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IDMA BULLETIN

VOL. NO. 52 | ISSUE NO. 11 (PAGES: 40) | 15 TO 21 MARCH 2021 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

IDMA and **APTAR Pharma** jointly organizing a Webinar on **"Rethinking Active Packaging: Derisking Drug Product Stability with Novel Material Science Solutions"** on **Tuesday, 30th March 2021** at **4.00 p.m.**

(More details on Page No. 37)

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 52 **Issue No. 11** **14 to 21 March 2021**

Life Science Companies Investing Billions in North Carolina

In a flurry of expansions, International Pharmaceutical and Medicine Manufacturing companies announced $2.3 billion in facilities investment in North Carolina in 2020.

The 10 announcements began with Eli Lilly and Company's decision to build a $474 million plant that will provide drug formulation, finishing and packaging for its products - initially focusing on two diabetes treatments. Thermo Fisher Scientific wrapped up the year with a $500 million plan to expand its sterile drug product development and commercial manufacturing of critical medicines, therapies and vaccines.

In between, Grifols Therapeutics announced an expansion of its blood plasma operations. Merck is building a facility to produce its bladder cancer drug. ApiJect Systems is planning a "gigafactory" with a potential cost of $785 million and able to produce 3 billion single-dose injectables annually. Emerging gene-and cell-therapy companies are planning more than $250 million in facilities.

These announcements - creating 2,800 jobs - mean significant growth in North Carolina's already strong life sciences workforce. At the end of 2020, more than 30,000 people were employed in life sciences production and manufacturing companies. They make an array of products including small-molecule pharmaceuticals, monoclonal antibodies, industrial enzymes, vaccines, and cell-and gene-based therapies.

"Life sciences is a leading sector in North Carolina's overall strong economy," said Christopher Chung, Chief Executive Officer of the Economic Development Partnership of North Carolina (EDPNC), which supports companies seeking to invest in North Carolina.

"Our biotech and life science project wins in 2020 included high-quality and diverse manufacturers on the cutting edge of innovation," Chung added. "Last year's results show we are a state known for forging new technologies and therapies, both in developing and making those products here in North Carolina."

North Carolina's pharmaceutical manufacturing companies are supported by a portfolio of Rresearch and Development companies, Contract Research Testing, and Broader Support companies. All combined, North Carolina's life sciences sector includes 775 companies with 67,000 employees, with another 2,500 experienced in supporting life sciences.

The cluster's key ingredient for success is a talented workforce. Each year, North Carolina's universities award 4,900 life sciences and 4,500 engineering degrees. The NCBioImpact training partnership brings together university and community college educators with industry to produce industry-specific training programs. The NC Community Colleges deliver customized training programs, including for incumbent workers. North Carolina State University's Biomanufacturing Training and Education Center provides hands-on training in a simulated cGMP environment. The Biomanufacturing Research Institute and Technology Enterprise at North Carolina Central University conducts research on biomanufacturing processes. And the NC Pharmaceutical Services Network delivers training that includes short courses tailored to oral solid dose production.

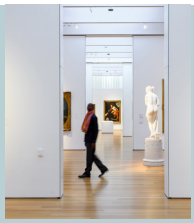
Training programs are key for companies such as FUJIFILM Diosynth Biotechnologies, which began a $54 million expansion in North Carolina in 2020. The 31,778-square-foot facility will increase the company's capacity for cell culture and microbial production. FUJIFILM is also one of the US leaders in the fight against the COVID-19 pandemic, partnering to produce the Novavax vaccine. Vaccine producers Pfizer and Merck also have production facilities in North Carolina.

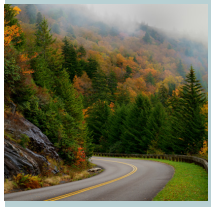
The robust growth in pharmaceutical and biologics manufacturing in 2020 helped North Carolina win the top "2020 State of the Year" honor from Business Facilities magazine. The honor recognizes the state's success in winning projects that create capital investment and new jobs.

"Our world-class academic base, our long-term commitment to workforce development, our magnetic business climate are proving to be increasingly attractive to companies choosing to make major investments in relocation and expansion," said Bill Bullock, Senior Vice President of Economic Development and Statewide Operations for the North Carolina Biotechnology Center, a state-funded nonprofit dedicated to growing the state's life sciences cluster.

Indian companies interested in North Carolina should contact **Rahul Padmanabha**, Director of investment for EDPNC's India office: **rahul.padmanabha@edpnc.com** or **+91 914 899 1212.** For more information, visit **EDPNC.com/India**





IT'S ALMOST UNFAIR TO THE OTHER 49 STATES.

Work. Life. And everything that makes both fulfilling. You'll find open minds, open spaces and open opportunities in North Carolina. Ranked #1 for business by Forbes three years running, with the lowest corporate tax rate in the US, low costs of doing business, and cost of living almost 5% below the national average.

Here you'll find a biotechnology ecosystem that runs deep and wide, across more than 775 companies and 67,000 employees, fueled by a highly educated workforce, major research universities and significant private sector R&D investment.

The EDPNC can connect you with available sites; in-depth workforce, community and infrastructure data; potential supply chain partners; and information on our incentives packages.

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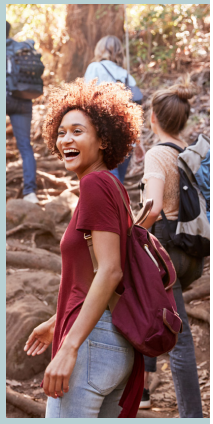



ALL IN NORTH CAROLINA

ECONOMIC DEVELOPMENT PARTNERSHIP of NORTH CAROLINA




MoEF&CC approves Environmental Clearance for API and Intermediates as Single category instead of individual Products - reg.

MoEF&CC Office Memorandum Ref.F.No.22-33/2019-IA.III, dated 28th January 2021

1. *Chairman/Member Secretaries of all the Expert Appraisal Committees,*
2. *Chairperson/Member Secretaries of all the SEIAAs/ SEACs,*
3. *All the Officers of IA Division.*

1. The Ministry is in receipt of representations for issuance of Prior Environmental Clearance under the provisions of EIA Notification, 2006 and subsequent amendments, for the 'API and Intermediates' as single category instead of individual products in order to provide flexibility to the industry to change the raw material mix and/or product mix within the sanctioned pollution load.

2. The matter has been examined in the Ministry. It is hereby directed that henceforth all the EACs/SEACs shall appraise the proposals for Prior Environmental Clearance under the provisions of EIA Notification, 2006 and subsequent amendments under the category of the schedule of EIA Notification, 2006, for the 'API and Intermediates' as single category instead of individual products. Accordingly, the EAC/ SEAC shall clearly recommend the permissible pollution load i.e. quantity and quality, including composition, of emissions, discharges and solid waste generation from such activity for inclusion in the Prior Environmental Clearance.

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

Sharath Kumar Pallerla, Director-IA (Policy), Impact Assessment Division, Ministry of Environment, Forest and Climate Change, New Delhi.

IDMA and BDMAI Joint Submission on Environmental Approvals – regarding Bulk Drug Industry

IDMA and BDMAI have made a joint submission on 1sr February 2021 to Shri Rameshwar Prasad Gupta, IAS, Secretary, Ministry of Environment, Forest & Climate Change (MoEFCC), New Delhi with copy to Ms S Aparna, IAS, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi as below:

"We thank you for the MoEF&CC Office Memorandum F.No.22-33/2019-IA.III dated 28.01.2021, confirming future appraisals of all proposals for Environmental clearance under provisions of EIA Notification 2006 and subsequent amendments under the category of the schedule of EIA Notification 2006 for the "API and Intermediates" as single category instead of individual products. *(The Office Memorandum is published in IDMA Bulletin issue dated 30 January 2021 - page no.17)*

This was a long pending request of Pharma Industry and it is a very welcome step in the right direction, which will help accelerate growth of API industry. While the notification refers to only "Prior Environmental Clearance….and subsequent amendments", it is silent as to how currently valid/under renewal EC/ CTE / CTO mentioning individual products can be converted into single category documents. There are also no specific guidelines for SPCBs to this effect. As the wording stands, only a handful of new (greenfield) units, and those whose EC is up for amendment will get benefit of this notification while omitting most of the existing units with valid EC/CTE /CTO. Thus, our request for a corrigendum to this OM laying down simple procedure for existing / under renewal ECs / CTEs / CTOs for amendment from existing individual product names to a single category. Unless this is done,

all the good intentions of MoEF will remain just on paper with no immediate relief at the ground level to majority of API manufacturers.

Further, the OM is silent on issue of "removal of cap on Production quantity". It was agreed as per Minutes against Issue-1 (see below) that only the quantity and quality of effluent (pollution load) need to be regulated.

Decision: The Secretary, EF&CC has agreed in-principle and directed to initiate amendment in EIA Notification, 2006 regarding permitting the change in product mix or raw material mix including no cap on increase in the production quantity without prior environmental clearance as long as there is 'no increase in pollution load'……

We assume that this will be covered in soon to be announced comprehensive amendment to EIA Notification 2006, if not we request that a separate OM be issued on this subject.

Some other issues were also discussed in this meeting regarding change of "Product Mix" for which we hope similar OMs are in the offing. As regards the simplification of application forms for ToR and EC, we have already shared our suggestions with Secretary, Pharmaceuticals and hope the same must have been forwarded to you by now. We look forward to a meaningful discussion on the same with your officials at their earliest convenience.

We once again thank you very much for your kind acceptance of our proposals for simplification of operating procedures without effecting the cause of environmental protection."

IDMA & BDMAI joint representation on 09.03.2021 to Shri Rameshwar Prasad Gupta, IAS, Secretary, Ministry of Environment, Forest & Climate Change with copy to Ms S Aparna, IAS, Secretary, Department of Pharmaceuticals, New Delhi

"We thank you for OM dated January 28, 2021 and current Notification No.S.O.980(E) dated 02.03.2021 whereby all fresh ECs are to be issued as single category of "API & Intermediates" and all manufacturing units are exempted from requirement of prior EC for increase in production quantity/modernizations/change of product mix/change of equipment as long as pollution load remains the same as certified by Competent Designated Authority.

This Notification will help the expansion plans of the MSMEs as they will be exempted from requirement of prior EC as long as pollution load remains the same. We appreciate this initiative.

Although, with this Notification our concerns regarding delays in expansion of production capacity on account of issuance of EC are suitably addressed, for the benefit to percolate to the ground level, these relaxations need to be further integrated with other documents such as:

(a): Consent to Establish (CTE).

(b): Consent to Operate (CTO).

Both these documents are issued by State Pollution Control Boards (SPCBs). OM and the Notification do not make any mention as to how these documents will be integrated with the changes as notified.

Further, these changes are applicable only to new ECs, and existing ones which are coming up for renewal, thereby effectively omitting vast number which are not due for renewal. Simple procedure needs to be laid down for amendment of all existing ECs to single category as "API & Intermediates". The effect will be prospective. Same will be the need for existing CTEs and CTOs. Necessary amendments are needed for EC/CTE/CTO.

We request you to kindly issue the necessary Guidelines/Directions to all SPCBs to adopt and integrate the changes in their operational document.**"**

IDMA & BDMAI Joint Representation to Secretary, Department of Pharmaceuticals on Environmental Issues – reg.

IDMA and BDMAI jointly submitted the following representation on 12th March 2021 to Ms S Aparna, IAS, Secretary, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi on Environmental Issues in response to Office Memorandum No.22-33/2019.IA.III, dated 28.01.2021 of MoEF&CC:

"Greetings from Indian Drug Manufacturers' Association.

You will recollect that we had forwarded to you our representation to Secretary, Environment on the subject of Office Memorandum dated 28th January 2021, as above reference 2, which provides for new Environmental Clearance (EC) and existing ones coming for renewal, to be issued for single category of "API & Intermediates" which will be pollution load based without being Product and Production Volume specific. We had also informed you that this effectively leaves out vast majority of ECs which were issued or were under consideration by MoEF&CC/ State Environment Impact Assessment Authorities (SEIAAs) prior to date of this Office Memorandum. A simple procedure needs to be laid down for these to be suitably amended to reflect the flexibility as now available as per the Office Memorandum.

We have been informed that permitting changes in existing Environmental Clearances would amount to "retrospective amendment" and that is why MoEF cannot do so. We fail to understand how this would be so. Amendment would be effective from the date made "prospectively". We would greatly appreciate your taking up this matter with the Secretary, Environment, as it is very important that a solution be found at the earliest.

Further, on 02.03.2021 MoEF&CC has issued another Notification which also addresses one of our long pending request for allowing "changes" in production/products "without prior EC", as long as Pollution Load remains unchanged.

Unfortunately, both documents refer only to EC and there is no mention of the State level subsequent permissions such as Consent to Establish (CTE) and Consent to Operate (CTO). We understand that both these being State subjects, MoEF&CC is not in a position to direct the States by a Central Circular. We feel that the Centre can at least write to the States for doing the needful by making suitable amendments in States' regulations.

Without the States also making necessary and timely amendments, industry will not get benefit as desired by MoEF&CC. We request DoP to suitably communicate with at least the States where there is major concentration of API units (Andhra Pradesh, Telangana, Karnataka, Punjab, Maharashtra, Gujarat, Tamil Nadu, Madhya Pradesh) by explaining the need for them to also make these changes in the procedure followed by them at the operational level to integrate the same with relaxations as in case of EC.

For your kind information we are also attaching copy of our letter dated 9th March 2021 addressed to Secretary, Environment on the same subject. Thanking you and with best regards".

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MoEF&CC Notification *re.* Environmental Clearance - reg.

Gazette Notification No.S.O.1247(E), dated 18th March, 2021

Whereas, the Central Government in the erstwhile Ministry of Environment and Forests, in exercise of its powers under sub-section (1) and clause (v) of sub-section (2) of section 3 of the Environment (Protection) Act, 1986 has published the Environment Impact Assessment Notification, 2006 (hereinafter referred to as the EIA notification) vide number S.O.1533(E), dated the 14th September, 2006, making the requirement of prior environmental clearance, from the concerned regulatory authority, mandatory for all new projects or activities listed in the Schedule to the EIA notification, their expansion and modernization and/or change in product mix, as the case may be;

AND whereas, paragraph 9 of EIA Notification, 2006 and subsequent amendments defines the validity of Environmental Clearances for different class of projects or activities;

AND whereas, the Central Government deems it necessary to provide certain provisions for the projects which have not been able to complete the construction and commissioning of the proposed activities within the validity period of the Environmental Clearance granted and have submitted de-novo due to the expiry of the validity of the Environmental Clearance.

Now, therefore, in exercise of powers conferred by sub-section (1) and clause (v) of sub-section (2) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government hereby makes following further amendments in the notification of the Government of India, in the erstwhile Ministry of Environment and Forests, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii) vide number S.O. 1533 (E), dated the 14th September, 2006, namely:-

In the said notification, in paragraph 7, in sub-paragraph 7(i), under the sub-heading number II, Stage (2) – Scoping, after the serial number (ix), the following shall be inserted, namely:-

"(x) Notwithstanding anything contained above, the projects where construction and commissioning of proposed activities have not been completed within the validity period of the Environmental Clearance (EC) and a fresh application for EC has been submitted due to expiry of the said period of the EC, the concerned Expert Appraisal Committee or State Level Expert Committee, as the case may be, may exempt the requirement of public hearing subject to the condition that the project has been implemented not less than fifty percentage in its physical form or construction".

F.No. 22-37/2020-IA.III

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

Note: *The Principal Notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii) vide number S.O. 1533 (E), dated the 14th September, 2006 and was last amended vide the Notification Number S.O. 980(E), dated 2nd March, 2021.*

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Draft of Plastic Waste Management (Amendment) Rules, 2021 published - reg.

Gazette (Environment) Notification No.G.S.R.169(E), dated 11th March 2021

The following draft notification which the Central Government proposes to issue, in exercise of the powers conferred by sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), for making certain amendments in the Plastic Waste Management Rules, 2016, issued vide G.S.R.320(E), dated the 18th March, 2016, is hereby published as required under sub-rule (3) of rule 5 of the Environment (Protection) Rules, 1986, for information of the public likely to be affected thereby and notice is hereby given that the said notification will be taken into consideration by the Central Government on or after the expiry of sixty days from the date on which copies of this notification as published in the Gazette of India are made available to the public;

Any person interested in making any objection or suggestion on the proposals contained in the draft notification may do so in writing within the period so specified through post to the Secretary, Ministry of Environment, Forest & Climate Change, Indira Paryavaran Bhawan, Jor Bagh Road, Aliganj, New Delhi - 110 003 or electronically at email address: **satyendra.kumar07@nic.in**, **amit.love@nic.in.**

DRAFT NOTIFICATION

Whereas, the Plastic Waste Management Rules, 2016 were notified by Ministry of Environment, Forest and Climate Change vide G.S.R.320(E), dated the 18th March, 2016 bringing new provisions for effective and improved

collection, segregation, processing, treatment and disposal of the plastic waste in an environmentally sound manner thereby, reducing the plastic waste generation and its impact on the environment;

Whereas, the Rules, inter alia, prohibit the use of plastic bags, sheets or like with thickness less than 50 microns. Also sachets using plastic material, as per the Rules, shall not be used for storing, packing or selling gutkha, tobacco and pan masala.

Whereas, many State Governments through their own notifications have imposed partial or complete ban on the use of plastic carry bags/single-use plastic items in their respective States.

Whereas, a preliminary analysis of the State level action on restriction/prohibition of plastic carry bags and some single-use plastic items suggests that many challenges have been faced in the implementation of these regulatory provisions. However, some States have reportedly achieved considerable success.

Whereas, considering the high environmental costs associated with management of single-use plastics, particularly the adverse effect on marine environment, and the need for a definitive action supplementing the initiative undertaken by various States/UTs to combat plastic pollution, it is proposed that a prohibition on the manufacture, use, sale, import and handling of some of the single-use plastic items may be imposed on a pan India basis.

Now, therefore, in the exercise of the powers conferred by sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), read with clause (d) of sub-rule (3) of rule 5 of the said Environment (Protection) Rules, 1986 the Central Government hereby publishes this draft notification as required under sub-rule 3 of rule 5 of the said Environment (Protection) Rules, 1986, which shall on and from the date of its final publication make the following amendments in the said notification, namely:-

1. (1) These rules may be called **Plastic Waste Management (Amendment) Rules, 2021.**

(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the said rules, in Rule 2(1), after the word Importers, the word, “brand-owner”, “plastic waste processor (recycler, co-processor, etc.)” shall be inserted.

3. In the said rules, in rule 3,

i. after clause (n), the following clause shall be inserted namely:-

“(na) Non-woven plastic bag-Non-woven plastic bag is made up of sheet or web structured fabric of entangled fibers or filaments (and by perforating films) bonded together by mechanical or thermal or chemical means. The Non-woven fabric is a flat or tufted porous sheet that is made directly from fibres, molten plastic or plastic films.”

after clause (q), the following clause shall be inserted namely:-

“(qa) Plastic Waste Processing - means any process by which plastic waste is handled for the purpose of reuse, recycling, co-processing or transformation into new products.

iii. after clause (v), the following clause shall be inserted namely:-

“(va) Single-use plastic item.”

“is a plastic commodity intended to be used once for the same purpose before being dispose of or recycled.”

iv. after clause (v), the following clause shall be inserted namely:-

(vb) Thermoset plastic-is a plastic which becomes irreversibly rigid when heated, and hence cannot be remoulded into desired shape.

v. after clause (vb), the following clause shall be inserted namely:-

(vc) Thermoplastic – is a plastic which softens on heating and can be moulded into desired shape.

4. In the said rules, in rule 4,-

i. In sub-rule (1) clause (c), the word 'fifty' may be read as 'one hundred and twenty (120) with effect from 30.09.2021'

ii. In sub-rule (1) clause (h), after the words, “carry bags”, the words, “and commodities” is inserted.

iii. In sub-rule (1) clause (h), after the words, “compostable plastic carry bags”, the word, “and/or commodities” is inserted.

iv. After sub-rule (1) clause (i), following clause shall be inserted:

j. Each sheet of non-woven plastic carry bag shall not be less than 60 (GSM per square meter) or 240 microns in thickness with effect from 30.09.2021.

5. In the said rules, in rule 4, following sub-rule shall be inserted:

(1) The manufacture, import, stocking, distribution, sale and use of following single-use plastic commodities shall be prohibited from 1st January, 2022: Ear buds with plastic sticks, plastic sticks for balloons, plastic flags, candy sticks, ice-cream sticks, polystyrene [Thermocol] for decoration.

(2) the manufacture, import, stocking, distribution, sale and use of following single-use plastic commodities shall be prohibited from 1st July, 2022:

i. single-use plastic (including polystyrene and expanded polystyrene) items:

plates, cups, glasses, cutlery such as forks, spoons, knives, straw, trays, wrapping/ packing films around sweet boxes; invitation cards; and cigarette packets, plastic/PVC banners less than 100 micron, stirrers.

ii. the above provision shall not apply to commodities (including carry bags) made of compostable plastic material.

6. In the said rules, in rule 5, sub-rule (1), clause (d), the word "2000" may be read as "2016".

7. In rule 6, sub-rule (2), after clause (a), following clause is inserted:-

(a1) Ensuring that provisions pertaining to restrictions/ prohibition on single-use plastics are adhered to.

8. In rule 7, sub-rule (1), after clause (a), following clause is inserted:-

(a1) Ensuring that provisions pertaining to restrictions/ prohibition on single-use plastics are adhered to.

9. In the said rules, in rule 9,-

i. under sub-rule (1) after the words, "local body concerned", the words, "as per guidelines issued from time to time under these Rules" is inserted.

10. In rule 11, sub-rule (1).

a. after the words 'plastic carry bag' the words 'plastic packaging' shall be inserted.

b. in clause (a), for the words 'manufacturer' the words 'producer/brand-owner' shall be inserted and after the word 'carry bag' the words 'plastic packaging used by the brand owner' shall be inserted

c. in clause (b), after the words 'multilayered packaging' the words '(excluding multilayered packaging used for imported goods)' shall be inserted.

d. in clause (c), after the words 'name and certificate number' the word 'of producer' shall be inserted.

10. In rule 12-

a. in sub-rule (2), after the words 'waste generator' the words 'restriction/prohibition on' shall be inserted.

b. in sub-rule (3), after the words 'waste generator' the words 'restriction/prohibition on' shall be inserted.

11. In rule 13,

a. in Sub-Rule (1) after the word Union Territory concerned the word 'or the Central Pollution Control Board' is inserted.

F.No.17-2-2001 (Pt)-Part I-HSMD

Naresh Pal Gangawar,
Joint Secretary,
Ministry of Environment,
Forest and Climate Change,
New Delhi.

Note:

i. The Principal Rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number GSR 320(E), dated the 18th March, 2016.

ii. Plastic Waste Management (Amendment) Rules, 2018, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number GSR 285(E), dated the 27th March, 2018.

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Advisory Board for Prevention of illicit Traffic in NDPS – reg.

Gazette Notification No.G.S.R.193(E), dated 16th March 2021

1. In exercise of the powers conferred by clause (a) of Section 9 of the Prevention of Illicit Traffic in Narcotic Drugs and Psychotropic Substances Act, 1988 (46 of 1988) and in supersession of the Notification of the Government of India, Ministry of Finance, Department of Revenue No. G.S.R.182(E), dated 17th March, 2020 except as respects things done or omitted to be done before such supersession, the Central Government hereby constitutes an Advisory Board for a period of one year, consisting of :-

2. (i): Hon'ble Mr Justice D N Patel, Chief Justice, Chairperson.

(ii): Hon'ble Mr Justice J R Midha, Member

(iii): Hon'ble Mr Justice C Hari Shankar, Member

3. This Notification shall come into force with effect from **23rd March, 2021.**

F.No.U-11016/01/2011-PITNDPS

Surendra Kumar Gupta, Director (PITNDPS), Department of Revenue, Ministry of Finance, New Delhi.

Footnote: *The Notification No.G.S.R. 182(E) dated 17th March, 2020 was published in the Gazette of India (Extraordinary) Part II, Section 3, Sub-section (i) on 17th March, 2020.*

● ● ●

DPCO, 2013: Monitoring of MRP of Medical Devices notified/regulated as 'Drugs' under D&C Act, 1940 and the D&C Rules, 1945 - reg.

NPPA Addendum/Order dated 12th March, 2021

To:

All Manufacturers/Importers of non-scheduled Medical Devices (24 categories);

Medical Devices Industry Associations namely MTaI, AiMeD, CII, FICCI, USIBC, AMCHAM, AdvaMed with a request to disseminate this OM among Member Companies and ensure compliance of the same.

1. The undersigned is directed to refer to the Office Memorandum dated 16th February 2021 issued by National Pharmaceutical Pricing Authority (NPPA) on the captioned subject wherein it was directed to submit price related information in the prescribed format for 24 categories of non-scheduled Medical Devices for the period specified therein.

2. In this connection, NPPA has received representation from various Companies/Industry Associations seeking extension of the date for submission of the requisite data. It has also been requested that requirement of CA/CMA certification of the data may be relaxed.

3. A Consultation was held with the Industry Associations on 11th March 2021 in the matter and it has been agreed to extend the time line upto **15th April 2021** for submissions to be made in compliance of the abovementioned OM.

4. Further, the information can also be submitted duly certified by the Chief Financial Officer (CFO) of the Company. It is, however, emphasized that the onus of the authenticity of the data submitted shall rest with the Company concerned.

5. The data is to be submitted from the year in which a particular Medical Device was notified.

6. The data submitted in response to the OM dated 16th February 2021 shall be used as per the mandate of Drugs (Prices Control) Order, 2013.

File No.20(8)/09/20 19/Div.III/NPPA

Alok Ranjan, Asst. Director (Med. Dev.), National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

● ● ●

NPPA fixes retail prices of 3 formulations after expiry of exemption granted under para 32 of DPCO, 2013 based on the decision of 84th Authority meeting dated 10.03.2021 - reg.

NPPA Notification No.S.O.1235(E), 17th March, 2021

In exercise of the powers conferred by paragraphs 5, 11 and 15 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S. O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA), hereby fixes, the price as specified in column (6) of the table herein below as the retail price, exclusive of Goods and Services Tax, if any, in relation to the formulation specified in the corresponding entry in column (2) of the said Table with the strength, unit and name of manufacturer & marketing company, as specified in the corresponding entries in columns (3), (4) and (5) thereof;

TABLE

Sr. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Prasugrel Hydrochloride + Aspirin Capsule	Each capsule contains: Prasugrel Hydrochloride 10 mg (as film coated), Aspirin 75 mg (as enteric coated)	1 Capsule	M/s Torrent Pharmaceuticals Pvt. Ltd.	20.16
2.	Insulin Human Injection	Insulin Human Injection, 200IU/ml	1 ML	M/s Wockhardt Ltd	106.65
3.	Isophene Insulin Human Suspension + Insulin Human Injection	70% Isophene Insulin Human Suspension and 30% Insulin Human Injection, 200IU/ml	1 ML	M/s Wockhardt Ltd	106.65

Note:

(a) The manufacturer of above mentioned formulations i.e. "new drug" under paragraph 2(u) of the DPCO, 2013 shall fix the retail price as specified in column (6) of the table hereinabove.

(b) The manufacturer may add goods and services tax only if they have paid actually or it is payable to the Government on the retail price mentioned in column (6) of the above said table.

(c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (6) of the above table as per provisions contained in paragraph 11 of the DPCO, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(d) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(e) The above mentioned retail price is applicable only to the individual manufacturer / marketer as mentioned above i.e. who have applied for the same by submitting Form-I for price fixation / revision as stipulated under DPCO, 2013 and subject to fulfilment of all the applicable statutory requirements as laid down by the Government under relevant statutes/ rules, including manufacturing license permission from the Competent Authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturer/marketing companies.

(f) In case the retail price of any of the aforesaid formulations is not complied with, as per instant price notification and notes specified hereinabove, then the concerned manufacturer/marketing company shall beliable to deposit the overcharged amount along with the interest thereon under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.

(g) Consequent to the issue of ceiling price of such formulation as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

PN/216/84/2021/F

F.No. 8(84)/2021/D.P/NPPA-Div-IIs

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

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Extension of revised ceiling price of Heparin Injection based on the decision of 84th Authority Meeting - reg.

NPPA Notification No.S.O.1236(E), dated 17th March, 2021

1. The ceiling prices of Heparin Injection 1000IU/ml and Heparin Injection 5000IU/ml fixed under Para 19 of the DPCO, 2013 vide notification S.O. 2151(E) dated 30.06.2020 and extended upto 31.03.2021 vide S.O. 4333(E) dated 03.12.2020, issued by National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India are further extended upto 30.09.2021 or until further order, whichever is earlier.

2. All the notes and other contents mentioned in the original order S.O. 2151(E) dated 30.06.2020 read with extension order S.O.4333(E) dated 03.12.2020 shall remain the same and are applicable except that in Para 6, Notes (a) and Note (k) for the phrase "31st March 2021" it is to be read as "30th September 2021 or until further order, whichever is earlier".

PN/216/84/2021/F

F.No.8(84)/2021/D.P/NPPA-Div-II

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

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Extension of WPI on the S.O. 4538(E) dated 18.12.2019 of Drugs (Prices Control) Order, 2013 based on the decision of 84th Authority Meeting - reg.

NPPA Notification No.S.O.1237(E), dated 17th March, 2021

1. In the S.O. 4538(E) dated 18.12.2019, for the phrase "The price of the Synchrobreathe Inhaler Device as specified in column (5) of the above said table would remain fixed irrespective of the subsequent change in the ceiling price of the formulation (a) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI and (b) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI of M/s Cipla Ltd." mentioned in Note (e) it is to be read as follows "The price revision based on Wholesale Price Index (WPI) as per para 16 of DPCO, 2013 would be applicable on the price of the Synchrobreathe Inhaler Device as specified in column (5) of the above said Table from the next year".

2. All other notes and contents mentioned in the S.O. 4538(E) dated 18.12.2019 shall remain the same and are applicable.

PN/216/84/2021F

F.No.8(84)/2021/D.P/NPPA-Div-II

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

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Extension of WPI on the S.O. 4539(E) dated 18.12.2019 of Drugs (Prices Control) Order, 2013 based on the decision of 84th Authority Meeting - reg.

NPPA Notification No.S.O. 1238(E), dated 17th March, 2021

1. In the S.O. 4539(E) dated 18.12.2019, for the phrase "The price of the digital dose counter as specified in column (6) of the above said table would remain fixed irrespective of the subsequent change in the ceiling price of the formulation (a) Budesonide 100mcg+ Formeterol 6mcg per dose Inhaler 120 MDI (b) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI and (c) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI of M/s Glenmark Pharmaceuticals Ltd having digital dose counter." mentioned in Note (e) it is to be read as follows "The price revision based on Wholesale Price Index (WPI) as per para 16 of DPCO, 2013 would be applicable on the price of the Digital Dose Counter as specified in column (6) of the above said Table from the next year".

2. All other notes and contents mentioned in the S.O. 4539(E) dated 18.12.2019 shall remain the same and are applicable.

PN/216/84/2021/F
F.No.8(84)/2021/D.P./NPPA-Div.II

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

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Movement in Wholesale Price Index (WPI) for the preceding Calendar Year 2020-reg.

NPPA Office Memorandum dated 18th March 2021

1. Based on the Wholesale Price Index (WPI) data available in the website of the Office of the Economic Advisor, Department for Promotion of Industry and Internal Trade, Ministry of Commerce and Industry, the annual change in the WPI works out as **0.53638%** during the calendar year 2020 over the corresponding period in 2019.

2. This is brought to the notice of all concerned for further action as per the provisions of DPCO, 2013.

F.19(119)/2021/DP/NPPA/Div.II (Vol-II)

Shiv Shanka Ojha, Joint Director (Pricing), National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Pharmaceutical Pricing Authority, New Delhi.

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Government appoints new Analysts at RDTL at Gauhati - Superseded to the Notification Number S.O.282(E), dated 28th February, 2005 - reg.

Drugs & Cosmetics Notification No.S.O.1170 (E), dated 12th March, 2021

In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with rule 44 of the Drugs and Cosmetics Rules, 1945, and in supersession of the notification of the Government of India in the Ministry of Health and Family Welfare number S.O.282(E), dated the 28th February, 2005, except as respects things done or omitted to be done before such supersession, the Central Government hereby appoints-

(1) Shri Amar Jyoti Chamuah - Junior Scientific Assistant;

(2) Shri Dilip Kr. Sarkar - Junior Scientific Assistant;

(3) Smt. Rinku Kalita - Junior Scientific Assistant; and

(4) Shri Arun Kumar Das - Junior Scientific Assistant,

at the Regional Drugs Testing Laboratory, Guwahati as Government Analysts for the whole of India in respect of all classes of drugs except the classes of drugs mentioned below, namely:-

(i) Sera;

(ii) Solution of Serum Proteins intended for injection;

(iii) Vaccines (parenteral and Oral);

(iv) Toxins;

(v) Antigens;

(vi) Anti-toxins;

(vii) Sterilized Surgical Ligature and Sterilized Surgical Sutures;

(viii) Bacteriophages;

(ix) Anti-sera for veterinary use;

(x) Vaccine for veterinary use;

(xi) Toxoid for veterinary use;

(xii) Diagnostic Antigens for veterinary use;

(xiii) VDRL Antigen;

(xiv) Human Blood and Human Blood Products including components, to test for freedom for HIV antibodies;

(xv) Blood Grouping reagents and diagnostic kits for Human Immunodeficiency Virus, Hepatitis B surface Antigen and Hepatitis C Virus; and

(xvi) Condom.

F.No.X.11014/13/2020-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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MCA established the Central Scrutiny Centre for scrutiny of Straight Through Processes (STP) e-forms - reg.

Corporate Affairs Notification No. S.O.1257(E), dated 18th March, 2021

1. In exercise of the powers conferred by sub-sections (1) and (2) of section 396 of the Companies Act, 2013 (18 of 2013) (hereinafter referred to as the Act), the Central Government hereby establishes a Central Scrutiny Centre (CSC) for carrying out scrutiny of Straight Through Processes (STP) e-forms filed by the companies under the Act and the rules made thereunder.

2. The CSC shall function under the administrative control of the e-governance Cell of the Ministry of Corporate Affairs.

3. The CSC shall carry out scrutiny of the aforesaid forms and forward findings thereon, wherever required, to the concerned jurisdictional Registrar of Companies for further necessary action under the provisions of the Act and the rules made thereunder.

4. The CSC shall be located at the Indian Institute of Corporate Affairs (IICA), Plot No.6, 7, 8, Sector 5, IMT Manesar, District Gurgaon (Haryana), Pin Code-122050.

5. This notification shall come into force from the **23rd March, 2021.**

F.No.A-42/10/2021-Ad.II

Anjali Bhawara,
Special Secretary,
Ministry of Corporate Affairs,
New Delhi.

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Documents required to be submitted for applying import authorization for import of Denatured Ethyl Alcohol - reg.

DGFT Trade Notice No.46/2020-21, dated 16th March 2021

To,
All Importers/Members of Trade,
All Designated Issuing Agencies under FTAs/PTAs.

1. Reference is invited to the applications being submitted by the applicant for import authorization for import of restricted item Denatured Ethyl Alcohol (DEA). At present the applicants are filing online application (ANF 2 M) along with infom1ation in Proforma as circulated by Trade Notice No.27/ 2019-20 dated 29th July, 2019.

2. In consultation with Ministry of Chemicals and Petrochemicals and in order to expedite the process for approval of authorization for import of Denatured Ethyl Alcohol (DEA), the applicants will have to submit the following additional documents along with the prescribed ANF 2 M Form. The additional information is to be provided in Proforma and includes:-

(a) Imports and usage pattern of last five years; indicating year wise production of finished product/products mentioning Chemical/IUPAC (International Union of Pure and Applied Chemistry) name and its chemical structure and corresponding consumption of Denatured Ethyl Alcohol also wit h balance remained at the plant site at the closing of each year. Further, to submit the quantity of Denatured Ethyl Alcohol available at the plant site, both in terms of volume and weight, as on date of the application. Complete and detailed step wise production process with balanced chemical reactions involved that is stoichiometric material balance with calculation (step wise material balance) for each of the products consuming denatured ethyl alcohol.

(b) Approved installed capacity of the finished products, produced at the plant site; consuming denatured ethyl alcohol along with a copy of the approval from Government of India/ State Government (such as IEM (Industrial Entrepreneur Memorandum)/MSME registration; authentic document of Government of India/State Government).

(c) Valid Environmental clearance for each of the products being manufactured at the plant site along with documentary evidence.

3. All the documents must be duly self-attested by the authorized person of the firm.

4. Accordingly, henceforth, all applicants who intend to import Ethyl Alcohol Denatured will submit above information/documents for consideration/processing of their application.

F.No.01/53/8/55063/AM21/Ethyl Alcohol/IC

Shyama Prasad Roy, Joint Director General of Foreign Trade, Directorate General of Foreign Trade, Department of Commerce, Ministry of Commerce and Industry, New Delhi.

Proforma for Import of Denatured Ethyl Alocohl

Name of the Firm:

IEC No:

Financial Year	Import of DEA	Production of finished product(s) with chemical name	Con-sumption of DEA	Balance Quantity	Quantity of DEA at plant site on the date of application	
					Volume	Wt.

(Chemical structure, complete and detailed step wise production process with balanced chemical production process with balanced chemical reactions involved i.e. Stoichiometric material balance with calculation (step wise material balance) for each of the product consuming Denatured Ethyl Alcohol are to be provided on separate sheet(s).)

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DGFT amends the para 4.97 j of the Handbook of Procedures, 2015-20 - reg.

DGFT Public Notice No.43/2015-2020, dated 17th March 2021

In exercise of powers conferred under paragraph 1.03 of the Foreign Trade Policy (2015-2020), the Director General of Foreign Trade hereby amends the para 4.97 j) of the Handbook of Procedures, 2015-20 which was notified vide Public Notice 25 dated 13.10.2020, as below:

Existing Para	Amended Para
j) In the online module for filing claims under RoSL, applications containing shipping bills with Let Export Order (LEO) date between 01.10.2017 and 06.03.2019 are required to be submitted separately. Similarly, separate application containing shipping bills with LEO date before 01.10.2017 needs to be submitted. Last date for submitting applications containing shipping bills with LEO date from 01.10.2017 to 06.03.2019 would be 30.06.2021. The last date for filing applications containing shipping bills with LEO date before 01.10.2017 would be notified at a later date.	j) In the online module for filing claims under RoSL, applications containing shipping bills with Let Export Order (LEO) date between 01.10.2017 and 06.03.2019 are required to be submitted separately. Similarly, separate application containing shipping bills with LEO date before 01.10.2017 needs to be submitted. Last date for submitting applications containing shipping bills with LEO date from 01.10.2017 to 06.03.2019 would be 30.06.2021. The last date for filing applications containing shipping bills with LEO date before 01.10.2017 **would be 31.12.2021.**

Effect of this Public Notice: The last date for applying for Rebate of State Levies (RoSL) claim under a scrip mechanism for Shipping Bills prior to 01.10.2017 is notified.

F.No.01/61/180/14/AM21/PC-3

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

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Enlistment under Appendix 2E - Agency Authorized to issue Certificate of Origin (Non-Preferential) - reg.

DGFT Public Notice No.42/2015-2020, dated 17th March, 2021

1. In exercise of powers conferred under paragraph 2.04 of the Foreign Trade Policy 2015-2020, the Directorate General of Foreign Trade hereby authorizes the following agency to issue Certificate of Origin (Non-Preferential):

M/s The Plastic Export Promotion Council
Ground Floor, unit No.2, 8-Wing,
Dynasty Business Park,
Chakala, Andheri (East),
Mumbai 400059

2. Accordingly, name of the above mentioned agency is added at Serial No.33 (Maharashtra) of Appendix 2E [List of Agencies Authorized to issue Certificate of Origin (Non-Preferential)] to Appendices & Aayaat Niryat Forms of FTP (2015-20).

3. **Effect of this Public Notice:** M/s The Plastic Export Promotion Council is enlisted under Appendix 2E of FTP (2015-2020) for issuing Certificate of Origin (Non-Preferential).

File No.01/93/180/42/AM-20/PC.II(B)/E-23707

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

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Amendment in Appendix 2E (List of Agencies to issue CoO-Non Preferential) *re.* change in Indian Chemical Council branch address for CoO - reg.

DGFT Public Notice No.41/2015-2020, dated 16th March, 2021

In exercise of powers conferred under paragraph 2.04 of the Foreign Trade Policy 2015-2020, the Director General of Foreign Trade hereby makes the following amendment at S.No.9 under the subheading Maharashtra in Appendix 2E (List of Agencies authorized to issue Certificate of Origin-Non Preferential) of the Handbook of Procedures, 2015-2020 to reflect the change in branch office address as under:

Sr. No.	Existing Address	New Address
9	Indian Chemical Council Sir Vithaldas Chambers, 16 Mumbai Samachar Marg, Mumbai-400023. And its branch at: a. 332-A, Sant Nagar, Ground Floor East of Kailash, New Delhi-110065. b. Shantiniketan 8th Floor, 8 Carmac Street, Kolkata-700017. c. Kurian Complex, III floor 140-A, Nelson Manickam Road, Chennai-600029.	Indian Chemical Council Sir Vithaldas Chambers, 16 Mumbai Samachar Marg, Mumbai-400023. And its branch at: a. **Indian Chemical Council - Northern Region, 206, Ansal Bhawan, K.G. Marg, New Delhi-110001.** b. Shantiniketan 8th Floor, 8 Carmac Street, Kolkata-700017. c. Kurian Complex, III floor 140-A, Nelson Manickam Road, Chennai-600029.

File No.01/93/180/01/AM-20/PC.II(B)/Part.1/E-23274

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

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

Patent Applications for New Inventions

Lok Sabha Starred Question No. 62

Shri Ramcharan Bohra:

Q. Will the Minister of **SCIENCE AND TECHNOLOGY** be pleased to state;

(a): the number of patent applications filed for new inventions by Indian Scientists in comparison to the scientists in other developed/developing countries during the last three years; and

(b): the steps taken by the Government to address the issue of slow progress rate in the field of Research and Development in the country?

Answered on 5th February 2021

A. (a) & (b): A statement is laid on the Table of the House:

STATEMENT AS REFERRED IN REPLY TO PARTS (a) and (b) OF LOK SABHA STARRED QUESTION NO. 62 - PATENT APPLICATIONS FOR NEW INVENTIONS

(a): As per data available from World Intellectual Property Organization's (WIPO), IP Statistics, released on January 5, 2021, India ranks 8th in patent filed by resident Scientists/ Innovators from respective country. Country-wise data pertaining to patents filed by resident researchers/ scientists/innovators at top 10 patent offices in last three years, including India, is given below:

Year			2017	2018	2019	Growth in 2019 from 2018
Country of Origin	Origin (Code)	Type				
China	CN	Resident	1245709	1393815	1243568	-10.8%
United States of America	US	Resident	293904	285095	285113	+0.006%
Japan	JP	Resident	260292	253630	245372	-3.2%
Republic of Korea	KR	Resident	159084	162561	171603	+5.6%
European Patent Office	EP	Resident	78555	81565	82584	+1.2%
Germany	DE	Resident	73345	73333	73448	+0.16%
Russian Federation	RU	Resident	23115	25333	23764	-6.2%
India	IN	Resident	14961	16289	19454	+19.4%
Australia	AU	Resident	2503	2757	2637	-4.4%
Canada	CA	Resident	4053	4349	4238	-2.5%

Source: WIPO statistics database. Last updated: January 2021 (accessed on January 27, 2021)

(b): No Sir. The progress in recent past has not been slow. The Gross expenditure on R&D (GERD), in the country has been consistently increasing over the years and has been tripled in last 10 years. The Ministry of Science and technology through its three wings i.e. Department of Science Technology (DST), Department of Biotechnology (DBT) and Department of Scientific and Industrial Research (DSIR)/ Council of Scientific and Industrial Research (CSIR) is implementing various schemes and programmes. These initiatives not only promote Science, Technology and Innovation (STI) ecosystem in the country but also reach out to various cross sections of the society through support in:

- Research& Development.
- Human Capacity Building.
- Innovation, Technology, Development and Deployment for Socio Economic Development.

Together a vast network of 70 Institutes across the country working in niche research areas of Science & Technology (S&T) has been created.

Some of the noteworthy schemes and programmes of the Ministry are:

- Fund for Improvement of S&T Infrastructure (FIST).
- Sophisticated Analytical Instrument Facilities (SAIF).
- Intensification of Research in High Priority Areas (IRHPA).
- Innovation in Science Pursuit for Inspired Research (INSPIRE).
- Women Scientist Scheme (WOS) and Biotechnology Career Advancement & Reorientation Programme (BioCARE).
- Technology Business Incubators (TBI).
- National Initiative for Development and Harnessing Innovations (NIDHI).
- Technology Mission Initiative.

- State Science and Technology Programme (SSTP).
- Science and Society Programme (SSP).
- Tribal Sub Plan (TSP).
- Scheduled Caste Sub Plan (SCSP).
- Mission Programme on Characterization of Genetic Resources.
- National Mission on Interdisciplinary Cyber-physical Systems.

Due to implementation of these schemes and programmes:

- India ranks 3rd in the No. of Ph.D. degrees awarded (24,474) in Science and Engineering.
- India ranks 3rd in terms of No. of papers published as per National Science Foundation. (NSF) database with 1,35,788 publication in Science and Engineering (2018).
- Our gender participation in R&D has increase to 16.6% (as per R&D statistics 2019-20). from 13.9% (as per R&D Statistics 2017-18).
- No. of researchers per 1 million have increased to 255 in 2017 as compared to 110 in 2015.
- Numerous state of art research facilities have been created across country in more than 600 academic Institutes and PG College benefitting more than 1 lakh researchers.
- More than 14 lakhs school students were engaged under INSPIRE program.
- More than 45,000 scholarship /fellowship were given under INSPIRE, CSIR-NET and HRD Schemes of DBT.
- More than 2,500 young scientists were supported under National Postdoctoral Fellowships, INSPIRE Faculty Programme and Scheme for Young Scientists and Technologists (SYST).
- More than 50 accomplished overseas scientists have been identified for collaborative research visits under Visiting Advanced Joint Research (VAJRA) programme.
- Four STI Hubs for tribal population and & seven STI hubs for SC Population have been established for socio-economic development of disadvantaged section of the society.
- More than 150 Technology Business Incubators (TBI), 50 Bio-incubators, nearly 3800 entrepreneurs were supported under Innovation and Entrepreneurship development programmes of DST & DBT and it has generated more than 60,000 jobs in last five years.

Apart from the achievements mentioned above this year the during the budget announcement Government has allocated of Rs.50,000 crore over 5 years for the National Research Foundation (NRF) and autonomous body envisaged to support researchers working across several streams of S&T especially in Universities. Besides this Rs.4000 crore was allocated for Deep Ocean Mission over five years.

These significant efforts have accelerated the progress of R&D in the country tremendously which is evident from the no. of publications, patents and Ph.Ds awarded.

Minister of Health and Family Welfare; Minister of Science and Technology; and Minister of Earth Sciences Dr Harsh Vardhan

GST on Hand Sanitisers

Lok Sabha Unstarred Question No: 976

Shri Hibi Eden:

Q. Will the Minister of **FINANCE** be pleased to state;

(a): whether the Government plans to reduce Goods and Services Tax (GST) rates on hand sanitisers in line with the Supreme Court judgement in the Commissioner of Central Excise vs Wockhardt Life Sciences Limited case;

(b): if so, the details thereof;

(c): whether the Government has taken any steps to reduce GST rates on medicaments; and

(d): if so, the details thereof?

Answered on 8th February 2021

A. (a) & (b): The GST rates on goods are notified based on recommendations of the GST Council. No recommendation regarding reducing GST rate

on hand sanitisers has been received from the GST Council.

(c) & (d): On the recommendations of GST Council, GST rates were reduced from 12% to 5% on specified Ayurvedic, Unani, Siddha, Homeopathic or Bio-chemic systems medicaments.

Further exemption from IGST on imports has been given to:

(i): Medicines/drugs/vaccines supplied free of cost by United Nations International Children's Emergency Fund (UNICEF), Red Cross or an International Organization subject to specified conditions.

(ii): Lifesaving Medicines for personal use supplied free of cost by overseas supplier, subject to specified conditions.

Minister of State in the Ministry of Finance (Shri Anurag Singh Thakur)

Clearance of Dues of MSMEs

Lok Sabha Unstarred Question No: 988

Shri Balashowry Vallabbhaneni:

Q. Will the Minister of **FINANCE** be pleased to state;

(a): whether the Ministry's directive of clearing the dues of Micro, Small and Medium Enterprises (MSMEs) by the States, Centre and Corporations has strictly been adhered to;

(b): if not, the details of dues pending for MSMEs by the States, Centre and Corporations;

(c): whether it has come to the notice of the Ministry that the dues to MSMEs are gradually mounting and as of October, 2020, there are nearly Rs. 1,000 crore dues to MSME sector; and

(d): if so, the action taken by the Ministry to clear the dues of MSMEs?

Answered on 8th February 2021

A. (a) to (c): As soon as the Government announced the directive as regards clearing of dues of the Micro, Small and Medium Enterprises (MSMEs), Ministry of MSME got active to play an important role in clearance of dues to the MSMEs.

(i): Government has taken many steps to get the dues payable to the MSMEs cleared by public sector units of State and Central Governments. The Ministry has taken up the subject vigorously with the Central Ministries, Central Public Sector Enterprises (CPSEs) and State Governments and the Corporate entities. But, it is to be noted that the Central Government cannot issue any directions to, or force, State Governments or State PSEs to pay the dues.

(ii): The status of monthly payments by Central Ministries and CPSEs to MSMEs dues after Atma Nirbhar Bharat package is given below:-

Reported Month	Total Dues at beginning of the month (in Rs. Crores)	Paid during the month (Rs. Crores)	Pending at the end of month (in Rs.Crores)
May 2020 (25 Ministries & 79 CPSEs Reported)	2349.53	1787.89	561.64
June 2020 (25 Ministries & 86 CPSEs Reported)	2553.94	1905.11	648.83
July 2020 (30 Ministries & 108 CPSEs Reported)	4124.34	3155.16	969.19
August 2020 (26 Ministries & 104 CPSEs Reported)	3811.13	2954.48	856.65
September 2020 (25 Ministries &105 CPSEs Reported)	4858.18	3814.44	1043.74
October 2020 (26 Ministries & 108 CPSEs Reported)	5124.13	4102.43	1021.70
November 2020: (26 Ministries &110 CPSEs Reported)	5184.92	4279.67	905.24
December 2020: (26 Ministries & 105 CPSEs Reported)	6499.92	4821.90	1678.02

(d): Other steps taken by Government to clear the dues of MSMEs are as below:-

In order to promote greater discipline and timeliness in payment to vendors, the government has issued guidelines that whenever a Consignee Receipt and Acceptance Certificate (CRAC) in the Government

e-Market place (GeM) is issued by a buyer and payment is not made within 10 days thereafter, the buyer organization is required to pay penal interest @ 1% per month for the delayed payment beyond the prescribed timeline till the date of such payment.

In order to provide relief from the problem of delayed payment from the MSMEs under the 'MSME outreach programme', Ministry of MSME has issued a notification dated 02.11.2018 with the direction that all CPSEs and all companies with the turnover of Rs.500 Crore or more shall be required to get themselves on boarded on the Trade Receivables Discounting System (TReDS) platform. TReDS platform provides an option to MSMEs to discount invoices to raise short-term credit from banks to tide over delays in payments. SIDBI on 26.08.2020 informed/announced about the fees exemption for on boarding of registration of MSMEs on the TReDS till 31.03.2021. The Government of India has also publicized the exemption of fees and charges for registration on TReDS platform to the MSMEs.

(TReDS Bills Discounted during Covid Period)		
Date	**No. of invoices discounted**	**Value of discounted invoices (Rs. in cr.)**
December, 2020 (Cumulative)	1201995	28,119
April, 2020 to December, 2020 (during Covid period)	**472035**	**10,285**

The Minister of State in the Ministry of Finance (Shri Anurag Singh Thakur)

Concession under CSR

Lok Sabha Unstarred Question No: 1018

Shri Sangamlal Kadedin Gupta:

Shri Manoj Kumar Tiwari:

Shri Ramdas Chandrabhanji Tadas:

Shri Chandra Prakash Joshi:

Q. Will the Minister of **CORPORAT AFFAIRS** be pleased to state;

(a): whether any concession regarding utilizing CSR funds have been provided to the companies during this year due to COVID-19 pandemic;

(b): if so, the details thereof; and

(c): the manner in which the companies have utilized the said concession along with the manner in which audit is undertaken in this regard?

Answered on 8th February 2021

A. (a) to (c): Ministry vide General Circular no.10/2020 dated 23.03.2020 clarified that Corporate Social Responsibility (CSR) funds may be spent by the companies for various activities related to COVID-19 under item nos. (i) and (xii) of Schedule VII of the Companies Act, 2013 ('Act') which relates to promotion of health care, including preventive health care and sanitation, and disaster management. Further, Companies (CSR Policy) Rules, 2014 were amended to enable companies to undertake CSR activities in their normal course of business for undertaking research and development of new vaccine, drugs and medical devices related to COVID-19 for three financial years in collaboration with any of the institutes or organisations mentioned in item no. (ix) of the Schedule VII of the Act.

The entire CSR architecture is disclosure based and CSR mandated companies are required to file details of CSR amount spent annually in MCA21 registry, which is available in public domain at www.csr.gov.in. As per the Act, companies are required to hold Annual General Meeting (AGM) within six months from the end of financial year. Thereafter, financial statements and board report containing disclosure about CSR, are to be filed in MCA21 registry within 30 days of the AGM. Thus, for the ongoing financial year no filing has been made by CSR mandated companies

The Minister of State for Finance and Corporate Affairs (Shri Anurag Singh Thakur)

Indian Pharma garners global recognition with its capability in COVID-19 vaccine

COVID-19 has given an excellent recognition to Indian Pharma. In the short-term, the world will continue to focus on the capability of Indian Pharma companies in producing COVID-19 vaccines. In fact, India's 'vaccine diplomacy' is much-followed and admired, especially when seen against 'vaccine nationalism' demonstrated by some regions, says ***Dr R Ananthanarayanan,*** *MD & CEO, Strides Pharma Science, in an email interview to* ***Nandita Vijay.***

Excerpts:

How would you portray the current Pharma scene in India and globally during Covid and post pandemic? What are visible trends you sight?

Although India has been widely known as the Pharmacy of the World, it has seldom got its fair share of recognition before the pandemic. Historically, India played a key role in making drugs affordable and accessible. COVID-19 has enabled recognition for Indian Pharma.

In the short-term, the world will continue to focus on the capability and output of Indian Pharma companies in producing Covid-19 vaccines. In fact, 'vaccine diplomacy' has become an admired move by India especially when seen against 'vaccine nationalism' demonstrated by some regions. In the longer term, several issues such as the debate on generics in the US and geo-political problems closer home in India may have an impact on business, although it is too soon to comment. Broader issues such as regulatory compliance or even e-commerce have acted as a differentiator and disruptor respectively. Initiatives by the Government such as the Production Linked Incentive (PLI) scheme could also lead to a significant impact on cost, exports and indeed, even the global supply chain.

What could be the positive and negative impacts of the Union Budget 2021 on your financial projects for the next fiscal…Customs Duty Drawback among others?

Due to the pandemic, the industry had high expectations from the Union Budget of 2021. Healthcare did get a big boost with increased outlay of Rs.223,846 crore, including Rs.35,400 crore for Covid-19 vaccination programme allocation and Rs.64,184 crore for a new scheme to reinforce the country's primary, secondary and tertiary health infrastructure. Such allocations are extremely welcome and laudable. From a Pharma business perspective, going forward, we look forward to support on incentives for R&D and lower GST for life-saving drugs as these will greatly help pharmaceutical manufacturers.

How much and what type of technology adoption enabled Strides to sustain its operations during the Covid-19 pandemic?

The Pharma industry especially generic player has always been resistant to making changes to the traditional way of operation and digital adoption. This has primarily been due to lack of employee awareness, perception and regulatory constraints. However, the current pandemic has forced us to break these shackles and re-orient ourselves and reimagine business and operations.

When the lockdown started, Pharma companies were classified as an essential service and technology enabling remote connectivity and Work From Home to keep manufacturing plants running.

Being a pharmaceutical company, we already had some advantages of sanitization and gowning process in place, but that had to be significantly augmented. We pruned down employee loading at each operation station, primarily packaging, to ensure social distancing. This threw up ideas on new ways of operation like replacing door handles with foot door openers to ensure contactless movement to change rooms, entry to plants and rest rooms.

An internal mobile application was developed to continuously touch base with employees, check well-being, receive feedback and address concerns. It enabled contact tracing among employees to ensure safe work environment. Being a part of regulated industry, compliance and audits are a regular feature. In the new normal, virtual reality/ wearables allowed internal audits and training.

Business continuity plans provided additional focus on 3Ps: People, Patients and Purpose. We are using the experiences of the last year in creating a roadmap for 'Future of Work'. This would involve using digitization, remote working and leveraging technology from a forward-looking perspective. We have put in motion workgroups with cross-functional experts to demystify the future of work. Our three guiding principles are: simplification, continuous learning and resilience. We see a confluence of digital technology and talent maximization to reimagine the new ways of working.

Could you detail on this statement during the Q3 corporate results 'extremely weak flu season in the US impacts demand for winter portfolio, select products continue to witness price erosion'. Also in Q3, what factors enabled Strides to report an impressive performance in the regulated markets?

Typically, November to March is the flu season in the US characterized by a sharp pick-up in our winter products. This year, lower incidence of the flu was accompanied by higher use of flu vaccines which led to weak demand for the winter portfolio in Q3. Additionally, patient footfalls at hospitals and pharmacies continued to remain below pre-Covid-19 levels leading to subdued demand for a few products and a softer off-take by wholesalers. However, we reported a steady performance, and continue to remain optimistic about our US business based on market share and ramp-up of new launches. In the medium term, the US business will continue to benefit from our focused product selection strategies with relentless supply commitments and customer advocacy.

Our Other Regulated Markets (ORM) business delivered a strong bounce-back in Q3 led by healthy volume traction across UK, EU, Australia and South Africa. Going forward, our order book continues to remain healthy with new launches to gain momentum.

Our core business markets are the US and ORM where portfolio maximization strategy is yielding the desired results. Our US strategy to build front-end and taper partner business is playing out to plan. Front-end business now contributes 86% of our US revenues with superior supply chain execution through compliant manufacturing and continued focus on new products. Through R&D investments we would develop a range across multiple therapeutic segments, leverage portfolio fungibility across ORM to unlock value.

Could you throw more light on the Florida plant? Going by the 86% revenues generated and the ANDA, would Strides slate more investments?

The US retail business is largely serviced by our Indian facilities. Our Singapore facility presently manufactures oral solids for procurements administered by the Department of Veterans Affairs (VA). In FY'20, Strides acquired, the US FDA approved Florida manufacturing facility specialising in soft-gel capsules for which we rank as among the leading global manufacturers. This site augmented our capacity and is an alternate to support our growth plans in retail and the VA business. Currently, the Florida site is undergoing technology transfer. Some filings are on with more in due course as we plan to invest in diverse products.

Coming to Strides vaccine production plan could detail on this facility location, status of line-equipment installation and at what stage are the discussions to partner with related global developers for manufacturing?

The vaccine suite is part of the Stelis Biopharma, Bengaluru. The equipment installation of the vaccine lines is approaching completion and qualification has commenced. This will give high-speed filling lines with an annual capacity of 500 million doses of liquid vaccines or 300 million doses of lyophilized vaccines (10 dose MDV). The suite will cater to vaccine types: viral vector, protein subunit, RNA and DNA. Stelis is presently in advanced discussions with global Covid-19 vaccine developers to offer manufacturing services.

Strides Pharma Board of Directors approved in-principle the demerger of its biotech business under Stelis Biopharma. The transaction is subject to approval from shareholders, meeting customary closing conditions.

Strides has been recognized for its antiretroviral drugs, but not much is discussed about it, could you tell us the reason?

All that can be said is that Strides, develops and manufactures anti-retroviral and anti-malarial for the institutional business, and for Africa. As one of the leading Indian suppliers of drugs in this segment, we continue to be part of the fight against global pandemics.

Source: Nandita Vijay, Pharmabiz, 15.03.2021

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New compound targets enzyme linked to autoimmune disorders, severe COVID-19

When the body detects a pathogen, such as bacteria or viruses, it mounts an immune system response to fight this invader. In some people, the immune system overreacts, resulting in an overactive immune response that causes the body to injure itself, which may prove fatal in some cases.

Now, scientists from Nanyang Technological University, Singapore (NTU Singapore) have created a compound that could help to reduce this over-activation without impairing the body's entire immune response.

An overactive immune system leads to many autoimmune disorders - when the immune system mistakenly attacks healthy tissues - such as rheumatoid arthritis and type 1 diabetes. More recently, it has also been linked to severe COVID-19 infections, in which immune-system signalling proteins ramp up to dangerous levels, leading to damage to the body's own cells.

This compound designed by the NTU research team, called ASO-1, targets tyrosine kinase 2 (TYK2), a member from the Janus kinase (JAK) family of enzymes that play a key role in regulating the body's immune response. A recent study led by the University of Edinburgh and published in the leading scientific journal Nature found that high levels of TYK2 have been associated with severe COVID-19.

Through lab experiments using human cells grown in a dish, the NTU scientists found that ASO-1 potently reduced TYK2 levels over a sustained period and inhibited immune signalling pathways that have been associated with autoimmune disorders.

This points to the potential of the ASO-1 compound forming the basis for treatment of autoimmune conditions, said the team led by Professor Phan Anh Tuan from NTU Singapore's School of Physical and Mathematical Sciences (SPMS).

Professor Phan, who is also the interim Director of the NTU Institute of Structural Biology, said: "Human genetic studies have suggested that deactivating TYK2 could provide protection against a broad range of autoimmune conditions such as rheumatoid arthritis, psoriasis, lupus, and type 1 diabetes."

Dr Lim Kah Wai, NTU Senior Research Fellow and co-lead author of the study, added: "With the UK-led study of critically ill COVID-19 patients published in Nature linking high TYK2 expression to severe COVID-19, ASO-1 could be a therapeutic agent worth investigating further. We are planning to conduct further pre-clinical work to validate its therapeutic potential."

The findings were published in February in the scientific journal Immuno Horizons, a publication of The American Association of Immunologists, and the research team has filed a patent for the compound they designed.

Targeting genetic material that leads to TYK2 production:

A number of drugs that reduce inflammation resulting from an overactive immune response target the Janus kinase (JAK) family of four proteins: JAK1, JAK2, JAK3 and TYK2.

Recently, TYK2 has emerged as researchers' preferred target. As the structures of the four members are highly similar, it is important to selectively target TYK2 to limit unwanted side effects.

The ASO-1 compound designed by the NTU research team is an antisense oligonucleotide (ASO). ASOs are a type of RNA therapeutics - they target the messenger RNA (mRNA), which carries genetic instructions that cells 'read' to make proteins. ASO-1 is designed to bind to TYK2 mRNA, thus preventing cells from producing TYK2 protein.

The research team conducted lab experiments on human cell cultures and found ASO-1 to be highly potent and selective for TYK2, with no effect against the other JAK proteins. Dr Lim noted that this high potency of ASO-1 rivals that of recent ASO drug candidates that have advanced to clinical trials or have been approved for clinical use.

The NTU team discovered ASO-1 from over 200 potentially effective ASOs, which were designed based on their in-house expertise on nucleic acids.

The team has established an integrated platform spanning the design, synthesis, and cellular testing of RNA therapeutics. TYK2 stands among a range of therapeutic targets for immunology and cancer therapy, which is the primary focus of the team.

The NTU researchers plan to partner several academic collaborators to test ASO-1 in animal models and are open to industrial collaboration on the development of the ASO-1 compound towards clinical use.

(Story: Materials provided by Nanyang Technological University. Note: Content may be edited for style and length).

Source: Nanyang Technological University, Science Daily, 10.03.2021 (Excerpts)

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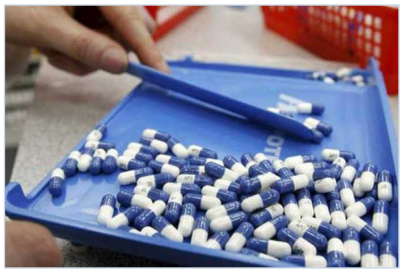
NATIONAL NEWS

Pharma MSMEs seek Government intervention to tackle shortage, price increase of raw materials

Caution that if the situation continues, there could be a scarcity of medicines in the country



The Pharma MSME segment informs that COVID-19 has impacted it adversely and they are facing the brunt in the form of a decrease in demand, shortage of working capital, non-availability of finance/funding by financial institutions, shortage of input materials, exorbitant increase in raw material cost, cancellation of export orders, logistic problems, non-availability of manpower etc. So, the MSME segment of the Pharma industry is seeking the Government authorities' intervention to deal with the challenges.

B R Sikri, Chairman, FOPE, highlighted, "The factors that have compounded the issue are the unavailability of APIs and an exponential increase in their prices. It is well-known that the Pharma industry depends on China for APIs. About 70 percent of the APIs required is sourced from China in addition to other KSMs used by the industry. In addition to APIs and KSMs, prices of other input materials such as plastic, PVC, diesel, IPA, aluminium, PET bottles and other packaging materials have gone up un-proportionately.

However, the industry cannot pass on the increase to the consumers as a major section of drug formulations/ medicines comes under Drugs Prices (Control) Order, 2013 where retail prices are capped. Moreover, if a formulation becomes unviable due to these factors, its discontinuation for production and sale attracts penal provisions under DPCO, 2013.

The DPCO 2013 caps the prices of finished formulations, but has no control over the prices of API and other input materials used in the manufacture of finished formulations. On the export front, the MSME segment is facing cancellation of export orders due to disruption caused by COVID-19 and also because foreign buyers are averse to increase in prices due to escalation in the cost of input materials."

"FOPE had taken up this issue with the Government for a proportionate increase in the prices of finished formulations or ensuring the availability of APIs at the pre-COVID-19 level. Unfortunately, nothing happened so far," informed Sikri.

Harish Jain, Secretary, Karnataka Drugs and Pharmaceutical Manufacturers Association expressed, "Pharma industry, in last few months, post lockdown is badly affected by a sudden increase in prices of key inputs and their scarcity. SMEs are especially affected since due to working capital constraints inventory levels are usually low. The industry is facing issues to honour contracts like Government tenders, exports and contract manufacturing."

Jain further added, "Availability also has become an issue, which is forcing many SME to work. If the situation is not controlled on a war footing, it may lead to a scarcity of medicines. Already many Government tenders are seeing default as well as lack of suppliers which, is affecting poor patients. Over and above that Industry is not able to increase the prices due to restrictions imposed by DPCO."

Aparajita Lark, MD, Lark Laboratories and VP, FOPE said, "There is an unprecedented increase in all inputs for Pharma products manufacturing. To list a few examples, foils and PVC which was Rs.87 per kg has gone up to Rs.167 per kg. Prices of empty capsules of all sizes, eg, size 0 have risen from Rs.85 to Rs.125. Propylene glycol, a solvent used in all liquid formulations, has increased from Rs.70 per kg to Rs.500 per kg, price of

bottles and caps increased have also increased by 10 percent.

These are creating financial trouble for manufacturers. The sudden rise in the raw material prices is significantly affecting the MSME players therefore there is a need for the authority to intervene and provide the solution."

She further added, "The skyrocketing prices of input material cost is making it difficult for us to manage current orders and also book new orders. It is largely affecting MSMEs because they work on low margins. If it continues then companies may not be able to continue production which will lead to a shortage of medicines in the market."

Sikri further explained, "The other key factor for stress on this segment is the inverted duty structure on APIs and finished formulations. The APIs attract 18 percent GST whereas finished formulations are taxed at 12 percent resulting in accumulation of ITC, which has not been refunded by the respective State Governments, putting immense pressure on the working capital of the units and liquidity squeeze. The issue was taken up with the Government but remains unresolved so far."

Source: Usha Sharma, Express Pharma, 16.03.2021

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IPC issues Notices to DCGI, SLAs for omission of Monographs of certain drugs from IP

The Indian Pharmacopoeia Commission (IPC) has issued notices to the Drug Controller General of India (DCGI), State Licensing Authorities (SLAs), Government analysts and Drug Testing Laboratories towards omission of Monographs of Lorcaserin Hydrochloride Hemihydrate and Lorcaserin Tablets from the Indian Pharmacopoeia (IP).

The Commission has urged all stakeholders in the country to bring the same to the notice of all authorities under their control for compliance on the same.

In the notice, IPC Secretary-cum-Scientific Director Dr Rajeev Singh Raghuvanshi stated, "Based on the safety Clinical Trial and possible risk of cancer associated with lorcaserin, manufacturers have voluntarily withdrawn the said product from the US Market. Subsequently to safeguard the public health, the manufacturer has also voluntarily withdrawn the distributed product from the Indian market. In view of the same, monographs of lorcaserin hydrochloride hemihydrate and lorcaserin tablets are omitted from the IP 2018."

IPC recently released the Guidance Document for Drafting and Formatting of Monographs for IP to guide the stakeholders including drug manufacturers, analysts and academicians on drafting of drug monographs before their inclusion in the Indian Pharmacopoeia.

In this Guidance Document, emphasis has been given to elaborate IP monographs under the categories of Active Pharmaceutical Ingredients (APIs), dosage forms and pharmaceutics.

IP is a compilation of official standards for drugs manufactured and/or marketed in India. A monograph states the quality or test parameters, the acceptance criteria and details of the tests that are to be performed to determine compliance with the criteria.

In other words, a pharmacopoeial monograph provides a reliable basis for making an independent and objective judgement as to the quality of a pharmaceutical substance.

As IP standards are statutory, it is important that the contents of monographs are unambiguous, acceptance criteria are clearly spelt out and the methods of evaluation provide all the details for carrying out the tests and assays, including the equipment, reagents and other ancillary materials that are to be used.

The Guidance document is a guide for drafting and elaboration of the monographs to the stakeholders of the IP especially industries, testing laboratories and academicians. The aim is to provide guidance for drafting clear unambiguous texts, with similar requirements presented in the same way in each monograph.

Source: Shardul Nautiyal, Pharmabiz, 15.03.2021

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NPPA extends deadline till April 15 for devices companies to submit price related info for price monitoring exercise

The National Pharmaceutical Pricing Authority (NPPA) has extended deadline till April 15, 2021 for medical devices manufacturers of all non-scheduled medical devices covering 24 categories to submit price related information for price monitoring exercise from the earlier deadline of March 11, 2021.

NPPA on Februray 16, 2021 had issued an Office Memorandum (OM) wherein it was directed to submit price related information in the prescribed format for 24 categories of non-scheduled medical devices.

"In this connection, NPPA has received representation from various companies and industry associations seeking extension of the date for the submission of the requisite date. A consultation was held with the industry associations on March 11, 2021 in the matter and it was agreed to extend the timeline upto April 15, 2021 for submission to be made in compliance to the OM," as per the notice of NPPA.

The NPPA in exercise of powers of para 29 of Drugs Prices Control Order (DPCO)-2013 had directed manufacturers and importers of all non-scheduled medical devices of 24 categories to submit price related information in the prescribed format duly certified by Practicing Chartered Accountant (CA) within 21 days of issue of this office memorandum (OM) price monitoring exercise.

The Maximum Retail Price (MRP) of non-scheduled medical devices notified/regulated as drugs under Drugs and Cosmetics (D&C) Act, 1940 are governed under the provisions of Para 20 of the DPCO-2013.

Further Para 25 of DPCO-2013 provides that every manufacturer/importer shall issue a price list and supplementary price list in Form-V to the dealer State Drugs Controllers (SDCs) and the government from time to time.

NPPA had earlier notified all medical devices as drugs under the provisions of the DPCO-2013 with effect from April 1, 2020 in pursuance of notification dated February 11, 2020.

In order to monitor the MRP of the non-scheduled medical devices under para 20 of DPCO 2013 vide OM dated May 12, 2017, NPPA had collected price related information for all the 19 categories of non-scheduled medical devices for the year 2014 to 2017. Further Union health ministry vide notification dated December 3, 2018 and December 27, 2019 had notified four medical devices.

"Thus, with effect from 1st April, 2020, all medical devices shall be regulated by the Government as drugs for quality control and price monitoring. Therefore, the MRPs of all the medical devices would be monitored by the Government under the provisions of Para 20(1) of the DPCO, 2013 to ensure that no manufacturer or importer increases the MRP of a drug more than ten percent of MRP during preceding twelve month and where the increase is beyond ten percent of Maximum Retail Price, it shall reduce the same to the level of ten percent of Maximum Retail Price for next twelve months," NPPA in its Notification had stated.

Further, as per Para 20(2) of the DPCO, 2013 read with the Essential Commodities (EC) Act, 1955, the manufacturer/importer shall also be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to penalty.

Government is today regulating 24 categories of medical devices which have been notified or regulated as drugs under D&C Act, 1940 and D&C Rules, 1945. Of the above, four medical devices viz (i) Cardiac Stents (ii) Drug Eluting Stents (iii) Condoms and (iv) Intra Uterine Device (Cu-T) are scheduled medical devices for which ceiling prices have been fixed.

Source: Shardul Nautiyal, Pharmabiz, 17.03.2021

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India working to develop patient-centric medication management and patient safety culture: Expert

India is now working to develop a patient-centric medication management and patient safety culture. This is where the increasing importance of pharmacists at every outlet is mandated to enable safe prescription practices and prevent unsafe use of medicines.

Efforts are now on by India to further strengthen its Pharmacovigilance programme. The objective is to encourage reporting and learning from errors. Healthcare workers are empowered and trained to reduce errors. These include implementation of extensive Pharmacovigilance interventions, Adverse Drug Reactions, close monitoring of side effects and medication errors.

The need of the hour is to create a blame-free environment. We need to ensure patient-centric services by the pharmacists in hospitals and in community to improve safe use of medicines. Therefore, the time has come for pharmacists to take the rein in hands and plug all the gaps resulting in unsafe use of medicine, stated Dr Suresh R Saravdekar, Vice-Chairman-Hospital division, IPA.

As a consultant in medication management, Institute of Medical Sciences, Benares Hindu University, Dr Saravdekar noted that ADRs are detected only through pharmacovigilance. It is imperative to focus on the same because counterfeit medicines are supplied by fraudulent suppliers. Drug interactions with drug and with food, and self medication by patients and community is rampant too.

At the patient level Pharmacovigilance interventions must focus on education & counselling, improve compliance to the medication management. There is a need to highlight the hazards of self-use of medicines. Here the labeling should display information on proper use of medicines and hospital outpatient departments must display the Pharmacovigilance interventions.

At the doctor and nursing level, use of digital prescriptions will prevent medical emergencies due to illegible prescription. A pop up and menu driven prescriptions linked to all data related to correct dose, route, time and duration of administration and drug-drug and drug-food interactions should be monitored. There is also need for use of standard check lists to avoid errors at administration level, he added.

Only the use of well-designed medication systems, standard operating procedures and education and training programmes for safer practice can allow Pharmacovigilance interventions at purchasing level. The purchaser should do risk assessment of labelling and packaging as an integral part of medicine procurement, and should identify any risks to patient safety.

Wherever significant risks are identified, alternative medicine products with safer designs should be procured if they are available. If there are no alternatives for a particular medicine product then the manufacturer is informed. We need to introduce caution in use measures are introduced into SOPs and in hospital formulary pharmacovigilance interventions at regulator level, he said.

Noting the challenges in this space, Dr Saravdekar, said the current design for labelling and packaging prioritises are concerns. It is not patient-centred, but, rather, relies on an assumption of perfect performance by healthcare professionals. This results in same trade names for different medicines and look-alike and sound alike names of medicines.

Even as India is now working to develop a patient centric medication management, regulation and innovative labeling need to also be focused, he said.

Source: Nandita Vijay, Pharmabiz, 15.03.2021

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BIRAC invites research proposals from biotech companies for BIPP scheme

The Biotechnology Industry Research Assistance Council (BIRAC), under its advanced technology scheme Biotechnology Industry Partnership Programme (BIPP), has invited fresh proposals from biotech companies for providing support on a cost sharing basis targeted at development of novel and high risk futuristic technologies mainly for viability gap funding and enhancing existing R&D capacities of start-ups and SMEs in key areas of national importance and public good.

DBT is operating this scheme through BIRAC, a not-for-profit public sector undertaking set up by DBT to nurture the biotech innovation ecosystem, support start-ups and SME's for innovation research and promote affordable product development through Public-Private-Partnership.

Main features of this programme are that it is an advanced technology scheme for high risk, transformational technology/process development from proof-of-concept to validation leading to high value product commercialization; it supports new and futuristic technology development with major social bearing but uncertain market driven demand; and also it supports start-ups, SMEs and other biotech companies on cost sharing basis.

The programme is focused in the areas of components of diagnostic kits including reagents, probes, primers and other components needed for diagnostics, development of novel technologies for production of monoclonal antibodies for therapeutic applications and diagnostics, new methods/ technologies for vaccine delivery and cold chain distribution of vaccines and cost effective production technologies for Industrially relevant bio-based import substitutes.

Another area of the programme include field usable diagnostic kits for disease and algal toxins relevant to aquaculture, microfluidics based diagnostics relevant to veterinary sciences, cost effective production technologies for APIs, intermediates, high value products, polymers, surfactants, fine chemicals, dyes, pigments, flavors and fragrances and repurposing of drugs.

A single or consortia of Indian companies Small, Medium or Large having DSIR recognized in-house R&D units, alone or in collaboration with a partner from another company/institute/organization/university are eligible for this programme. Financial support is extended as grants-in-aid with a matching contribution by company. The main industry applicant should have DSIR recognized in-house R&D unit or alternatively, the applicant should be incubated at an Incubation Centre/Biotech Park which has a valid SIRO/ DSIR Certificate. The interested biotech companies can apply for the proposal till March 31 this year.

Source: Neethikrishna, Pharmabiz, 15.03.2021

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API Monitoring Cell

To make India self-reliant in production of Active Pharmaceutical Ingredients (APIs), the Central Government has recently initiated several steps. In this direction, the Government has approved a total expenditure outlay of Rs.9,940 crore. Under this project, the Government approved a scheme of promotion of mega bulk drug parks for financing common infrastructure facilities in three bulk drug parks in different states with a financial implication of Rs.3,000 crore during the next five years. The Government will give grants-in-aid to states with a maximum limit of Rs.1,000 crore for each bulk drug park. These bulk drug parks will have common facilities such as solvent recovery plant, distillation plant, power and steam units, common effluent treatment plant, etc. More importantly, the Central Government approved the Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and APIs in the country with financial implications of Rs.6,940 crore for the next eight years. It is sure that the Covid-19 outbreak and the subsequent disruption in supply of APIs from China to India has finally made the alarm bell ringing and has woken up the Indian Government from its self-imposed slumber on framing a conducive policy on APIs to end the country's over-dependence on China for APIs. Better late than never, the Government's initiatives are definitely a right step in this direction as it can restore the Indian API industry's past glory if the scheme is implemented in letter and spirit. Till two decades ago, the country has been producing most of the APIs required in the country and even exporting a major part of the same to Europe and the US. But, the high cost of production because of comparatively low scale of operations and higher input costs rendered the domestic API production economically unviable. And stringent environmental regulations added fuel to the fire, forcing the Pharma companies to turn to China which emerged as a producer of cheap APIs with huge capacities and lower cost of production.

Apart from over-dependence on China, gyrating prices of APIs have also been a major issue the country has been facing periodically. The major reason for this is that the country, at present, does not have a mechanism to check rising prices of APIs on the lines of National Pharmaceutical Pricing Authority which regulates the prices of drug formulations. For regulating the prices of APIs, experts in the industry have been putting forward a proposal to establish an 'API Monitoring Cell' to curb the malpractices in APIs and excipients businesses in the country. That the Government was also seized of the issue was evident from the fact that the Union Health Ministry, at the Indian Pharmaceutical Association Forum meet held at CDSCO headquarters in New Delhi on August 28, 2018, had declared that the Government will establish an API Monitoring Cell to control the twin issues of poor quality of APIs and overcharging of APIs by the importers taking advantage of the situation arising out of the disruption in its supply. Unfortunately, as is the case with several other proposals, this proposal has also been gathering dust in the shelves of the Department of Pharmaceuticals for the last more than two and a half years. As the API prices and its quality will have a direct bearing on the pharmaceutical industry, an API Monitoring Cell is the need of the hour.

Source: Ramesh Shankar, Pharmabiz-Editorial, 10.03.2021

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Health Ministry to amend provisions for grant of Form 29 to boost R&D

The Union Health Ministry will soon amend provisions for grant of Form 29 to boost Research and Development (R&D) in the area of pharmaceuticals country. Form 29 is a license to manufacture drugs for the purpose of examination, testing and analysis. The Ministry's decision in this regard is based on recommendations from the industry as well as the Drugs Technical Advisory Board (DTAB).

As of today, New Drugs and Clinical Trials (NDCT) Rules, 2019 stipulates that permission in Form CT-11/14/15 needs to be obtained for grant of Form 29. Industry has long been suggesting that in line with international practices, requirements of Form CT-11/14/15 and Form 29 should be abolished. Alternatively, only one requirement i.e., Form-29 should be mandated.

Accordingly, the necessary amendments should be made in the Drugs and Cosmetics (D&C) Rules, 1945 and the NDCT Rules, 2019. DTAB has considered the proposal to examine the requirement of Form CT-11/14/15 and Form 29 as prescribed in the NDCT Rules, 2019 and D&C Rules, 1945 respectively.

DTAB was apprised that, earlier, as per D&C Rules, only Form 29, No Objection Certificate (NOC), irrespective of BE and Non-BE purpose, was required to be obtained for grant of Form 29. Industry representatives have been raising the concern stating that India is having such stringent and excessive requirements for developing product for examination, test, analysis, Clinical Trials (CT) or bio-equivalence (BE) study. Because of these excessive requirements, industries are facing difficulties in registration of their product in India as well as globally.

DTAB deliberated the issue and recommended that provision may be made for notification of information by the applicant relating to manufacture of new drug for test and analysis under Form CT-10/12/13 except for batches manufactured for Clinical Trial or BA/BE studies.

It further recommended that with regards to grant of license in Form-29, timeline may be specified as seven working days for its issuance by licensing authority, failing which it shall be considered deemed approved. In both the cases, however, the facility shall remain open for regulatory inspections. Accordingly, the necessary amendments should be made in the D&C Rules, 1945 and the NDCT Rules, 2019, DTAB recommended.

Source: Shardul Nautiyal, Pharmabiz, 12.03.2021

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Multiplex PCR test proves to be better alternative to diagnose gastrointestinal infections: Experts

Multiplex Polymerase Chain Reaction (PCR) test has demonstrated its superiority in diagnosing gastrointestinal infections and has proved to be a rapid, sensitive and specific alternative to conventional detection methods, according to experts. The conventional tests include stool culture, microscopy for ova and parasite, ELISA and rapid lateral flow test that can only test one to a few bacterial pathogens per test and takes anywhere between 30 minutes to three days.

As against this, molecular tests such as PCR help with faster and accurate diagnosis of the causative organism. As the detection is based on presence or absence of virulence associated genes of the organism, the identification is highly specific. Over and above this, the fact that presence or absence of all the probable causative organism can be carried out at one go, it negates the need for a cumbersome step-by-step process to arrive at the final diagnosis.

Dr Gunisha Pasricha, Principal Scientist, MedGenome Labs informed, "MedGenome's Gastrointestinal Pathogen Panel is a qualitative multiplex PCR-based test to detect and differentiate nine species of groups of bacteria, four parasites and five viruses that can all cause gastroenteritis in humans in a single test. It is a new and innovative tool to help in the diagnosis of gastrointestinal diseases and will help the clinicians take an informed decision for the patient."

Gastrointestinal infectious diseases are very common worldwide and an important cause of morbidity and mortality, particularly in infants in developing countries like India. According to WHO, globally, there are nearly 1.7 billion cases of childhood diarrheal disease each year and it kills around 525,000 children under? ve every year. Diarrhoea and other intestinal infections are caused by a wide range of bacteria, viruses, protozoa, and parasites.

The traditional culture and microscopy procedures are time-consuming, lack sensitivity and require special laboratory setup and well-trained staff. However, based on the advancement in the molecular diagnostics and with the introduction of commercially available tests, traditional diagnostic techniques have been continuously replaced by these newer rapid antigen detection and molecular-based methods.

MedGenome's new offering of the Gastrointestinal Pathogen Panel is a qualitative multiplex PCR-based test which helps detect and differentiate within less than three hours species or groups of bacteria and five viruses that can all cause gastroenteritis in humans.

"We are all aware about RT-PCR and how it is considered as gold standard for Covid-19 diagnosis. In gastrointestinal infections, our Gastrointestinal Pathogen Panel can test multiple pathogens in a single test. It is a qualitative multiplex PCR test that detects DNA or RNA of pathogens causing common gastrointestinal infections from stool samples," Dr Pasricha further informed.

Individuals suffering from diarrhoea with fever, severe abdominal cramps, signs of sepsis, moderate to severe disease, high risk of spreading disease to others and during known or suspected outbreaks, presenting with

dysentery, symptoms lasting more than seven days and immunocompromised patients with diarrhea are eligible for the test.

Talking about steps in conducting the test, Dr Pasricha explained, "Once the stool specimen reaches the lab, we have a pre-analytical check which is the first level of quality check. Once we have this passed through Quality Control (QC), the sample is proceeded for the lab protocols. The next step that follows is the nucleic acid (DNA and RNA) extraction. The extracted nucleic acid is now used to identify the target genes using the specific primer probes for the pathogens listed in the panel. The outcome is then shared with the treating clinician in terms of a report."

Source: Shardul Nautiyal, Pharmabiz, 20.03.2021

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FEATURE

Healthcare 3D Printing Market to Grow at 18% CAGR

As per our research report, the global healthcare 3D printing market size is forecasted to be growing at a CAGR of 18% between 2020 to 2025. 3D printing provides a huge promise in the world of health care, particularly because of the potential to create highly personalized items at the point of care. However, this situation still poses obstacles to effective supervision. Also, 3D printing continues to help humanity fight the pandemic in numerous ways.

The medical sector is considered the most innovative in modern therapies, and technologies have been developed. Not to mention the innovations that push all this forward. There's no lack of miracles because that's all going on. Now there's also 3D printing in healthcare. Aprecia Pharmaceuticals' Spritam for epilepsy is the first and only FDA-approved 3D-printed drug. 3D printing, also known as additive manufacturing, uses a layer-by-layer additive process to manufacture physical, personalized medical devices and products from a three-dimensional data file. It is known that medical applications for 3D printing, both current and future, would bring about innovative improvements. They may be grouped into many wide categories, including the production of personalized prosthetics, implants and anatomical templates, tissue and organ manufacturing, the manufacture of specialist surgical instruments, medicinal science in the manufacture of drugs, dosage forms, delivery & discovery, and manufacturing of medical devices.

Besides, it offers many benefits over conventional reconstructive surgeries by lowering the procedural complications inherent in complicated operations, decreasing the vulnerability to infection, and reducing the period of anesthesia exposure. Moreover, 3D printing technology allows surgeons to increase the success rate of complex operations. The benefits of implementing 3D printing in medicine include not only customization and customization of medical devices, medications, and supplies but also cost-effectiveness, improved efficiency, the democratization of production and production, and enhanced cooperation.

Driving Factors:

The global market for healthcare 3D printing has expanded due to developments in medical research, testing, and analysis. Selective Laser Sintering (SLS) is widely using printing, showing the highest growth in the market. In the medical sector, 3D printing technology is gaining momentum. 3D printing allows archetypes and blueprints for objects and objects, and this process plays a vital role in many industries. The use of 3D printing in the healthcare sector has reshaped the healthcare industry's rising complexities worldwide. Industries like hip and knee braces to dental crowns, hearing aids and prosthetic limbs, and orthotics accessories showing substantial market growth. Hence, the medical implants healthcare 3D printing market is registering the highest CAGR growth. With these subtleties in mind, it is clear that the global healthcare 3D printing market expands at a sound pace in the times ahead.

Apart from these, recent technical inventions in 3D printing in healthcare are the crucial factors responsible for the healthcare 3D printing market's success. Fused Deposition Modeling (FDM) technology accounts for the largest market share in the market. Computer-assisted manufacturing tools and increasing demand for the minimum cost of 3D printers also allowed more hospitals to set up 3D printing labs. Several firms are rapidly focused on creating new 3D-printed devices and technology to satisfy the emerging need for 3D printing in the healthcare market. Also, the healthcare 3D printing industry shows substantial growth as a result of Government action to develop healthcare facilities and increase investment in the R&D industry. Also, healthcare practitioners are rapidly pursuing 3D printing because it decreases the complications involved with anesthesia during long procedures and strengthens healthcare.

Rising demand for implants customizations during surgical procedures coupled with growing R&D investments, growing clinical usage of 3D printing in pharmacology such as polypill that is used for the treatment of numerous diseases, collaborations between academic institutions, hospitals, and companies, increasing geriatric population drives the 3D printing medical devices market.

Restraining Factors:

However, Stringent regulatory process for the approval of 3D-printed medical devices, a Dearth of skilled professionals coupled with the high cost of 3D printing software, high printers' costs, and biocompatibility issues 3D-printed medical devices are the major factors hampering the growth of the market.

Market Opportunities:

Furthermore, untapped markets in the developing countries, direct digital manufacturing, the reconfiguration of supply chain models of medical device suppliers, the expiry of core patents in the coming years, and the rising demand for organ transplantation are projected to create growth opportunities for market players. Personalized digital data also provides a roadmap for the future. The recent popularity in 3D printing of tablets will open new doors for applying 3D printing technology in the pharmaceutical industry.

Impact of COVID-19 on the global Healthcare 3D printing Market:

In the event of a COVID-19, open-source systems facilitate quick improvement based on the contributions of many people who work remotely. The citizen supply chain focused on 3D printing was reported to be a powerful approach during COVID-19. This approach can be found in a variety of manufacturing sectors. The multiple problems facing healthcare facilities were brought to the fore in 2020 due to the pandemic, including shortages of prescription materials, supply chain delays, and a lack of Personal Protective Equipment (PPE) for healthcare employees. The industry's responsiveness has eased some of the big shortages faced by the healthcare sector in the battle against COVID-19.

Over the six months of 2020, 3D printing has proven its worth by manufacturing on-demand medical supplies such as PPE and COVID-19 research swabs. 3D printing emerged as a vital pandemic method because the materials used to build PPE parts, test swabs, ventilator components, and other short supply products could be manufactured and produced locally. Biocompatible materials have allowed these materials to be produced, tested, validated, and easily applied to patients. Businesses, hospitals conducted many projects and partnerships, and researchers used 3D printing after the COVID-19 pandemic and to support local 3D printing activities that can be life-saving.

The FDA also issued emergency use authorizations as it did in response to the COVID-19 pandemic for such 3D-printed ventilator units, leading to the prominent growth of the market. The scalability and durability of the technology will continue to support the healthcare sector even after the pandemic's conclusion. Also, limitations on transport and commerce, quarantine, border controls, and interruption of production significantly affect the global supply chain of essential medical products. Fortunately, 3D printing technology can be an efficient solution to this issue. Using this technology, the developed open-source prototypes of medical devices are widely shared.

This research report on the global healthcare 3D printing market segmented and sub-segmented into the following categories and analyzed market size and forecast for each segment until 2025.

Healthcare 3D Printing Market - By Component:

- System/Device
- Materials
- Services

Healthcare 3D Printing Market - By Technology:

- Droplet Deposition (DD)
- Fused Deposition Modeling (FDM) Technology
- Low-temperature Deposition Manufacturing (LDM)
- Multiphase Jet Solidification (MJS)
- Photopolymerization
- Stereolithography (SLA)
- Continuous Liquid Interface Production (CLIP)
- Two-photon polymerization (2PP)
- Laser Beam Melting
- Selective Laser Sintering (SLS)
- Selective Laser Melting (SLM)
- Direct Metal Laser Sintering (DMLS)
- Electronic Beam Melting (EBM)
- Laminated Object Manufacturing

Healthcare 3D Printing Market - By Application:

- External Wearable Devices
- Clinical Study Devices
- Implants
- Tissue Engineering

Healthcare 3D Printing Market - By End-User:

- Medical & Surgical Centers
- Pharmaceutical & Biotechnology Companies
- Academic Institutions

Healthcare 3D Printing Market - By Region:

- North America
- Europe
- Asia Pacific
- Latin America
- The Middle East and Africa

Geographically, North America, followed by Europe, is expected to account for the leading share in the global Healthcare 3D Printing Market during the forecast period. Simultaneously, the Healthcare 3D Printing Market is predicted to register the fastest CAGR between 2020 to 2025 among all regions.

Source: Press Release, Pharmiweb.com, Global Pharma News & Resources: 12.03.2021 (Excerpts)

Indian Drug Manufacturers' Association (IDMA) and **Aptar Pharma** is organizing a Webinar on **"RETHINKING ACTIVE PACKAGING: DERISKING DRUG PRODUCT STABILITY WITH NOVEL MATERIAL SCIENCE SOLUTIONS"** on the **Tuesday, 30th March 2021** at **4.00 p.m.**

The Webinar shall be presented by:

- **Mr Francois Bidet, VP Business Development, EMEA, Aptar CSP Technologies**

For the past several decades, **Aptar Pharma, who are our Members,** have been providing drug delivery solutions that help improve and save patient lives.

Stability challenges are likely to increase with the development of more potent APIs, larger molecules, and modified release tablets. Innovative and evolving dosage forms, such as chewable, micro-tablets and orally disintegrating tablets, also face heightened stability and shelf life challenges. These deficiencies are often linked to the presence of moisture and/or oxygen in the packaging headspace.

In this webinar, you will learn how active packaging solutions offer a practical way to increase efficiency and effectiveness of pharmaceutical packaging technology across a range of applications. Explore how 3-Phase Activ-Polymer™ technology can be integrated into blister packaging, stick packs, inhalers, medical devices, bottles, and more to control moisture and/or oxygen in the packaging headspace, ensuring drug product stability and enhancing shelf life.

Key Learning Objectives:

- Understand the impact of packaging choices on stability and shelf life of drugs.
- Review best practices and new techniques for the management of microclimate in packaging.
- Learn about the benefits of active packaging in challenging environments.

Kindly note that there are no registration fees for this webinar but prior registration is compulsory – Please find attached the registration link for the webinar

Looking forward to your support and participation in making this webinar a grand success.

Thanks & regards,

Daara B Patel
Secretary – General, **IDMA**

Indian Drug Manufacturers' Association 102, A Wing, Poonam Chamber, Dr. A. B. Road, Worli, Mumbai-400 018. Maharashtra, India. Tel No. 022 24974308 / 24944624/ Website: www.idma-assn.org	**Prachi Singhai** Manager Marketing & Communication, India & S E Asia **Aptar Pharma** R 854, TTC Industrial Estate, Thane Belapur Road, Rabale, Mumbai, Maharashtra 400701 India (phone) +91 22 6195 1946 | (mobile) 00 91 9892026098 **prachi.singhai@aptar.com/ www.aptar.com**

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