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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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★ **Single window nod on anvil, to spur investment: Piyush Goyal** *(Page No. 27)*

★ **Hand Sanitizer as 'Drug' exempted from requirement of Sale Licence for Stocking or Sale** *(Page No. 13)*

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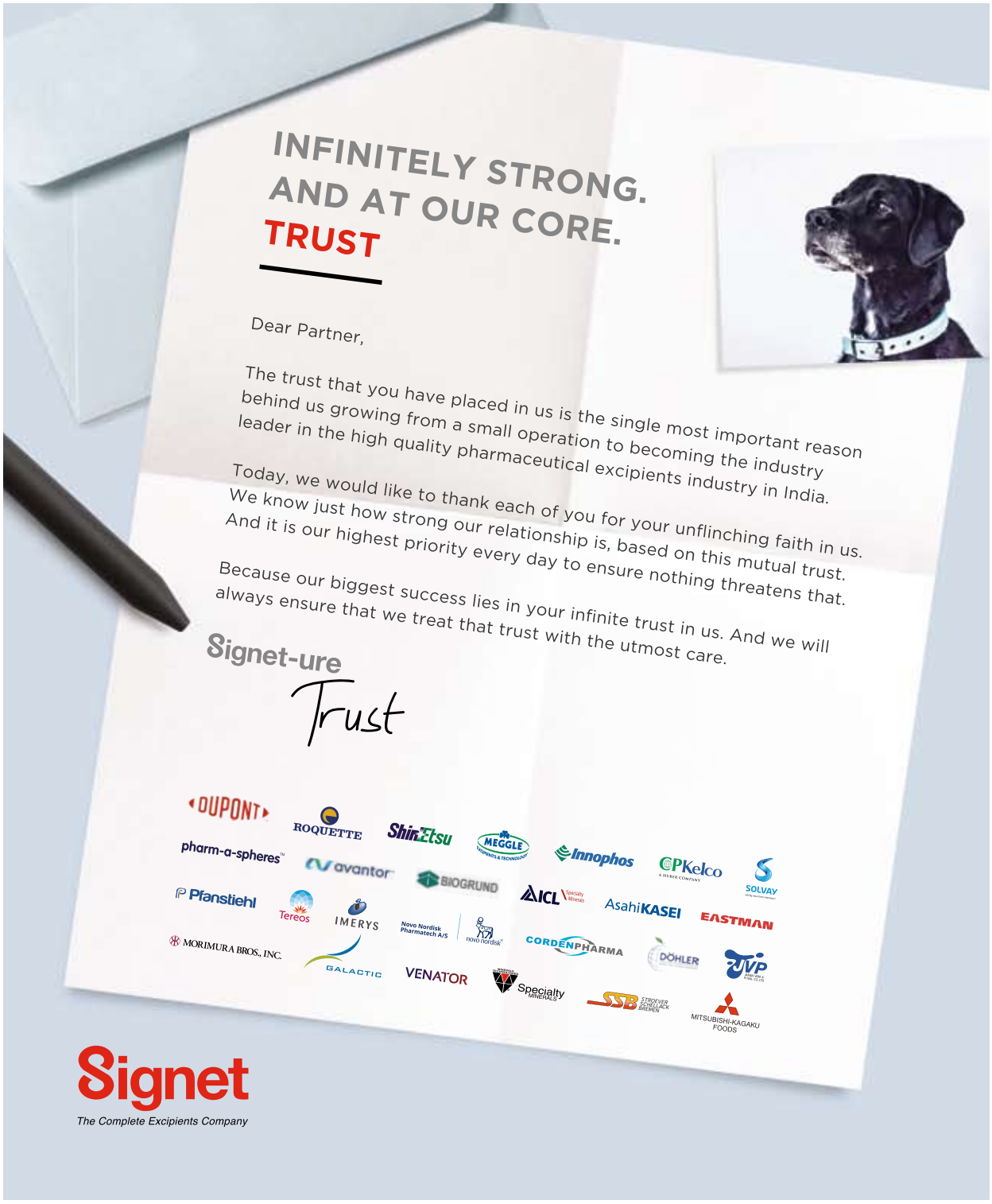
★ **High-level Government panel suggests Single-Window system for New Drug Approvals** *(Page No. 24)*

★ **DoP directs Pharma PSUs to clear outstanding dues of MSMEs** *(Page No. 31)*

★ **COVID-19 vaccines should be made public for global good: WHO Director-General** *(Page No. 33)*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IDMA BULLETIN

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IDMA request to allow import of Palladium and other precious metals on Advance Payment - for use in production of Drugs and Pharmaceuticals – reg.

The Association has submitted the following representation on 10th July 2020 to Dr P K Mishra, IAS, Principal Secretary to the Prime Minister of India, Office of Prime Minister of India, New Delhi on the above subject. Similar representations have been submitted to Shri Shaktikanta Das, IAS, Governor, Reserve Bank of India, Mumbai, Dr Ajay Bhushan Pandey, IAS, Finance Secretary, Dr Anup Wadhawan, IAS, Commerce Secretary and Dr P D Vaghela, IAS, Secretary, Department of Pharmaceuticals, New Delhi:

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

During the COVID-19 pandemic the Indian Pharma Industry, and especially our Members, have been working day and night to ensure that there are no shortages of medicines in the market, as committed to the Hon'ble Prime Minister.

With the Government's support, our Members all over the country have managed to keep production running with the available resources for supplying to domestic market and for fulfilling export commitments.

We are now informed by our Members that Reserve Bank of India is not permitting import of precious metals such as Palladium and others against Advance Payment. You will appreciate that these precious metals are used in production of Life-saving Drugs. For instance, Palladium metal is used as catalyst in manufacture of some Life-Saving Drugs as below:

Sr. No.	Drug Name	Therapeutic segment	Remark
1	**Pregabalin**	Neuropathic pain	
2	**Alpha Ethyl PAB**	Alzheimer disease	Intermediate for Vinpocitine
3	**Aceclofenac**	Anti Inflammatory	
4	**Trimetazidine**	Anti Angina	Cardiac drug
5	**Dabigatran**	Heart stroke and systemic embolism	Cardiac drug
6	**Lisinopril**	Anti hypertensive	

The Reserve Bank of India, we are informed, had issued a Notification that "advance remittance for import of precious metal is not allowed". This is an old Notification but has been enforced now.

Our Member Manufacturer, who has been regularly importing Palladium metal from Japan on Advance Payment informs us that at present, suppliers of palladium metal are not willing to supply material without Advance Payment. The suppliers are also not willing to accept payment through bank Letter of Credit as an alternative.

Even when representations were made to RBI and approached through a reputed bank, RBI has refused to allow import against any advance payment. The Notification from RBI is basically oriented towards import of Gold for the purpose of Jewellery manufacturing. RBI has failed to recognise the need for requirement of precious metals for the purpose of manufacturing lifesaving medicines in pharmaceutical industry.

Import of Palladium sponge (powdered or granular form of palladium metal) is urgently required to continue production of the drugs mentioned above.

We request your indulgence and direction to concerned authorities to allow these precious metal imports by the pharmaceutical manufacturers against Advance Payment.

We look forward to your continued support. Thanking you".

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OBITUARY

Shri J B Mody

Shri Jyotindra Bhagwanlal Mody, popularly known as Jyotibhai by his peers and respectfully addressed by others as Shri J B Mody, passed away peacefully on 21 July 2020. He was 91.

Shri Mody was a pioneer Member of IDMA and was Joint Secretary in the early years of the Association. Shri Mody later on became President of IDMA in 1981 and held office for 2 years. He was also the Chairman of Chemexcil before the formation of Pharmexcil.

Shri Mody supported IDMA in many ways at all times. The main conference hall at IDMA Secretariat is named 'Shri J B Mody Conference Room' in grateful acknowledgement of his support. Also every year, IDMA recognises top ranking B Pharm students in Universities for their achievement and they are awarded the IDMA J B Mody Best Student Award.

He was Chairman and Managing Director of the Company M/s J B Chemicals and Pharmaceuticals Ltd (JBCPL), headquartered in Mumbai, that he established in 1976. Over the years JBCPL has won many awards in India and abroad for quality products and manufacturing practices, and was featured in the Forbes Global list 100 for "Best under $1 Billion" in Asia-Pacific in 2004. JBCPL is also known as Unique Pharmaceutical Laboratories, a division of JBCPL in India and international markets,

Shri Mody took his CSR seriously very early in life, and over the years set up schools, colleges and hospitals in Gujarat, from where he began his mission. He was bestowed with the Lifetime Achievement Award by AIOCD AWACS in 2017.

We pray to God to grant eternal peace to his noble soul, and strength to his near and dear ones and all at JBCPL to bear this irreparable loss.

HOMAGE TO IDMA STALWARTS

Dr R S Joshi

Dr R S Joshi

IDMA & Gujarat State Board Members will always be grateful to Dr Joshi for the excellent services rendered by him. Dr R S Joshi was the Executive Secretary of IDMA Gujarat State Board for Two Decades. Dr Joshi will always be remembered for his tireless, diligent and dedicated services and especially for his invaluable contribution towards the initiatives & activities of IDMA-GSB & IDMA Head Quarters during his tenure.

We pray to the Almighty God to grant eternal peace to the departed soul and to give strength and courage to his family to bear this irreparable loss.

Mr D D Chopra

Mr D D Chopra

IDMA will always be grateful to Mr D D Chopra for his expert advice and excellent support in IDMA initiatives & activities. Mr Chopra was one of the Senior IDMA Executive Committee Members.

Mr Chopra was known for his expert advice on pricing & related matters.

We pray to the Almighty God to grant eternal peace to the departed soul and to give strength and courage to his family to bear this irreparable loss.

Mr K D Vora

Mr K D Vora

IDMA will always be grateful to Mr K D Vora for his excellent support in IDMA initiatives & activities. Mr Vora was one of the Senior IDMA Executive Committee Members. He was the Chairman of the Public Relations Committee for many years. Mr Vora was also associated with Kapol Co-Operative Bank.

We pray to the Almighty God to grant eternal peace to the departed soul and to give strength and courage to his family to bear this irreparable loss.

Mr K C Kohli

Mr K C Kohli

IDMA will always be grateful to Mr K C Kohli for his expert advice & excellent support as an Advisor to IDMA on Pricing related issues, DPCO & NPPA matters. Mr Kohli has assisted IDMA in preparing several representations to the Government on various issues.

We pray to the Almighty God to grant eternal peace to the departed soul and to give strength and courage to his family to bear this irreparable loss.

CONGRATULATIONS

Cachet awarded with 'Best Companies to Work For - 2020' by Silicon India

Making it to Silicon India's 2020 List

Today the modern workplace is continuously evolving at lightning speed with allocated teams, brand new business models, complex security issues, increasing blend of work and home life, etc. As a result, job aspirants are also seeking such collaborative work environments which promote good work culture that provides flexible working hours, an informal work culture, fair remuneration, etc. Thus, Cachet Pharmaceuticals today is focusing on increasing our productivity and brand value by trying to meet such expectations to the best of our capacity. Allowing employees to work remotely is a change many Pharmaceutical companies have already adopted. Technology is expanding, work places are spanning their reach and organizations are honing their benefits with added focus and attention concerning diversity in work space.

Reconnoitering the above, Silicon India has curated a list of companies with impeccable work culture under the category "Best Companies to Work for - 2020". An expert panel consisting of Silicon India Editorial Board, CEO's and industry leaders have researched, evaluated and come up with the names of the front runners in the best workplace segment.

An annual listing of 'Best Companies to Work for 2020' not only represents organizations offering fascinating work culture and benefits to the employees but also recognizes employees evolving requirements at their work place. The 42 year old pharmaceutical company, Cachet is manufacturing and marketing a wide range of pharmaceuticals and nutraceuticals. Currently spearheaded by Mr Satish Kumar Singh, Managing Director, Cachet is growing by leaps and bounds and emerging as one of the best workplaces. It is only with sheer hard work, dedication and focus Cachet Pharmaceuticals has made it to the esteemed 2020 list.

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INDIAN PHARMACOPOEIA

IPC Issues draft Monographs on Favipiravir API & tablets, Remdesivir API & Inj.

The Indian Pharmacopoeia Commission has issued **New Monographs** on 22 July 2020 as below for comments:

1. Atenolol & Amlodipine Tablets
2. Favipiravir API
3. Favipiravir Tablets
4. Remdesivir API
5. Remdesivir Injection

Interested Members may download the draft monographs from IPC website: **http://www.ipc.gov.in/**

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Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India

Gazette Notification No.F.31026/16/2020-Policy, dated 21st July, 2020

1. Background:

1.1. Drugs play a major role in healthcare delivery in the country. Continuous supply of drugs is necessary to ensure delivery of affordable healthcare to the citizens. Any disruption in supply of drugs can have significant adverse impact on drug security of the country.

1.2. Indian pharmaceutical industry is the 3rd largest in the world by volume and 14th largest in terms of value. India contributes 3.5% of total drugs and medicines exported globally. However, despite these achievements, India is significantly dependent on import of some of the basic raw materials, viz., bulk drugs that are used to produce the finished dosage formulations. India imports bulk drugs largely for economic considerations. Bulk drugs accounted for 63% of the total pharmaceutical imports in the country during FY 2018-19.

1.3. A committee on drug security constituted by the Department of Pharmaceuticals collated the details of APIs imported in the country and identified 53 APIs for which the country is heavily dependent on imports. A list of such APIs is given in **Annexure A.**

1.4. Drug security of the country is dependent upon our ability to ensure un-interrupted supply of quality bulk drugs and also our capacity to upscale their manufacturing to meet emergency situations. Self-reliance in manufacturing of drugs is, therefore, highly desirable.

1.5. With a view to attain self-reliance and reduce import dependence in critical APIs, a scheme called "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India" has been approved by the Government of India on 20th March, 2020.

2. Objective:

The scheme intends to boost domestic manufacturing of identified KSMs, Drug Intermediates and APIs by attracting large investments in the sector and thereby reduce India's import dependence in critical APIs.

3. Scope:

Under the Scheme, financial incentives shall be given based on sales made by selected manufacturers for 41 products. These 41 products, which cover all the identified 53 APIs, are listed in **Annexure B.**

4. Quantum of Incentive:

Financial incentive under the scheme shall be provided on sales of 41 identified products for six (06) years at the rates given below:

4.1. For fermentation based products, incentive for FY 2023-24 to FY 2026-27 would be 20%, incentive for 2027-28 would be 15% and incentive for 2028-29 would be 5%.

4.2. For chemical synthesis based products, incentive for FY 2022-23 to FY 2027-28 would be 10%.

5. Target Segments:

Four Target Segments covering 41 products are listed in **Annexure B.**

6. Applicability:

The scheme is applicable only for greenfield projects.

7. Eligibility

7.1. Support under the scheme shall be provided only to manufacturers of critical KSMs/DIs and APIs registered in India.

7.2. Eligibility shall be subject to threshold investment in green field projects as given in **Annexure C.**

7.3. Eligibility under the scheme shall not affect eligibility under any other scheme and *vice-versa*.

8. Tenure of the Scheme:

The tenure of the scheme is from FY 2020-21 to FY 2029-30.

9. Application Window:

The application window for receiving the applications shall be 120 days.

10. Base Year:

Financial Year 2019-20.

11. Financial Outlay:

Total financial outlay of the scheme is Rs. 6,940 crore.

12. Basis of Computation:

Assessment of threshold investment and sales of manufactured products shall be based on details furnished to the Departments/Ministries/Agencies and Statutory Auditor certificates.

13. Approval and Disbursement Process:

13.1. Application under the Scheme can be made by any manufacturer registered in India.

13.2. An initial application, complete in all aspects, shall have to be submitted within the application window.

13.3. Eligible applications will be appraised and considered for selection.

13.4. Incentive shall be released to selected applicants, meeting the required thresholds and whose disbursement claims are found to be in order.

14. Project Management Agency:

14.1. The Scheme shall be implemented through a Nodal Agency.

14.2. Such Nodal Agency shall act as a Project Management Agency (PMA) and be responsible for providing secretarial, managerial and implementation support.

14.3. Detailed constitution, functioning and responsibilities of the PMA will be elaborated in the Scheme guidelines.

14.4. For carrying out activities related to the implementation of the Scheme, PMA would, inter alia, be responsible for;

14.4.1. Appraisal of applications and verification of eligibility for support under the Scheme.

14.4.2. Examination of claims eligible for disbursement of incentive under the Scheme.

14.4.3. Compilation of data regarding progress and performance of the Scheme including threshold investment and sales of manufactured goods of applicants selected under the Scheme.

15. Empowered Committee (EC):

15.1. An Empowered Committee (EC) comprising of following members shall be formed under the Scheme:

CEO, NITI Aayog (Chairman).

Secretary, Department of Pharmaceuticals.

Secretary, Department of Chemicals and Petrochemicals.

Secretary, Department for Promotion of Industry & Internal Trade.

Secretary, Department of Commerce.

Secretary, Ministry of Environment, Forest and Climate Change.

Secretary, Department of Health & Family Welfare.

Experts may be invited as special invitees, as may be felt necessary, from time to time.

15.2. The Empowered Committee will be assisted by a Technical Committee of experts constituted by Department of Pharmaceuticals.

15.3. The EC will consider applications, as found eligible by the PMA, for approval under the Scheme.

15.4. The EC will consider claims, as examined and recommended by the PMA, for disbursement as per the laid down procedure and guidelines.

15.5. The EC will conduct a periodic review of the projects of the selected applicants with respect to their investments, employment generation and production under the Scheme.

15.6. The EC will also be authorized to carry out any amendments in the Scheme and the guidelines except revising the incentive rates, ceilings or eligible products.

15.7. Detailed constitution, functioning and responsibilities of the EC will be elaborated in the Scheme guidelines.

16. The detailed guidelines of the scheme will be uploaded on the website of the Department.

17. This Notification supersedes the earlier Notification of Department of Pharmaceuticals issued on this subject vide Notification No 31026/16/2020-Policy dated 2nd June, 2020.

Navdeep Rinwa,
Joint Secretary,
Department of Pharmaceuticals,
Ministry of Chemicals and Fertilizers,
New Delhi.

Annexure A

List of identified products

S. No.	Name of the product	S. No.	Name of the product
1.	Amoxicillin	28.	Ciprofloxacin
2.	Azithromycin	29.	Losartan
3.	Erythromycin Stearate/ Estolate	30.	Telmisartan
4.	Ceftriaxone	31.	Artesunate
5.	Cefoperazone	32.	Norfloxacin
6.	Cefixime	33.	Ofloxacin
7.	Cephalexin	34.	Metronidazole
8.	Piperacillin Tazobactam	35.	Sulfadiazine
9.	Sulbactam	36.	Levofloxacin
10.	Dexamethasone	37.	Meropenem
11.	Prednisolone	38.	Paracetamol
12.	Metformin	39.	Tinidazole
13.	Gabapentin	40.	Ornidazole
14.	Rifampicin	41.	Ritonavir
15.	Vitamin B1	42.	Diclofenac Sodium
16.	Vitamin B6	43.	Aspirin
17.	Clindamycin Phosphate	44.	Levetiracetam
18.	Clindamycin HCL	45.	Carbidopa
19.	Streptomycin	46.	Levodopa
20.	Neomycin	47.	Carbamazepine
21.	Gentamycin	48.	Oxcarbazepine
22.	Doxycycline	49.	Valsartan
23.	Potassium Clavulanate	50.	Olmesartan
24.	Oxytetracycline	51.	Atorvastatin
25.	Tetracycline	52.	Acyclovir
26.	Clarithromycin	53.	Lopinavir
27.	Betamethasone		

Annexure B

Target Segments

I. Fermentation based KSMs/Drug Intermediates

1. Penicillin G
2. 7-ACA
3. Erythromycin Thiocynate (TIOC)
4. Clavulanic Acid

II. Fermentation based niche KSMs/Drug Intermediates/APIs

5. Neomycin
6. Gentamycin
7. Betamethasone
8. Dexamethasone
9. Prednisolone
10. Rifampicin
11. Vitamin B1
12. Clindamycin Base
13. Streptomycin
14. Tetracycline

III. Key Chemical Synthesis based KSMs/Drug Intermediates

15. 1,1 Cyclohexane Diacetic Acid (CDA)
16. 2-Methyl-5Nitro-Imidazole (2-MNI)
17. Dicyandiamide (DCDA)
18. Para amino phenol

IV. Other Chemical Synthesis based KSMs/Drug Intermediates/APIs

19. Meropenem
20. Atorvastatin
21. Olmesartan
22. Valsartan
23. Losartan
24. Levofloxacin
25. Sulfadiazine
26. Ciprofloxacin
27. Ofloxacin
28. Norfloxacin
29. Artesunate
30. Telmisartan
31. Aspirin
32. Diclofenac Sodium
33. Levetiracetam
34. Carbidopa
35. Ritonavir
36. Lopinavir
37. Acyclovir
38. Carbamazepine
39. Oxcarbazepine
40. Vitamin B6
41. Levodopa

Annexure C

Eligibility Threshold Criteria

Sr. No.	Segment	Threshold Investment
1.	Fermentation based 04 KSMs /Drug Intermediates	Rs. 400 crore
2.	Fermentation based 10 niche KSMs / Drug Intermediates / APIs	Rs. 50 crore
3.	Key Chemical Synthesis based 04 KSMs /Drug Intermediates	Rs. 50 crore
4.	Other 23 Chemical Synthesis based KSMs / Drug Intermediates /APIs	Rs. 20 crore

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Scheme for Promotion of Bulk Drug Parks - reg.

Gazette Notification No.F.31026/16/2020-Policy, dated 21st July, 2020

1. Background:

1.1. Drugs play a vital role in healthcare delivery in the country. Continuous supply of drugs is necessary to ensure delivery of affordable healthcare to the citizens. Any disruption in supply of drugs can have significant adverse impact on drug security of the country.

1.2. Indian pharmaceutical industry is the 3rd largest in the world by volume and 14th largest in terms of value. India contributes 3.5% of total drugs and medicines exported globally. However, despite these achievements, India is significantly dependent on import of some of the basic raw materials, viz., bulk drugs that are used to produce the finished dosage formulations. India imports bulk drugs largely for economic considerations. Bulk drugs accounted for 63% of the total pharmaceutical imports in the country during 2018-19.

1.3. Future growth of pharmaceutical sector is contingent upon our ability to ensure uninterrupted supply of quality bulk drugs and our capacity to upscale their manufacturing during emergency situations. Self-reliance in manufacturing of bulk drugs is, therefore, highly desirable.

1.4. With a view to significantly bring down the manufacturing cost of bulk drugs and thereby increase the competitiveness of the domestic bulk drug industry by providing easy access to standard testing & infrastructure facilities, a scheme called "Promotion of Bulk Drug Parks" has been approved by the Government of India on 20th March 2020.

2. Objective:

2.1. To promote setting up of bulk drug parks in the country for providing easy access to world class common infrastructure facilities to bulk drug units located in the parks in order to significantly bring down the manufacturing cost of bulk drugs and thereby make India self-reliant in bulk drugs by increasing the competitiveness of the domestic bulk drug industry.

2.2. To help industry meet the standards of environment at a reduced cost through innovative methods of common waste management system.

2.3. To exploit the benefits arising due to optimization of resources and economies of scale.

3. Scope:

Financial assistance under the Scheme will be provided for creation of common infrastructure facilities in three Bulk Drug Parks proposed by State Governments and selected under the scheme.

4. Financial Assistance:

Financial assistance to a selected Bulk Drug Park would be 70% of the project cost of common infrastructure facilities. In case of North Eastern States and Hilly States (Himachal Pradesh, Uttarakhand, Union Territory of Jammu & Kashmir and Union Territory of Ladakh) financial assistance would be 90% of the project cost. Maximum assistance under the scheme for one Bulk Drug Park would be limited to Rs. 1000 crore.

5. Common Infrastructure Facilities:

The common facilities provided to individual bulk drug units in the Bulk Drug Park such as central effluent treatment plant, solvent recovery and distillation plant, steam generation and distribution system, common cooling system and distribution network, common logistics facilities, advance laboratory testing centre, emergency response centre, centre of excellence etc.

6. Financial outlay:

The total financial outlay of the Scheme is Rs.3,000 crore.

7. Tenure of the Scheme:

The tenure of the Scheme is from FY 2020-2021 to FY 2024-2025.

8. State Implementing Agency:

8.1 A Bulk Drug Park project selected under the Scheme will be implemented by a State Implementing Agency (SIA).

8.2. SIA shall be a legal entity set up by the concerned State government for the purpose of implementing the Bulk Drug Park project.

9. Scheme Steering Committee:

9.1. The proposals under the scheme will be approved by the Scheme Steering Committee (SSC) constituted by Department of Pharmaceuticals (DoP).

9.2. The composition of the SSC is as follows:

Secretary, DoP	-	Chairperson
Financial Adviser, DoP	-	Member
Joint Secretary, Ministry of Environment, Forest and Climate Change	-	Member
Joint Secretary, Department for Promotion of Industry and Internal Trade	-	Member
Joint Secretary, Department of Health and Family Welfare	-	Member
DCGI, Central Drugs Standard Control Organisation	-	Member
Joint Secretary (Policy), DoP	-	Convenor

The SSC may invite representatives of Industry Associations, R&D Institutions and other Government/Private sector expert organizations as special invitees as may be necessary from time to time.

9.3. The SSC shall take all decisions required for successful implementation of the scheme, including any modifications if required.

10. The detailed guidelines of the scheme will be uploaded on the website of the Department.

11. This Notification supersedes the earlier Notification of the Department of Pharmaceuticals issued on this subject vide no.31026/16/2020-Policy dated 2nd June, 2020.

Navdeep Rinwa, Joint Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, New Delhi.

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Hand Sanitizer as 'Drug' exempted from requirement of Sale Licence for Stocking or Sale - reg.

Gazette Notification No.S.O. 2451(E), dated 27th July, 2020

1. Whereas, there has been an outbreak of COVID-19 pandemic in India and worldwide;

Whereas, several representations requesting to exempt hand sanitizers from the requirement of sale licence under the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 and the provisions of the Drugs and Cosmetics Rules, 1945 for stocking or sale of the drug have been received;

Whereas, the Central Government is satisfied that hand sanitizers are essential to meet the requirements of emergency arising due to COVID-19 pandemic and their easy availability is made in public interest;

Whereas, the Central Government considers it necessary that hand sanitizers are required to be made widely available to the public at large;

Now, therefore, in exercise of the powers conferred by section 26B of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, hereby directs that the drug, namely, hand sanitizer shall be exempted from the requirement of sale licence for its stocking or sale under the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, subject to the condition that provisions of condition (17) of rule 65 of the said Rules are complied with by the person stocking or selling hand sanitizers.

2. This order shall come into force on the date of its publication in the Official Gazette.

F. No. X.11014/3/2020-DR

Dr Mandeep K Bhandari, Joint Secretary, Department of Health and Family Welfare, Ministry of Health and Family Welfare, New Delhi.

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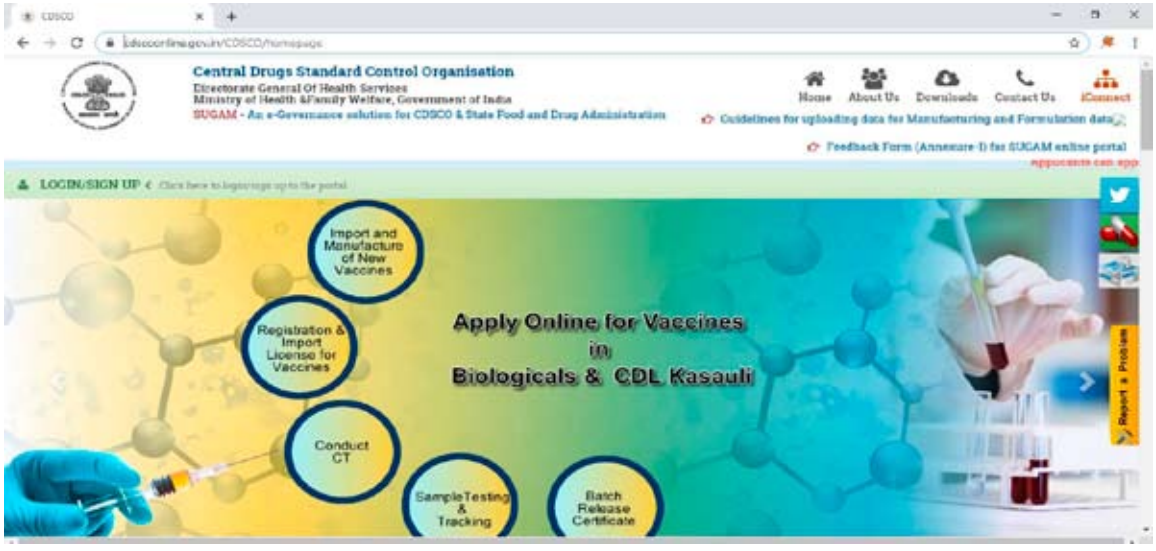
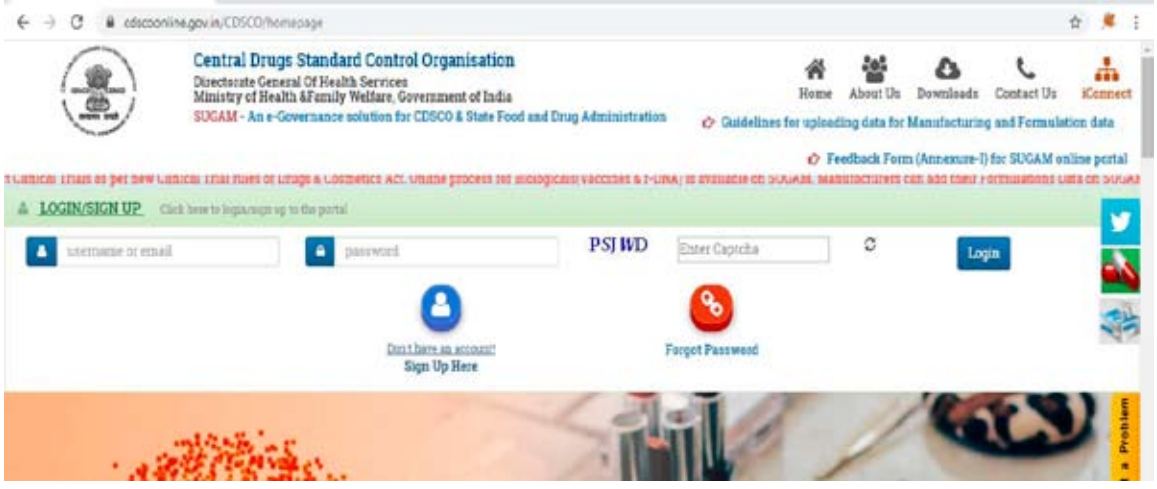
The following is a Step-by-Step Instructions Guide for filing online for grant of permission for Drugs imported in bulk for Non-Medicinal Use as per Rule 43 of Drugs and Cosmetics Rules 1945. It is provided Courtesy Dr Rubina Bose, Dy DC(I), West Zone, CDSCO.

GUIDE FOR DUAL USE APPLICATION AT SUGAM PORTAL

1. **Go to SUGAM PORTAL** https://cdscoonline.gov.in/

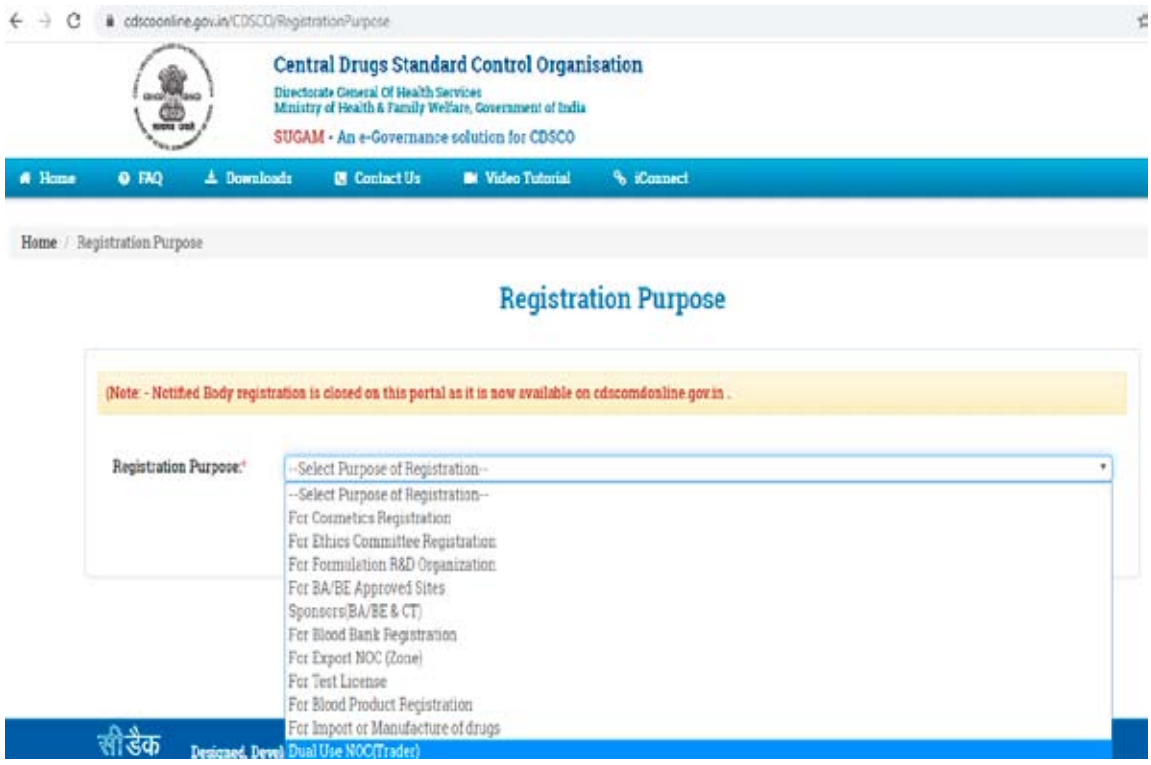


2. **Click on Login/Sign UP.**

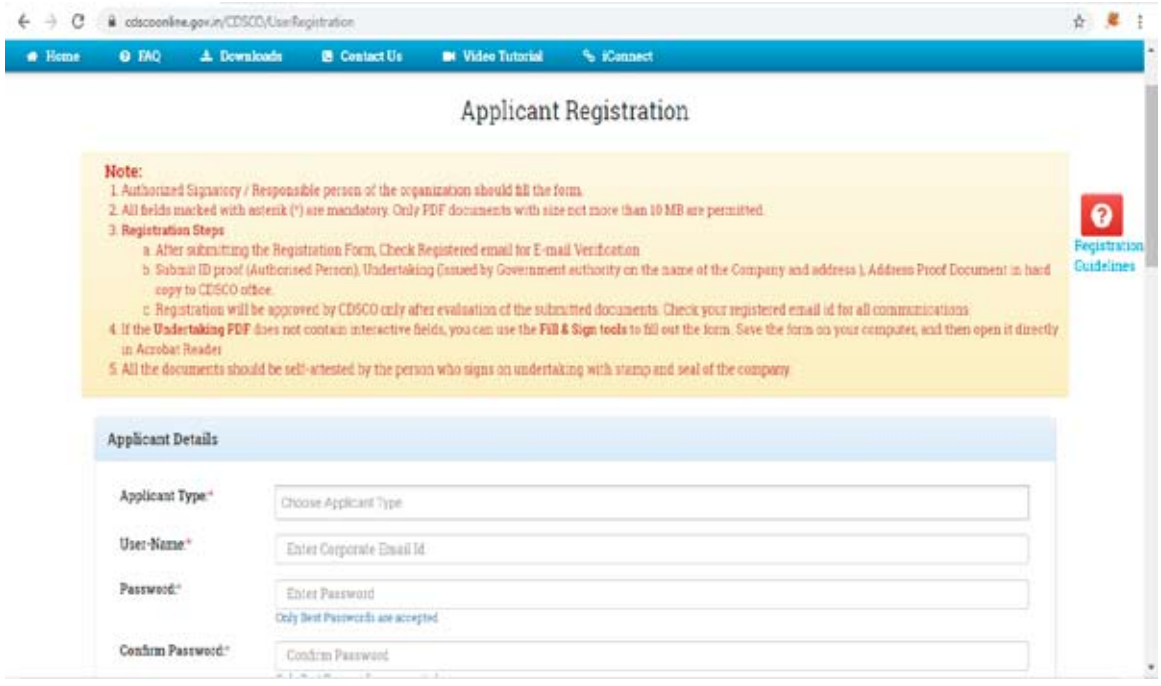


3. **The applicant, who are holding Drugs or Cosmetics license under Drugs and Cosmetic Act and Rules and registered under Corportate, Importer, Indian Agent, manufacturing site, Cosmetics etc and having SUGAM credential (User ID & Passwords) may directly login and submit the application with respective segments.**
4. **The Dual Use Item Import Applicant whether manufacturer/ importer/ trader etc other than Drugs category industry like Textile / Paint / Paper / Food / Cement etc are required to registered by using** Don't have an account! Sign Up Here.

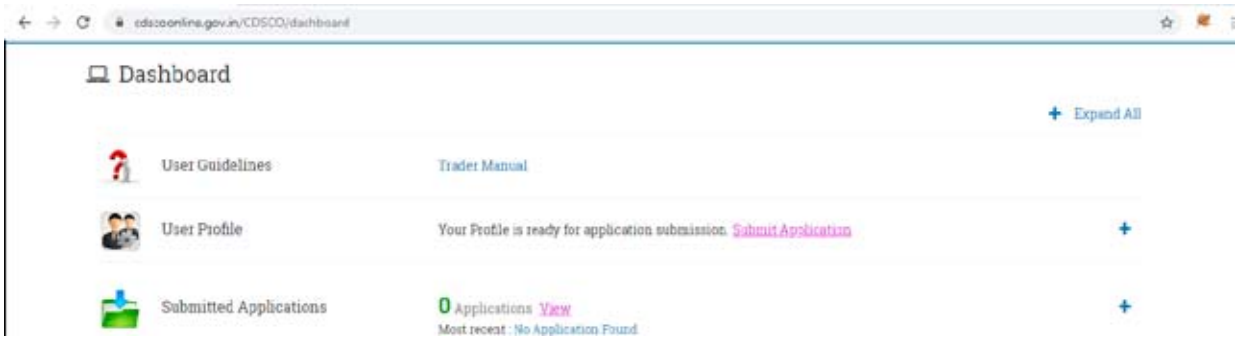
5. **Select Registration Purpose from drop down list as Dual Use NOC (Trader);**



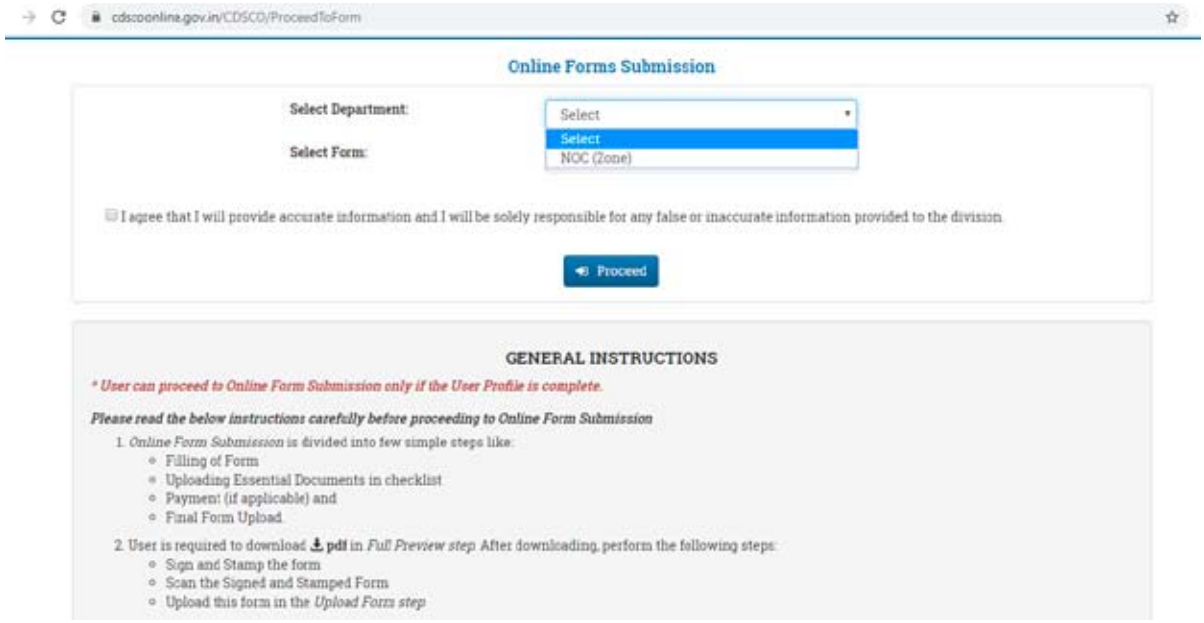
6. **Fill the form carefully, uploaded 03 documents as mentioned on the form (NMT 10 MB) and submit the form. The OTP shall be generated on mobile or email for verification. Then the user ID and password is active to make the application.**



7. **Use the user ID and password for login and your Dashboard will appear. Go to the <u>submit application</u> tab.**



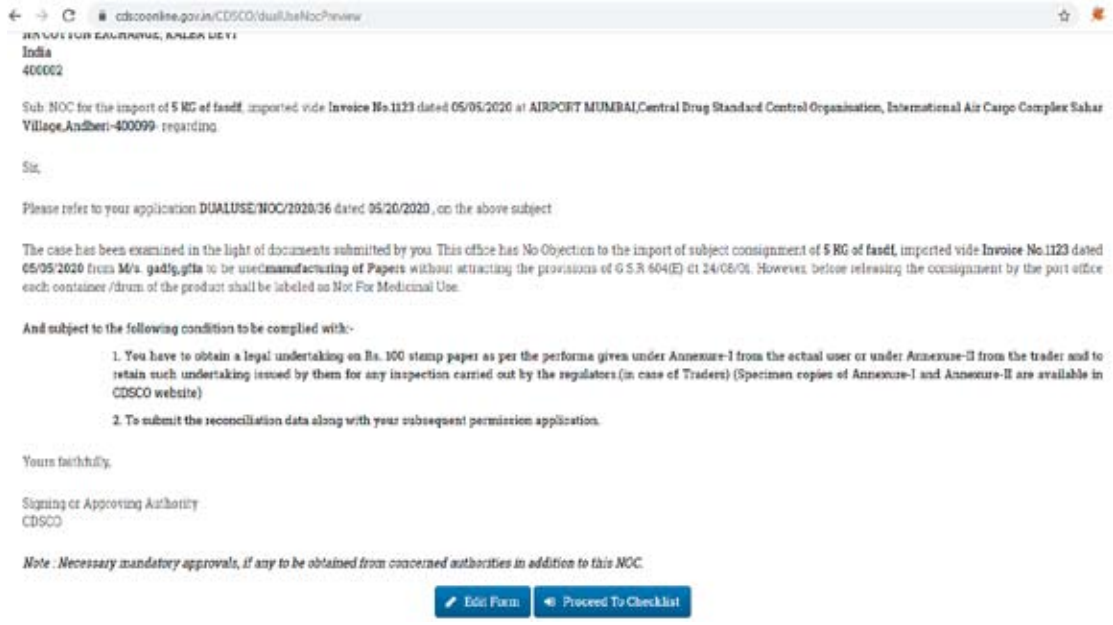
8. **Select Department : <u>NOC (ZONE)</u> and Select Form : <u>Dual USE NOC</u> and check t☑ox for agreement to self statement and click on Proceed**



9. **Following 03 steps shall be displayed;**

10. **Step 1, Fill the Form carefully as the same information shall be captured on Final Dual Use NOC, which can be verified at Step 2 Preview, and if any correction is required, then click on Edit Form, and if the NOC details are correct then click on Proceed to Checklist.**

Note: Information mentioned on the form cannot be corrected, after proceed to checklist and by CDSCO office.



cdscoonline.gov.in/CDSCO/dualUseNocPreview

India
400002

Sub :NOC for the import of 5 KG of fandf, imported vide Invoice No.1123 dated 05/05/2020 at AIRPORT MUMBAI,Central Drug Standard Control Organisation, International Air Cargo Complex Sahar Village,Andheri-400099- regarding.

Sir,

Please refer to your application DUALUSE/NOC/2020/36 dated 05/20/2020 , on the above subject

The case has been examined in the light of documents submitted by you. This office has No Objection to the import of subject consignment of 5 KG of fandf, imported vide Invoice No.1123 dated 05/05/2020 from M/s. gadfg,gfda to be usedmanufacturing of Papers without attracting the provisions of G.S.R 604(E) ct 24/08/06. However, before releasing the consignment by the port office each container /drum of the product shall be labeled as Not For Medicinal Use.

And subject to the following condition to be complied with:-

1. You have to obtain a legal undertaking on Rs. 100 stamp paper as per the performa given under Annexure-I from the actual user or under Annexure-II from the trader and to retain such undertaking issued by them for any inspection carried out by the regulators.(in case of Traders) (Specimen copies of Annexure-I and Annexure-II are available in CDSCO website)

2. To submit the reconciliation data along with your subsequent permission application.

Yours faithfully,

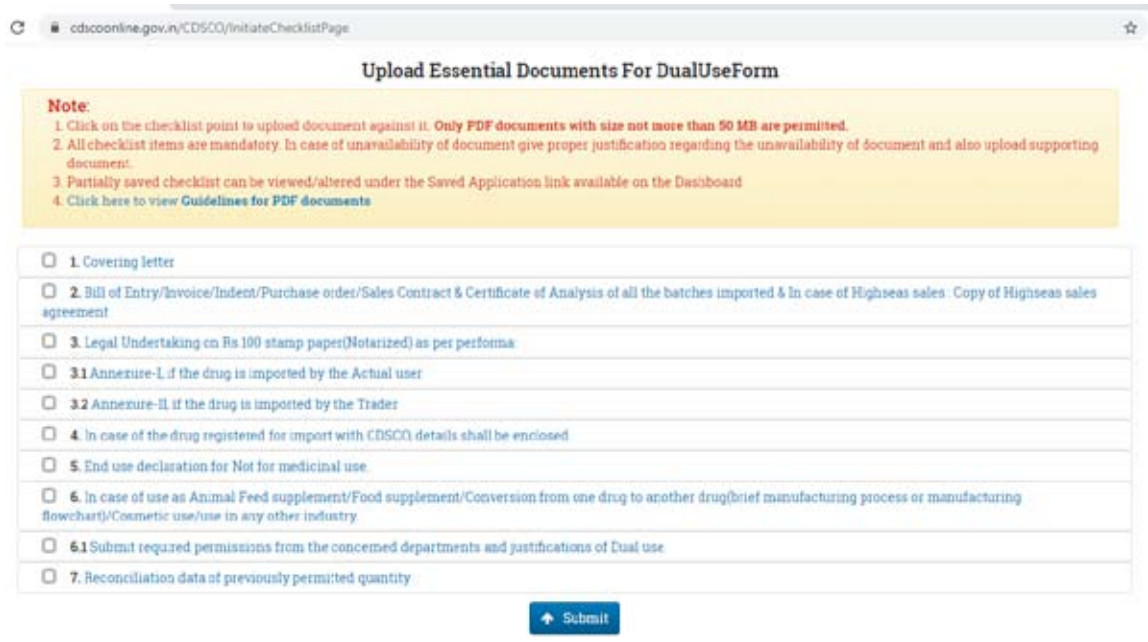
Signing or Approving Authority
CDSCO

Note : Necessary mandatory approvals, if any to be obtained from concerned authorities in addition to this NOC.

Edit Form | Proceed To Checklist

11. **Step 3 : Checklist**

Upload the scan pdf copy of 07 docuemnts duly digitally signed by the authorized signatory (Not More than 50 MB Size) and submit the application.



cdscoonline.gov.in/CDSCO/InitiateChecklistPage

Upload Essential Documents For DualUseForm

Note:
1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 50 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
3. Partially saved checklist can be viewed/altered under the Saved Application link available on the Dashboard
4. Click here to view **Guidelines for PDF documents**

- ☐ 1. Covering letter
- ☐ 2. Bill of Entry/Invoice/Indent/Purchase order/Sales Contract & Certificate of Analysis of all the batches imported & In case of Highseas sales : Copy of Highseas sales agreement
- ☐ 3. Legal Undertaking on Rs 100 stamp paper(Notarized) as per performa
- ☐ 3.1 Annexure-I, if the drug is imported by the Actual user
- ☐ 3.2 Annexure-II, if the drug is imported by the Trader
- ☐ 4. In case of the drug registered for import with CDSCO, details shall be enclosed
- ☐ 5. End use declaration for Not for medicinal use.
- ☐ 6. In case of use as Animal Feed supplement/Food supplement/Conversion from one drug to another drug(brief manufacturing process or manufacturing flowchart)/Cosmetic use/use in any other industry
- ☐ 6.1 Submit required permissions from the concerned departments and justifications of Dual use
- ☐ 7. Reconciliation data of previously permitted quantity

Submit

12. **The unique application number shall be generated, which can be used for communication reference, if required.**

13. **For software related help, you may contact to IT Helpdesk of CDAC, provided at SUGAM Portal.**

Rs. 100/- stamp Paper with Notary

Annexure I (For Manufacturer)

Legal Undertaking for the Import of Drugs as per provisions of Schedule D of Drugs and Cosmetic Rules 1945 to be submitted by the Actual Users to The Central Drugs Standard Control Organisation (CDSCO) Zonal office.

I/We.....S/o.....
having premises at .....aged about .....do hereby solemnly affirm state and undertake as under:
1. That I am the importer of..... (Name of the drug) from..... (Name and full address of the Manufacturer) of..... (Quantity) vide Bill of Entry No.....dated.....

2. That I undertake to use..... (Quantity) of above said drug for Non-Medicinal purpose/ as a phrama aid / as a drug intermediate to manufacture other drugs only.(delete whichever not applicable).

3. That I undertake to maintain books and records of transaction of above said drug for which NOC will be granted.

4. That I undertake to allow the Drug Inspectors from the CDSCO to inspect the books and records as well as the actual usage of (Name of the drug) as and when required.

5. I state that that consignment document like Certificate of Analysis, Bill of Entry, invoice etc. clearly mentions —Not for Medicinal Use□ or (—for use as pharma aid□).

6. That the bags/containers carrying (Name of the drug) along with other requirements of labelling and packaging also mentions ——Not For Medicinal Use□ or (—for use as pharma aid□).

DEPONANT VERIFICATION

Verified on this .....day of..... (Month & Year) that the contents of my above undertaking are true and that no part it is false and that nothing material has been concealed here from.

DEPONANT

Rs. 100/- stamp Paper with Notary

Annexure II (For Trader)

Legal Undertaking for the import of Drugs as per provisions of Schedule D of Drugs and Cosmetic Rules 1945 to be submitted by the Importer/Trader to The Central Drugs Standard Control Organisation (CDSCO) Zonal Office.

I/We.....S/o.....
.. having premises at
.....aged about .....do
hereby solemnly affirm state and undertake as under:

1. That I am the importer/trader of..... (Name of the drug) from..... (Name and full address of the Manufacturer) of..... (Quantity) vide Bill of Entry / Purchase order no.....dated.....

2. That I undertake to sell..... (quantity) of above said drug for Non-Medicinal purpose / as a phrama aid / as a drug intermediate to manufacture other drugs only (delete whichever not applicable).

3. That I undertake to maintain books and records of transaction of above said drug for which NOC will be granted.

4. That I undertake to allow the Drug Inspectors from the CDSCO to inspect the books and records as well as the actual usage of said drug as and when required.

5. That the bags/containers of the said drug along with other requirements of labelling and packaging also mentions —Not For Medicinal Use□.

6. That the data of my previous transaction is annexed with this undertaking (Optional in cases of subsequent transaction).

DEPONANT
VERIFICATION Verified on this .....day of..... (Month & Year) that the contents of my above undertaking are true and that no part it is false and that nothing material has been concealed here from. DEPONANT

Reconciliation Data to be submitted for Import of Dual use Items by the manufacturer:

1. **Name of the Dual use item:**
2. **Name and address of the Importer(Manufacturer/ Trader):**
3. **IEC Code of Importer(Manufacturer/Trader):**
4. **GST IN No:**

S. No	B. E. No. & Date	Invoice No. & Date	Quantity approved vide DDC(I) office letter Ref. No. & Date	Total Qty Imported	Issued for production of	For B. No. (Production B. Nos) as per batch records	Qty Issued & Date as per Warehouse records	Balance Qty	Qty in Ware House (Balance Qty + old balance of the same)	To whom sold with contact details

Submitted By:
Name:
Designation:

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Common FDA-approved drug may effectively neutralize virus that causes COVID-19

A common drug, already approved by the Food and Drug Administration (FDA), may also be a powerful tool in fighting COVID-19, according to research published this week in Antiviral Research.

SARS-CoV-2, the virus that causes COVID-19, uses a surface spike protein to latch onto human cells and initiate infection. But heparin, a blood thinner also available in non-anticoagulant varieties, binds tightly with the surface spike protein, potentially blocking the infection from happening. This makes it a decoy, which might be introduced into the body using a nasal spray or nebulizer and run interference to lower the odds of infection. Similar decoy strategies have already shown promise in curbing other viruses, including influenza A, Zika, and dengue.

"This approach could be used as an early intervention to reduce the infection among people who have tested positive, but aren't yet suffering symptoms. But we also see this as part of a larger antiviral strategy," said Robert Linhardt, lead author and a Professor of Chemistry and Chemical Biology at Rensselaer Polytechnic Institute. "Ultimately, we want a vaccine, but there are many ways to combat a virus, and as we've seen with HIV, with the right combination of therapies, we can control the disease until a vaccine is found."

To infect a cell, a virus must first latch onto a specific target on the cell surface, slice through the cell membrane, and insert its own genetic instructions, hijacking the cellular machinery within to produce replicas of the virus. But the virus could just as easily be persuaded to lock onto a decoy molecule, provided that molecule offers the same fit as the cellular target. Once bound to a decoy, the virus would be neutralized, unable to infect a cell or free itself, and would eventually degrade.

In humans, SARS-CoV-2 binds to an ACE2 receptor, and the researchers hypothesized that heparin would offer an equally attractive target. In a binding assay, the researchers found that heparin bound to the trimeric SARS-CoV-2 spike protein at 73 picomoles, a measure of the interaction between the two molecules.

"That's exceptional, extremely tight binding," said Jonathan Dordick, a Chemical and Biological Engineering Professor at Rensselaer who is collaborating with Linhardt to develop the decoy strategy. "It's hundreds of thousands of times tighter than a typical antibody antigen. Once it binds, it's not going to come off."

Internationally recognized for his creation of synthetic heparin, Linhardt said that, in reviewing sequencing data for SARS-CoV-2, the team recognized certain motifs on the spike protein and strongly suspected it would bind to heparin. In addition to the direct binding assay, the team tested how strongly three heparin variants - including a non-anticoagulant low molecular weight heparin - bind to SARS-CoV-2, and used computational modeling to determine the specific sites where the compounds bind to the virus. All the results confirm heparin as a promising candidate for the decoy strategy. The researchers have subsequently initiated work on assessments of antiviral activity and cytotoxicity in mammalian cells.

"This isn't the only virus that we're going to confront in a pandemic," Dordick said. "We don't really have great antivirals, but this is a pathway forward. We need to be in a position where we understand how things like heparin and related compounds can block virus entry."

In previous work, a team led by Linhardt and Dordick demonstrated the decoy strategy on viruses with a mechanism similar to SARS-CoV-2. In 2019, the team created a trap for dengue virus, attaching specific aptamers - molecules the viral latches will bind to - precisely to the tips and vertices of a five-pointed star made of folded DNA. Floating in the bloodstream, the trap lights up when sprung, creating the world's most sensitive test for mosquito-borne diseases. In work prior to that, they created a synthetic polymer configured to match the sialic acid latch points on influenza virus, reducing influenza A mortality in mice from 100% to 25% over 14 days.

"This innovative approach to effectively trapping virusus is a prime example of how biotechnology approaches developed at Rensselaer are being brought forward to address challenging global health problems," said Deepak Vashishth, the Director of the Center for Biotechnology and Interdisciplinary Studies at Rensselaer, of which both Dordick and Linhardt are a part. "Professors Dordick and Linhardt have worked collaboratively across disciplines, and their research shows promise even beyond this current pandemic."

"Characterization of glycosaminoglycan and novel coronavirus (SARS-CoV-2) spike glycoprotein binding interactions" was published in Antiviral Research. At Rensselaer, Linhardt and Dordick were joined on the research by Fuming Zhang, and also by researchers at the University of California San Diego, Duke University, and the University of George, Athens with support from the National Institutes of Health.

Source: Rensselaer Polytechnic Institute, Science Daily, 15.07.2020 (Excerpts)

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Swedish firm's ColdZyme mouth spray deactivates 98.3% of COVID-19 virus: Study

Swedish life science company Enzymatica has announced that the preliminary results of an *in vitro* study showing the ability of the mouth spray ColdZyme to deactivate SARSCoV-2, the virus causing the COVID-19 pandemic. The study demonstrated that ColdZyme deactivates SARS-CoV-2 Coronavirus by 98.3 percent.

The results indicate that ColdZyme can offer a protective barrier against harmful viruses such as SARS-CoV-2 by local virus deactivation in the oral cavity, the company said in a regulatory filing on Monday, 20.07.2020. The medical device ColdZyme is a mouth spray that forms a barrier in the oral cavity against common cold viruses. The barrier solution of the device is mainly composed of glycerol and Atlantic cod trypsin.

"The goal of the present study was to determine the ability of ColdZyme to deactivate SARS-CoV-2 known to cause the COVID-19 pandemic. A virucidal efficacy suspension test was conducted using ColdZyme against SARS-CoV-2. ColdZyme deactivated SARS-CoV-2 by 98.3% (1.76 log10) in 20 minutes. "Furthermore, no cytotoxicity was detected for ColdZyme at any dilution tested. The study was conducted by the US Company Microbac Laboratories Inc - an independent, accredited and certified laboratory," the company statement said.

The *in vitro* study was based on a standardized and validated methodology, i.e. ASTM International test method designated E1052 "Standard Test Method to Assess the Activity of Microbicides against Viruses in Suspension", it added. "Even if the current *in vitro* results cannot be directly translated into clinical efficacy, it is very interesting that ColdZyme is able to effectively deactivate SARS-CoV-2 *in vitro* since it constitutes a proof-of-principle that can be taken further into clinical studies. Thus, the results indicate that ColdZyme can offer a protective barrier against SARS-CoV-2," said Claus Egstrand, Enzymatica's Chief Operating Officer.

Previous *in vitro* results made with the same method showed that ColdZyme is effective against another Coronavirus, HCoV-229E, one of the causes of the common cold, and in comparison to SARS-CoV-2 belongs to another subgroup within the corona family. The aggregated results indicate that ColdZyme can be effective against a variety of Coronaviruses, the company added.

SARS-CoV-2 actively replicates in the throat and shows high viral shedding also at a time of mild symptoms. Therefore, ColdZyme sprayed onto the mouth and throat could lower the risk of infection, and decrease the viral load locally. The lowered viral load may decrease viral shedding and thus minimize the spread of SARS-CoV-2, it added.

Source: cnbctv18.com, 21.07.2020 (Excerpts)

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Anti-cholesterol drug fenofibrate can 'downgrade' COVID-19 to common cold: Hebrew University Professor

A health worker performs a COVID-19 test at a Test Iowa site at Waukee South Middle School, Tuesday, July 14, 2020, in Waukee, Iowa. (Photo|AP)

A widely used anti-cholesterol drug, fenofibrate, can "downgrade" the danger-level of Coronavirus to that of a

common cold, a Hebrew University (HU) academic has claimed after testing it on infected human tissue.

Professor Yaakov Nahmias, Director of HU's Grass Center for Bioengineering, in a joint research with Benjamin tenOever at New York's Mount Sinai Medical Center, found that the novel Coronavirus is so vicious because it causes lipids to be deposited in the lungs and that fenofibrate can undo the damage.

"If our findings are borne out by clinical studies, this course of treatment could potentially downgrade COVID-19's severity into nothing worse than a common cold," Nahmias was quoted as saying in a press release issued by the HU.

The two researchers focused on the ways in which SARS-CoV-2 changes patients' lungs in order to reproduce itself. They discovered that the virus prevents the routine burning of carbohydrates. As a result, large amounts of fat accumulate inside lung cells, a condition the virus needs in order to reproduce.

"This new understanding of SARS CoV-2 may help explain why patients with high blood sugar and cholesterol levels are often at a particularly high risk to develop COVID-19," they noted. "Viruses are parasites that lack the ability to replicate on their own, so they take control of our cells to help accomplish that task.

By understanding how SARS-CoV-2 controls our metabolism, we can wrestle back control from the virus and deprive it from the very resources it needs to survive," Nahmias explained. Having drawn this conclusion, the two researchers began to screen FDA-approved medications that interfere with the virus' ability to reproduce.

In their lab studies, the cholesterol-lowering drug fenofibrate, sold under the brand name Tricor, showed extremely promising results. By allowing lung cells to burn more fat, fenofibrate breaks the virus' grip on these cells and prevents SARS CoV-2's ability to reproduce. In fact, within only five days of treatment, the virus almost completely disappeared, the researchers claim.

"With second-wave infections spiking in countries across the globe, these findings could not come at a better time," Nahmias was quoted as saying, adding that "global cooperation may provide the cure". "The collaboration between the Nahmias and tenOever labs demonstrates the power of adopting a multi-disciplinary approach to study SARS-CoV-2 and that our findings could truly make a significant difference in reducing the global burden of COVID-19," tenOever added.

While there are many international efforts currently underway to develop a Coronavirus Vaccine, studies suggest that vaccines may only protect patients for a few months, the University's press release said. Therefore, blocking the virus' ability to function, rather than neutralising its ability to strike in the first place, may be the key to turning the tables on COVID-19, it added. *(The findings of the research will appear in this week's Cell Press' Sneak Peak).*

Source: PTI, The New Indian Express, 20.07.2020 (Excerpts)

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NATIONAL NEWS

Consumer Protection Act 2019 in force from 20 July 2020

The newly enacted Consumer Protection Act comes to force from Monday (July 20), replacing more than three decades old Consumer Protection Act, 1986.

The new Consumer Protection Act 2019 seeks to revamp the process of administration and settlement of consumer disputes, with strict penalties, including jail term for adulteration and misleading ads by firms.

The bill, among other things, proposes setting up of a Central Consumer Protection Authority (CCPA) to promote, protect and enforce the rights of consumers as a class. The CCPA would make interventions to prevent consumer detriment arising from unfair trade practices. The agency can also initiate class action, including enforcing recall, refund and return of products.

The Bill also envisages simplified dispute resolution process, has provision for Mediation and e-filing of cases. The Consumer will be able to file cases in the nearest commission under the jurisdiction of which he resides. Consumers can file complaints from anywhere and they do not need to hire lawyer to represent their cases. For mediation, there will be strict timeline fixed in the rules.

On misleading advertisements there is provision for jail term and fine for manufacturers. There is no provision for jail for celebrities but they could be banned for endorsing products if it is found to be misleading. For the first time

there will be an exclusive law dealing with Product Liability. A manufacturer or product service provider or product seller will now be responsible to compensate for injury or damage caused by defective product or deficiency in services.

There is also a provision for class action law suit for ensuring that rights of consumers are not infringed upon. The authority will have power to impose a penalty on a manufacturer or an endorser of up to 10 lakh rupees and imprisonment for up to two years for a false or misleading advertisement.

Product liability provision to deter manufacturers and service providers from delivering defective products or deficient services. The Bill also enables regulations to be notified on E-commerce and direct selling with focus on protection of interest of consumers.

Source: Edited by Reema Sharma, Zee Media Bureau, https://zeenews.india.com/, 20.07.2020

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Silver lining! India turned net Exporter of Chemicals after 10 years in FY 20

India turned a net exporter of chemicals and related products for the first time in at least a decade in FY20, according to the latest Commerce Ministry data. While these are still early days to forecast a trend, the data come as a relief at a time when the country is battling the Covid-19 pandemic and the government is seeking self-sufficiency in this critical segment, especially in pharmaceuticals.

While exports of such products — including drug formulations, bulk drugs and drug intermediates, organic chemicals, agro chemicals and fertilisers — rose 3% year-on-year to $45 billion in FY20, imports stood at $44.3 billion, down 7.3%. In contrast, India's overall goods exports contracted by 5.1% in FY20, while its imports shrank by 7.8%.

The chemical and related products are clubbed together in 15 broad categories. The data lend some credence to the claim that with right policy interventions, India's chemicals sector can be a sustained driver of its merchandise exports.

Importantly, over the past decade through FY20, exports of the chemicals and related products more than doubled from $20.8 billion in FY11 to $45 billion last fiscal, outperforming the overall goods exports that rose from $250 billion to just $313 billion during this period. Consequently, the share of the chemicals segment in the country's merchandise exports, too, jumped from 8.3% in FY11 to 14.4% in FY20, having emerged as a key driver of export growth. Such imports rose up from $29.5 billion to $44.3 billion in the past decade.

Exports of drug formulations and biologicals remained the biggest driver of this growth, having witnessed a leap from $6.3 billion in FY11 to $15.9 billion in FY20. Organic chemical exports leaped from $3.8 billion to $8.3 billion during this period, while residual chemicals and allied products jumped from $2 billion to $5.6 billion. Agro chemicals exports climbed from $1.1 billion to $3.4 billion in the past decade. However, the outbound shipment of bulk drugs and intermediates remained almost stagnant in all these years — from $3.6 billion in FY11 to $3.9 billion last fiscal.

However, the dependence on imports, mainly of raw materials, is too strong in certain segments. For instance, the imports of organic chemicals and residual chemicals & allied products stood at $19.7 billion, or almost 45% of the total chemical and related item imports in FY20, having risen from $12 billion in FY11. China alone accounts for two fifths of India's organic chemical imports, which are mostly used in making finished products for both domestic consumption and exports.

R Uday Bhaskar, Director-General at Pharmaceutical Export Promotion Council (Pharmexcil), said India's pharma exports, the biggest category within the chemicals and related products segment, touched $20.58 billion in FY20, while such imports were to the tune of $6.25 billion. As much as 70% of the exports are typically formulations and 25% Active Pharmaceutical Ingredients. Imports comprised finished drug formulation and APIs, amounting to about $3.5 billion and almost $3 billion, respectively, in FY20.

Source: Banikinkar Pattanayak, Financial Express.com, 20.07.2020

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Hand sanitisers under Schedule K: Pharma cos happy, regulators cite concerns

As per an order by the Central Government, hand sanitisers will be classified under Schedule-K of the Drugs and Cosmetics Rules 1945. This will permit the sale of this product without a sale license. However, manufacturers will need to obtain manufacturing licenses.

It is learnt that the Government's move came after receiving several representations from the industry and looking at the need to ensure the availability of hand sanitisers in the country to fight the COVID-19 pandemic. The Government is planning to include the word 'hand sanitiser' in the column heading 'Class of Drugs' at entry number 12 of the Schedule-K of the Drugs and Cosmetics Rules 1945.

This move has elicited mixed views:

Harish Jain, Secretary, Karnataka Drugs and Pharmaceutical Manufacturers Association opined, "Hand sanitisers are classified as drugs by virtue of Sec 3(b)(ii) of Drugs and Cosmetics Act. They are used for prevention of disease and is an important component in the fight against the COVID-19 pandemic.

Many state Governments have appealed to the industry to make hand sanitisers available in every distribution channel, including grocery stores. Considering the above and as well the fact that these are for external use only and made out of ingredients which are proven to be safe, it is imperative that this legal impediment to make this product available easily is rectified without any further delay."

However, Dr G L Singla, Retired Drug Controller of Haryana expressed concerns about the move and said, "By including sanitisers in Schedule-K of the Drugs and Cosmetics Rules 1945, such products would be openly sold by grocery stores, petty shop keepers etc (without obtaining any drugs sale license) across the country.

In my opinion, it would be cumbersome for the drug regulators to ensure availability of quality sanitisers/control the quality of the sanitisers as per the statutory provisions under the Act, keeping in view the bitter experience about their quality issues which we had in last two to three months, where a number of sanitisers manufactured and sold were found to be misbranded, substandard, adulterated with toxic substances like methanol in place of ethanol etc."

Some also express fears that the unregulated sale of such formulations containing 70 percent alcohol or more, that too in bigger packs sizes (exceeding 30 ml), can pose another problem as alcoholics might use these products for intoxication.

Speaking on this problem and the earlier measures which were taken to prevent it, Singla informed, "To prevent such abuse even homoeopathic preparations containing alcohol exceeding 12 percent are required to be packed in 30 ml as per the statutory provisions enshrined in Drugs and Cosmetics Act 1940 and Rules 1945."

A senior drug regulator from Haryana too shared similar views and said that once hand sanitisers are exempted from sale licence everybody will jump into this trade. Regulatory control will loosen as they will be sold on even footpaths.

He also pointed out that whenever regulatory grip is loosened the quality of a product becomes substandard. Unlicensed manufacturers will come up focusing far-flung areas, which are not easily accessible, he cautioned. The term 'sanitiser' is not defined under the Drugs and Cosmetics Act 1940/Rules 1945. Therefore, many other questions arise. For instance, will any product labelled as a 'sanitiser' will be able to enjoy exemption under Schedule K? Thus more clarity on this issue is awaited.

Source: Thehealthmaster.com, 20.07.2020

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High-level Government panel suggests single-window system for new drug approvals

A high-level committee has proposed a single-window approval system to speed up availability of new drugs in the country, even as the world is in a rush to find vaccine and cure for the Covid-19 pandemic.

The committee, set up by the Cabinet Secretary after Prime Minister Narendra Modi sought overhauling of the country's drug regulatory system, has suggested restructuring the process of permission for new drugs by allowing parallel submission of applications for new drug approval and for grant of import licence and manufacturing license.

Under the present system of sequential processing, getting import licence for a new drug can take about a year. It takes 90 days to get permission to import and market a new drug. Once it is obtained, then the company requires an import registration certificate. The duration specified for processing this application is 270 days. After getting the RC, it takes at least 30 more days to get the import license.

A parallel application system "will reduce the processing duration by about 3-6 months", the committee said in its interim report submitted to the Prime Minister's Office. It has also recommended that market authorisation be permitted simultaneously, thereby reducing the time duration by 2-3 months.

The committee was formed after Modi raised concerns over the ability of the regulatory framework to keep pace with industry and scientists. The panel has suggested allowing companies to manufacture unapproved new drugs that are still under clinical development to enable faster access. "Specific provisions under the new drugs and clinical trial rules may be incorporated," the report said.

At present, an NOC (no-objection certificate) has to be obtained to manufacture new biological entities, or new drugs. The committee has suggested that in case the manufacturer is already holding a licence to manufacture the same category of drugs, regulator Central Drugs Standard Control Organisation (CDSCO) should process the application within seven days from the date of application, failing which it is deemed approved.

If the manufacturer is not holding a license to manufacture the same category of drugs, the NOC should be issued within 30 days, it said. The committee also observed that multiple agencies are involved in drug discovery at the preclinical stage, resulting in delays. "The applications are processed sequentially, leading to delay in approvals," it said.

It has also recommended setting up a timeline for disposal of applications failing which the proposals shall be deemed approved. At present, it takes about eight months to reach the preclinical stage. To start with, it requires an approval from a review committee in genetic manipulation, besides institutional bio safety approvals during research and preclinical toxicity studies.

Similarly, in case of live modified organism, genetic engineering appraisal committee approval is required before commercial production. Institutional ethics committee approvals are required for registration of animal house facilities and testing protocol approval. The committee has recommended that a sub-committee under RCGM (review committee on genetic manipulation) be formed to carry out all functions of RCGM in respect of r-DNA derived drugs and should be permanently housed in CDSCO.

RCGM, which monitors the safety of ongoing research projects and activities involving genetically engineered organisms and hazardous organisms, functions under DBT. A similar procedure is followed for genetically engineered organisms.

It takes average six months to get approval from a panel overseeing activities involving large-scale use of hazardous microorganisms. The expert committee has suggested framing a timeline of 30 days for disposal of applications, failing which proposals shall be deemed to have been approved by the committee. The committee has also recommended bringing all vigilance programmes like pharmacovigilance, materiovigilance, biovigilance and haemovigilance under the direct supervision of CDSCO.

Source: Teena Thackar, The Economic Times, 20.07.2020

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Covid-19 pushes up sales of cardiac, anti-diabetic drugs

The changes in the medication needs of the masses due to the novel Coronavirus pandemic seems to impacting the operation of pharmaceutical companies with those dealing in respiratory, anti-diabetic, cardiac therapies performing much better than others having anti-infective, gastro, vitamin or pain therapies in their portfolio.

The sudden change in preferred therapies by masses has just taken a sharp turn from pre-Covid period when gastric, vitamin therapies were most widely used. Probably the concern that Coronavirus impacts adversely chronic heart, lung and diabetics severely had turned people into buying more of medicines for these ailments.

In the month of June, demand for Cardiac drugs registered the strongest growth of 15.9 percent y-o-y in terms of value and Anti-Diabetic segment grew at 12.7 % yoy due to continued buying during the period of the lockdown. Similarly, the Neuro segment (+14.6 percent y-o-y) saw higher demand but surprisingly value growth for respiratory went down to 4.5 percent even though Covid-19 is known to impact this critical functioning of the human body.

Segments in acute therapies like anti infective, Gynaec/ Vitamins, pain, gastro where the demand for drugs has always remained higher than others, declined year-on-year in June clearly bringing out the shift in drug use by Indians, especially during the time of lockdown. The first quarter period (April-June) is seasonally a strong quarter for acute therapies and the demand loss is, thus, unlikely to fully recover.

According to a Emkay research report, the changing preference of drugs by people has also had an impact on the Indian pharmaceutical industry with companies having stronger drug brands dealing with respiratory, cardiac and anti-diabetic therapies (in chronic care) registering growth higher than the industry average.

Accordingly, while Dr Reddy's Labs, Alkem having higher drug concentration in acute exposure category underperformed while the Indian Pharmaceutical Market (IPM), Sun Pharma, Torrent Pharma, Lupin, outperformed the market due to their high chronic portfolio.

Cipla, Glenmark outperformed due to strong respiratory demand, while IPCA benefitted from high Hydroxychloroquine sales, which has been touted as wonder drug having potential to positively impact severe Covid-19 patients.

The brokerage report said that after falling for two straight months due to Covid-19, Indian Pharmaceutical Market (IPM) growth recovered (+5.8 percent y-o-y) in June, led by Cardiac and Anti-Diabetes segments. Volumes fell 1 percent y-o-y (vs 16/13 percent fall in April/May) but closer to normal levels of last year. On moving average turnover basis, IPM growth stood at 7 percent y-o-y, while volume growth was flat. "We expect a gradual recovery from Q2 and 6-8 percent growth for FY21," the report said.

Source: IANS, ET Healthworld, 17.07.2020

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Health Ministry to introduce QR code for drugs sold in domestic market to control spurious and substandard drugs

The Union Health Ministry is gearing up to introduce a unique Quick Response (QR) code for drugs sold in the domestic market to curtail the menace of spurious and substandard drugs in the country. The QR code will help track and trace medication during the entire supply chain and ensure its authenticity.

A high-level panel, headed by Union Health Secretary, has been set up to work on a framework to implement QR code for drug packs a couple of days back following a meeting of key officials from the Health Ministry, Department of Pharmaceuticals (DoP), Commerce Ministry, NITI Aayog and Prime Minister's Office in this regard. The panel is likely to submit its report in three weeks. Earlier all these authorities had come out with different models of drug authentication system leading to confusion among drug makers.

In fact, the Union Commerce Ministry has been trying to implement barcoding for exports of drugs since 2011 but it is yet to be executed smoothly. The Directorate General of Foreign Trade (DGFT) has extended the date of implementation of track and trace system for drug formulations with respect to maintaining the parent-child relationship in packaging levels and its uploading on central portal till October 1, 2020 for both SSI and non-SSI manufactured drugs in view of the Coronavirus outbreak and lockdown announced by the Government to curtail its spread.

Last year, the Central Drugs Standard Control Organisation (CDSCO) had issued a draft Notification mandating every Active Pharmaceutical Ingredient (API) manufactured or imported in India shall QR code on its label at each level packaging that store data or information readable with software application to facilitate tracking and tracing.

The stored data shall include unique product identification code, name of the API, brand name (if any), name and address of the manufacturer, batch number, batch size, date of manufacturing, date of expiry or retesting, serial shipping container code, manufacturing licence number or import licence number and special storage conditions required (if any).

The DoP in its revised Public Procurement (Preference to Make in India), Order, 2017 dated January 14, 2019 had made it mandatory for all medicines procured under public procurement to have barcode/QR code at primary level packaging from April 1, 2019. Later DoP deferred its implementation till April 1, 2020.

In 2018 CDSCO came out with track and trace mechanism for top 300 drug brands. The CDSCO's proposal, cleared by the Drugs Technical Advisory Board during a meeting in May 2018, was to print a 14-digit number on the labels of the top 300 pharmaceutical brands identified by it on the basis of moving annual total data obtained from AIOCD AWACS, along with a mobile number of the manufacturer.

Since the numbers would be unique to each strip and bottle sold in the market, a consumer could easily check authenticity of drugs by sending a message to the given number and get details of the manufacturer, batch number, expiry data etc. The implementation of barcoding on drug packs was of voluntary nature.

Taking serious note of the spread of counterfeit drugs, NITI Aayog proposed a plan to put the entire drugs inventory made and consumed in the country on blockchain which stops the entry of fake drugs into the supply chain. It uses a highly scalable transparent protocol to assign every manufactured product an asset. The assets are then added to the blockchain and assigned a unique identification

number, commonly referred to as hash. The technology then verifies the hashes to find out whether or not the product in question is counterfeit or legitimate.

Expressing concern over multifarious directions regarding tracking and tracing being issued by various departments, the drug industry demanded implementation of a single drug authentication system.

Commenting on the Government's initiative to introduce track and trace system for drugs sold in the local market, Dr Viranchi Shah, Senior Vice President, Indian Drug Manufacturers' Association (IDMA) said "Similar attempts have been made by the Commerce Ministry for exported drugs since 2011 but there have been several hurdles in its implementation. The Government should ensure that the industry and regulators jointly work out a feasible plan to implement the QR code on the drug pack in the long run."

Echoing his view, Ashok Kumar Madan, Executive Director, IDMA said, "Barcoding on exported medicines is yet to be implemented smoothly. The industry has time and again raised difficulty in its implementation. Barcoding has increased the cost of drug exports leading to a decline in competitive advantage of exporters. Drug units require a minimum investment of Rs. 25 crore to Rs. 30 crore to put in place a barcoding mechanism. An assembly line costs Rs. 1.5 crore to Rs. 2 crore. The drug production also gets slowed down. On top of all that several importing countries do not require barcoding on Pharma products as they lack mechanism to scan the barcode while several other countries have their own track and trace mechanism. Indian track and trace Guidelines can be implemented only after importing countries' acceptance of these Guidelines."

Over the last few years, various departments have proposed different models of drug authentication which created confusion among drug manufacturers. Last year CDSCO came out with a draft Notification introducing QR code for APIs. QR code is hardly effective for APIs sold by vendors in small quantities, he pointed out, adding that Rule 96 of Drugs and Cosmetics Rules, 1945 clearly mentions labeling specifications which include details of products and their manufacturers.

The QR code will put it in machine readable form. Its implementation can be done, once repercussions of COVID-19 pandemic subside, he stated.

Nipun Jain, Chairman, Small and Medium Pharma Manufacturers Association (SMPMA) said, "A meeting of stakeholders should be convened to discuss the implementation of QR code on medicine packs. Besides this, the experience of large companies voluntarily implementing QR code on top 300 drug brands should be shared by the drug regulatory body which would offer learning experience to other drug makers especially MSMEs. Funds need to be allocated to Pharma MSMEs to help them implement track and trace mechanism."

Source: Laxmi Yadav, Pharmabiz, 18.07.2020

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Single window nod on anvil, to spur investment: Piyush Goyal

Government creating land bank, says Goyal

The Government will soon set up a Single Window System (SWS) for clearances and approvals for industry, and is working on creating a land bank with a view to attract investments, Commerce and Industry Minister Piyush Goyal said.

He said six States had already given their consent for the land bank, and potential investors would be able to locate and identify land from their distant offices for industries without frequently visiting the offices of land-owning agencies.

"The Government is soon going to set up a Single Window System for clearances and approvals of industry in the country. This would be a genuine single window and all the concerned State Governments and Central Ministries are being taken on board," Mr Goyal said.

He said a nodal officer had been appointed in every Central department, and project development cells are being set up which will help in the development of investible projects in coordination between the Central and State Governments. The Government, he added, had identified 20 industrial sectors to focus on.

Source: PTI, The Hindu, 27.07.2020

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CSIR suggests cap on Remdesivir price

The Council of Scientific and Industrial Research (CSIR) has suggested regulating price of the experimental Covid-19 medicine Remdesivir used in hospitalised

patients who are on oxygen support on the basis of a cost analysis of the API used in the formulation.

The proposal states that the price of the drug can come down substantially and CSIR has submitted its recommendations depicting scope for sizeable reduction in cost of treatment with regard to the drug used for treating severely ill patients, sources said.

"The proposal to cap the price of the drug is under active consideration by the drug price regulator, National Pharmaceutical Pricing Authority (NPPA)," an official told.

Remdesivir is currently priced in the range of Rs 4,000-Rs 5,000 per vial and the total cost for the drug during treatment is estimated between Rs 40,000 and Rs 55,000. The drug — originally developed by American firm Gilead — has been launched in India by a number of generic drug makers who entered a licensing agreement with the drug's patent holder.

Remdesivir is in high demand after the intravenously-administered medicine helped to shorten hospital recovery time in a Clinical Trial and is now part of the standard treatment protocol for Covid-19 suggested by the Health Ministry.

Source: The Health Master, 18.07.2020 (Excerpts)

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Zydus Cadila aims to complete trial of coronavirus vaccine by March: Chairman Pankaj Patel

AFP- "We are looking at about seven or a little more than seven months for the vaccine, provided the data is encouraging and the vaccine is proven to be effective during the trials," Chairman Pankaj Patel.

India's Zydus Cadila plans to complete late-stage trials for its novel Coronavirus Vaccine candidate by February or March and could produce up to 100 million doses a year initially if it is successful, the Company Chairman said,

Cadila's vaccine candidate, known as ZyCov-D, is one of dozens being developed around the world to fight the Coronavirus pandemic. "We are looking at about seven or a little more than seven months for the vaccine, provided the data is encouraging and the vaccine is proven to be effective during the trials," Chairman Pankaj Patel told *Reuters* in an interview.

"We are also open to discussing partnerships with Pharma companies in various geographies, but it is a bit premature right now, and we will be doing so at the end of Phase 1 and 2 trials," he said. Early-stage Phase 1 and 2 human trials are likely to be concluded in the next three months, he said.

Cadila, among India's top 10 drugmakers by revenue, is also planning to produce the drug Remdesivir that is in high demand globally after it showed promise in treating severe patients with COVID-19, the disease caused by the novel Coronavirus.

Cadila was among several Indian firms that reached an agreement with the US firm Gilead Sciences last month, gaining a license for developing countries, including India, to make and sell the drug. Patel said Cadila had the capacity to produce up to 400,000 doses of Remdesivir in the first month after it wins regulatory approval to make it in India.

Source: The Economic Times, 21.07.2020

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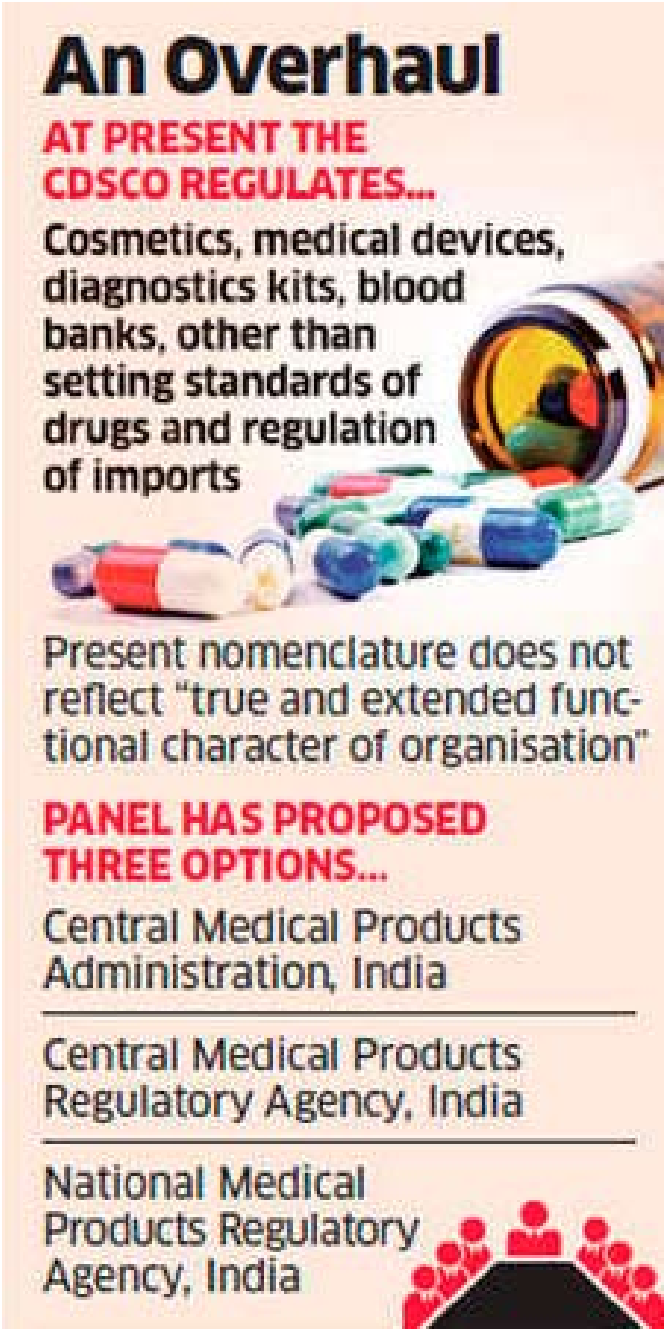
Panel recommends renaming India's drug regulator for better international visibility

A high-level committee has recommended renaming India's drug regulatory authority to give it national and international visibility.

The present nomenclature of Central Drugs Standard Control Organisation (CDSCO) does not reflect the "true and extended functional character of the organisation" that regulates cosmetics, medical devices, diagnostics kits, blood banks, other than setting standards of drugs and regulation of imports, the panel said in its report.

It has proposed three options — Central Medical Products Administration, India (CMPA), Central Medical Products Regulatory Agency, India (CMPRA), and National Medical Products Regulatory Agency, India (NMPRA) — to rename the agency. It would be possible to rename CDSCO with an executive order by the government since the nomenclature is not mentioned under the Drugs and Cosmetics Act, 1940, the panel said.

It has also suggested that the organisation should be headed by a Medical Products Controller General of India, which should be at the level of Additional Secretary. At present the post of Drug Controller General (India) is equivalent to the level of Joint Secretary.



"The changes are required to enhance the visibility and stature of the organisation at a global level," the committee said in its report. ET has seen a copy of the report. The panel has also recommended bringing ayurveda, yoga & naturopathy, unani, siddha and homoeopathy (Ayush) and medical devices under the ambit of the new organisation. It has recommended five verticals — new drugs, cosmetics and clinical trials; biologicals; AYUSH; medical devices; and legal, enforcement and investigation. Each level should be headed by a Controller at the level of Joint Secretary with decision-making powers for disposal of all technical matters, it said. There should also be a separate cadre for medical devices vertical. The committee has also recommended replacing the archaic 1940 Drugs and Cosmetics Act with a new Drugs and Cosmetics and Medical Devices Act.

The Government plans a major overhaul of the country's drug regulatory authority in a bid to bring changes in line with global standards and to deliver services efficiently. The committee has suggested a slew of measures to reduce the number of regulatory steps and time taken for approvals, to fast track introduction of new drugs in the country, and facilitate coordination between multidisciplinary institutions such as Indian Institute of Science and IITs for promoting innovation in new devices and diagnostic kits. Drug discovery and research in institutes are largely limited to academic purposes rather than translational research, it said.

There is a gap in the ecosystem in respect of research capability, skill, and use of technology, among others as compared to regulatory authorities of other countries like US FDA, TGA (Australia), MHRA (UK), and PMDA (Japan). "Approvals granted by these authorities are accepted globally," the report said. In 2017, top drugs advisory body Drugs Technical Advisory Board (DTAB), too, had recommended renaming CDSCO.

The committee said the regulatory reforms are essential to build image of Indian drug regulators and also "to make a transparent, reliable, fool proof drug regulatory system in India in order to ensure reliance on our regulatory system by other countries. This would enable us to minimise the inspections of Indian companies by outside agencies and at the same time gain international confidence on our system," the committee opined.

It has also recommended amendment to the Drugs and Cosmetics Act to incorporate clinical trials, approval of new drugs, procedure for import and export on the lines of allopathic drugs.

The committee has said that at present the organisation lacks monitoring of adverse events. There are inadequate testing laboratories, manpower, and training to regulators. There are no offices of CDSCO in foreign countries from

where major import occurs. "There is also a problem of over concentration on pre market rather than post market monitoring," it said. The committee has suggested strengthening of infrastructure by opening zonal and sub zonal offices of CDSCO in all major states.

To reduce delays and inefficiency disposal of files, it has recommended that the present system of sending it to the Directorate General of Health Services (DGHS) and then to the drug division of the Health Ministry should be changed. "In order to expedite the decision making the CDSCO files be sent to the Ministry of Health which may consider taking technical inputs on case to case basis, if required from the DGHS," it said.

Earlier Prime Minister Narendra Modi had raised concerns over the ability of the regulatory framework to keep with the industry and scientists. Tasked to reform the drug regulatory system of India a committee was then formed by the Cabinet Secretary in May this year.

Source: Teena Thacker, The Economic Times, 18.07.2020

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Mahamana Declarations on Ayush to boost Indian traditional medicine

The Mahamana Declarations on Ayush, an independent initiative, has been devised to give a fillip to Ayurveda, Unani, Siddha and Homoeopathy systems of medicine. Promoted by the Faculty of Ayurveda Institute of Medical Sciences (IMS) at the Banarus Hindu University (BHU), Quality Council of India (QCI), FICCI and Patient Safety and Access Initiative, its effort is to expand the reach and use of this Indian traditional medicine. The whole idea was conceptualised by Prof Bejon Kumar Misra, adviser-consultant, IMS, BHU who also leads the patient groups of the country.

"Though the Ministry of Ayush has nothing to do with it, we are in regular touch with them and the nine Special Interest Groups (SIGs) created for the purpose', said Prof Misra who added that the Secretary, Ministry of Ayush, inaugurated the international seminar on 'The role of Ayush during COVID-19' which led to the formation of the Mahamana Declarations. There is an urgent need for people to remain healthy because of the COVID-19 pandemic. It is here we see that Ayush can play a significant role. Our view is that consumers must be empowered to make an informed choice based on credible information on Ayush, Misra told.

The objective of the Mahamana Declarations is to integrate the best of ayurvedic and modern systems of medicine. A nine-member working group is constituted to oversee the implementation of the nine key concepts within the next 12 months. This will be through an action plan by SIG to focus on patient first, value of Ayush, amend standards of Ayush medicines, strong regulatory body, institutionalize Ayush, make Ayush popular and create an Ayush leadership.

This is where Mahamana comes in to encourage Ayush and ensure it gets a level-playing field with Pharmaceuticals which are medicines with chemical ingredients. We are looking at how natural ingredients can be used to keep healthy and to a certain extent be able to deliver reliable outcomes on treatments based on good clinical trials and science-based documentation, he added. Consumers should be empowered to make an informed choice. That was the whole idea of getting into this Mahamana Declarations. Ayush was not getting recognition in the public domain and only few people were opting for this system of medicine in spite of the availability of dedicated facilities, said Prof Misra.

Though there is a separate Ministry to support Ayush, there are a lot of gaps in terms of educating patients about the benefits and advantages of Aysuh. This is not just in India but globally too. India became the Pharmacy of the World because the generic medicines being manufactured and exported which were acknowledged to be of good quality and were also affordable. This is how with generic formulations, Indian Pharma catapulted to become a global supplier of several leading brands. Hence, patient organisations have decided that when this could be achieved for Pharmaceuticals, why can it not be achieved for Ayush, he said.

The nine-member committee has Prof Y B Tripathi, Chairman and Dean Faculty of Ayurveda IMS BHU, Varanasi. The members are Meenakshi Datta Ghosh, former Secretary Government of India, Dr K K Aggarwal, former President, Indian Medical Association, Prof (Dr) Tanuja Nesari, Director All India Institute of Ayurveda, New Delhi, Prafull D Sheth, Former Vice-President FIP, Arvind Varchaswi, Managing Director Sri Tattva, Bengaluru, Prof R N Acharya, dean Gujarat Ayurveda University, Jamnagar, Prof Bejon Kumar Misra, and Prof (Dr) K N Dwivedi, HoD Dravyaguna Faculty of Ayurveda, IMS BHU, Varanasi.

Source: Nandita Vijay, Pharmabiz, 23.07.2020

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Brinton Pharmaceuticals gets DCGI nod to market Favipiravir Drug

Brinton Pharmaceuticals on Thursday, 23.07.2020 said it has received approval from Drugs Controller General of India (DCGI) to market favipiravir drug under the brand name Faviton for treatment of Covid-19 patients with mild to moderate symptoms. Faviton will be available in 200mg tablets and priced Rs.59 per tablet. It will be available in a strip of 10 tablets and a box of 50 tablets, and will have a 90-day shelf-life.

"We always wanted to launch 'evidence-based cure' to combat Covid-19. Our strategic intent will be to improve the access through our strong distribution network that will help make Faviton available across all COVID treatment centers and our MRP is Rs.59 per tablet," Rahul Kumar Darda, CMD, Brinton Pharmaceuticals said.

Since it is an orally administered medication, it is more convenient compared to intravenously administered medicines. In India, Favipiravir was first approved by regulatory authorities in June under emergency use authorization to treat Covid-19 patients, the company said in an official statement. Company officials said emerging favorable global clinical evidence suggests, favipiravir is an effective treatment option for mild to moderate Covid-19 patients.

Covid-19 has so far claimed nearly 30,000 lives in India with the total number of positive cases touching the 12,41,654 mark. For the second day in a row, recoveries in a single day continue to witness a significant rise. The last 24 hours saw the highest-ever single day recovery and discharge of patients at 29,557. While the total number of recovered cases has jumped to 7,82,606, the recovery rate rose to 63.18%. Higher number of patients getting cured and discharged has contributed to increasing gap between recovered and total active cases which was pegged at 3,56,439 on Thursday, 23.07.2020.

The Union Government continued to coordinate with States and Union Territories by sending central teams of experts to areas witnessing increase in caseload. "The Case Fatality Rate currently in India is 2.41% and further steadily declining. This has also helped in reducing the actual case load of COVID-19 cases which remains confined to 4,26,167 active patients only," said a statement from Union Health Ministry.

Meanwhile, SwasthVayu, a 'Made in India' non-invasive ventilator is being developed by the National Aerospace Laboratories (NAL), Bengaluru in collaboration with Manipal Hospitals, Bengaluru and Council of Scientific and Industrial Research (CSIR) - Institute of Genomics and Integrative Biology (IGIB).

Public health experts have called for further improving the health infrastructure and making medicines available. "Our health infrastructure needs to be revamped significantly as the number of cases is rising and in the future those who would test positive may encounter serious conditions compared to the fact that now many patients have stayed in their residences while under medication and in the process of recovery," said Arup Mitra, a Health Economist and Professor of Economy at Institute of Economic Growth, Delhi University.

Source: Neetu Chandra Sharma, Livemint, 24.07.2020 (Excerpts)

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DoP directs pharma PSUs to clear outstanding dues of MSMEs

The Department of Pharmaceuticals (DoP) has directed Pharma Public Sector Undertakings (PSUs) to clear outstanding dues of Micro, Small and Medium Enterprises (MSMEs) following a media report. The DoP's move came after Chronicle Pharmabiz on June 23, 2020 carried a report stating that Pharma MSMEs have been waiting for clearance of their dues pending with PSUs for years.

The PSU section of DoP had on July 16, 2020 written to Chairman and Managing Director of Indian Drugs and Pharmaceuticals Ltd (IDPL) and Managing Directors of Hindustan Antibiotics Ltd (HAL) and Rajasthan Drugs and Pharmaceuticals Ltd (RDPL) instructing them to take steps to clear dues of Pharma MSMEs. It has been more than 45 days since the instructions regarding release of pending dues of PSUs have been issued by Prime Minister and Finance Minister, Pharma PSUs such as IDPL, HAL, RDPL under DoP are yet to initiate the process of clearing dues of Pharma MSMEs.

Finance Finister Nirmala Sitharaman in May stated that pending dues of MSMEs would be cleared in 45 days to boost their liquidity in the backdrop of Rs. 20 lakh crore economic package announcements. On May 20, 2020 the Finance Ministry directed all concerned administrative ministries of Central Public Sector Enterprises (CPSEs) to instruct their respective CPSEs to release the pending

payments to MSMEs immediately in line with the Government announcement made recently.

Prime Minister Narendra Modi also directed that clearance of all dues pending with PSUs should take place within 45 days to provide relief to MSMEs in distress due to the pandemic.

There are scores of Pharma MSMEs struggling to survive amid mounting losses caused by the Coronavirus pandemic. Most of them are awaiting clearance of their dues pending with Pharma PSUs viz IDPL, HAL, RDPL since years. Jocund India Limited which supplied raw material to IDPL, Rishikesh in 2011 is awaiting dues worth Rs.1,07,14,497.50 since February 2011 and earlier. Medicamen Biotech Limited which supplied raw material to HAL is yet to receive dues of more than Rs. one crore from the Pharma PSU.

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

Source: Laxmi Yadav, Pharmabiz, 21.07.2020

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Department of Pharma raises red flag on over-prescription of Remdesivir, Tocilizumab

In yet another move to ensure there is no scarcity of two drugs used in COVID-19 treatment -- Remdesivir and Tocilizumab, the Department of Pharmaceuticals has raised red flag on over-prescription, adding that over-prescription is leading to the drug being sold at higher prices, Government sources told. "The Department of Pharma has asked Health Ministry urging them to issue Guidelines/advisory or SoPs to curb the over-prescription of these drugs," the sources said.

This move comes after the Department of Pharmaceuticals took cognizance of complaints where doctors in private hospitals were over-prescribing the two drugs. "There have been cases where Remdesivir and tocilizumab have been prescribed even in cases where it is not required and hence we have asked the Health Ministry to work on a mechanism or an advisory through which doctors can be informed about conditions under which the two drugs should be prescribed," the sources said.

"Over-prescription is leading to drugs being sold at higher prices. Even hospitals are selling the drug at higher rates. The two drugs also have side-effects and doctors should consider those as well while prescribing," sources added. Remdesivir has been issued an Emergency Use Authorization (EUA) by the United States Food and Drug Administration (FDA) for the treatment of hospitalized patients with severe COVID-19 illness.

The four companies -- Hetero, Jubilant Life Sciences, Cipla and Mylan NV -- with which Gilead Sciences Inc have entered into non-exclusive licensing agreements have got permission from the Drug Controller General of India (DCGI) for manufacturing and distribution Remdesivir in the country. On July 20, US-headquartered pharmaceutical company Mylan launched Remdesivir under the brand name Desrem in India. The company has also launched a 24x7 helpline where patients and healthcare practitioners can access information about the drug and its availability.

Priced at Rs 4,800 per vial, the drug will be manufactured at the company's state-of-the-heart injectable facility in Bengaluru, which will work to service the demand in India and other export markets where Mylan has received a licence from Gilead for the commercialisation of Remdesivir, the company had said.

There have been many complaints in the past made to the Government regarding scarcity and over-pricing of Remdesivir and Tocilizumab. "While over-prescription of Remdesivir & Tocilizumab by Doctors is definitely a concern and leads to additional demand, it is really the unauthorized supply issue that must be addressed on priority by the Government," said Sachin Taparia, Founder & Chairman, LocalCircles.

Like others, LocalCircles too had raised the issue with the Government regarding overpricing and scarcity of Remdesivir and Tocilizumab in the country. "We have written to the respective Government stakeholders, asking them to consider implementing end to end traceability for drugs and vaccines prone to shortages", continued Taparia.

"The model we have proposed is one where the vaccine or drug manufacturer will have to ensure a functional process exists to mark every via with a unique serial number and barcode which can be scanned and tracked at the 2-3 tiers of the supply chain including at the point of final issuance to patient/hospital along with a digital signature of the doctor administering it. Similarly, the process would work for any issued but unused vials to ensure they don't

end up in the black market, something that was found in some cases of Remdesivir black marketing" said Taparia.

It was in June when the Government, after allowing restricted emergency use of antivirals Remdesivir and Favipiravir in COVID-19 patients, had issued guidance on the manner of supply of drugs to ensure their proper use. The Government had said that Remdesivir injectable formulations allowed for use in severe COVID-19 patients can't be sold off chemist counters and will only be supplied for use directly to hospitals and institutions. Later on, The Delhi Government's Drug Control Department on July 11, 2020, said that COVID-19 drug namely Remdesivir, Tocilizumab, Favipiravir should only be used for emergency purpose and directed the State Drug Controller to keep a strict vigil on the matter and check the selling of these medicines to prevent black marketing.

Source: Timsy Jaipuria, cnbctv18.com, 24.07.2020

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INTERNATIONAL NEWS

COVID-19 vaccines should be made public for global good: WHO Director-General

World Health Organization (WHO) Chief Tedros Adhanom Ghebreyesus on Monday, 20.07.2020 said that political leaders around the world should try to make the Coronavirus vaccines available to everyone "for the public good". Speaking during a press conference at WHO's Switzerland headquarters, he asserted the importance of ensuring equal access for all.

Fair distribution:

"For the fair distribution and specially access to the poor and those who cannot afford, the most important element will be political commitment, especially by our leaders. And with political commitment, of course, that's the only way you can get fair distribution", he said.

He also referred to "worrying patterns" in countries whereby the privilege of the affluent. "But one of the worrying patterns we see is some countries moving the other direction.

And when there is no consensus on having a vaccine, a global public good, it could be actually be owned by those who have money and those who cannot afford it may not have access to the vaccines. Some leaders have already have called and stressed the importance of making, when available, a vaccine or therapeutics global public good," he said.

While further talking about the vaccine, he said that the vaccines must not be seen as "charity" and should indeed be seen as a product for the global public good. Ghebreyesus further claimed that the WHO has formulated and finalised a vaccine distribution framework even before any official vaccine has been approved. Additionally, the WHO Chief added that how the fair distribution of vaccines will benefit the recovery of global economy.

"The advantage of using fairness or access to also poor countries is the world can really be lifted up and lift itself out of this pandemic together, which can speed up the economic recovery and the world, unless it's opened up its major part, I mean unless the whole world is opened up a in this globalized world, it would be a delaying the economic recovery," said Ghebreyesus.

Long way to go:

The emergencies chief of WHO, Michael Ryan said that the two new studies that offered new hope of a potential vaccine for the novel Coronavirus on Monday, 20.07.2020 are a "positive result" but warned that "there is a long way to go". "We now need to move into larger-scale real-world trials.

But it is good to see more data and more products moving into this very important phase of vaccine discovery," Dr Michael Ryan said. Ryan's comments came as scientists at Oxford University claimed their experimental vaccine

had exhibited a protective immune response in hundreds of people who received the vaccine.

Source: Wionews, 21.07.2020

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UK secures deals for 90m doses of Coronavirus Vaccine

The UK Government is investing millions to secure two more experimental vaccines against Covid-19, increasing the chances of obtaining a vaccine that works for the population. The agreement is to buy 90m doses of two vaccines, which would be enough to immunise frontline health workers and care staff, who will be the priority. The Government is effectively hedging its bets – the two vaccines work in a different way from the Oxford vaccine, of which it has already bought 100m doses.

It is also urging the public to sign up to take part in trials of Covid-19 vaccines, in the hope of having 500,000 people registered as willing to take part by October.

The Business Secretary, Alok Sharma, said the UK had signed a deal to buy 30m doses of the mRNA vaccine being developed by the German Company BioNTech with the pharmaceutical company Pfizer.

The companies recently announced positive results from Phase 1 trials, which show it is safe and produces an immune response – although with some side-effects at higher doses. The other vaccine is being developed by the French company Valneva, which unlike Oxford and BioNTech has not been viewed as one of the early front runners in vaccine research. The agreement is to buy 60m doses – in principle. If the vaccine is proven to be safe, effective and suitable, the UK has secured an option to acquire a further 40m doses.

"The hunt to find a vaccine is a truly global endeavour and we are doing everything we can to ensure the British public get access to a safe and effective Coronavirus vaccine as soon as possible," said Sharma.

"This new Partnership with some of the world's foremost pharmaceutical and vaccine companies will ensure the UK has the best chance possible of securing a vaccine that protects those most at risk."

Effectively three different approaches to making a vaccine are now covered. The Oxford/AstraZeneca vaccine is an adenoviral vaccine. More data on the early trials of the Oxford vaccine is expected later on Monday, 20.07.2020 and is likely to be promising. The BioNTech/Pfizer candidate is an mRNA vaccine – as is the vaccine being developed by Imperial, which has received research funding from the UK Government and entered human trials last month. These use the genetic code rather than the virus itself.

Valneva is working on a more traditional approach, using a whole inactivated virus. The Company works on vaccines to prevent neglected diseases that cause major disease burdens in some of the less wealthy countries of the world, such as the chikungunya virus. It also produces more lucrative vaccines for travellers, including Dukoral against cholera. Its Covid-19 vaccine uses the manufacturing technology for its Japanese encephalitis vaccine.

Part of the UK Government's enthusiasm for the Valneva vaccine is because its factory is located in Livingston, Scotland. The UK Government will contribute to the costs of Valneva's UK Clinical Trials and is negotiating funding to expand the Scottish factory, creating more jobs and boosting the local economy, it says.

The Government has launched a register for people who are willing to take part in the vaccine trials and is urging them to sign up. "A safe and effective vaccine is our best hope of defeating Coronavirus and returning to life as normal," said the Health Secretary, Matt Hancock.

"We have some of our best Scientists and Researchers working on this, but members of the public have a vital role to play too. So I urge everyone who can to back the national effort and sign up to the NHS Covid-19 vaccine research registry to help find a vaccine as soon as possible.

"Every volunteer will be doing their bit towards finding a vaccine for Covid-19 that will have the potential to save millions of lives around the world and bring this pandemic to an end." Chris Whitty, the Chief Medical Officer for England, said: "Thanks to Covid-19 patients' willingness to take part in treatment studies, we've been able to identify treatments that work and ones that don't, which has improved patient care world-wide.

"Now that there are several promising vaccines on the horizon, we need to call again on the generosity of

the public to help find out which potential vaccines are the most effective. Using a new NHS website developed in partnership between the National Institute for Health Research (NIHR) and NHS Digital, people across the UK can register their interest to be approached to join a vaccine study. Please go to the website and consider volunteering."

Source: Sarah Boseley,The Guardian, 20.07.2020 (Excerpts)

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Coronavirus: Oxford vaccine triggers immune response

A Coronavirus vaccine developed by the University of Oxford appears safe and triggers an immune response. Trials involving 1,077 people showed the injection led to them making antibodies and Tcells that can fight Coronavirus.

The findings are hugely promising, but it is still too soon to know if this is enough to offer protection and larger trials are under way. The UK has already ordered 100 million doses of the vaccine.

How does the vaccine work?

The vaccine - called ChAdOx1 nCoV-19 - is being developed at unprecedented speed. It is made from a genetically engineered virus that causes the common cold in chimpanzees. It has been heavily modified, first so it cannot cause infections in people and also to make it "look" more like Coronavirus.

Scientists did this by transferring the genetic instructions for the Coronavirus's "spike protein" - the crucial tool it uses to invade our cells - to the vaccine they were developing. This means the vaccine resembles the Coronavirus and the immune system can learn how to attack it.

What are antibodies and T-cells?

Much of the focus on Coronavirus so far has been about antibodies, but these are only one part of our immune defence. Antibodies are small proteins made by the immune system that stick onto the surface of viruses.

Neutralising antibodies can disable the Coronavirus. T-cells, a type of white blood cell, help co-ordinate the immune system and are able to spot which of the body's cells have been infected and destroy them. Nearly all effective vaccines induce both an antibody and a T-cell response.

Image copyright Oxford University. Image caption Sample from patients are analyzed as part of the trial.

Levels of T-cells peaked 14 days after vaccination and antibody levels peaked after 28 days. The study has not run for long enough to understand how long they may last, the study in the Lancet showed. Prof Andrew Pollard, from the Oxford research group told the BBC: "We're really pleased with the results published today as we're seeing both neutralising antibodies and T-cells.

"They're extremely promising and we believe the type of response that may be associated with protection. "But the key question everyone wants to know is does the vaccine work, does it offer protection... and we're in a waiting game."

The study showed 90% of people developed neutralising antibodies after one dose. Only ten people were given two doses and all of them produced neutralising antibodies. "We don't know the level needed for protection, but we can maximise responses with a second dose," Prof Pollard told the BBC.

Is it safe?

Yes, but there are side-effects. There were no dangerous side-effects from taking the vaccine, however, 70% of people on the trial developed either fever or headache. The researchers say this could be managed with paracetamol. Prof Sarah Gilbert, from the University of Oxford, UK, says: "There is still much work to be done before we can confirm if our vaccine will help manage the Covid-19 pandemic, but these early results hold promise."

What are the next steps in the trial?

The results so far are promising, but their main purpose is to ensure the vaccine is safe enough to give to people. The study cannot show whether the vaccine can either prevent people from becoming ill or even lessen their symptoms of Covid-19.

More than 10,000 people will take part in the next stage of the trials in the UK. However, the trial has also been expanded to other countries because levels of Coronavirus are low in the UK, making it hard to know if the vaccine is effective.

There will be a large trial involving 30,000 people in the US as well 2,000 in South Africa and 5,000 in Brazil. There are also calls to perform "challenge trials" in which vaccinated people are deliberately infected with Coronavirus. However, there are ethical concerns due to a lack of treatments.

When will I get a vaccine?

It is possible a Coronavirus vaccine will be proven effective before the end of the year, however, it will not be widely available. Health and care workers will be prioritised as will people who are deemed at high risk from Covid-19 due to their age or medical conditions.

However, widespread vaccination is likely to be, at the earliest, next year even if everything goes to plan. Boris Johnson said: "Obviously I'm hopeful, I've got my fingers crossed, but to say I'm 100% confident we'll get a vaccine this year, or indeed next year, is, alas, just an exaggeration. "We're not there yet."

What progress is being made with other vaccines?

The Oxford vaccine is not the first to reach this stage, with groups in the US and China also publishing similar results. The US Company Moderna was first out of the blocks and its vaccine can produce neutralising antibodies.

They are injecting Coronavirus RNA (its genetic code), which then starts making viral proteins in order to trigger an immune response. The companies BioNtech and Pfizer have also had positive results using their RNA vaccine.

Source: James Gallagher, Health and Science Correspondent, BBC News, 20.07.2020 (Excerpts)

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