31 of the Drugs and Cosmetics Rules, 1945, no drug shall be imported unless it complies with the standard of strength, quality and purity, provided that the licensing authority shall not allow the import of a drug with a less than 60 percent residual shelf life as on the date of import.

However, in exceptional cases, the licensing authority may, for reasons to be recorded in writing, allow the import of any drug with a lesser shelf life, but before its expiry. Welcoming the extension of deadline for importing medicines having residual shelf life under 60%, Sahil Munjal, Vice Chairman, Pharmexcil said, "This is much needed step taken by the CDSCO in the current situation of COVID-19 pandemic which led to disruption in freight movement causing delays in delivery of imported drugs.

There are lots of drugs stuck at the ports due to shortage of manpower and the lockdown situation in parts of the country and they are losing their shelf life. The patients need to have access to these medicines on time." Nipun Jain, Chairman of Small and Medium Pharma Manufacturers Association (SMPMA) said, "This is a praiseworthy step taken by CDSCO for ensuring adequate availability of required drugs during this pandemic."

*Source: Laxmi Yadav, Pharmabiz, 13.07.2020*

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## Industry urges Health Ministry not to make GMP Guidelines mandatory under Schedule M

Concerned over incorporation of strict WHO, ICH Guidelines in the proposed revision of Schedule M, the pharmaceutical industry in the country has urged the Union Health Ministry to revise the Schedule M with minimum rules and back it up with detailed Good Manufacturing Practice (GMP) Guidelines separately in line with the global practices.

The industry representatives made the appeal on July 16, 2020 at a consultation meeting called by the Ministry on finalization of draft Rule GSR 999(E) dated October 5, 2018 to revise Schedule M as per World Health Organisation (WHO)-GMP standards. The Ministry had published draft rules to amend GMP listed in Schedule M. The draft rules aim to bring India's extant GMP on par with the WHO-GMP. Currently, 1,000 drug units out of 8,500 drug units in the country are WHO-GMP compliant. 300 plants are US FDA compliant.

Majority of Indian drug manufacturers comply with the extant GMP, however, less than 15% of manufacturers are

WHO-GMP compliant, leading to dual standards of quality. The proposal to revise the GMP is in line with the Indian Government's goal of joining the Pharmaceutical Inspection Cooperation Scheme (PICS), a global mechanism to improve cooperation in GMPs between regulators. Mr S M Mudda, Chairman, Regulatory Affairs Committee, Indian Drug Manufacturers' Association (IDMA) said, "IDMA welcomes the move of the Government to upgrade the Schedule M in line with the globally followed Guidelines".

He, however, pointed out that the proposed Notification includes Guidelines in the form of mandatory requirements. The Guidelines help in the interpretation of the principles of GMPs and cannot be considered as legal requirements. The mandatory nature of Schedule M makes compliance with every provision a legal requirement and encourages enforcement approach. As a result, unfortunately, even a bona-fide and unintentional non-compliance of any of the provisions under the Drugs and Cosmetics Act and Rules is considered as an offence exposing the manufacturers/ dealers to legal actions.

IDMA has made a comprehensive representation to distinguish the principles of GMPs from the Guidelines proposed to be included in Schedule M, in line with the framework adopted by global regulators. The EU framework has Directives and Regulations that are mandatory in nature and include the Principles of GMPs. These are supported by GMP Guidelines, for the interpretation and implementation of the principles, which are not mandatory requirements.

He emphasised the need for a serious and active review with the industry stakeholders before introducing any changes to the provisions of the D&C Act and Rules to make such changes beneficial to the patients while making them easy to comply with by the industry since the industry is highly technical and knowledge-based. The requirements of GMP shall be amended to include the principles and concepts in the D&C Act & Rules, while the details shall be in the form of Guidelines and advisories. The Guidelines shall be dynamic and may be updated as per the prevailing situations and developments. The power to issue the Guidelines and changes shall be with DCGI, he added.

This framework will encourage all sectors, including MSME, to comply with the upgraded GMP requirements, said Mudda. He cautioned that the implementation of the proposed Schedule M in the current format will lead to serious issues of interpretation and compliance and consequently will hamper the growth of the industry. "IDMA agrees with the Government that there is a need to upgrade GMP. However, IDMA has expressed the opinion that the new revision of Schedule M must have minimal rules, but should be backed up with detailed GMP Guidelines. The elaborate Guidelines on each aspect must be published as Guidelines instead of rules, in line with international practices," said Dr Viranchi Shah, Senior Vice-President, IDMA.

Taking exception to the proposed revision of Schedule M making GMP requirements mandatory, Dr Rajesh Gupta, President of Himachal Drug Manufacturers Association and All India Head, Laghu Udyog Bharati (Pharma Wing) said, "The GMP Guidelines are never made part of any legislation world over. We are making WHO-GMP Guidelines rules, its compliance will be very challenging for the industry and a number of MSMEs will be in big trouble. 4,200 drug units are MSMEs out of 8,500 drug units in the country.

He said, "The aim of the amendment to Schedule M is to enhance capabilities of domestic drug makers and boost our exports. For this, the proposed amendment to Schedule M is unwarranted. The existing GMP Guidelines listed in Schedule M are effective in boosting efficiency of domestic industry. Considering divergent regulatory norms of importing countries, revision of GMP at par with WHO-GMP standards hardly warrants. The exporters dealing with CIS countries and Asian markets will only be benefitted from the revised GMP Guidelines. Those looking to export US, European Union, UK, Australia, South Africa etc need regulatory approvals from US FDA, EMA, MHRA, TGA, MCC respectively".

"The existing GMP Guidelines listed in Schedule M came into effect from July 1, 2005. Schedule M protocols have been revised to harmonize it along the lines of WHO and US FDA protocols. These revised protocols include detailed specifications on infrastructure and premises, environmental safety and health measures, production and operation controls, quality control and assurance and stability and validation studies. Ensuring compliance of the revised GMP Guidelines is needed rather than making WHO-GMP Guidelines Rules. Training programmes need to be conducted to sensitize the drug-makers on compliance of existing GMP Guidelines," he added. "We welcome the revision of GMP Guidelines as long as it is being implemented as Guidelines," said Dr Gupta.

*Source: Laxmi Yadav, Pharmabiz, 20.07.2020 (Excerpts)*

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FEATURE

# The Great Indian Vaccine Quest

***Raj Chengappa, Amarnath K Menon & Sonali***

To fight a war and win, Sun Tzu, the 6th century BCE Chinese military strategist and author of The Art of War, advises that you first know your enemy well. So, first let's get to know Covid-19, the world's Enemy No. 1 that has afflicted over 12 million people in 213 countries and territories and caused more than half a million deaths, at last count. In India alone, there are 700,000 cases with over 20,000 dead, putting us in the unenviable position of being No. 3 in the list of countries with the biggest toll of Covid cases, behind only Brazil and the United States. A recent study by MIT predicts that given the size of India's population, we may have as many 270,000 cases a day by February 2021. This could eventually make us the worst-affected country in the world if no vaccine is found to treat the virus by then.


The micro-organism responsible for the pandemic is a formidable opponent that can rapidly fell humans a zillion times its size in huge numbers. To get an idea of how small this silent, insidious assassin really is, think of this: a thousand of them could fit into a grain of salt with ease. With the virus first being reported in Wuhan, China, in late 2019, the World Health Organization (WHO) termed it Coronavirus Disease 2019 or Covid-19 because of its descent from the corona family of viruses, which have a zoonotic origin (passed on from animals to humans). The ancestor of the corona viruses was first discovered in the 1960s and got its name from its crown-like shape when viewed through an electron microscope. Seen through more powerful diagnostic viewing tools now, the virus appears spherical, and is studded with distinctive spikes known as peplomers. Multiplying rapidly in the sea of humanity, the virus has in just six months wreaked enormous havoc and distress on the world.

The battle against the Covid-19 pandemic is proving to be more daunting than policymakers and medical researchers had initially imagined. For decades, the milder cousins of Covid-19 caused about a quarter of the common colds in the world and were relatively harmless. In recent years, however, they have mutated into more deadly forms. In 2002, the Severe Acute Respiratory Syndrome Coronavirus (SARS-Cov) afflicted 8,098 people, mostly in China and Southeast Asian countries and killed 774. While the death rate was high, 1 out of 10 people died, the outbreak was brought under control in a year by isolating the afflicted.

*Test Phase: A scientist at the Bharat Biotech Lab in Hyderabad*

Ten years later, the virus mutated again, striking the Middle East, mainly Saudi Arabia, this time. The Middle East Respiratory Syndrome Coronavirus, or MERS-Cov, afflicted only 2,494 people, but the case fatality rate was a high 37 percent, which meant that one out of three people who got the disease died. In its newest avatar, Covid-19 is proving to be less fatal, killing less than two people out of every 100 afflicted, but it has been far more virulent, widespread and resilient than its predecessors. "It's a 21st century virus, smart, savvy and tough, and the challenge it poses should not be underestimated," says Pankaj Patel, Chairman, Zydus Cadila, the Ahmedabad-

based Pharma major that is researching ways to combat it.

Despite unprecedented total lockdowns of nations across the world, including in India, which shut down for three months, the virus shows no signs of peaking yet. On the contrary, there has been an alarming surge of fresh cases as countries remove restrictions on movement of people and allow them to return to business as usual. With the affliction and death rates continuing to mount and no proven drugs to cure the disease so far, medical institutions and pharmaceutical companies across the world are working at a feverish pace to find other ways of arresting its rapid spread. Their current best bet: a global vaccine to inoculate people and help them build immunity against the virus.

In an encouraging bit of news, the WHO reports that there are currently 136 potential candidates for a Covid-19 vaccine that research institutions across the world are testing, with 21 of them having reached the human clinical trials stage. Three of them, AZD1222 developed by the British-Swedish biopharma firm AstraZeneca and Oxford University, mRNA-1273 by the American biotech firm Moderna and CoronaVac by China's Sinovac Biotech, are at the final stage of human clinical trials, with results expected by the end of this year. Last week, two Indian companies, the Hyderabad-based Bharat Biotech and Zydus Cadila, joined the global quest, with the Indian Government clearing their respective vaccines, the COVAXIN and ZyCOV-D, for the early phases of human clinical trials.

Four other Indian institutions, including the Pune-based Serum Institute of India, the world's largest vaccine manufacturer, are in an advanced stage of vaccine research and are likely to apply for permission to start human trials soon. In Geneva, WHO Chief Scientist Dr Soumya Swaminathan told. "It's excellent that Indian R&D is coming up with vaccine candidates because earlier it was considered only a manufacturing hub of generic pharmaceuticals. The more participants we have, the better. Along with the many other participants across the world, they would help in finding out a vaccine or vaccines that will have lasting immunity and are safer for use."

However, controversy broke out over the Indian effort when an overzealous Indian Council for Medical Research (ICMR), the country's premier medical research agency, sent out a note telling the two Indian firms and their collaborators to ensure that Phase 1 and 2 trials were completed by August 15, India's Independence Day. Bodies of experts, such as the Indian Academy of Science, protested strongly against the imposition of such deadlines to rush through critical research. K I Varaprasad Reddy, Chairman, Shantha Biotechnics, Hyderabad (now a subsidiary of the French Sanofi), warns: "You cannot gloss over protocols and forego sequential safety in developing a vaccine. We cannot make a mockery of science. It will take at least 18 months to two years even in an emergency like situation. What is dangerous is the practice of Drug Controllers shortchanging on procedures to unveil a vaccine in a hurry." The ICMR was forced to clarify that the deadline was not binding but only "envisaged" and that the respective institutions should take all precautions to ensure that the trials are carried out with all the stipulated protocols.

The pushback from the Indian scientific community was important. While there was reason for both speed and optimism, vaccine development has always been a game of hits and misses. Some like those for polio and small-pox were revolutionary in their impact, while others like the flu vaccine flattered only to deceive (see Nearly on Target). A few resulted in complications in those who were administered the vaccine, forcing Governments to withdraw them and, in some cases, even pay heavy compensation. One such case is the influenza vaccine, which is the closest we have for a disease like Covid-19. Over a hundred laboratories worldwide monitor this virus under the WHO Global Influenza Surveillance Network and recommend the mixture of strains to be used in a vaccine in the coming flu season. It started in 1918, after the Spanish influenza pandemic broke out, claiming almost 12 million lives in India alone.

In 1976, fearing a recurrence of the Spanish flu, the US Government under President Gerald Ford launched the National Influenza Immunisation Program, or NIIP, and drew up plans to vaccinate the entire population. But after reports came in of one in every 100,000 vaccinated people developing a serious neurological disorder, the programme had to be shut down. Every year since then, an effective influenza vaccine has to be made afresh based on virus surveillance data and strict monitoring by the WHO.

More recently, in 2009, Norway reported complications in those who were administered a vaccine for the H1N1 pandemic when 1 in every 100,000 people who took the vaccine and were under 30 years of age developed narcolepsy, a debilitating sleep disorder. On the plus side, however, the vaccine reduced the risk of contracting influenza from those who were afflicted by as much as


Poonawalla has plenty of skin in the game, apart from developing two possible vaccines in his laboratory, he has tied up with the AstraZeneca/Oxford group to manufacture over 1 billion doses by 2021 if their vaccine is cleared. He has invested close to $100 million in getting production lines ready to meet the requirement, but says it is important that researchers follow all protocols and go through the routine regulatory hoops. He is planning manufacturing tie-ups with two other groups that are developing vaccine candidates. Asked him the basis on which he selects a group and he says, "I look at safety, proven track record and scalability of manufacturing of the vaccine. If you tick all these three boxes, you enter my gate. If not, you stay outside my factory till you do."

70 percent. There were similar contradictory results for the vaccine administered for dengue in 2017. While one study showed that it enhanced the disease by a statistically significant number in those that took it, others demonstrated that it did provide protection. Swaminathan acknowledges that there may be complications in the efficacy and safety of a vaccine and it is critical that countries using a vaccine have a vigilant safety monitoring system and educate the public about such complications. "There are always benefits and risks associated with such things, and countries have to be transparent and open about it, apart from [having] a proper testing, evaluating and monitoring system."

Despite the ICMR's push for a vaccine for Covid-19, many doubt we will have a vaccine before early 2021. That's because after trials on rodents and other animals, a vaccine, typically, has to go through three phases of human trials, a process that can take anywhere from six to nine months. Phase 1 of the trials focuses on the safety of the vaccine on a small group of respondents. Phase 2 tests efficacy, determining the required dosage for an effective immune response. Phase 3 puts the vaccine to test on a larger scale across age and population groups. On occasion, during emergencies, the last two phases are clubbed together. But the final stage does take time as it involves testing between 30,000 and 40,000 randomly selected people and a placebo group. Adar Poonawalla, CEO of the Serum Institute, says: "We should not be rushing through any of these stages. Nor should we be focusing on who is the first to bring out a vaccine; rather, it should be which candidate vaccine is the safest and most efficacious."

Poonawalla is right about safety being the top concern. Exposing a vaccine candidate to the disease to check if it works, also known as the human challenge study, is a subject of intense research on ethics. The consensus is that this can only be done in a crisis situation and if an effective cure is available. "During the trials of a malaria vaccine, people were exposed to the disease, but there was a very good cure for it at hand. Covid does not have the kind of guaranteed treatment needed for a human challenge study, even though there is a sense of urgency," says Dr Shahid Jameel, virologist and CEO of the grants body DBT/Wellcome Trust India Alliance. Ethics also involves taking the public and the medical community into confidence, as well as data-sharing. "A good study design and peer review are essential if a vaccine is to be taken seriously," says Partha P Majumder, Director, Indian Academy of Sciences. DBT, or the Department of Biotechnology, the nodal agency for the Indian vaccine initiative, was quick to play down the disquiet over the ICMR's initial circular. Renu Swarup, DBT Secretary, told. "We have a very strong regulatory system and are very proud of it. We have detailed guidelines for trials that match the best in the world. Apart from being scientifically and ethically very strong, they are rigorous too and we have the best experts for peer review." Swarup says the DBT is facilitating speeding up of the process by identifying in advance areas where the Phase 3 trials

could be conducted but without any compromise on quality of the research.

So, given the complications and the long gestation period required to develop a vaccine, should we be enthused by the flurry of global activity to find one? Yes, for several reasons. The only good news about Covid-19 is that it is a comparatively simple and stable virus which makes the task of developing a vaccine for it relatively easier. "Covid is mutating almost a thousand times slower than the influenza virus and India now has the strain which most companies in the West are also developing a vaccine for," says Dr Rakesh Mishra, Director of CSIR-Centre for Cellular and Molecular Biology. Past failures in vaccine development, he adds, need not cloud the future of a Covid-19 vaccine. Both tuberculosis and malaria pathogens are far more complex. TB, for instance, lurks in the body, making an immune response difficult to mount even in a vaccine.

Other researchers remain sceptical. Dr Jayaprakash Muliyil, Chairman of the Scientific Advisory Committee of the National Institute of Epidemiology, argues that we need more than one study to confirm whether a vaccine stimulates immunity against Covid-19. "There are also questions of how long the immunity will last and, most importantly, ensure that it does not cause any harm to those who take it," he says. Muliyil is a firm believer in natural herd immunity as the best way to halt the spread of the disease, and was not in favour of the lockdown that India opted for. We can build herd immunity if the virus spreads rapidly and infects a majority of the world's population, until it has no new hosts to spread to.


Swaminathan disagrees with this postulation and says that antibody surveys in most countries show that only 10 percent of the population has been exposed. Even in India, studies show that only 0.7 percent of the population in rural areas has developed antibodies. This means a majority of the population remains susceptible and vulnerable to Covid-19 and there is no question of their developing natural herd immunity for years. As Swaminathan puts it, "Herd immunity through natural infection will come only at a huge cost that people will have to pay in terms of lives and the economy." Social distancing and lockdowns, too, cannot be long-term strategies. Recent reports are warning of the long-term damage the virus inflicts on vital organs even in those who experience relatively mild symptoms. Nor are drugs like Remdesivir, currently being used to treat serious Covid-19 patients, devoid of harmful side-effects.

Another major factor in pushing for a vaccine is that there has been a quantum leap in vaccine technology and genome sequencing in the past two decades. All vaccines work on the basic principle of first defanging the virus and then injecting it into the human body to produce the desired antibodies to build immunity against the virus. The classical approach is what Bharat Biotech is using for its COVAXIN, an inactivated Covid-19 virus being injected into a person to produce antibodies and act as an immunity-booster. Inactivated vaccines have a well-proven and accepted track record against diseases such as polio and rabies. Bharat Biotech has tied up with the National Institute of Virology (NIV) in Pune to isolate the virus and produce the vaccine. Krishna Ella, its Chairman and Managing Director, says, "Our Research and Development and Manufacturing teams worked tirelessly to deploy our proprietary technologies towards this. We are hoping that the human trials will validate our efforts."

However, inactivated vaccines come with their own limitations. For one, you need booster doses, and two, even as experts argue that inactivated vaccines are an established approach, doubts have been raised about their safety and efficacy. Inactivated vaccines used against SARS and MERS had led to poorly-regulated inflammatory responses or cytokine storms in which the immune system overreacted. That is why in the past decade many vaccine

developers have moved towards decoding the genetic sequence of the virus and manipulating its DNA and RNA to render it harmless before injecting the vaccine. With ZyCOV-D, Patel of Cadila claims to have successfully established the DNA vaccine platform in the country. "We mimicked the DNA of the Covid-19 virus but without its harmful proteins to get the body to build immunity to it after it is injected. We are 100 percent made in India, *Atmanirbhar Bharat.*" DNA vaccines are stable and do not require cold-chain storage. They can also be manufactured with minimal bio-safety requirements.

Poonawalla, whose Partner AstraZeneca is using a replication-deficient viral vector based on a weakened version of the common cold virus, points out how these technologies are now like proven rocket launchers in a space programme. They can be safely used to test newer payloads, in this case, viruses. They can also be rapidly used to modify the vaccine in a couple of weeks in case the virus mutates to ensure that it still provides protection. There has also been tremendous progress in the synthetic production of RNA genes. The RNA vaccine that Moderna, Pfizer and BioNTech are developing is said to cut down on manufacturing time as well as develop a stronger immune response against a virus. The vaccine uses synthetically-produced RNA of a virus which, when administered, prompts the body's own muscles to produce the virus proteins that stimulate immune response. However, experts say that there are concerns that since it has never been tried on humans before, the risks are higher.

Each vaccine technology, therefore, comes with comparative advantages and disadvantages. Should any of these vaccines, Indian or foreign, prove successful, they are likely to raise issues of equitable distribution and pricing, something many global health organizations are concerned about. At present, the worldwide capacity for producing an influenza vaccine is about 6 billion doses year. Assuming the same for Covid would be a challenge for mass vaccination. Many countries, such as the US, have tied up with manufacturers to buy up the vaccines. "Middle-income countries will be at the greatest risk if we don't ensure equitable distribution and collaborate on a global level. Even in India, questions remain on how much will be pledged domestically and how much will be exported," says Dr Leena Menghaney, South Asia head of Medecins Sans Frontieres.

India is already preparing to not only block-book vaccines but also develop the logistics and cold chains required to deliver them swiftly to the public. Poonawalla says he has the capacity to make 700 million doses a year and could beef it up if needed. He plans to price his vaccine at Rs 1,000 a dose. Ella says his company can make 300 million doses and is looking for collaborators to up the capacity. Patel is also scouting for tie-ups to make his vaccine. NITI Aayog member Dr V K Paul, who is spearheading the Government's task force on vaccine development, says since they may not be able to deliver the vaccine to the entire population at the same time, priorities are being drawn up to see who should be given it first.

"The obvious priority is health professionals who are at the frontline of the battle and those with high risk of mortality from Covid-19, like people above 65 years of age and those with co-morbidities like diabetes and heart diseases," he says. For once it may be better to cross the bridge before you reach it.

*Source: indiatoday.in, 11.07.2020*

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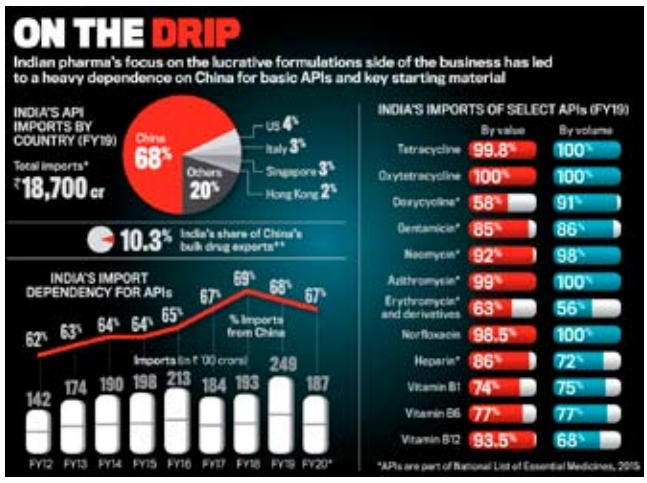
# A Bitter Pill: Pharmaceuticals

***Amarnath K Menon***

These are testing times for India's Rs 3.74 lakh crore pharmaceutical industry. Disruptions in the flow of Active Pharmaceutical Ingredients or API (which are the building blocks of medicines), Key Starting Material (KSM) and drug intermediates from China have made the industry wary. As of now, they are in two minds: whether to produce some of the material in India or turn elsewhere, perhaps to Europe, to source it, though it will be costlier. The rising cost of imported APIs has also hit cost of production and the margins of Indian firms. According to the Commerce Ministry, between March and May this year, there has been a 20 percent increase in drug prices due to the impact of Covid-19. India meets most of its API needs through imports from China. In 2018-19, APIs worth Rs 16,900 crore was imported, accounting for 67.6 percent of India's total imports while API exports to China were worth a mere

Rs 1,600 crore. This is a drastic comedown from the situation 25 years ago when much of the Pharma industry's needs were met by domestic API production. However, as the Indian Pharma industry moved up the value chain to make finished drugs, it began to rely more on China for low-cost raw material. Currently, domestic APIs (there are about 1,500 plants making APIs) accounts for just 10 percent of the market. The Government now plans tighter regulations and higher duties for imported Chinese APIs and KSM for medicines and even medical devices (China's share is about 11 percent in this). It's also working towards reducing import dependence so that in case tensions worsen between the two countries, India's drugs security is ensured. India is also likely to source more APIs from Germany, Sweden and Italy. The Indian Pharma industry is the third largest in the world by volume and 14th in terms of value. Currently, India imports more than 53 critical Pharma APIs, including those used in medicines for tuberculosis, steroids and vitamins, from China. Raw material include both API and inactive ingredients (excipients). The latter do not have direct therapeutic action but support or enhance drug stability/bio-availability or patient acceptability.




*Graphic by Tanmoy Chakraborty; *Apr-Dec 2019, **for 2018; Source: UN Comtrade (Source: KPMG/ CII)*

China's API market has diversified to over 2,000 molecules and over 7,000 manufacturers, with an annual production capacity exceeding two million tonnes. Chinese products are 25-30 percent cheaper than other markets and supplies are crucial because these are routine products used in high quantities. In 2019, China exported 10.1 million tonnes of APIs, up 8.83 percent year-on-year, says data from the China Chamber of Commerce. The country exports APIs to 189 countries and is a leader in the sector, accounting for 20 percent of the world's production. India's share in China's bulk drug exports was around 10.3 percent in 2018 but is probably less now, says Commerce Ministry sources.

Dependence on China can be curtailed but cannot be wholly stopped, admit industry insiders. The long-term challenge lies in loosening China's stranglehold over strategic industries which supply inputs to Indian firms. Back in 2014 itself, the Narendra Modi led NDA Government had declared that it wanted to make Indian industry competitive in the area. In fact, 2015 was declared the year of the API with then Union Minister Ananth Kumar saying the issue was a matter of national health security. Imports of APIs, though, continued to rise steadily. In 2019-20, it was worth Rs 24,900 crore, up from Rs 19,300 crore the previous year. Plans and initiatives to spur domestic manufacture have advanced at a slow pace till now.

*10.3% India's share of China's bulk drug exports in 2018. It's probably even less now, say Commerce Ministry sources. China is a global leader in the segment, exporting to 189 countries.*

From this month onward, the Government will put into effect a Rs 7,000 crore Production-Linked Incentive scheme aimed at promoting indigenous manufacturing of critical KSM, drugs, intermediates and APIs. It has identified 53 compounds, where imports are high, for manufacture in India such as those required for antibiotics, and medicines for heart ailments, diabetes, blood pressure and TB. It has also announced a 20 percent incentive on the incremental sale of some products. The Government will provide Rs 10 crore each to domestic companies to set up plants to produce 41 products covering the 53 crucial APIs. Incentives will be given on the condition that products be manufactured with complete backward integration and supplied only to domestic drug makers. "This should be leveraged to lower import dependence and also keep prices affordable," says G V Prasad, Chairman, CII National Committee on Pharmaceuticals and Co-Chairman and MD, Dr Reddy's Laboratories. "In the past few years, we have actively developed Indian sources based on price increases by China. That has helped partially. We

will now do more to accelerate the development of in-house sources as well as domestic sources for our raw material." The Department of Pharmaceuticals has also announced a scheme for promotion of bulk drug parks. The scheme proposes to give grant-in-aid with a maximum limit of Rs 1,000 crore for a bulk drugs park or 70 percent of a project's infrastructure costs. The scheme will be open till 2025. Incentives are important in the case of the bulk drugs industry because it is capital intensive and also needs huge tracts of land. Gujarat, Andhra Pradesh, Telangana and Tamil Nadu are already in the race to set up such parks. "A park with utilities such as a Common Effluent Treatment Plant will be attractive in terms of companies wanting to invest and build on scale," says Satish Reddy, President, Indian Pharmaceutical Alliance (IPA), and Chairman, Dr Reddy's Laboratories. "We need to get the competitive edge back and it is possible only with a fully integrated chain."

Ground-level infrastructure, ease of doing business, shared facilities like pollution treatment plants to lower costs, will all be looked at before a final call is taken. "We need to examine alternative sources for APIs even if they are costlier," says Sudharshan Jain, Director-General, IPA. But even if official clearances come by the end of 2020, it will be at least three years before the parks are up and running. "India can be an API and KSM hub, but for that to happen, we have to evolve a contract research and manufacturing services policy even as parks with advanced technology and stringent pollution norms come up," says Jayant Tagore, ex-President, Bulk Drug Manufacturers Association. Only then will India be able to meet the demands of both domestic and export markets.

Reducing the export-import imbalance, therefore, is still a long way off. However, Indian exports are growing. Total Pharma exports increased 7.57 percent y-on-y in FY20, to $20.6 billion or Rs 1.55 lakh crore. "Formulations apart, export of paracetamol and Hydroxychloroquine in the wake of the pandemic too has driven exports," says Pharmaceutical Export Promotion Council of India Director-General R Uday Bhaskar. Drugs and Pharma exports in May rose to Rs 14,959 crore, up from Rs 11,758 crore in the same month last year. The demand for Remdesivir and Dexamethasone will further boost exports in the coming months. "Several countries are using anti-viral drugs, in which India is strong, to treat Covid-19," says Bhaskar.

Despite China's commanding position, it is both a beneficiary of Indian Pharma imports and companies setting up offshore facilities or joint ventures there. Several Indian drugmakers already have their eyes on China. Aurobindo Pharma, for instance, is putting up an oral formulation manufacturing facility in Taizhou and has also entered into a joint venture. "Regulations have changed. Preference is there for FDA (US Federal Drug Administration) approved products and facilities in China," says Aurobindo Pharma MDN Govindarajan.

With the export potential high, more Indian companies may set up shop in China. The country gives extra incentives, including a three percent export subsidy to make its Pharma industry globally competitive. India is yet to do any such thing to match the API sector that China has built with state support. Indian drug makers need capital subsidy and big Pharma players will need compelling incentives if they are to get back into manufacturing these bulk drugs.

*Source: indiatoday.in, 04.07.2020*

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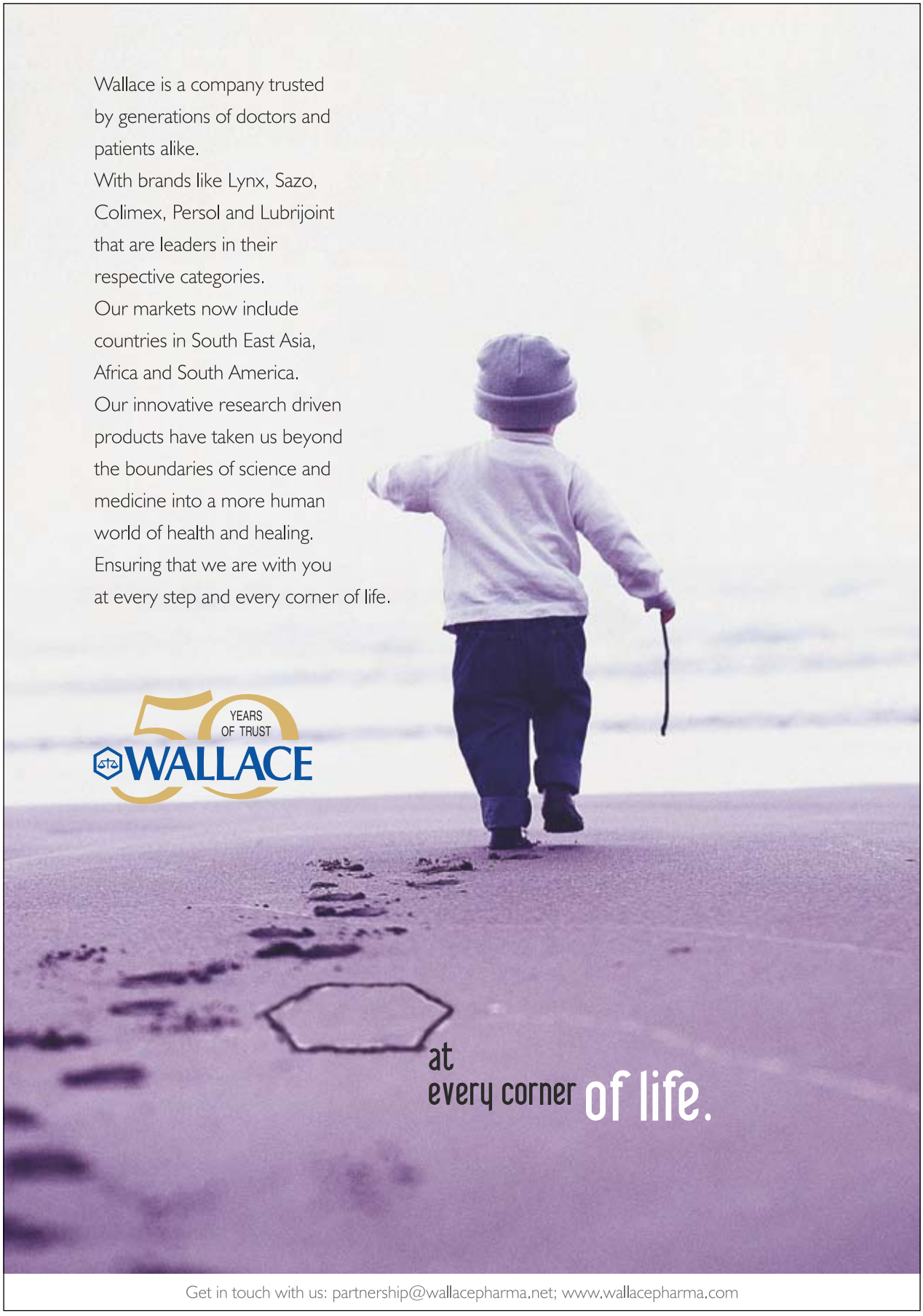
| 20-25 | 850-710 |
| 18-20 | 1000-850 |
| 16-20 | 1180-850 |
| 16-18 | 1180-1000 |
| 14-16 | 1400-1180 |
| 12-14 | 1700-1400 |
| 10-12 | 2000-1700 |

Signet

*The Complete Excipients Company*



Get in touch with us: partnership@wallacepharma.net; www.wallacepharma.com

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# Building a Connected Devices Eco-System for Digital Medicines

As Pharmaceutical companies around the world look to address the challenges of non-adherence to improve patient health outcomes, they turn to Aptar Pharma.

Today, we are leveraging decades of manufacturing excellence and proven device design to offer the widest portfolio of connected solutions and diagnostic tools across all our delivery routes. Complemented by our partnerships with leading digital healthcare platforms and key stakeholders in healthcare delivery models, we are building a connected device eco-system for digital medicines.

To see how you can move towards a connected future, contact with **Sai Shankar**, Vice President, Global Digital Healthcare Systems, at Aptar Pharma on **+1 847 800 6058** or email **sai.shankar@aptar.com**

Delivering solutions, shaping the future.

Aptar pharma

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