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IDMA BULLETIN

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We wish all our Members & Readers
"Happy Republic Day"
26th January

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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IDMA BULLETIN

Vol. No. 52 Issue No. 03 15 to 21January 2021

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Period from 1st April, 2020 to 31st March, 2021 not to be considered for calculation of validity of Prior Environmental Clearance in view of COVID-19 lockdowns – all activities to be treated as valid - reg.

Environment Notification S.O.221(E), dated 18th January, 2021

Whereas, the Central Government in the erstwhile Ministry of Environment and Forests, in exercise of its powers by 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 said 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 said notification, their expansion and modernisation and/or change in product mix, as the case may be, before any construction work or preparation of land by the project management except for securing the land;

And whereas, in view of the outbreak of Corona Virus (COVID-19) and subsequent lockdowns (total or partial) declared for its control, implementation of projects or activities in the field has been affected. Ministry of Environment, Forest and Climate Change is in receipt of number of requests for extension of the validity of prior environmental clearances beyond the maximum period allowed in the said notification, as the COVID-19 pandemic has not yet come to an end. The matter has been examined in the said Ministry and the concern is genuine keeping in view the fact that due to lockdowns (total or partial), continuation of activities in the field has been difficult.

Now, therefore, in exercise of the powers conferred by sub-section (1) and clause (v) of sub-section (2) of section 3 of the Environment (Protection) Act, 1986 (29 of 1986), read with sub-rule (4) of rule 5 of the Environment (Protection) Rules, 1986, the Central Government, after having dispensed with the requirement of notice under clause (a) of sub-rule (3) of rule 5 of the said rules in public interest, hereby makes the following further amendments in the notification of Government of India, in the erstwhile Ministry of Environment and Forests, number S.O.1533 (E), dated the 14th September, 2006, published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-section (II), namely:-

In the said notification,-

(i) in paragraph 7, in sub-paragraph 7(i), under sub-heading II. "Stage (2) – Scoping", after clause (viii), the following clause shall be inserted, namely:-

"(ix). Notwithstanding anything contained above, the period from the 1st April, 2020 to the 31st March, 2021 shall not be considered for the purpose of calculation of the period of validity of Terms of Reference granted under the provisions of this notification in view of outbreak of Corona Virus (COVID-19) and subsequent lockdowns (total or partial) declared for its control, however, all activities undertaken during this period in respect of the said Terms of Reference shall be treated as valid.";

(ii) for paragraph 9A, the following paragraph shall be substituted namely:-

"9A. Notwithstanding anything contained in this notification, the period from the 1st April, 2020 to the 31st March, 2021 shall not be considered for the purpose of calculation of the period of validity of Prior Environmental Clearances granted under the provisions of this notification in view of outbreak of Corona Virus (COVID-19) and subsequent lockdowns (total or partial) declared for its control, however, all activities undertaken during this period in respect of the Environmental Clearance granted shall be treated as valid.".

F.No.22-25/2020-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.4254(E), dated the 27th November, 2020.*

Draft FSS (Packaging) First Amendment Regulation 2021 – reg.

FSSAI Notification Ref.F.No.Std/SP-08/A-1.2019/N-01, dated 18th January 2021

1. The following draft of certain regulations further to amend the Food Safety and Standards (Packaging) Regulations, 2018, which the Food Safety and Standards Authority of India proposes to make with previous approval of the Central Government, in exercise of the powers conferred by clause (k) of sub-section (2) of section 92 read with section 23 of the Food Safety and Standards Act, 2006 (34 of 2006) is hereby published as required under sub-section (1) of section 92 of the said Act for the information of all persons likely to be affected thereby, and notice is hereby given that the said draft regulations shall be taken into consideration after the expiry of the period of sixty days from the date on which the copies of the Gazette containing this Notification are made available to the public;

2. Objections or suggestions, if any, may be addressed to the Chief Executive Officer, Food Safety and Standards Authority of India, Food and Drug Administration Bhawan, Kotla Road, New Delhi – 110 002 or send on email **regulation@fssai.gov.in.**

3. Objections or suggestions, received from any person with respect to the said draft regulations before the expiry of the period so specified, shall be considered by the Food Safety and Standards Authority of India.

Draft Regulations

1. (1) These regulations may be called the Food Safety and Standards (Packaging) First Amendment Regulations, 2021.

(2) They shall come into force with effective date for implementation to be either 1st January or 1st July subject to a minimum of 180 days from the date of their final publication in the official Gazette.

2. In the Food Safety and Standards (Packaging) Regulations, 2018 (herein after referred as said regulations), -

(1) In sub-regulation (4) of regulation 4, in clause (a), after second proviso, the following proviso shall be inserted, namely:-

"Provided further that other food grade packaging materials compatible with the water to be packaged may also be used. In such cases requirements of transparent bottle would not apply."

ADVT.III/4/Exty./465/2020-21

Arun Singhal, Chief Executive Officer, Food Safety and Standard Authority of India, Ministry of Health and Family Welfare, New Delhi.

Note : *The Principal Regulations were published in the Gazette of India, Extraordinary, Part III, Section 4 vide Notification Number File No.1-95/Stds/Packaging/SP(L&C/A)/FSSAI-2017, dated the 24th December, 2018.*

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Introduction of online e-PRC System for Application seeking Policy/Procedure relaxation in terms of Para 2.58 of FTP 2015-20 - reg.

DGFT Trade Notice No.38/2020-21, dated 15th January, 2021

1. Presently, this Directorate is receiving applications for seeking policy/procedure relaxation in terms of Para 2.58 of FTP 2015-20 in manual form (i.e. in the form of hard copy of prescribed format ANF 2D along with proof of payment of application fee and other related documents). As a consequence, rest of the process also happens in manual mode and takes time.

2. As a part of IT Revamp of the organisation, this Directorate has decided to introduce a new module (online e-PRC System) for seeking policy/ procedure relaxation in terms of Para 2.58 of FTP. Therefore, from 25.01.2021 onwards, all applications seeking policy/procedure relaxation are mandatorily required to be submitted online through the exporter's dashboard on the DGFT Website. Manual submission of application seeking policy/ procedure relaxation would no longer be allowed from 25.01.2021 onwards.

3. Accordingly, all exporters/importers seeking relaxation of FTP/HBP provisions are required to submit their application elcctroncially only. Physical copies of the application (s) seeking policy/procedure relaxation received after 25.01.2021 will not be acted upon by this Directorate.

4. Please navigate to **https://dgft.gov.in** → Services → Policy Relaxation Committee to access the new e-module. Please note that the entire process is designed to be paperless and contactless and any PRC submission, communication, clarification, correction as well as the approval on submitted applications would be electronic.

5. For any help and guidance on this new process, the Help manual & FAQs may be accessed on **https:// dgft.gov.in** → Learn → Application Help & FAQs. For any further assistance you may utilize any of the following channels:

i. Raise a service request/suggestion ticket through the DGFT Helpdesk service link under Services → 'Complaints & Suggestions'

ii. Call the toll-free Helpline number 1800-111-550

iii. Send an email to **dgftedi@gov.in**

F.No.01/60/162/384/AM21/PRC

Vijay Kumar, Additional Director General of Foreign Trade, Directorate General of Foreign Trade, Department or Commerce, Ministry of Commerce & Industry, New Delhi.

‘It’ll take 3-4 years to vaccinate 80% of population’

‘We are hoping by March, the Government allows us to export and give it to the private market’

IMAGE: A Serum Institute of India supply truck. The Serum Institute is the world’s largest maker of Vaccines. Photograph: Euan Rocha/Reuters

As the Serum Institute of India’s Covishield vaccine gets the thumbs up from the Indian regulator, the Pune-based firm’s CEO ***Adar Poonawalla*** speaks with ***Sohini Das*** on the road ahead.

Poonawalla says he will start ramping up once he has clarity on the supply contracts as it is a challenge to stockpile beyond a certain volume in the plant. He also says the special price of Rs.200 per dose is for the first 100 million doses supplied to the Government, while the MRP in the private market will be Rs.1,000 per dose.

The current licence given to the Serum Institute does not allow it to sell the vaccine in the private market or export it.

How many doses do you have and when will you start supplying them to the Government?

We have a stockpile of 50 million doses. We have no indication on how much the Government will take and how fast they will be able to take it. So we don’t want to make too much and have the material expire in our warehouse.

People were wondering if they can get the vaccine in the private market, but under the restricted licence I can only give it to the Government and not the private market or export it. If I make any more, I don’t know what I will do with it. I am going by their (Government’s) Guidance at the moment.

I have a commitment to supply to Covax, which is the African countries, Gavi etc, and then, of course, India. The Government will have to relax this norm and that I guess will happen over the next two months once it sees it has enough stocks.

Then we can give it to private hospitals, private markets and export it. It would take a month to get the World Health Organization’s pre-qualifications and other formalities.

We are hoping by March, the Government allows us to export and give it to the private market.

Is there a timeline to supply Covax?

Everyone (Covax) wants it early; they have said as soon as possible. We are trying to keep everyone happy and do the best we can. We are trying to give something to everybody to start with to protect the most vulnerable populations in their areas, and then we build from there.

There are the states in India, other African countries, countries like Bangladesh and Myanmar, and some others where we would supply eventually.

Will all of the 50 million doses you have now be supplied to the Indian Government?

Yes. A contract has not yet been signed. We are waiting for them to give us a purchase order or a letter that says that we want the vaccine, and tell us where to send it.

As soon as they give us that, within seven days we can send the vaccine to any part of the country in our refrigerated trucks.

Will the Centre or states buy the vaccine, and what will be its cost?

The purchase will be from the Centre. The Central Health Ministry will tell us how much to send and where. We are waiting for that. We are only going to deal with the Government of India on this. For the Government,

Covishield will have a special price of Rs.200 per dose for the first 100 million doses. After that we will see what the pricing should be.

Of course, in the private market, it would be much higher. The MRP will be Rs.1,000 per dose. We will receive Rs.600-Rs.700 at our end; the rest will go to the private distributors.

What is the current shelf-life allowed and when will you ramp up production?

At present, the shelf-life allowed is six months and we are submitting more stability data etc. This is also another reason why we do not want to make too much too soon. We can produce up to 100 million doses per month and I would ramp up once I get the permission to sell in private market and to export.

The problem is storing these huge and unprecedented volumes. Normally we make and send out of the factory. To store more than 50 million doses in the factory is challenging; that is why it is important to plan and ramp up only when I can actually supply.

This was very evident last month when I asked my guys to double the production and they asked where would they store it. It needs to be kept in a guarded secured cold room with proper provisions.

IMAGE: Boxes containing the vials of AstraZeneca's COVISHIELD, Coronavirus disease vaccine inside a cold room at the Serum Institute of India plant in Pune. Photograph: Francis Mascarenhas/ Reuters

Will your production be divided equally between India and Overseas?

I always maintained that it would be 50:50 for India and Overseas.

This is for the simple reason that India's population is so huge that even if we deliver 50 million doses abroad, at any given point we would also supply 30-40 million doses to India as well till we cover at least 80-90 percent of the population. This would take at least three to four years.

What is the update on the other vaccine candidates?

We are on track for the Novavax candidate and in two months we will have licensing for that as well. The unblinding of the data from the trials is expected in the next two months.

The RBD vaccine on Hepatitis B protein, a very safe platform (the in-house vaccine), is being tested and has completed Phase 2 abroad. Phase 2/3 is going on abroad and it is two to three months behind AstraZeneca.

By when can work begin on paediatric vaccines?

It will be four to five months at least before one can start trials on people below the age of 18. No one has recommended the vaccine to anyone below 18 yet.

One has to be extra careful with children; it can also be a lower dose. The scientists will work that out and look at the safety profiles. As adults, we have been exposed to so many colds and other viruses.

When we are given a chimp adenovirus, for example, as a vaccine carrying the SARS-COV-2 protein, one would react very differently from how a child may react who has not been exposed to many viruses yet. The immune systems will react differently.

The disease is not so bad in children, and that is the silver lining. We want to take time on this one.

Will COVID-19 vaccines account for the bulk of your revenues for FY22?

I do not want to speculate on revenues. Next March (2022) we do not know how much COVID-19 will contribute to our revenues. It would depend on how fast the people will take the vaccine and what hurdles be will there. Will I be sued; will I be stopped by courts -- these are all question marks.

You have asked the government to indemnify vaccine makers. What is the update?

All vaccine manufacturers have written to the Health Ministry. As the President of the Indian Vaccine Manufacturers Association, I have represented them. They will review it now and send it to the law ministry and take opinion.

During the period of the pandemic if there is an indemnity clause, it ensures the vaccination drive does not stop if, let's say, there is an injunction.

If there is an injunction and the court says that no more vaccine to be given to anyone pending further inquiry, many lives will be impacted (losing protection).

It is not about financial loss to the companies, but the entire government programme also stops. They will have to invoke some very high level Constitutional powers to over-rule such a situation. This has never been tested in our history.

Source: Business Standard/Rediff News, 11.01.2021 (Excerpts)

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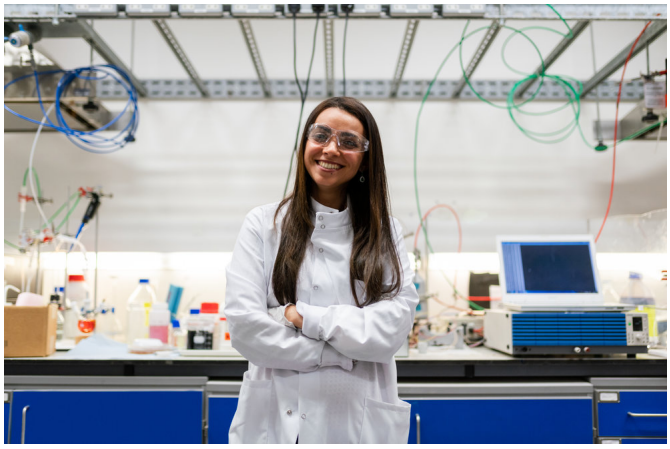
NEW DEVELOPMENTS

Single nanoparticles could pave the way for medicines on demand

For the first time, a single, twisted nanoparticle has been accurately measured and characterised in a lab, taking Scientists one vital step closer to a time when medicines will be produced and blended on a microscopic scale.



Physicists at the University of Bath who study materials on the nanoscale - that is, molecules 10,000 smaller than a pinhead - made their groundbreaking observations using a new method for examining the shape of nanoparticles in 3D. This technique, called the Hyper-Rayleigh Scattering Optical Activity (HRS OA) technique, was used to examine the structure of gold (among other materials), resulting in an exceptionally clear image of the 'screw thread' twist in the metal's shape.

Understanding the twists within a material (known as its chirality) is vital in industries that produce medicines, perfumes, food additives and pesticides, as the direction in which a molecule twists determines some of its properties. For instance, a molecule that twists clockwise will produce the smell of lemons while the identical molecule twisting anticlockwise (the mirror image of the lemon-smelling molecule) smells of oranges.

"Chirality is one of the most fundamental properties of nature. It exists in sub-atomic particles, in molecules (DNA, proteins), in organs (the heart, the brain), in bio-materials (such as seashells), in storm clouds (tornadoes) and in the shape of galaxies (spirals hurling through space)." said Professor Ventsislav Valev, who led the project.

Until now, physicists have relied on 200-year-old optical methods for determining the chiral properties of molecules and materials, but these methods are weak and require large amounts of molecules or materials to work. Through their use of a technique based on powerful laser pulses, Professor Valev and his team at Bath's Centre for Photonics and Photonic Materials have produced a far more sensitive probe for chirality, one that can detect a single nanoparticle as it floats freely in a liquid.

This discovery was made by Bath's Department of Physics in collaboration with the Department of Chemistry. The researchers' findings are published in *Nano Letters*. "This is both a record and a milestone in nanotechnology," said Professor Valev. "Pursuing this line of research has been one of the most rewarding achievements in my career."

"The observation by Valev's group is historic, and scientifically it inspires us in our work to synthesise new chiral 3D nanomaterials," said study co-author Professor

Ki Tae Nam from Material Science and Engineering at the Seoul National University in Republic of Korea.

The potential applications for ultra-sensitive chiral sensing are many. For instance, many Pharmaceuticals are chiral. Local Pharmacists will be able to harness the technology to mix substances in a completely new way, producing pharmaceuticals from minute droplets of Active Ingredients rather than from large beakers of chemicals.

"You'll be able to go to the chemist with a prescription and instead of receiving a medicine that has to be mixed from bottles of chemicals and then stored in the fridge for several days, you'll walk away with pills that are mini-labs. Upon cracking the pill, a precise number of micro-droplets will flow through micro-channels to mix and produce the needed medicine." said Professor Valev.

"For these mini-labs to produce chiral drugs, you'll need to know the number of molecules and catalysts within each micro droplet, as well as their chirality." said Ph.D., student Lukas Ohnoutek, who is the first author on the paper. "This is where our result is really important. We can now aim to produce microdroplets containing a single chiral nanoparticle, to use as catalysts in chemical reactions."

Professor Valev added: "Looking ahead, we can imagine building up chiral materials and even machines, one nanoparticle at a time, from such microdroplets. To do so would be amazing."

Source: My Vet Candy, 06.01.2021 (Excerpts)

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New findings help explain how COVID-19 overpowers the immune system

Seeking to understand why COVID-19 is able to suppress the body's immune response, new research from the USC Leonard Davis School of Gerontology suggests that mitochondria are one of the first lines of defense against COVID-19 and identifies key differences in how SARS-CoV-2, the virus that causes COVID-19, interacts with mitochondrial genes when compared to other viruses.

These differences offer possible explanations as to why older adults and people with metabolic dysfunction have more severe responses to COVID-19 than other individuals, and they also provide a starting point for more targeted experiments that may help identify therapeutics, said senior author Pinchas Cohen, Professor of Gerontology, medicine and biological sciences and dean of the USC Leonard Davis School.

"If you already have mitochondrial and metabolic dysfunction, then you may, as a result, have a poor first line of defense against COVID-19. Future work should consider mitochondrial biology as a primary target for SARS-CoV-2 and other Coronaviruses," he said. The study, published January 8 in the Nature journal Scientific Reports, expands on recent findings that COVID-19 mutes the body's innate inflammatory response and reports that it seems to be doing so by telling mitochondrial genes from their normal funtion.

"We already knew that our immune response was not mounting a successful defense to COVID-19, but we didn't know why," said lead author Brendan Miller, a senior doctoral student in the Cohen Lab at the USC Leonard Davis School. "What we did differently was look at how the virus specifically targets mitochondria, a cellular organelle that is a crucial part of the body's innate immune system and energy production."

Making use of the vast amounts of public data being uploaded in the early days of the virus outbreak, the research team performed RNA sequencing analyses that compared mitochondrial-COVID interactions to those of other viruses: respiratory syncytial virus, seasonal influenza A virus, and human parainfluenza virus 3. These reanalyses identified three ways in which COVID-19, but not the other viruses, mutes the body's cellular protective response.

Chief among their findings is that SARS-CoV-2 uniquely reduces the levels of a group of mitochondrial proteins, known as Complex One, that are encoded by nuclear DNA. It is possible that this effect "quiets" the cell's metabolic output and reactive oxygen species generation, that when functioning correctly, produces an inflammatory response that can kill a virus, they say.

"COVID-19 is telling the cell not to make these Complex One-related proteins. That could be one way the virus continues to propagate," said Miller, who notes that this, along with the study's other observations, still needs to be validated in a targeted experiment.

The study also revealed that SARS-CoV-2 does not change the levels of the messenger protein, MAVS mRNA, that usually tells the cell an attack has happened. Normally, when this protein gets activated, it functions as an alarm system, warning the cell to self-destruct so that the virus cannot replicate, Miller said.

In addition, the researchers found that genes encoded by the mitochondria were not being turned on or off by SARS-CoV-2 - a process that is believed to produce energy

that can help the cell evade a virus - at rates to be expected when confronted with a virus. "This study adds to a growing body of research on mitochondrial-COVID interactions and presents tissue-and-cell-specific effects that should be carefully considered in future experiments," said Cohen.

(Funding sources for the study include the National Institutes of Health, including grants R01AG061834 (Cohen) and P01AG034906 (Cohen), and the National Institute on Aging (AG000037, Miller). Dr Cohen is a co-founder, stockholder and board member of Cohbar Inc. Disclaimer: AAAS and EurekAlert! are not responsible for the accuracy of news releases posted to EurekAlert! by contributing institutions or for the use of any information through the EurekAlert system).

Source: University of Southern California, EurekAlert, 08.01.2021 (Excerpts)

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Scientists identify 'immune cop' that detects SARS-CoV-2

Scientists at Sanford Burnham Prebys Medical Discovery Institute have identified the sensor in human lungs that detects SARS-CoV-2 and signals that it's time to mount an antiviral response. The study, published today in Cell Reports, provides insights into the molecular basis of severe disease and may enable new strategies for the treatment and prevention of COVID-19.

"Our research has shown that MDA-5 is the immune cop that's tasked to keep an eye out for SARS-CoV-2 and call for back-up," says Sumit Chanda, Ph.D., Director of the Immunity and Pathogenesis Program at Sanford Burnham Prebys and senior author of the study. "MDA-5 recognizes replicating viruses in lung cells and activates interferon, the body's own frontline defender against viral invasion. Without a proper interferon response, viral infections can lead to deadly, out-of-control inflammatory reactions."

The new study surveyed 16 viral RNA binding proteins in human lung epithelial cells and identified MDA-5 as the predominant sensor responsible for activating interferon. MDA-5 detects double-stranded viral RNA - a form that the SARS-CoV-2 virus takes when it replicates to spread the infection. Prior to this research, it was known that activating interferon is key to a coordinated immune response to the virus, but the sentinel switch that controls the process was unknown.

"Understanding the biology of a virus and how it is detected is paramount to controlling infection and disease spread," says Chanda. "SARS-CoV-2 appears to disable the innate immune arm of our surveillance system, which, in the case of SARS-CoV-2 is controlled by MDA-5, and prevents the activation of interferon. It's the interferon response that drives the subsequent activation of many genes that exert antiviral activities - and data suggests that we need this activity to control early stages of viral infection and avoid the worst outcomes of COVID-19.

"Whether our bodies can defeat the virus's offensive tactics and activate interferon greatly influences the severity of disease. Past studies have shown that interferon responses are higher in patients with mild-to-moderate cases compared to reduced levels in critically ill patients," adds Chanda.

According to the World Health Organization, as of January 2020 there have been nearly 87 million confirmed cases of COVID-19, including nearly 1.9 million deaths. Although Remdesivir and two antibody treatments have received Emergency Use Authorization by the FDA, cases continue to rise. Newly approved vaccines are rapidly being deployed worldwide to end the crisis, however a handful of people are experiencing severe allergic reactions to the shots.

"There is still a tremendous need to develop effective therapies for COVID-19 and to prepare for future outbreaks," says Chanda. "It's possible that patients who become critically ill are deficient in the interferon signaling pathway. This research opens new avenues toward therapies that enhance the MDA-5 signaling to boost interferon levels early in infection to prevent severe disease.

"It also creates opportunities to develop COVID-19 vaccines that include an adjuvant(s) to enhance MDA-5 signaling. These would be formulations that use less 'vaccine' to minimize toxicity and side effects," adds Chanda.

(The first author of the study is Xin Yin, Ph.D., of Sanford Burnham Prebys and the Chinese Academy of Agricultural Sciences. Additional study authors include Paul D De Jesus, Kristina Herbert, Laura Martin-Sancho, Yuan Pu, Laura Riva, Chih-Cheng Yang and Sunny Yoh of Sanford Burnham Prebys; Jun Kanamune, Shimpei Gotoh and Yuki Yamamoto of Kyoto University; Kouji Sakai of the National Institute of Infectious Diseases (Tokyo); Judd F Hultquist of Northwestern University; and Lisa Miorin and Adolfo Garcia-Sastre of the Icahn School of Medicine at Mount Sinai.)

(Story: Materials provided by Sanford Burnham Prebys Medical Discovery Institute. Note: Content may be edited for style and length).

Source: Sanford Burnham Prebys Medical Discovery Institute, Science Daily, 12.01.2021 (Excerpts)

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Nutritional Calculation to be made based on recommended dietary allowance: FSSAI

The FSSAI has notified the provisions for nutritional information on labels of packaged food products under the Food Safety and Standards (Labelling and Display) Regulations, 2020. The regulation lays conditions for calculation of the nutritional information based on the recommended dietary allowance.

The regulation reads, "Nutritional Information per 100g or 100ml or per single consumption pack of the product and per serve percentage contribution to Recommended Dietary Allowance calculated on the basis of 2000kcal energy, 67 g total fat, 22 g saturated fat, 2 g trans fat, 50 g added sugar and 2000 mg of sodium (5 g salt) requirement for average adult per day, shall be given on the label containing: — (i) energy value (kcal); (ii) the amounts of (A) Protein (g); (B) Carbohydrate (g) and Total Sugars (g), added sugars (g); (C) Total fat (g), saturated fat (g), trans fat (other than naturally occurring trans fat) (g) and cholesterol (mg), provided that the content of saturated fat and trans fat may be declared on the label as "not more than" and saturated fat and trans fat to be given only if fat content is more than 0.5%, and (D) Sodium (mg)."

The explanation given by the FSSAI reads, "Serving or serve size means an amount of food customarily consumed per eating occasion or as defined on the label which is expressed in metric units. Additionally, it may also be given in common household measures like tea spoon, table spoon, cup that is appropriate to the food. Provided that the food claimed to be enriched with nutrients, such as, minerals, proteins, vitamins, amino acids or enzymes shall give the quantities of such added nutrients on the label."

Provisions were also made for Calculation of Nutrients, which include Calculation of Energy, and Calculation of Protein. The regulations also lay that nutritional information may additionally be provided in the form of Barcode/Global Trade Identification Number (GTIN).

Meanwhile, foods exempted from mandatory nutritional labelling include, 'unprocessed products that comprise a single ingredient; processed products which the only processing they have been subjected to is maturing and that comprise a single ingredient; waters intended for human consumption, including those where the only added ingredients are carbon dioxide; a herb, a spice or mixtures thereof/curry powder except sprinkler masala (masalas meant for direct consumption); salt and salt substitutes; table top sweeteners; coffee extracts and chicory extracts, whole or milled coffee beans and whole or milled decaffeinated coffee beans, coffee, decaffeinated coffee, soluble coffee powder, coffee chicory mixture; herbal and fruit infusions, tea, decaffeinated tea, instant or soluble tea or tea extract, decaffeinated instant or soluble tea or tea extract, which do not contain other added ingredients than flavourings which do not modify the nutritional value of the tea; fermented vinegars and substitutes for vinegar, including those where the only added ingredients are flavourings; flavourings, food additives, processing aids, food enzymes, gelatine, yeast; chewing-gums; alcoholic beverage; foods for special dietary uses (FSDU), foods for special medical purposes(FSMP), subject to the compliance of requirements specified in the food safety and standards (health supplements, nutraceuticals, food for special dietary use, food for special medical purpose, functional food and novel food) regulations, 2016'.

Source: Ashwani Maindola, FnBnews.com, 11.01.2021

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IPC invites stakeholders' suggestions on draft General Notices on Phytopharmaceuticals before February 28, 2021

The Indian Pharmacopoeia Commission (IPC) has asked for stakeholders suggestions on draft General Notices on Phytopharmaceutcal Drugs before 28th February, 2021. The stakeholders are invited to provide their comments to **lab.ipc@gov.in**. The draft for "General Notices on Phytopharmaceutcal Drugs" is being published by the IPC.

As per the Gazette Notification dated on March 19, 2019, G.S.R. 227(E), under Chapter I of Subsection (aa) of New Drugs and Clinical Trials Rules, 2018, "Phytopharmaceutical Drug" means a drug of purified and standardized fraction, assessed qualitatively and quantitatively with defined minimum four bio-active or phytochemical compounds of an extract of a medicinal plant or its part, for internal or external use on human

beings or animals, for diagnosis, treatment, mitigation or prevention of any disease or disorder but does not include drug administered through parenteral route.

The regulatory requirements for Phytopharmaceutical drug are under the purview of Central Drugs Standard Control Organization (CDSCO) as it differs from Ayurvedic, Siddha or Unani drugs which include all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of (disease or disorder in human beings or animals, and manufactured) exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani and other systems of medicine specified in the First Schedule.

However, Phytopharmaceutical drug are fraction of crude extract and are distinctly differentiated by being purified and standardized. A separate category of Phytopharmaceutical Ingredient (PPI) monograph has been included in IP where, an herbal drug/extract/ purified fraction has been characterized minimum of four marker compounds. However, such PPI monographs may or may not strictly meet the requirements of definition of Phytopharmaceuticals drugs. The inclusion criteria of herbal drugs monograph will also be applicable for PPI category monograph besides ensuring minimum four analytical markers.

The purpose of the PPIs monograph is to provide the scientific information on the quality standards and characterization of minimum four of its bio markers/ analytical markers in order to facilitate appropriate maintenance of the standards by the stakeholders. An example, the existing monograph in IP, namely Andrographis paniculata modified to provide for testing qualitatively/quantitatively for four bio/analytical markers such as, Andrographolide, Andrograpanin, Neo-andrographolide and 14-deoxy -11,12 didehydro andrographolide.

Such monographs are categorized with the suffix PPI next to the name of the monograph to denote that such ingredients demonstrate potentially meeting the defined criteria for a Phytopharmaceutical in IP.

However, the Phytopharmaceticals drugs dosage form monograph shall be included in IP only after the approval of CDSCO. It is to be recognized that mere inclusion of a monograph for an herb or extract or PPI in IP does not give it a status of drug and relevant regulations need to be complied with, and approval as a drug is to be obtained from the office of Drugs Controller General India (DCGI) after submission of relevant applications.

Source: Shardul Nautiyal, Pharmabiz, 16.01.2021

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Health Ministry lists precautions and contraindications for COVID-19 Vaccination

The Union Health Ministry has listed precautions and contraindications for Covid-19 vaccination along with a comparative factsheet for both the vaccines Covishield and Covaxin. The list contains information on vaccine platform, physical specifications, dosage, cold chain storage requirements, contraindications and minor AEFIs (Adverse Event Following Immunization).

In a letter to all states and Union Territories, the Ministry highlighted that under the Emergency Use Authorisation, the Coronavirus Vaccination is indicated only for people who are 18 years and above. If required, Covid-19 vaccine and other vaccines should be separated by an interval of at least 14 days.

"Pregnant and lactating women have not been a part of any Covid-19 vaccine Clinical Trial so far. Therefore, women who are pregnant or not sure of their pregnancy and lactating women should not receive Covid-19 vaccine at this time," the letter stated. "Interchangeability of Covid-19 vaccines is not permitted. The second dose should also be of the same Covid-19 vaccine which was administered at the first dose", the Ministry said in the statement.

In terms of contraindications, the vaccine is contraindicated for the persons with history of an anaphylactic or allergic reaction to a previous dose of Covid-19 vaccine, immediate or delayed allergic reactions to vaccines or injectable therapies, pharmaceutical products, food items, among others.

The letter stated that in case of persons having active symptoms of SARS-CoV-2 infection, Coronavirus infected patients who have been given anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma and acutely unwell and hospitalised patients due to any illness, the Covid-19 vaccination is to be deferred for four to eight weeks after recovery. For special precaution, vaccine should be administered with cautions in persons with history of any bleeding or coagulation disorder (like clotting factor deficiency, coagulopathy or platelet disorder).

"The following conditions are not contraindicated for Covid vaccine such as persons with past history of SARS-COV-2 infection, history of chronic diseases and morbidities (cardiac, renal, neurological), immuno-deficiency, HIV, patients on immune suppression due to any condition," the letter stated.

In the case of Covishied, some mild AEFI may occur like injection site tenderness, injection site pain, headache, fatigue, myalgia, malaise, pyrexia, chills and arthralgia and nausea. In case of Covaxin, some mild AEFIs may occur like injection site pain, headache, fatigue, fever, body ache, abdominal pain, nausea and vomiting, dizziness-giddiness, tremor, sweating, cold, cough and injection site swelling.

Source: Yash Ved, Pharmabiz, 16.01.2021

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MTaI urges Government to cut Customs Duties, Rollback Health cess to overcome pandemic challenges

The Medical Technology Association of India (MTaI) has urged the Government to reduce customs duties and rollback health cess in Union Budget 2021-22 to help the medical device sector overcome the severe financial crisis created by Covid-19 pandemic.

According to a whitepaper, jointly released by PricewaterhouseCoopers and MTaI last month, measures to control the spread of Covid-19 pandemic led to a sharp fall in revenues of hospitals, diagnostic centres, medical device firms and other constituents of healthcare ecosystem.

The shortfall in revenues forced these firms to postpone or cancel their capital expenditure plans. "Projects to increase healthcare access have been hampered by the pandemic and could potentially see delays in the near future," the whitepaper entitled 'The MedTech Industry in India – Covid-19 and Beyond' stated.

Even before Covid-19, the industry was reeling under 7-8% depreciation of Rupees against EUR and USD and policy decisions like imposition of additional 5% health cess ad valorem on imported medical devices and not reducing the customs duties in Union Budget 2020-21. Considering that more than 70% of demand for medical devices in India is met through imports, these factors kept healthcare costs for patients high.

MTaI Chairman and Director General Pavan Choudary said, "Respecting Prime Minister appeal to save the livelihood, the MedTech industry strived to protect jobs even during the Covid-19 pandemic. The global boards of MedTech firms displayed forbearance but if high customs duties and additional health cess continue they would grieve this erosion of their shrinking corpus."

"Health cess ad valorem and the current high customs duty regime on medical devices are also contrary to the vision of the Government to provide affordable healthcare to patients. The industry seeks immediate Government assistance by removal of health cess and reduction in customs duties in the upcoming budget," said Sanjay Bhutani, Director, MTaI.

Major concerns of the medical device industry that need to be addressed are that the high customs duties have adversely impacted the costs of products in India which contradicts the Government's efforts to provide low cost healthcare to the masses through ambitious schemes such as AB-PMJAY.

We seek reduction of customs duties (at the minimum, bring down to 2.5%) and rollback of the additional 5% health cess ad valorem imposed on imported medical devices at the earliest to affect the margins lost due to currency depreciation, Covid induced lockdown and the economic slowdown experienced thereafter.

It is worth noting that some segments of the industry experienced revenue downfall up to 85% due to postponement of elective procedures.

Additionally, since the custom duty regime on most medical devices in neighbouring countries of Nepal, Bangladesh, Sri-Lanka, and Bhutan is lower than in India, the duty differential could lead to smuggling of low-bulk-high-value devices. The result will not only be loss of revenue for the Government but also the patient will be beset with products which are not backed by adequate legal and service guarantees.

The customs duties on IVDs, which increased from 10% to 30% last year, that are imported from USA are also impacting the accessibility and affordability of diagnostics services in India.

India imports 60% of its diagnostics, most of which include tech-intensive testing methodologies such as molecular testing etc which serve the priority diseases like HIV, hepatitis, cancer markers, among others and are not domestically produced. Increasing customs duty of such preventive tests for critical diseases like cancer and HIV will severely affect the accessibility to affordable healthcare.

GST should not be charged on free goods and samples of healthcare products as it is needed to promote expansion of healthcare sector through reduced costs improving patient accessibility. GST on medical devices is taxed @12%; it should be brought at par with preferential products and taxed at lower rate of 5%. Spare parts to be used for medical equipment should be charged at the same rate of customs duty and GST.

Tax holiday should be provided to medical device R&D centres under the Income Tax Act to boost investment in setting up in-house R&D capabilities. We also seek tax incentives for the industry for developing global patents from India and tax deduction on income made by individuals or a company for rewards earned on patent development or patent licensing.

Healthcare services are currently exempt from GST. As a result, hospitals are not able to claim GST input. This results in higher cost of treatment for the patient. Once zero rated, hospitals will be able to avail GST credit on inputs, leading to lower healthcare services cost.

Expenditure on CSR is being disallowed in tax computation. CSR expenditure has been mandated under law and therefore should be claimable as tax deductible expenditure. Non-deductibility is pushing corporates to structure their CSR spends to maximise tax benefits which is leading to tax litigation cases as well and causing undue suffering to genuine corporates that wish to comply with this social obligation.

Currently, there are no tax benefits on export income. Export being a growth engine for the economy, it is important that efforts should be made to make it competitive in the international market. India's export performance in last 2 to 3 years has been on a decline which impacts the balance.

Source: Pharmabiz, 16.01.2021

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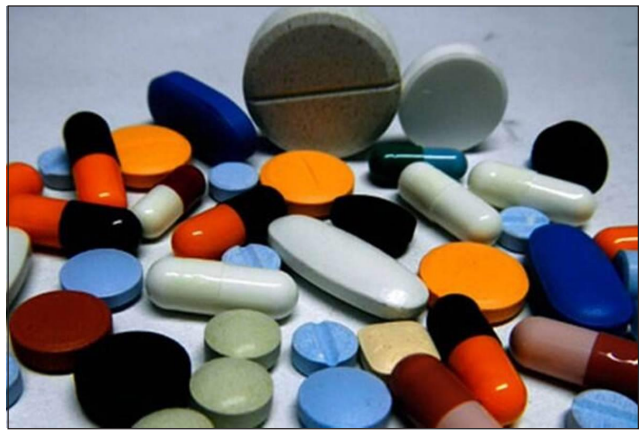
COVID PUSH: Pharma exports surge 16%, defy broader gloom

The rise is remarkable, especially in the light of initial Covid-induced disruptions in the supply chain and the temporary restrictions on the exports of 26 drug formulations and Active Pharma Ingredients (APIs) — including paracetamol, tinidazole and metronidazole — to keep domestic supplies steady.



A rise in India's pharmaceutical exports also propped its outbound shipments of the borader chemicals segment and reversed a potential fall.

India's pharmaceutical exports grew an impressive 16% year-on-year in the first eight months of this fiscal, defying an almost 18% contraction in the overall mechandise exports, as the Covid-19 pandemic caused a spurt in demand for medicines, especially from the largest market — the US.

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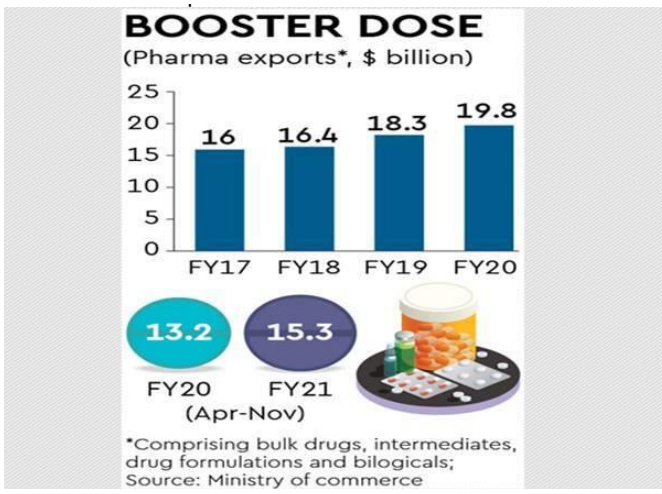
Exports of the pharmaceutical products — comprising drug formulations and biologicals, bulk drugs and drug intermediates — hit $15.3 billion between April and November, against $13.2 billion a year ago, showed the Commerce Ministry data. The data don't include exports of certain fine chemicals.



Excluding the outbound shipments of pharmaceuticals, overall goods exports would have shrunk at a faster pace of almost 20% until November this fiscal, against 18%. The US, which was hit the hardest by the pandemic, typically makes up for about 30% of India's exports.

The Commerce Ministry data showed that while exports of drug formulations and biologicals jumped by close to 18% to $12.4 billion, those of bulk drugs and intermediates rose by just over 10% to $2.9 billion. Meanwhile, imports of these pharmaceutical products rose by close to 9% on year in the April-November period to $4.2 billion. The Indian Pharmaceutical Industry is both an exporter to as well as importer of bulk drugs (APIs and intermediates that give medicines their therapeutic value) from China, the epicentre of the Covid-19. As much as 65-70% of these raw materials are imported from China. The increase in exports suggests raw material imports from China have largely stabilised now.

A rise in India's Pharmaceutical Exports also propped its outbound shipments of the borader chemicals segment and reversed a potential fall. Exports of chemicals and related products rose to $30.7 billion until November, up 2.4% from a year earlier.

Source: Banikinkar Pattanayak, Financial Express, 15.01.2021

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Budget 2021 Indian Pharma: Kiran Mazumdar-Shaw, Pankaj R Patel on Policy Supported Innovation, Roadmap & More

Union Budget 2021: Coping with COVID-19 has not just been a healthcare crisis but also a major learning lesson on the need to invest in the creation of a robust healthcare support system. But to get there, prominent industry leaders from the Indian Pharma Industry, feel the Union Budget could play an important role. The much-awaited budget, they feel, could make a beginning by announcing measures aimed at putting in place a policy-supported innovation roadmap for India – One that not only incentivizes the industry to invest more into research but also have policy enablers that address regulatory and financial concerns. Discussing these and more are Indian pharmaceutical industry leaders – Pankaj R Patel, Chairman, Zydus Cadila, and Dr Kiran Mazumdar-Shaw, Chairperson, Biocon at an online meet organized by Financial Express Online on what the Indian Pharma can expect from the Union Budget 2021.

Other than a Pharma innovation policy that can help the industry make a deeper impact, Patel speaks of the measures that can also help the industry make a greater dent in the global market, where India has not just to compete and also collaborate with China. Kiran Mazumdar-Shaw, while seeking measures that can help India transition from being a volume player to a substantial value player in the global market. She also sought ways to incentivize investments for startups and to support risk capital. Much like the way private sector involvement in COVID-19 testing helped in rapid rollout of testing, ways to enable similar Public-Private Involvement in vaccine rollout and its financing is also the way forward.

Source: Financial Express Online, 15.01.2021

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Need to strengthen healthcare infra following Centre's imposition of Health Cess: Experts

Experts have recommended that there is a need to strengthen healthcare infrastructure following the Government's imposition of health cess on the import of medical and surgical instruments. This imposition, announced by the Finance Minister in her budget speech last year, was introduced with the twin objective of providing impetus to the domestic industry for medical and surgical instruments/equipment and the development of healthcare infrastructure.

It is also noteworthy that the ultimate impact of this imposition will be borne by the common man who will pay the incremental cost for sourcing quality healthcare. According to Ayush A Mehrotra, Partner, Khaitan & Company, "One of the tested strategies may be granting incentives on raw materials or components for manufacturing and provide tax benefits to manufactures of medical and surgical instruments."

He further explained that while the intention of the Government, for introducing this rather protectionist policy, is in line with the long-term goal of "Make in India" and "Vocal for Local", but a singular plan of action such as this policy may not prove effective to face the challenge. The imposition of a non-creditable health cess on a pricecaped industry, which is heavily dependent on imports, appears to be a knee-jerk action with expectations

of a miraculous and instant change for this technology-sensitive industry.

It has been emphasized that the Government should introduce focused measures to create a world-class healthcare infrastructure along with developing the medical device manufacturing sector. "Another low hanging fruit in this direction is to grant exemption from health cess on domestic sales by Export Oriented Units (EOUs) and Special Economic Zones (SEZs), as highlighted by the Export Promotion Council. Further, concessional rates of health cess for a specified time period to allow the recovery of the industry from the adverse impact of Covid-19 pandemic, may also prove helpful," said Upkar Agarwal, Associate, Khaitan & Company.

According to Rajiv Nath, forum Coordinator, Association of Indian Medical Device Industry (AiMeD), "The Health cess is very well-intentioned and needed as a twin strategy to foster the creation of healthcare infrastructure and encourage Make in India to address our 85% import dependence and an import bill of Rs.42,000 crore by giving nominal tariff protection to domestic manufacturers. However, the cess collected was to be used judiciously to help create healthcare infrastructure which is also inadequate in India.

The onset of Covid-19 exposed the soft underbelly of healthcare insecurity of India with huge over-dependence on imports and the nation had to undergo a lengthy lockdown as the country prepared to build the health care and medical devices manufacturing infrastructure and inventory of vital Covid-19 related medical devices like ventilator, masks, thermometer and PPE kits." He further said that consumers are not gainers from low duties if they have to pay the misleading excessively artificially inflated MRP and have exposure to inconsistent prices that are linked to a volatile currency exchange rate.

Echoing similar views, Ayush Mehrotra said, "At this stage, it is also pertinent to note the legacy issues regarding utilization of Cesses, as highlighted by Comptroller and Auditor General of India in its report of FY 2018–2019, whereby the Government retained Rs.1.1 lakh crore out of Rs.2.75 lakh crore, collected by way of different cesses, in Consolidated Fund of India instead of transferring in a dedicated reserve fund, much less utilizing it. Thus, the long-term objective of developing the health infrastructure is likely to wriggle with the ghost of the past."

Source: Shardul Nautiyal, Pharmabiz, 13.01.2021

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NPPA asks Companies to provide data on issuance of list of 324 Overcharging Cases related to DPCO violations

The National Pharmaceutical Pricing Authority (NPPA) has directed pharmaceutical companies to provide relevant data based on the updated provisional list of 324 Overcharging Cases under litigation related to Drug Prices Control Order (DPCO) - 1979, 1987, 1995 and 2013 violations. The concerned companies may provide their feedback within 15 days from the date of publication of this provisional list which is January 11, 2021. As per the NPPA order issued, the companies have been directed based on the subject cited and to state that National Pharmaceutical Pricing Authority has taken up an exercise to update the database in respect of Overcharging Cases (OC) under litigation relating to DPCO - 1979, 1987, 1995 and 2013. The data available in respect of such OC cases has been updated.

NPPA order further stated, "It has been decided to upload the provisional list of OC cases under litigation on the website of NPPA so that companies involved may see the status of their case and if there is any discrepancy in the provisional list, the concerned companies may provide appropriate information or feedback. Such feedback from the companies would help in timely updation and reconciliation of data."

Feedback from companies, seeking any modifications in the provisional list, should be appropriately backed by supporting documents. Th interest amount in respect of cases included in the provisional list have been updated wherever possible upto November 30, 2020. Any payment/ part - payment made has been adjusted from overcharged amount while updating the interest, due to which in some cases the date of updation on interest may vary.

In case any modification, addition or deletion is required in the provisional list, the concerned company may provide relevant data within15 days on the publication of this list. The data provided by the company shall be examined by NPPA. If found correct, required modifications, additions or deletions shall be done in the provisional list, the NPPA order stated. The national drug pricing regulator NPPA had earlier last year in February asked for suitable responses from manufacturers on 228 cases of DPCO-2013 violation following Show Cause Notices (SCN).

It was recommended that in cases where companies had not submitted data even after issuance of SCN

as required by NPPA Guidelines, the SCN may be converted into a demand notice and the company given last opportunity to submit data failing which action will be taken as per the law of the land. Further, it was also decided to examine the cases and related recommendations and undertake necessary changes in the existing NPPA Guidelines. It was also decided that CA audited data may be certified by the statutory auditor of the manufacturer or company and countersigned by the respective Company Secretary.

As per a Notification, NPPA has proposed to set up Price Monitoring and Research Units (PMRUs) in states and Union Territories (UTs) across the country to support state drug controllers and itself to check drug price ceiling violations. PMRU is aimed at keeping a tab on drug price ceiling violation and to ensure that the purpose of the DPCO-2013 is achieved effectively and in a proper manner. The Union Territory of Jammu and Kashmir and states like Maharashtra, Gujarat, Uttar Pradesh (UP) and Rajasthan are some of the latest states where PMRUs have been set up.

Source: Shardul Nautiyal, Pharmabiz, 12.01.2021

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FPME urges DGS to provide Guidelines for migrating simplified registration to digital registration process

The Federation of Pharmaceutical Merchant Exporters and Allied Products (FPME) has urged the Directorate General of System (DGS) to provide Guidelines for migrating simplified registration to digital registration process with fixed time lines for MSME Pharma exporters. The association also requested DGS to provide process to attach documents and date for simplified registered exporters, as registration will only add cost.

"We appreciate DGS's initiatives to provide custom related services online to exporters via ICEGATE portal. ICEGATE has provided exporters simplified registration option which is really simple and easy. However, there need to have password which is sent by ICEGATE," FPME in a statement said. The association stated that there is no process outline for exporters to approach for the same and only after simplified password issued by ICEGATE, the registration is possible and post registration, the exporter is not able to upload documents and supporting as same is required to any change in bank account. "Converting registration from simplified registration to digital registration is not available and exporter is stuck even if he has registration under simplified registration option," the association added.

"Under ICEGATE registration via digital signature, first and foremost requirement is for class three digital key, which most exporters do not require and do not have. Insisting for new class three digital key will add to unnecessary trouble and cost which exporters have to bear," FPME further said. "The merchant exporters have been regularly working hard to bring in the foreign exchange to India by exporting various pharmaceutical and other allied products. We have been working very hard and keeping India in forefront even during the times of pandemic like the other Covid warriors," stated FPME Managing Committee Member Ashutosh Jagnani. The main objective of FPME Association is to represent pharmaceutical and allied product merchant exporters in government, semi-government, regulatory, legislative and other trade and industry bodies for policy development and interventions.

Source: Yash Ved, Pharmabiz, 12.01.2021

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Change Curriculum to Industry Needs

Of late, there is an outcry from the Pharma industry experts that the pharmacy courses being offered by various institutions across the country must be tuned into the needs of the industry's requirements and standards. Otherwise, they argue, the employability of pharmacists in pharmaceutical companies, which are looking to adapt new technologies in the changing times, may reduce in the years to come. It is a fact that a lot of changes are happening in the pharmaceutical industry in the world. And India is no exception. It is growing with different formulation technologies, so the requirement today is entirely different. But unfortunately, the present curriculum of the pharmacy courses is not adequate to meet the growing industry demands. The present syllabus is very old and the students following it cannot be absorbed into the production units. The industry experts are of the view that alignment of curriculum with that of industry is necessary to address the challenges to be faced by the industries which are adapting newer technologies. The pharmaceutical industries have diverse sections and divisions like API-R&D, formulation R&D, Clinical Research, Analytical, Quality Assurance, Industry Regulatory affairs, Intellectual Property, Soft

skill Development, and many more. These sections have their individual necessities of proficiency and expertise. In order to cater to these needs, the pharmacists should be acquainted with necessary cognitive domains. Experts also feel that pharmacy education in India lacks the direction not just in terms of curriculum but also in terms of advanced laboratories and the required faculty. The syllabus is focused towards manufacture of medicines and not on the nuances of drug discovery.

The industry experts' concern is absolutely relevant as it stems from the fact that the pharmacy students who come out of the institutions hardly know anything about the industry. About 98 percent of the students do not even know about the industry operations. Definitely, they need to be taught further about industry and production for which the education system needs some fundamental changes. The PCI must change the syllabus and come out with a newer curriculum for industry requirements as a lot of changes are happening in the industry. The Indian pharmaceutical industry, for that matter the Pharma industry world over, is witnessing unprecedented changes, both in technological and other areas. Obviously, the requirement is entirely different today. The present syllabus is not adequate to make the students future-ready. So, it is time the PCI takes up the issue seriously and revise the syllabus in consultation with industry experts. It will go a long way in providing the much needed employment opportunities to thousands of pharmacy students every year.

Source: Ramesh Shankar, Pharmabiz-Editorial, 06.01.2021

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Industry urges Centre to urgently settle all 324 DPCO Overcharging Cases

In response to the National Pharmaceutical Pricing Authority (NPPA)'s recent directive to the pharmaceutical companies, the industry has asked the Government to urgently settle all 324 overcharging cases which are under litigation since past two to four decades related to DPCO violations. The drug pricing regulator NPPA had recently directed all the concerned companies to provide relevant data based on the updated provisional list of 324 overcharging cases under litigation related to Drug Prices Control Order (DPCO) of 1979, 1987, 1995 and 2013 violations.

The concerned companies have been asked to provide their feedback within 15 days from the date of publication of this provisional list which was January 11, 2021. "Cases need to be settled on priority as they have been under litigation for as old as 40 years or so. There have been several representations made followed by the constitution of a Drug Prices Liabilities Review Committee (DPLRC) under a Retired Judge. But nothing has been achieved till date. These cases should be brought under some kind of Amnesty scheme at the earliest for their settlement in the interest of the Government and industry," said an industry source on conditions of anonymity.

As per the NPPA order issued, the companies have been directed based on the subject cited and to state that NPPA has taken up an exercise to update the database in respect of Overcharging Cases (OC) under litigation relating to DPCO - 1979, 1987, 1995 and 2013. The data available in respect of such OC cases has been updated.

NPPA order further stated, "It has been decided to upload the provisional list of OC cases under litigation on the website of NPPA so that companies involved may see the status of their case and if there is any discrepancy in the provisional list, the concerned companies may provide appropriate information or feedback. Such feedback from the companies would help in timely updation and reconciliation of data." Feedback from companies, seeking any modifications in the provisional list, should be appropriately backed by supporting documents. The interest amount in respect of cases included in the provisional list have been updated wherever possible upto November 30, 2020. Any payment/part - payment made has been adjusted from overcharged amount while updating the interest, due to which in some cases the date of updation on interest may vary.

The data provided by the company shall be examined by NPPA. If found correct, required modifications, additions or deletions shall be done in the provisional list, the NPPA order stated. The national drug pricing regulator NPPA had earlier last year in February asked for suitable responses from manufacturers on 228 cases of DPCO-2013 violation following Show Cause Notices (SCN). It was recommended that in cases where companies had not submitted data even after issuance of SCN as required by NPPA Guidelines, the SCN may be converted into a demand notice and the company given last opportunity to submit data failing which action will be taken as per the law of the land.

Further, it was also decided to examine the cases and related recommendations and undertake necessary changes in the existing NPPA Guidelines. It was also decided that

CA audited data may be certified by the statutory auditor of the manufacturer or company and countersigned by the respective Company Secretary.

Source: Shardul Nautiyal, Pharmabiz, 15.01.2021

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Maharashtra FDA all set to launch PMRU to track drug price violations by companies

The Maharashtra Food and Drug Administration (FDA) is all set to kickstart operations of its Price Monitoring and Research Unit (PMRU) with a team of seven people in Mumbai headquarters to track price violations by pharmaceutical companies across the state. "A team of seven people are in the process of being recruited for the successful implementation of the PMRU for all the 36 districts of Maharashtra as National Pharmaceutical Pricing Authority (NPPA) has recently allocated Rs.33.88 lakhs for the same", according to a senior official associated with the development.

With the setting up of PMRUs, violations of drug ceiling pricing reported will be dealt timely with the help of the state NPPA cell in coordination with the NPPA in cases of contraventions to the provisions of Drug Price Control Order (DPCO-2013). Under the proposed scheme, the cell is to be headed by one person along with a team of NPPA officials whose strength will vary as per the size of the Pharma industry in the respective states.

Maharashtra falls under the category of A states and NPPA has accordingly sanctioned the budget as per the categorization. NPPA has categorised the states based on three categories, i.e. based on maximum, minimum and least number of pharma companies in the state for better division of work. Gujarat, Karnataka, Andhra Pradesh are among other states which fall under A category.

PMRUs have also already been set up in 15 states including Kerala, Gujarat, Odisha , Rajasthan, Punjab, Haryana, Tripura, Uttar Pradesh, Nagaland, Mizoram, Union Territory of Jammu and Kashmir, Andhra Pradesh, Telangana and Karnataka. NPPA had in 2016 proposed a plan to set up a ceiling price violation cell in each state to take action for any contravention to the provisions of Drug Price Control Order (DPCO-2013).

As per a Notification, NPPA had proposed to set up PMRUs in states and Union Territories (UTs) to support State Drug Controllers and through initiating a Central scheme of assistance at state level and UTs. A Total 21 states had given their consent for the formation of the PMRU in the past two years. These were Assam, Gujarat, Haryana, Maharashtra, Manipur, Odisha, Punjab, Tripura, Mizoram, Rajasthan, Chhattisgarh, Bihar, Nagaland, Goa, Delhi, Tamil Nadu, Madhya Pradesh, Uttarakhand, Puducherry, Andhra Pradesh and Kerala.

The NPPA has only an office in the national capital with no state level branches. The PMRUs were conceptualised to resolve this problem and the draft was announced way back in 2015. "Each unit will function under the direct supervision of the State Drug Controller. PMRUs will be the key collaborating partners of NPPA, with information-gathering mechanisms at the grassroots level. PMRUs will also ensure that the benefits of DPCO percolate down to the grassroots level. The Central funding will be for an initial period of five years subject to a mid-term review," the notification stated.

Through the price monitoring cells, NPPA will closely work with the state drug regulators to find out any discrepancies that affect the consumers. The officials heading the cell will report their findings to the NPPA directly in case they find any Pharma company violating the law by selling the drugs above the ceiling price.

NPPA held a meeting with all the State Drug Controllers in 2016 in Delhi to set up price monitoring cells in all the states across the country. While the expenditure related to manpower, amenities and other infrastructural cost will be borne by the Centre, state Government will have to provide the space for setting up the office within the state drug regulatory office, as per the plan.

Source: Shardul Nautiyal, Pharmabiz, 14.01.2021

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Industry stakeholders raise concerns about price increase of PVC granules

The rising prices of PVC granules in India are adversely affecting finished formulations of Pharma products and it is also affecting the sector's growth, say stakeholders. The industry has also requested the authorities to intervene and streamline the prices. They have said that it may be allowed to suspend production of a few products until the matter gets resolved.

The stakeholders claim that the industry is already facing several other issues, like GST refunds which are held up despite clearance in Icegate, increasing freight costs

of shipping liners, shortage of containers and demand of PVC suppliers for advance payments.

An industry insider has pointed out that the constraints have become more stringent for Small and Medium Pharma Manufacturers. The PVC value in the production of Pharma products is less than three percent of the cost of the whole product. But, gradually, rates of PVC granules have risen from Rs.105 to Rs.175 on a weekly basis from the month of August till November last year and thereafter on a daily basis subsequently leading to erratic or even no supply of the same.

Nipun Jain, Chairman, Small and Medium Pharma Manufacturers Association (SMPMA), said, "As informed by PVC suppliers there is a severe shortage of PVC resin, which is imported from China and the price of PVC resin has increased significantly from Rs.105 per kg in August 2020 to Rs.180 now. Although it is a very small component, the main issue which the industry is facing is a shortage of material. We do not have the clarity on reasons for the shortage, but earlier the lead time was approximately three to five days after placing an order which has increased drastically now and now ranges between 20-25 days. And due to these factors, our whole export consignments are held up."

Reportedly, some members of the Small and Medium Pharma Manufacturers Association have already conveyed that they would like to suspend some Pharma products' manufacture till March 2021 to absorb the losses.

Dr Viranchi Shah, National Vice President, IDMA, informed, "Recently there has been a surge in rates of PVC used for primary packing of medicines. The industry has experienced some escalation in rates of a few other inputs too. This has a direct upwards impact on the production costs of medicines. We hope that this is temporary, but if this pattern persists or if those prices do not normalise soon, the industry will have to consider a way to offset this extra cost of production."

Sandeep Modi, Secretary and Director, Federation of Pharmaceuticals and Allied Product Merchant Exporter and Director, Infugen Pharma, pointed out, "PVC is important majorly in Pharma packaging, as well as in the medical device sector. The increased cost of PVC material has impacted the exporters, as many devices made of PVC have increased significantly. For example, IV fluid administration set cost has doubled, IV fluid bottles made of PVC, costing has increased, but the industry cannot increase its price due to DPCO, PET bottles for liquid orals are also facing the same fate."

Harish Jain, Secretary, Karnataka Drugs and Pharmaceutical Manufacturers Association, informed, "Rigid PVC film is extensively used in packaging of oral solid dosage forms in the Pharma industry. Recently there has been a huge increase in the price from Rs.110 per kg to Rs.185 per kg. Supply also has been hampered. I understand from our vendors that PVC granules prices have been increased by their supplier who has a virtual monopoly. Another reason cited is anti-dumping duty. Price increase and supply shortage have made the situation very serious and if the trend is not arrested, there may be a potential shortage of medicines in the country. The Government, particularly NPPA, should engage with the PVC vendors and ensure there is no shortage of this essential input. It is also advised that the Government should withdraw anti-dumping duty with immediate effect."

Source: Usha Sharma, Express Pharma, 17.01.2021

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IPC to amend Monographs of Vaccines and Immunosera for human use in IP 2018

The Indian Pharmacopoeia Commission (IPC) has asked stakeholders for suggestions with reference to amendments in Monographs of Vaccines and Immunosera for human use, blood and blood related products and biotechnology derived therapeutic products in Indian Pharmacopoeia (IP) 2018.

IP standards are authoritative in nature and are enforced by the regulatory authorities for quality control of medicines in India. During quality assurance and at the time of dispute in the court of law the IP standards are legally acceptable. This is a relevant development as human vaccines and immunosera have taken centre stage in drug discovery and development with enhanced safety profiles for human use among others like blood and blood related products. The amendments will bring about upgradation in the IP standards.

As per the IPC notice, stakeholder's may provide comments within 45 days of upload of the monographs to **lab.ipc@gov.in**.

The significant features of IP-2018 are framed in accordance with the essential prerequisite for harmonization of analytical methods with those accepted internationally for monitoring drug standards. These include general chemical tests and Thin Layer Chromatography (TLC) for identification of an article have been almost eliminated and more specific infrared, ultraviolet spectrophotometer and HPLC tests have been given emphasis. The concept of relying on published infrared spectra as a basis for identification has been continued.

The edition of IP-2018 was released in September, 2017. It is in 4 volumes incorporating 220 new monographs covering Chemical: 170, Herbal: 15, Blood and Blood related products : 10, Vaccines and Immunosera for Human use: 02, Radiopharmaceutical Monographs: 03, Biotechnology Derived Therapeutic Products: 06, Veterinary Monographs: 14, besides 366 revised Monographs and 7 omissions.

India is one of the leading manufacturers of vaccines worldwide and supplies large quantities of basic and advanced vaccines across the globe. Vaccines have greatly reduced the prevalence of diseases and they continue to be important for global health today.

IPC as an autonomous Institution of the Union Health Ministry sets standards of drugs in the country with a vision to promote the highest standards of drugs for use in human and animals. It has basic function to update regularly the standards of drugs by publishing official written standard in the form of IP.

IPC also provides measurement standards in the form of IPRS which act as a finger print for identification of an article under test and its purity as prescribed in IP. The IP, or any part of it, has got legal status under the Second Schedule of the Drugs & Cosmetics Act, 1940 and Rules 1945 there under.

Source: Shardul Nautiyal, Pharmabiz, 18.01.2021

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Pharma industry has risen to occasion during the pandemic: Satish Reddy

He said the crisis itself presented the industry with several opportunities and allowed us to think differently

The Indian Pharma Industry has risen to the occasion and has made efforts to ensure that medicines and vaccines reach people during the pandemic, Dr Reddy's Laboratories Chairman Satish Reddy said on Friday, 15.01.2021. Speaking at the 25th Wharton India Economic Forum, he said the Indian Pharma industry ensured the continuity of supplies.

He said the crisis itself presented the industry with several opportunities and allowed us to think differently. It asked us to act with a sense of urgency in the interest of the patients because they are looking at us for affordable and accessible medicines, he added.

Talking about the opportunities provided by COVID-19, Reddy said that when it came to therapeutics, Indian companies have risen to the occasion, they did it by re-purposing the drugs. They worked in a collaborative manner with the regulator, to ensure the medicines reach the market fast without compromising any safety standards, he said.

"About vaccines, India is in the forefront", even before to the pandemic, around 60 percent of the global production of vaccines came from India, he said. When the pandemic came, it was incumbent upon Indian vaccine manufacturers to develop their own vaccines, which some companies such as Zydus and Bharat Biotech have done, and also there were collaborations, partnering with other companies, he added.

Serum Institute of India partnered with Oxford University, Dr Reddy's partnered with Gamaleya Institute of Russia. "This augurs well for the industry because they have risen to the occasion, shown a sense of urgency, got therapeutics and vaccines to the market and not only to supply to the Indian market but to the global market," Reddy said.

Currently, the Indian Pharma industry is about USD 40 billion, with potential in the next 10 years to go to USD 120 billion to 130 billion. This can be done by building on the existing strengths, and by building on the newer strengths, which can take us there, he added.

Right on the top of this is innovation in terms of value creation, another big opportunity in terms of value creation is in Biosimilars. There is also a tremendous opportunity in Active Pharmaceutical Ingredients and in generics also, Reddy said.

He added that Indian companies also have proved their mettle in complex and specialty generics. Speaking on

the occasion, Lupin Managing Director Nilesh Gupta said the Indian Pharma industry took proactive actions during the pandemic and ensured that manufacturing continued unhindered. We have actually grown from strength to strength. Manufacturing did not stop for a single day despite all kinds of challenges, he added.

Source: PTI, Business Standard, 16.01.2021 (Excerpts)

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Liquidity infusion, tax relief and GST waiver crucial for survival: Healthcare Chiefs

The Covid-19 aftermath now makes Indian healthcare providers to pursue the Union Government to infuse liquidity, tax relief and waivers including GST abolition into the Budget 2021. This according to the healthcare Chiefs is crucial for the sector's survival.

The year 2020 with Covid-19 pandemic has brought out the fact that a strong healthcare infrastructure is absolutely essential for a sustainable economy. It is important to at least double the healthcare budget from last year's meager allocation to improve access to affordable care, stated Dr Azad Moopen, founder Chairman and Managing Director, Aster DM Healthcare.

The budget should also be able to create capacities for vaccinating India's large population against which is key to end the pandemic and revive the economy. Allocation of sufficient funds to cover about 40% of the low-income population who fall under the Ayushman Bharat scheme through free vaccination shall help, added Dr Moopen.

Echoing Dr Moopen's view was Dr Somesh Mittal, MD&CEO Vikram Hospital, Bengaluru who said the pandemic has adversely impacted private healthcare which is having to battle on many fronts. Now the recovery is slow therefore relief measures from the Government in the budget are anticipated. Due to lockdown and Covid protocols, private hospitals faced financial losses while still continuing to serve patients. It is vital to consider the healthcare's burden of low financial performance by providing some relief.

Government should also come up with certain support measures for healthcare workers so that they can sustain through these tumultuous times. The positive actions anticipated in the Budget 2021 will help rejuvenate the healthcare sector," added Dr Mittal. According to Dr Ashutosh Raghuvanshi, MD & CEO, Fortis Healthcare, there is an urgent need to fast track the recovery of private healthcare providers, support infrastructure building, facilitate medical research investment whilst enhancing skill development of healthcare workers.

This is an opportunity to offset the challenges and gaps in our healthcare system by allocating more resources to encourage the PPP model, push digital health, boost local manufacturing of healthcare equipment, take steps to improve Patient-Doctor Ratio and encourage scientific costing and market-based fair pricing. Our strategy must integrate preventive and curative services, and make healthcare more affordable for the people of India, said Raghuvanshi.

Dr Manish Mattoo, Zonal Director, Fortis Hospitals, Bengaluru said that the expectations are for more Public-Private Partnerships especially in Tier 2 & Tier 3 segment that would bring in investment and expertise to upgrade healthcare infrastructure. We are also hopeful of better reimbursements in the *Ayushman Bharat* packages to encourage broader participation of the private sector."

Chiping in views from a diagnostic sector perspective, Ameera Shah, Promoter & Managing Director, Metropolis Healthcare said despite the overwhelming infrastructure challenges, this industry has played an unrelenting role to save patient lives during the pandemic. It is vital to strengthen the provisioning of Public-Private-Partnerships to ensure quality healthcare and also encourage investments. Government should also allocate funds towards universal vaccine coverage to combat a further surge in infections.

A Ganesan, Group Vice Chairman, Neuberg Diagnostics noted, "We need to needs to reinvent the health system as the gaps and fragilities are identified. Therefore, areas such as GST on all supplies/services to hospitals and laboratories should be removed. Hospitals and labs have no output GST liability and hence the input credits cannot be availed by the lab. In case, the GST is abolished on supplies to hospitals and labs, the price to consumers will come down significantly.

Source: Nandita Vijay, Pharmabiz, 18.01.2021

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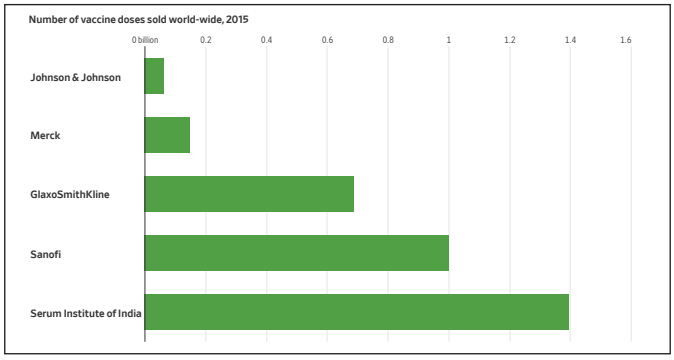
India's Vaccine Colossus is a Model for the World to follow

Mike Bird

Serum Institute to manufacture vaccines not just for the world's second-most populous country, but likely many others too



Source: Access to Vaccines Index

India has authorized two Covid-19 vaccines for use, putting its enormous vaccine-manufacturing capacity in the spotlight. Large parts of the rich world may have something valuable to learn.

The Serum Institute of India is the world's largest manufacturer of vaccines by volume, founded over 50 years ago by now-multibillionaire Cyrus Poonawalla. It will likely provide not only almost all the vaccines administered in India, but many elsewhere in the world too, once exports are permitted later in the year.

Research by Fitch Solutions outlines three groups of Asian economies this year: Those that can plausibly vaccinate most of the people in priority groups such as health-care workers and the elderly by June, those that can do so by September and those that will take longer. India is by some distance the lowest-income country in the first group of economies, which includes Hong Kong, China, Singapore and Malaysia. Wealthier South Korea and Thailand will take longer.

The Serum Institute's work requires a reliable and large domestic supply of the vials in which the vaccines are sealed and transported, ensured by companies such as Schott Kaisha and Piramal Glass. The existence of the world's largest vaccine manufacturer helps to establish the basis for a domestic network of suppliers.

Global supply chains and international trade have actually held up remarkably well under extreme circumstances over the past year. There is no need to reshore enormous amounts of manufacturing capacity, and any attempt at even halfway autarky will make all parties involved—importers and exporters—less prosperous.

But countries could take a leaf from India's book when it comes to manufacturing crucial items that might encounter massive demand surges, and where national priorities come to the fore. Doing so is unrealistic for every small and middle-size country, but production could be organized at the level of regional blocs such as the Association of South-east-Asian Nations. The pandemic hit Latin America harder than many other parts of the world, but its limited vaccine production means most nations there have a long wait ahead of them.

Workers at the Serum Institute of India in Pune.
PHOTO: /ASSOCIATED PRESS

Such a company need not be a Government Enterprise. As noted, the Serum Institute was founded as and remains a private company, though it cooperates closely with the Government. Establishing similar capacity could be achieved by cooperation on health-care regulation to create large regional markets, and the right financial incentives. The principle applies as clearly to personal protective equipment as it does to vaccines. Many far richer countries have fretted about shortages of such vital components because they are usually imported, and supplies are now uncertain with demand sky-high. Given the achingly slow pace at which European vaccines are being rolled out, the Indian program may well end up as a model for the world.

Source: wsj.com, 07.01.2021 (Excerpts)

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Regulations for 3D Printing

Ambika Khanna, *Senior Researcher, International Law Studies Programme, Gateway House*

3D printing (3DP), a critical emerging technology, has come into the limelight in the last decade. Industries such as Pharmaceuticals, Bio-medicine, aviation and automobiles have rapidly adopted 3D printing. Space agencies such as NASA and India's ISRO have been using 3 DP components in spacecraft. Its use is becoming so pervasive, that the 3 DP industries are expected to grow dramatically from $ 9.9 billion in 2018 to $4 2.9 billion by 2025.

However, despite its huge potential and significance for the digital economy, there is no global policy on 3 DP. While it has mostly escaped relevant regulation in countries such as India, in some countries the regulation is centred only around singular sectors such as medical devices. Now, industries across the board and around the world are looking at 3 DP to define the future of technology, and Governments must focus their attention on regulating 3 DP as a whole and sector-wise wherever the need arises.

The countries leading in the implementation and regulation of 3 DP are China, the US and the EU. China has been working extensively to develop its 3 DP market and the regulations to govern it. In 2017, it formulated an action plan for the development of the 3 DP industry 'Additive Manufacturing Industry Development Action Plan (2017-2020)'. A year later, China's Center of Medical Device Evolution, issued Guidelines for the regulation and registration of 3 DP medical devices including custom-built additive-produced medical devices. China has since released several Guidelines for different 3 DP medical devices including a 2020 technical guidance for 3D printed artificial vertebrae and an acetabular cup.

The US Government too is keeping pace. In 2017, the Food and Drug Administration (FDA) issued Guidance for additive manufactured medical devices, including recommendations for testing of devices that include at least one additively manufactured component or additively fabricated step.

In the aerospace industry, the Federal Aviation Administration (FAA) has developed an eight-year Additive Manufacturing Roadmap which will cover manufacturing and certification policies. FAA has also approved the manufacturing of 3D printed components for commercial engines. The US, through the introduction of several bills before the Congress, has tried to curb and control the misuse of 3D printing of firearms. However, none of these has seen the light of day yet.

The EU has specific legislation for the use of 3DP for manufacturing of medical devices. During COVID-19, it issued special Guidelines on using 3D printing for providing COVID-19 relief. In fact, the pandemic has accelerated the importance and implementation of 3DP. In March this year, an Italian start-up, Issinova, used 3D printing to manufacture respiratory valves to swiftly meet a supply shortage, arising out of increased demand, in a hospital.

These were made under the EU COVID-19 Guidelines for 3DP medical devices. Recently, the US FDA allowed 3D manufacturing of ventilator tubes and other accessories. So did the UK. With 3DP set to dominate the future of manufacturing, standardisation is a key concern. Therefore, the International Standards Organization (ISO) is currently developing a standard on 3D printing: IEC CD 23510.

ASTM International and ISO set up a working group in 2016 which has been recommending standards on additive manufacturing. It has created a framework on 3DP called the additive Manufacturing Standards Structure. ISO already has various standards on additive manufacturing, some of which have been developed while others are under development.

This Policy Guidelines required for 3DP, an important component of smart manufacturing. One of the salient features of the National Policy on Electronics, 2019 is to promote R&D and start-ups in emerging areas of technology including additive manufacturing. However, domestic manufacturing has yet to realise the full potential of 3DP.

Currently, India has only some sector-specific laws, such as in medicine, which can be interpreted to include

3DP. In the Medical/ Pharmaceutical field, where 3DP is most used, 3D printed objects include:

(a): Anatomical elements of the human body (organs, bones, glands, etc.);

(b): Pharmacological, immunological or metabolic in nature (e.g. medicines like tablets, capsules, etc.) and;

(c): Those that assist in the treatment, monitoring, alleviation, etc. (e.g. ventilators, scanning machines, medical instruments like forceps, scalpels, protective gear, etc).

India's Drugs and Cosmetics Act, 1940 does not specifically include such 3D printed objects but the Ministry of Health and Family Welfare expanded the definition of 'drugs' under the Act in February 2020 to include appliances whose function is the diagnosis, prevention or treatment of a disease. However, there is lack of clarity on the applicability of this legislation to 3D printed devices.

Similarly, while the Transplantation of Human Organs and Tissues Act, 1994 deals with transplantation of organs from a person-donor, transplanting a 3D printed organ/gland is beyond the scope of this legislation. These laws must be amended to include 3D printed devices and organs, or separate Policy Guidelines must be established for these.

The COVID-19 pandemic will certainly boost the use of 3DP. Any relief material, cure or preventive vaccine or drug that is discovered can quickly go into mass production using 3DP. This is an opportune moment for India to consider a comprehensive policy on 3DP or even the principles that should govern 3D printing. It can be the model for Global Guidelines. The comprehensive policy should address:

(a): purchase of 3D printers and scanners;

(b): manufacturing processes using 3D printers;

(c): quality of input material and final product;

(d): classification of computer-aided design (CAD)/ digital file, and whether it is a good ora service, which will determine its sale, distribution and taxation;

(e): product sale and distribution, including intermediary liability;

(f): Governing body and single window clearance for businesses;

(g): Standardisation:

(i): 3DP should be explicitly included under the Bureau of Indian Standards (BIS), the nodal standards body in India, BIS' compulsory registration scheme for printers.

(ii): BIS should consider establishing separate standards for input units used in 3DP, in addition to standards for the final product;

(iii): Central Drugs Standard Control Organisation, which sets the standards for drugs that are manufactured in and imported into India, should set standards for 3D printed medical devices and drugs.

While policy and standards will create a conducive framework for the regulated growth of 3DP in India, the Government needs to supplement this impetus with fiscal and tax incentives for those businesses adopting 3DP.

There are examples to follow; For instance, Australia, to promote advanced manufacturing including 3DP, created an ecosystem which included different funds for R&D and capital investments in emerging tech companies, and innovation labs that support new ventures in this sector. Recently, India announced Production-Linked Incentives for electronics manufacturing and the domestic manufacture of medical devices and drugs.

The Government is also in the process of considering similar schemes for other sectors such as auto components. Such incentives should be considered for 3D printing, across sectors.

With India's increased focus on self-reliance, 3DP can be a game-changer especially in critical sectors where India is heavily reliant on raw material or final product from countries such as China. Sectors such as electronics, Pharma, aviation or defence, can all be developed at home with a focus and clear policy on 3DP, with enormous benefit to the economy.

Source: Manufacturing Today India, 05.01.2021 (Excerpts)

2021 could be the Year of Quantum Drug Discovery

Nicole Hemsoth

While this New Year might not mark the moment when the first drugs are discovered via molecular dynamics simulations running on a full-scale quantum, there are several signs that a number of important collaborations between the few quantum vendors and major biotech companies are announced.

This means more internal labs dedicated to refining relevant algorithms, which could spur the industry ahead in the quantum computing space. It also incentivizes the quantum hardware vendors to understand how potential high-value users will want to interact with their devices in terms of programmatic stack, on-prem, and via cloud interfaces.

This is all coming at an important time because so far, commercial use of quantum computing has been limited. The use cases there are for the most part are interesting but if put into production, would rarely justify the operational cost of a quantum computer. If the life sciences industry gets serious about quantum, the game is really on.

There have been a growing number of academic papers on the algorithmic sides of molecular dynamics and related algorithms and applications relevant to biotech, but the actual enterprise mission from the large Pharma companies has been scant, lumping quantum in with other broad initiatives like AI integration, for example. In 2021 and ahead, however, the impetus and funding are in place, especially with COVID in the picture, for more forward-looking technologies that emphasize time to result—something that quantum computing has going, if it can be proven at reasonable scale and accuracy.

The interest in quantum for drug discovery is not just about hype, there are real potential solutions to some future problems traditional simulations might run into in the future, including scalability and computing capacity. While MD codes have impressive scalability on the world's largest supercomputers, with quantum, there is (in theory) to the number of molecules that can be run through in a single simulation via quantum methods. Not only will the results be far delivered faster (nearly instant/wall clock time, the development of such algorithms has its own timescale) the limits of computational capacity would no longer be a constraint.

Just today, Boehringer Ingelheim, a large European research and drug discovery company (19 billion revenue) became the first Pharma company to partner with Google for quantum computing efforts. The drug discovery giant also created an internal lab to collaborate on how AI and quantum will integrate with their current Pharma R&D plans.

"Extremely accurate modelling of molecular systems is widely anticipated as among the most natural and potentially transformative applications of quantum computing," says Ryan Babbush, Head of Quantum Algorithms at Google. Therefore, Google is excited to partner with Boehringer Ingelheim to explore use cases and methods for quantum simulations of chemistry. Boehringer Ingelheim brings both an impressive quantum computing team and deep expertise in real world applications of these capabilities in the Pharmaceuticals space,"

"Quantum computing has the potential to significantly accelerate and enhance R&D processes in our industry. Quantum computing is still very much an emerging technology. However, we are convinced that this technology could help us to provide even more humans and animals with innovative and ground breaking medicines in the future," Michael Schmelmer, Member of the Board of Managing Directors of Boehringer Ingelheim says. He adds that Boehringer Ingelheim is significantly increasing its investment in a broad range of digital technologies, encompassing key areas such as Artificial Intelligence (AI), machine learning, and data science to better understand diseases, their drivers and biomarkers, and digital therapeutics.

Early experiments are important for the burgeoning quantum industry but molecular dynamics simulations running on traditional high performance computing systems are set to be the norm for the next several years at the very least. The performance of these applications has increased dramatically with GPU and other accelerators, along with the scalability and efficiency.

Further, the results can be validated. If quantum is another "black box" with big promise but no reproducibility, its integration into MD/drug discovery workflows might only be relegated to finding a molecular needle in a haystack and passing the heavy lifting with reproducibility onto the supercomputers.

Still, time to market is everything in drug discovery. If there was a silver bullet for at least starting the search in the right spot, there's nothing to be lost in exploring a new area like quantum.

Boehringer Ingelheim is in front of a trend we expect to begin this year. For now, however, most Pharma companies include quantum as one of several emerging trends they're paying attention to. Roche has a general article about quantum on its website. Novartis CEO lists quantum along with other tech trends like telemedicine and counts it is off on the horizon. Others have been quiet entirely on the subject.

So, in the spirit of a new year, we predict that we will see stake-in-the-ground quantum computing in-house quantum labs at Pfizer, Johnson & Johnson, Novartis, and Merck, among others. More specifically, these will be separate from AI focused R&D labs. While Google took the lead on Boehringer Ingelheim's quantum collaboration, we expect to see IBM take a significant role in other commercial Pharma collaborations.

Quantum computing has had quite a bit of credence in research and academia but the enterprise use cases have been relatively slim with questionable real-world application value and ROI—at least currently. If Pharma comes out as the early adopter expect the entire quantum hardware market to explode sooner than anyone would have expected.

Source: www.nextplatform.com, 11.01.2021 (Excerpts)

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An unlikely Nation is kicking this Pandemic: Guess which. Then Why?

Mary Beth Pfeiffer

She is a Gynecologist. He is a surgeon. They are married and both 77 years old. In mid-November, they were diagnosed with COVID-19, first her, then him. Their paths diverge at this point, but not to worry.

She took the drug Hydroxychloroquine. He took *ivermectin.* They are both well now – walking, golfing, doing yoga — seven weeks later. The couple's brush with COVID might have ended very differently. In the United States, patients 75 to 84 years old die at 220 times the rate of adults under 30. But these two elderly, otherwise healthy physicians live in India. They were able to get early home treatment that is virtually, and unconscionably, unheard of in many western countries.

"Without any treatment, we know that the virus enters the cells and replicates there," Dr Makarand Paranjpe told me by phone from his home in Pune, where he had quarantined through a fever and other symptoms. "They can create disease that gets much more severe." Which, of course, is the point of treating early. Stop the progression ASAP.

From the outset, India, a nation of both economic vigor and poverty, knew it had to act decisively. It did. India locked down early and long; it promoted masks, tested millions, and, as with the Pune couple, treated the infected early.

Ten months into its battle with the SARS-CoV-2 virus, India is on track to become an unexpected warrior in the fight against this global pandemic. Although the densely populated nation has four times the population of the US., India has less than half the US, COVID deaths. And India isn't just beating the poorly performing US. In all, 98 nations have higher death rates than India.

It may be tempting to attribute this startling news to imperfect data from a developing country. But doctors in India, Indian press reports, and even the Wall Street Journal have taken note of a sea change in COVID there. "In September, India was reporting almost 100,000 COVID-19 cases a day, with many predicting it would soon pass the US in overall cases," the WSJ wrote on December 30. "Instead, its infections dropped and are now at one-fourth that level."

Dr Anil K Chaurasia, a Physician in Lucknow, in the state of Uttar Pradesh, watched this trend unfold. Starting about mid-September, "a clear decline in COVID cases and fatalities in India was noticeable," he told me in a text

message. The "steep decline in cases and fatalities is still continuing." Like a lot of western reporting, the WSJ article held fast to an accepted COVID theme. The Indian miracle was due to masks, it asserted, since they are worn by 88 to 95 percent of a population "bombarded" with public-service reminders. The article cited German research that showed masks work.

Fair enough. However, many factors are likely at play in India, including its painful yet supported national shutdown and individual state efforts at contact tracing and testing. But a pivotal role in any illness is surely the availability of treatments to resolve illness before crisis.

Late last March, as the US argued over the merits of Trump-endorsed Hydroxychloroquine and studies failed in late-stage patients, India decided to recommend the drug in its National Guidelines. HCQ "should be used as early in the disease course as possible, and should be avoided in patients with severe disease," the directives wisely state. As a precaution, authorities suggested an EKG to monitor for a rare heart arrhythmia that several COVID studies have since shown to be minimal.

The Power of one State:

But a crucial turn for India may have come in August when the Indian state of Uttar Pradesh recommended use of another drug: *Ivermectin*, which is coming on fast as a leading COVID treatment — without the baggage of at-turns effective but vilified Hydroxychloroquine.

This was no small move. Were it a country, UP's more than 230 million citizens would rank it fifth worldwide. As India's largest state, its embrace of *ivermectin* may have changed the treatment landscape across India.

"This authentication of *ivermectin* revived the faith of people," Dr Chaurasia told me, "and net result was a massive inclination to take these drugs" — both *ivermectin* and Hydroxychloroquine. By the end of 2020, Uttar Pradesh — which distributed free *ivermectin* for home care — had the second-lowest fatality rate in India at 0.26 per 100,000 residents in December. Only the state of Bihar, with 128 million residents, was lower, and it, too, *recommends ivermectin.*

But Uttar Pradesh did more than treat 300,000 mild cases at home through 2020; it also opted to use *ivermectin* to prevent infection. It seems a young health officer's COVID response teams had taken the drug and remained well – something prophylaxis studies support. UP, then had contacts of COVID patients take it, with similar success. "Recognizing the sense of urgency," Amit Mohan Prasad, a UP, health official, wrote in a December 30 article, "we decided to go ahead."

Such urgency is in short supply in the US, where the single-minded focus is on vaccination. Nonetheless, a group of doctors called Frontline COVID Critical Care Alliance is pressing for adoption of *ivermectin* immediately as an adjunct and bridge to vaccination. Its logic is twofold: *Ivermectin* has a known safety profile, as a life-saving drug given to millions since the 1980s, and 46 COVID studies, including 18 peer-reviewed, have shown "high efficacy."

However, even India is holding back, perhaps temporarily. The Indian Council of Medical Research declined in October to recommend *ivermectin* nationwide, citing, as other such entities have, the need for more data. Similarly, COVID Guidelines in bordering Bangladesh make no mention of the drug, despite successful studies done there.

In India, premier medical centers have, nonetheless, adopted it. In Bangladesh, doctors are using combination *ivermectin/doxycycline* therapy for home care, as are major hospitals in Dhaka for inpatients.

"The economy is flying," Dr Tarek Alam, who led several studies on the drug's efficacy, told me in an email. "Hospitals have empty COVID beds and the initial demand for ICU has come down." Indeed, Bangladesh – the world's most densely populated country — has an even lower fatality rate than India, ranking 126th globally.

Tipping Point?

Significantly, *ivermectin* received a tentative endorsement recently in research funded by the World Health Organization-hosted program Unitaid. After analyzing 11 randomized control studies, Dr Andrew Hill concluded: "If we see these same trends consistently across more studies, then this really is going to be a transformational treatment."

The agency is publicly acknowledging movement. "Preliminary data is promising," Herve Verhoosel, a spokesman, wrote in a statement, "but there is the need to await the results of further trials before determining next steps." More information is always better. But at what point, in a pandemic, is there enough?

Last spring, when COVID was new, Dr Dhananjay Bakhle, an MD in pharmacology in Pune, observed something. "Many doctors were afraid to use HCQ," he told me. "I was appalled since the solution was available." He began treating infections among 15,000 workers of

the pharmaceutical company where he directs medical research. Just 3 of 270 patients were hospitalized; he said, and none died.

"I trusted HCQ from the beginning," Bakhle told me, "and I didn't trust *ivermectin."* He was unsure both of dosing and how the anti-parasitic drug worked. So he did studies in his own laboratory, to test the drug's anti-viral mechanism, that he hopes to publish. "I changed my mind about *Ivermectin* in the last three to four months." Still, he sees HCQ as his top choice, while adding *ivermectin* frequently. He uses the drug alone when HCQ is contraindicated.

That was the case with his cousin Dr Paranjpe, who Bakhle treated in consultation with another physician. Did the drug make the difference for him, I asked Dr Paranjpe.

"I can't pinpoint if it was because of *ivermectin,"* he said. He also took doxycycline, zinc, aspirin, quercetin and, starting on day nine, the steroid Dexamethasone for inflammation. While his wife, Meera, had a mild and quickly resolved infection with HCQ, he suffered through days of low fever and body pain. Paranjpe may not know for sure what worked, but he does know this: He was happy to get early treatment at home In India. "Definitely, it is helping," he said.

A few days later he emailed an update. "Meera and myself, we both are feeling completely normal," he wrote. "There are no residual symptoms." I'll end this with the Worldometer COVID statistics for January 7, 2021.

India:

- New Cases: 18,106
- New Deaths: 234

United States:

- New Cases: 279,154
- New Deaths: 4,207

Trial Site Editor Comment:

Importantly, the national laws, cultures and approaches are in fact, quite different between India and the United States. As *TrialSite* is a United States-based digital media platform, importantly we share that the proper path forward for acceptance of a new treatment approach is via the National Institutes of Health (NIH) COVID-19 Protection Treatment Guidelines. TrialSite doesn't endorse any particular approach but rather seeks to provide unbiased, independent news, information and opportunity to bring more transparency and accessibility to research, with the aim of advancing biomedical research to benefit all humanity.

Currently, *Ivermectin* is recommended only for research and has a rating of AIII. Although we have been constructively critical of what is a national research treasure, TrialSite recently commended the Panel for inviting members of the Front Line COVID-19 Critical Care Alliance (FLCCC) and Dr Andrew Hill, a consultant associated with the University of Liverpool in the UK, to present their findings to date.

This was an important milestone as the Panel associated with that apex national research agency now looks into the accumulating data. The NIH's Panel will hopefully consider risk-based approaches (much like they have done with highly novel monoclonal antibodies), seeking a way to ensure early-stage treatment in combination with the vaccine rollout over the next year.

In parallel, other mission-critical agencies such as the Department of Defence could potentially benefit from economical approaches to both pre-exposure prophylaxis (PrEP) as well as post-exposure prophylaxis (PEP). We encourage multiple pathways toward that end, from promising research from AstraZeneca (AZD7442—originating from some brilliant researchers at Vanderbilt and the company) to innovative approaches such as the large United Health and Lilly home-based clinical trial to the potential of *Ivermectin* as a generic treatment.

Fully overcoming COVID-19 in the USA necessitates a combination of more harmonized behavior (e.g., social distancing, masks, etc., across the 50 states) plus effective early stage as well as later-stage treatments and, of course, the vaccines. With two vaccines currently authorized on an emergency basis, other promising ones could be underway sooner rather than later.

The broader economy, society as well as health and vitality of the nation—one that importantly sets a precedent for so many positive forces around the world—benefits from an open, proactive, and progressive approach that includes a dynamic interchange between research, regulatory, the clinic and caregiver—driven by an unbiased recognition of the accumulating data inspired by the most rational of decision making. The NIH made such a move the other day.

(*Mary Beth Pfeiffer is an investigative journalist and book author)*

Source: Trial Site News, 09.01.2021 (Excerpts)

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