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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT (APPQM)

A VIRTUAL TRAINING PROGRAM - SERIES 2 Starts 3rd Week of January 2021

(Details on Page Nos. 4 & 5)

HIGHLIGHTS

★ **India and South Africa seek waiver from WTO on COVID-19 prevention and treatment – ask all countries to agree not to grant or enforce Patents** *(Page No. 16)*
★ **'Spices, COVID-19 and Low hanging fruits for the Pharmaceutical Industry': Dr D B Anantha Narayana** *(Page No. 6)*
★ **A Conversation with FDA India Office: Dr Letitia Robinson, Country Director and Dr Sarah McMullen, Deputy Country Director, US FDA India Office** *(Page No. 8)*
★ **New US FDA Guidance on ANDA to benefit Indian Companies to get faster generic drug approvals** *(Page No. 29)*
★ **Interest subvention for MSMEs: Modi Government extends Scheme validity to March 2021** *(Page No. 31)*

A Publication of
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IDMA BULLETIN

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MBA-STYLE INTERNATIONAL EDUCATIONAL PROGRAM FOR POTENTIAL LEADERS

Empowerment
Through Education
Living A Dream, Building A Future

ADVANCED PROGRAM IN PHARMACEUTICAL QUALITY MANAGEMENT

A VIRTUAL TRAINING PROGRAM - SERIES 2 Starts 3rd Week of January 2021

For further information / queries, please open the below links on our website www.idma-assn.org:

Circular / Covering Note	NSF Presentation	WHY APPQM? By Mr S M Mudda	APPQM 5 Modules	APPQM Series 1 FEEDBACK	REGISTRATION FORM

APPQM FOR DEVELOPING CHANGE AGENTS FOR QUALITY EXCELLENCE

APPQM - Program Modules

1. **Pharmaceutical Quality Management Systems – Best Industry Practices**
   (How to ensure your QMS drives business improvements)
2. **Managing Change: Change Control and Deviations**
   (Advanced problem solving, deviation management, report writing and change management)
3. **Human Factors – Getting people to follow the rules**
   (How to improve performance, reduce human error, embed a quality mind-set & keep your people)
4. **Transforming Data into Information – the Practical Application of Statistics to Transform your Business**
   (The practical application of statistics to transform your business)
5. **Quality by Design, Process Validation and Technology Transfer**
   (Building a foundation for Product Quality and Knowledge Management)

Advantages of NSF's Virtual Training

- NSF's virtual training combines live instructor-led virtual classrooms and self-paced learning online (easy to navigate e-learning) to provide participants with an interactive and engaging learning experience.
- Enhanced Virtual Interactivity – such as polls, etc.
- Virtually managed Break-out rooms - These are as good as physical break out groups
- Use of Team works – specially smaller group sizes
- Use of Tasks and Case Studies
- Courses managed Brilliantly by NSF - Each course is managed on NSF Learning Management System (LMS), with electronic course material
- Time for self-study each day.
- Guest Speakers (including MHRA, US FDA ex-regulators) enhance the modules and motivate the delegates

Additional Benefits:

- Safety of Individuals during this COVID-19 pandemic.
- Reduction in Course Fees **(from £8000 to £3300)**
- Saving of time especially travel time to venue in Bangalore and travel & hotel stay expenses

Why APPQM in INDIA?*

When launching the first series of the APPQM, we at IDMA along with NSF, UK reflected on the perceived trust deficit with international regulators despite being regarded as a 'Pharmacy of the World' and offered a global education program APPQM, in collaboration with NSF Health Sciences, UK, as a collective proactive response from the industry. We boldly stated APPQM would be Unique, World-Class and transform the operation efficiency of companies attending. Well, did series one live up to expectations?

Over 40 delegates attended series one.

This is what they thought:

"Transformative", "world-class", "best business investment we've ever made", "life changing", "worth every penny and more", "my company will be sending more delegates to series two", "has helped transform our quality culture" are just some examples of the feedback we've received from APPQM delegates.

Nearly 30 'work placement projects' have been completed by APPQM delegates.These have generated $ millions in savings for their parent companies, improved their operational efficiency (profit), regulatory compliance and reduced risk.

*Please visit IDMA website for details of benefits

Current Challenges & APPQM

In this challenging times, the pharmaceutical industry will become competitive only if the 3 factors - **Legacy & Reputation** (License to Operate), **Profit & Efficiency** (Cost Control) and **Customer service** are balanced and managed well.

The COVID-19 pandemic has created unique challenges as well as opportunities for the industry. In the absence of any regulatory inspections happening until quarter III of 2021 and reduced physical oversight by the corporate QA functions, the external interventions on the site will be reduced. There is an urgent need to use this time for building a strong leadership at the site for quality and compliance.

We recommend the virtual APPQM for the site teams for keeping themselves updated with the changing regulatory expectations in the post COVID-19 phase, once the physical inspections start.

The need of the hour is to focus on long term preventive measures aimed at achieving continual improvements rather than short term Compliance-Oriented approach.

Please don't get left behind and register for the second series of APPQM to have a competitive edge in the global market and to be future ready.

REGISTRATION FEE FOR SERIES TWO

The Registration Fee for **APPQM SERIES 2** is restructured at

Rs.3,15,000/- (Rupees Three Lakh Fifteen Thousand Only) Plus 18% GST Per Participant.

You can initially block the seats by paying an advance amount of Rs.1,00,000/- (Rupees One Lakh Only) and balance 15 days before commencement of the program.

Registration Procedure :

Please fill the Registration Form and send it to

Melvin Rodrigues actadm@idmaindia.com 9821868758	**Batul** technical@idmaindia.com 9920045226

For further information / queries :

You may also contact **Mr. S. M. Mudda**, @ **mudda.someshwar@gmail.com** / 9972029070

We sincerely hope that you see the benefit of attending this World-Class, MBA style, education program in order that you may reap the same benefits.

Sincerely Yours,

S M MUDDA Chairman, Regulatory Affairs Committee, IDMA & Program Director, APPQM	**MAHESH H DOSHI** National President, IDMA	**DR. GEORGE A PATANI** Hon. General Secretary & Vice Chairman, Industry Institution Interaction Committee, IDMA	**DAARA B PATEL** Secretary – General, IDMA

SPICES, COVID-19 AND LOW HANGING FRUITS FOR THE PHARMACEUTICAL INDUSTRY

Dr D B Anantha Narayana

Dear Reader,

Since the time the COVID-19 pandemic hit, the whole world is racing to develop vaccines. Vaccines that are in the development stage are also not a panacea. Preliminary studies have revealed that the 'antibodies' formed post vaccinations do not last long, vaccination with some of them resulting in potential protection for just 2 to 3 months. This would mean a need for repeated vaccinations? Concurrently, some scientists thought that vaccination of the Asian Population with BCG Vaccines, may have played a role to reduce the incidence and morbidity due to COVID-19 in Asian nations and the data for India on the spread, recovery and mortality reflect this to some extent.

In many Asian nations and in India, it is common advice by grandmothers to prescribe "Pepper Rasam", (a form of light soup with lentils and pepper) to ward off allergic rhinitis and viral attacks. I vouch for its effectiveness having experienced its benefits umpteen times to stop my running nose, viral attack, and low immune status. Regular consumption of spices in small quantities are known to benefit to keep healthy and fight various types of viral attacks.

What about Spices consumed in these nations? This question has been evaluated on the basis of scientific data. Elsayed and co-workers exactly looked at the potential correlation between COVID-19 and spice consumption. COVID-19 data from 163 countries including total cases, total deaths, and total recovered were reviewed after due normalizations to population numbers and other factors. The consumption figures of spices in these nations were looked into. A clear interrelated prevalence between the total number of COVID-19 cases per million populations and the grams of spice supply per capita per day were seen. Nations with lower consumptions of spices per capita showed greater number of COVID-19 cases per million populations. Only exceptions were Luxemburg and Iceland which showed greater number of COVID-19 cases relative to the trend. Although it is widely accepted that there is no genetic pre-disposition and SARS-CoV-2, is capable of affecting all races, the mortality rate associated with COVID-19 varies among different ethnic groups. For example, COVID-19 fatalities in New York City were*

Dr D B Anantha Narayana, is the Chief Scientific Officer, AYURVIDYE TRUST, Bangalore. He Championed the Notifications of Supplements and Nutraceuticals Regulations, FSSAI, 2016 Updated in 2017 and Phytopharmaceuticals as Drugs under Drugs & Cosmetics Act & Rules, 2016. He is a recipient of Indian Drugs award for Contribution to IDMA and Indian Drugs and is a recipient of Eminent Pharmacist's Award of IPA, 2007. Currently is an expert member, amongst others contributing significantly to 1) Member-Expert committee – Non-Specified Foods & Food Ingredients – FSSAI, 2) Chairman-Expert Committee –Advertisement and Claims – FSSAI, 3) Chairman-Scientific Panel – Nutraceuticals of FSSAI. 4) Chairman – Phytopharmaceuticals and Herbal products of Indian Pharmacopeia Commission 5) Member-Steering Committee of NMPB, Ministry of Ayush.

He continues to guide youngsters in research and also guides many startup firms in the area of Supplements/Nutraceuticals, Foods, herbals and cosmetics.

considerably less among South Asians compared to other ethnicities. A breakdown of COVID-19 fatalities among Whites, Hispanics, Blacks, and Asians was 27%, 34%, 28%, and 7% compared to their populations of 32%, 29%, 22%, and 14%, respectively. Interestingly, Asians suffered from only 7% of the COVID-19 fatalities despite their 14% population in the city. In this regard, Asians had a 50% lower than expected fatality rate. Elsayed reported that "the nations which had lower consumption of spices per capita, had higher number of deaths per million.

A number of spices have demonstrated their immunity enhancing benefits and published scientific literature is full of data. Capsicum (Chillies), ginger, turmeric, cinnamon, cumin, fenugreek and black pepper are known to work on T-Cells, CD counts, provide anti-inflammatory effects through action on Interleukins and other immune markers. Pepper and Cinnamon show their effect on respiratory conditions. Garlic another spice widely consumed is known for its antibacterial and anti-viral properties.

No wonder, India which is a source for a number of spices saw a growth in the export of spices in the last few months. Most Indians are also drinking one or the other recipe of spices as "Kadha" (an herbal decoction as tea) ever since COVID-19 hit and one wing of the Ministry of Health recommended to drink such a kadha with basil, cinnamon, ginger and pepper daily.

The pharmaceutical industry seems to be in their own world in pursuit of vaccines or repurposing drugs approved in other nations for generic use. Use of Social distancing, wearing masks and washing of hands have all played their role in reducing the impact of COVID-19 to whatever extent they have. Prevention is playing the role primarily advocated by all experts. Products that can enhance innate immunity using spices and their extracts can be a good methodology to support the preventive approach.

Entry of the virus to the body via air borne droplets is through the oral route and nasal route. Development of an effective oral gargle or a mouth wash and an effective nasal spray or drops that can give a lining to the nostrils and "catch & kill" the virus within the oral cavity and nose respectively are additions to these measures. An oral gargle liquid formulated with distilled oils or extracts of selected spices that have anti-bacterial activity can be thought of and achieved. Formulated with such natural actives, they need not be "spit out" but swallowed post washing or gargling. The stomach's acidic nature is adequate to further kill and destroy the bacteria and the viruses that might have entered the mouth. Number of actives are available for such a use and selection carefully and good formulation methodology will potentially also be IPR protectable. Even a well formulated "spray like a mouth freshener" can be another option for such a product. Formulation of a nasal spray or a drop with 'oleaginous' base can be ideal for giving a good coating to the nostril's lining. Consideration of distilled oils, that dissolve in vegetable oils offer a wide range of actives from the natural kitty. If one does not want to consider natural actives, anti-microbial actives from the synthetic molecule libraries can be used. In a pandemic situation, consumers would be willing to do many things and asking them to use a mouth wash and apply a nasal drop would be convincing given the marketing muscle of the pharmaceutical and FMCG firms. These are low hanging fruits that seems to have missed the Research & Development heads and the business heads, perhaps in their quest for "Curative and big ticket items".

Would some Indian Pharma firm, known for their Jugaadu ability and increasingly innovative strategy catch these fruits?

*(*Yehaya Elsayed and Naveed Ahmed Khan, ACS Publications, https://dx.doi.org/10.1021/acschemneuro.0c00239)*

Courtesy: Indian Drugs, Guest Editorial, Vol. 57 (07) July 2020

● ● ●

A Conversation with FDA India Office

Letitia Robinson, Ph.D. *Country Director and* ***Sarah McMullen, Ph.D,*** *Deputy Country Director, US FDA India Office*

The Presentation on US FDA Administration was made by Dr ***Letitia Robinson, Country Director US FDA, India Office and Dr Sarah McMullen, Deputy Country Director US FDA India Office at a Video Conference organized as part of the Annual Convention series of Indo American Chamber of Commerce (IACC) on 24 September 2020***

U.S. FOOD & DRUG ADMINISTRATION

A Conversation with FDA India Office

Letitia Robinson, PhD
Country Director
And
Sarah McMullen, PhD
Deputy Country Director

2020 IACC Annual Convention Series
September 24, 2020

Disclaimer

The opinions and information in this presentation are those of the author(s), and do not necessarily represent the views and/or policies of the U.S. Food and Drug Administration

About U.S. FDA

- FDA is responsible for assuring the safety, effectiveness, quality and security of food, medical products, cosmetics, tobacco, vaccines and other biological products, and veterinary drugs in the U.S.
- Food, Drug and Cosmetic Act (FD&C) - primary legislation we enforce and from which we derive our authority
- FDA-regulated products account for about 20 cents of every dollar of annual spending by U.S. consumers, or approximately $2.5 trillion.
- The FDA FY 2020 budget is $3.16 billion + user fees and includes 17,800 full time equivalents.

Did you know? The creation of the Pure foods and Drugs Act, 1906 was spurred on by Upton Sinclair's "The Jungle"

3

Regulatory Framework for Drugs

- What is a drug?
  - A substance recognized by an official pharmacopoeia or formulary.
  - A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
  - A substance (other than food) intended to affect the structure or any function of the body.
  - A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
  - Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

4

FDA Authority To Regulate Drugs

- Two primary laws
  - Food, Drug and Cosmetic Act (FD&C)
  - Public Health Service Act (sec 351 and 361)
- Promulgated into regulations
  - Regulations primarily located in 21 CFR 200s and 600s
- FDA's Center for Drug Evaluation and Research (CDER) has the primary responsibility in regulation of human drugs

Did you know? The original FD&C required drugs to be safe. It wasn't until 1962 that drugs had to be effective!

5

What does a drug consist of?

- Active pharmaceutical ingredient (API) or drug substance
  - An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.
- Excipient (inactive ingredients)
  - Processing aides that do not have a pharmacological activity
- Drug product
  - The finished dosage form that contains a drug substance, generally, but not necessarily in association with other active or inactive ingredients.

Did you know? Blood is a drug, FD&C 1940

6

FDA Drug Categories

- Over-the-counter (OTC)
  - FDA defines OTC drugs as safe and effective for use by the general public without a doctor's prescription
- Investigational New Drug (IND)
  - An Investigational New Drug Application (IND) is a request for Food and Drug Administration (FDA) authorization to administer an investigational drug to humans.
- New Drug Application (NDA)
  - An application to market a new drug, or a new indication for an existing drug
- Abbreviated New Drug Application (ANDA)
  - Another term for a generic drug. A generic drug is the same as a brand name drug in dosage, safety, strength, how it is taken, quality, performance, and intended use. By law, a generic drug product must contain the identical amounts of the same active ingredient(s) as the brand name product.

Did you know? FDA's Center for Veterinary Medicine (CVM) regulates animal drugs, but not animal vaccines. Animal vaccines are regulated by US Dept of Agriculture's (USDA) Animal and Plant health Inspection Service (APHIS)

7

FDA's Role in Drug Development

- Discovery and Development
  - Typically not within the work of FDA
- Preclinical Research
  - FDA requires researchers to use good laboratory practices (GLP), defined in medical product development regulations, for preclinical laboratory studies.
- Clinical Research
  - Drug developers or sponsors must submit an IND to FDA before clinical trials can begin. FDA monitors clinical trials and inspects data at trial sites. Trial data is submitted to FDA for review for safety and efficacy.
- FDA Review
  - Once FDA receives an NDA, the review team decides if it is complete. If it is not complete, the review team can refuse to file the NDA. If it is complete, the review team has 6 to 10 months to make a decision on whether to approve the drug. FDA may also request a pre-approval inspection of the manufacturing facility.
- FDA Post-Market Safety Monitoring
  - Through out the product life-cycle, FDA monitors approved drugs for safety and conducts inspections of manufacturing facilities

8

Medical Devices: Legislative Mandates

Year	Legislation
1938	Federal Food, Drug, and Cosmetic Act of 1938 (FD&C Act or FDCA)
1968	Radiation Control for Health & Safety Act (RCHSA)
1976	***Medical Device Amendment of 1976***
1988	Clinical Laboratory Improvement Amendments (CLIA)
1990	Safe Medical Devices Act (SMDA)
1992	Mammography Quality Standards Act (MQSA)
1992	Medical Device Amendments
1997	Food & Drug Administration Modernization Act (FDAMA)
2002	Medical Device User Fee and Modernization Act (**MDUFMA**)
2005	Medical Device User Fee Stabilization Act (MDUFSA)
2007	Food and Drug Administration Amendments Act of 2007 (FDAAA), **MDUFA II**
2012	FDA Safety and Innovation Act (FDASIA), **MDUFA III**
2017	FDA Reauthorization Act of 2017 (FDARA), **MDUFA IV (FY18 – FY22)**

9

What Are Regulated Medical Devices?

10

Medical Device Classification System Risk Categorization

Device Class and Regulatory Controls

- Class III – High Risk
  - ~ *120 Generic Product Types*
  - – General Controls
  - – Premarket Approval
- Class II – Medium Risk
  - ~ *800 Generic Product Types*
  - – General Controls and
  - – Special Controls
- Class I – Low Risk
  - ~ *780 Generic Product Types*
  - – General Controls

16 Medical Specialties "Panels" Classifications

862 – Chemistry/Toxicology	**878** – General Plastic Surgery
864 – Hematology/Pathology	**880** – General Hospital
866 – Immunology/Microbiology	**882** – Neurological
868 – Anesthesiology	**884** – Obstetrical/ Gynecological
870 – Cardiovascular	**886** – Ophthalmic
872 – Dental	**888** – Orthopedic
874 – Ear, Nose and Throat	**890** – Physical Medicine
876 – Gastro/Urology	**892** – Radiology

11

Establishment Registration & Medical Device Listing

Establishment Registration

- Manufacturers and Initial Distributors of Medical Devices
- Electronically Submitted
- Foreign Manufacturers Must Designate a U.S. Agent
- FY21 Annual Registration Fee: $5,546

Medical Device Listing

- Devices made at the registered establishment facility.
- Activities performed on the devices.
- FDA Pre-Market Submission Number for premarket approval or premarket notification devices – such as 510(k) or PMA.
- Electronically Submitted

https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing

12

Globalization…By the Numbers

FDA-regulated products originate from more than 150 countries and approximately 135,000 FDA-registered foreign facilities.

About 13% of all food consumed by U.S. households is imported, including 53% of the fresh fruit, 29% of the vegetables and 93% of the seafood.

About 70% of the biologics and 35% of the medical devices used in the U.S. are imported.

About 20 million shipments of imported food and about 24 million shipments of medical products were offered for import into the United States.

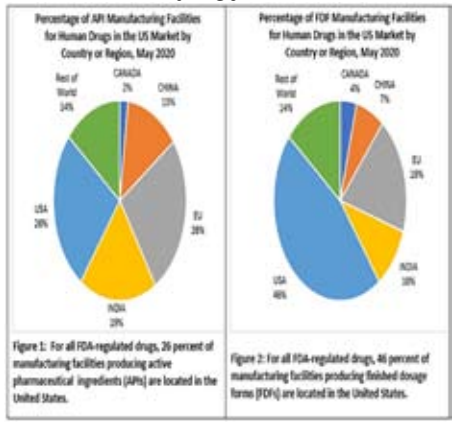
13

A Brief History Lesson

- Historically, drug production was based domestically – recent decades moved out of U.S.
- Before 2012, the FD&C Act required inspections of domestic drug manufacturers every 2 years.
  - Did not address the schedule for foreign establishments
- The rise of globalization resulted in a large imbalance where by domestic manufacturers were held to a different schedule of inspection than foreign establishments – without considering "**risk**"
- FDA mandated to inspect registered "never inspected sites"

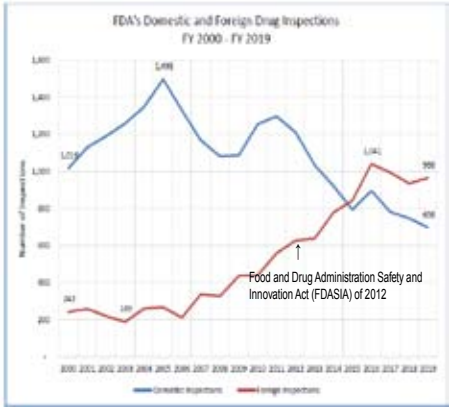
14

Globalization of pharmaceuticals for the U.S. market



15

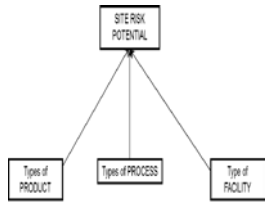
Domestic vs Foreign Establishment inspection by fiscal year



16

FDA's Risk-Based Site Selection Model

- FDA implemented the risk-based approach to prioritizing human drug manufacturing sites for routine CGMP surveillance inspection
- Considers risk related to drug (drug substance and finished product) quality as may arise from violations of the CGMP requirements in the FD&C Act (section 501(a)(2)(B)) and related regulations (e.g., 21 CFR parts 210 and 211).



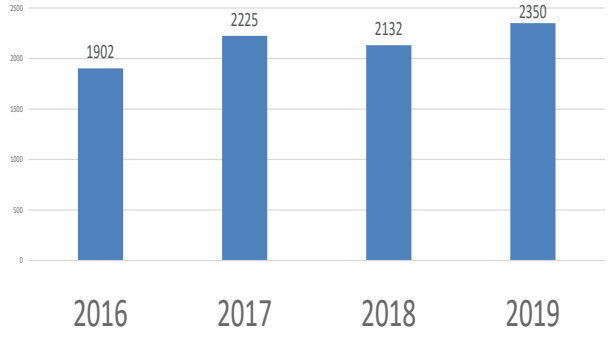
17

India

- Largest number of FDA-registered drug manufacturing facilities outside of the U.S.
- India is one of the largest exporters of drug products to the U.S.

18

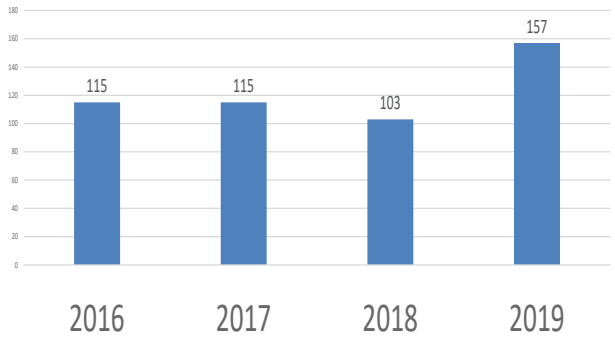
Indian Drug Firms Registered with FDA



21CFR207.29(b) – "*Annual review and update of registration information. Registrants must review and update all registration information required under 207.25 for each establishment*" See 21CFR207 subpart B for complete details for registration

19

New Drug Registrations in India



This chart shows all "New" registrations – it includes currently registered firms that register a new process with FDA, such as "packager"

20

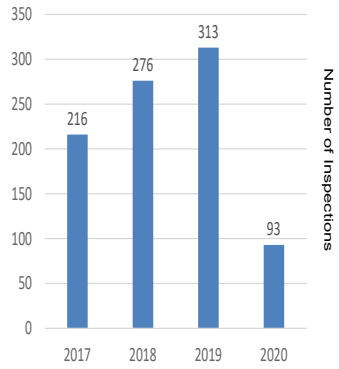
2020 Inspections during a Pandemic

- On March 3, 2020 - FDA suspended on-site inspections (possible exception if there is a great risk of harm to public health)
- FDA is using section 704(a)(4) of the Food, Drug and Cosmetic Act to request for records in lieu of inspections

Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers

Guidance for Industry

FDA Inspections of Indian Drug Firms by Fiscal Year (FY)



FY begins October 1st ends September 30th of the following year, for example FY19 = 10/1/2019 to 9/30/2019, FY2020 data does not include 704(a)(4) reviews

21

Compliance Rate by Country/Region

https://docs.house.gov/meetings/IF/IF02/20191210/110317/HHRG-116-IF02-Wstate-WoodcockMDM-20191210.pdf

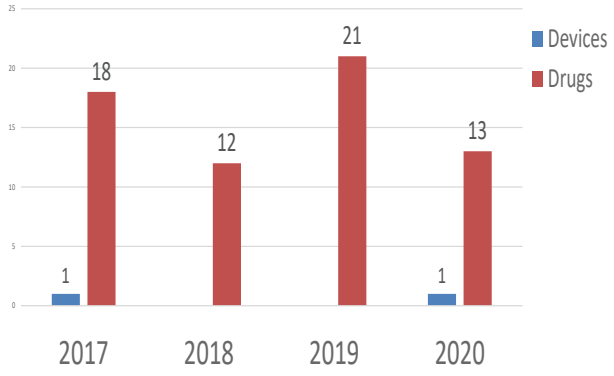
22

What Tools Does FDA Have to Enforce Regulations and Laws?

- Warning Letters
- Untitled Letters
- Import Alerts
- Administrative Detention
- Regulatory Meetings
- Injunctions
- Seizures
- Consent Decrees

23

Warning Letters Issued to India Drug and Device Manufacturers



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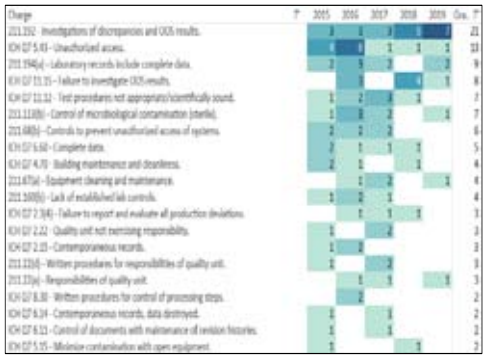
Top 20 Citations/Observations Non-OTC Warning Letters to Firms in India FY2015-2019



54 Non-OTC India Warning Letters Issued FY2015 to FY2019

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Some Key Findings From the Data

- Most Warning Letters issued to drug manufacturers in India are not for initial inspections.
- Topics of Warning Letters include:
  - Inadequate controls for sterile drug manufacturing
  - Lack of Data Integrity/Inadequate OOS investigations
  - Poor cross contamination controls

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FDA's International Activities

- Collecting and sharing intelligence and information
  - Increased knowledge of global landscape and regulatory environment within a country or sub-region
  - Conducting inspections in countries with facilities that export to the U.S. market
  - Identify, catalyze, and/or facilitate targeted engagements to support FDAs mission
- Assure the safety of imported products
  - Informing foreign industry about U.S. requirements
  - Catalyzing stronger capabilities of foreign regulatory authorities

Reference: https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OfficeofInternationalPrograms/default.htm

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Office of Global Policy and Strategy

- **Office of Global Policy and Strategy Foreign Offices:**
  - Belgium
  - China
  - Chile
  - Costa Rica
  - India
  - Mexico
  - Amsterdam
- **Positions at posts**
  - Director
  - Deputy Director
  - International Relations Specialists
  - Consumer Safety Officers
  - Locally Employed Staff

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Office of Global Policy and Strategy

OGPS Mission:

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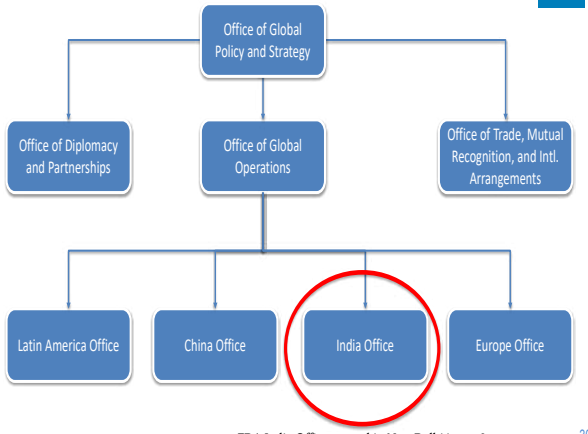
Office of Global Policy and Strategy



FDA India Office opened in New Delhi in 2008

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FDA India: Working with Government of India (GOI)

- Statement of Intent signed by FDA and Ministry of Health and Family Welfare, February 10, 2014
- U.S. and India sign Memorandum of Understanding, February 24, 2020

31

FDA & GOI MOU: Early Results

- COVID-19
  - FDA and the Federal Trade Commission (FTC) worked together in identifying firms promoting unapproved drugs or false and/or misleading claims
- Close working relationship and communication with the Central Drugs Standard Control Organisation (CDSCO) and Ministry of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)
  - AYUSH orders firms to cease advertisement

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FDA & GOI: Information Sharing

- COVID-19:
  - FDA India Offices shares FDA COVID-19 resources with stakeholders and distributes COVID specific guidance documents
- Emerging issues:
  - International Regulators' call concerning methanol and 1-propanol contaminated hand sanitizers
- General:
  - FDA engages with CDSCO and the states regularly - as it relates to information sharing, GCP and GMP inspections, regulatory forums and others

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FDA India Office: Communication on Emerging Issues

- Communication not limited to GOI
- Information sharing and outreach with industry:
  - 2019 ISPE South Asia Pharmaceutical Manufacturing Conference at Bangalore, September 25-27, 2019
  - IPA 4th Advanced GMP Workshops 2019 at Goa, November 11-12, 2019
  - 2019 DIA-USFDA-EMA-EDQM API Quality and Supply Chain Integrity Workshop at Ahmedabad & Hyderabad, November 18-22, 2019
  - ISCR Annual Conference at Mumbai, January 23-24, 2020
  - BioAsia 2020 at Hyderabad, February 17-19, 2020
  - 5th India Pharmaceutical Forum 2020 at Mumbai, February 27-28, 2020
  - Pharmaceutical Quality for Global Stakeholders Webinar, July 22, 2020

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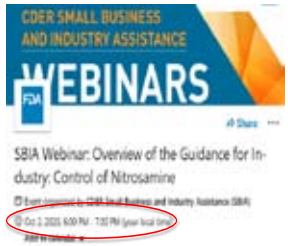
Collaboration on Emerging Issues: Spotlight on Nitrosamines


FDA Provides Guidance to Industry for Detecting and Preventing Nitrosamines in Drugs



To Register: https://www.fda.gov/drugs/news-events-human-drugs/sbia-webinar-overview-guidance-industry-control-nitrosamine-impurities-human-drugs-10022020-10022020

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U.S. FDA COVID-19 activities

- Established COVID-19 web site
- Coronavirus Treatment Acceleration Program (CTAP)
- COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders
- Request of records in lieu of inspections
- Emergency use authorizations
- Monitoring drug shortages
- Enforcement against false and misleading COVID-19 treatment claims - close communication with AYUSH
- Warning consumers and regulators about the dangers of hand sanitizers and publishing a list of "Hand sanitizers consumers should not use"

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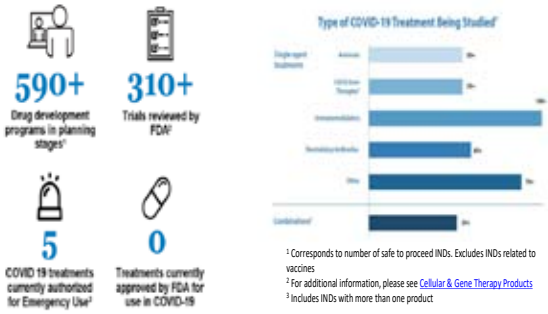
Coronavirus Treatment Acceleration Program (CTAP)



[1] Corresponds to number of safe to proceed INDs. Excludes INDs related to vaccines
[2] For additional information, please see Cellular & Gene Therapy Products
[3] Includes INDs with more than one product

[1]Active Pre-INDs. Excludes vaccines.
[2]Safe to proceed INDs. Excludes vaccines.
[3]Please see the Emergency Use Authorization webpage for more details. This number includes 1 EUA authorizing both medical devices and a drug for emergency use.

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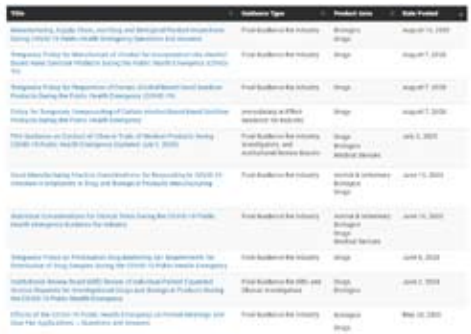
FDA COVID-19 Related Guidance (Drugs)



Recently added: "Manufacturing, Supply Chain, and Drug and Biological Product Inspections During COVID-19 Public Health Emergency Questions and Answers"

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Emergency Use Authorization-Drugs

Date of first EUA Issuance	Product	Authorized Use
April 30, 2020	Fresenius Medical, multiFiltrate PRO System and multiBic/multiPlus Solutions	To provide continuous renal replacement therapy (CRRT) to treat patients in an acute care environment during the COVID-19 pandemic.
May 1, 2020	Remdesivir for Certain Hospitalized COVID-19 Patients	To only treat adults and children with suspected or laboratory confirmed COVID-19 and severe disease defined as SpO2 94% on room air, requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) ***Updated as of 8/27/2020 - treatment of all hospitalized adult and pediatric patients with suspected or laboratory-confirmed COVID-19, irrespective of their severity of disease.***
May 8, 2020	Fresenius Kabi Propoven 2%	To maintain sedation via continuous infusion in patients older than age 16 with suspected or confirmed COVID-19 who require mechanical ventilation in an ICU setting
August 13, 2020	REGIOCIT replacement solution that contains citrate for regional citrate anticoagulation (RCA) of the extracorporeal circuit	To be used as a replacement solution only in adult patients treated with continuous renal replacement therapy (CRRT), and for whom regional citrate anticoagulation is appropriate, in a critical care setting

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COVID-19 Vaccine Activity

- Coronavirus Treatment Acceleration Program, or "CTAP"
- FDA is taking action to help facilitate timely development of safe, effective COVID-19 vaccines
- FDA is engaged in public-private partnership to speed the development of COVID-19 vaccine and treatment options.
  - Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
- *Final Guidance for Industry Development and Licensure of Vaccine to prevent COVID-19 – Guidance for Industry* (CBER, June 2020)

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COVID-19-Related Medical Device Imports

- **Device Type Informs FDA Import Considerations**
  - ***Medical Device*** – Subject to Emergency Use Authorization (EUA)
  - ***Medical Device*** – Subject to Enforcement Discretion Policy
  - ***Medical Device*** – Subject to routine regulatory requirements
  - ***Non-Medical Device*** – Not Subject to FDA Regulatory Requirements – Industrial/Manufacturing-Related
- **FDA Ventilator and Mask EUAs**
  - EUA Criteria/Conditions Must be Met
  - Appropriate Labeling
  - Liability Protections

https://www.youtube.com/watch?v=iGkwaESsGBQ

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- **FDA Website**
  - Information and Questions/Answers about Medical Devices – such as Respirators, Face Masks, and PPE
  - **FDA Contacts**
    - Import Regulatory Requirements
    - cdrhimport@fda.hhs.gov
    - General Import Procedures
      - cdrhimport@fda.hhs.gov
    - Specific Import Entries
      - https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/fda-import-offices-and-ports-entry

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COVID- 19 Inspection Updates

- In-person inspections are not being conducted unless they are mission critical and are evaluated on a case-by-case basis.
- Remote assessments:
  - Are NOT inspections and do not replace an inspection
  - No written observations (FDA 483) issued on remote assessments
  - Do not result in a final agency classification (NAI, VAI, or OAI)
- FDA is working to resume routine surveillance onsite inspections for certain U.S. establishments.

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Remote Drug reviews: 704(a)(4)

- "704(a)(4) records request" is in advance of or in lieu of an inspection.
- Under the authority of section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 374(a)) and FDA Safety and Innovation Act (FDASIA), Section 706
- 704(a)(4) records requests are occurring via email for Preapproval Inspections (PAIs) and surveillance of manufacturers.
- Records are received via email or electronic drop-box system.
- Firms receive a confirmation email that records were received

Outcomes vary based:

- On the type of inspection
- If all requested records were submitted
- Any concerns noted in the record review

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FDA India Office: We want to hear from you!

- We maintain an electronic mailbox to assist stakeholders in navigating FDA's regulations
- Assist with questions you may have:
  - Recent pharmaceutical-related inquiries include: hand sanitizers, how to register, COVID-19 and "in-person" inspections"
  - Ask us, we are here for you
  - Our mailbox: US-FDA-INO@fda.hhs.gov

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U.S. FOOD & DRUG ADMINISTRATION

Thank you for your time!

US-FDA-INO@fda.hhs.gov

*(Interested Members may email to IDMA at **actadm@idmaindia.com** for a soft copy of the Presentation in PDF. Please mention your company name in the email).*

India and South Africa seek waiver from WTO on COVID-19 prevention and treatment – ask all countries to agree not to grant or enforce Patents

ATTENTION MEMBERS

In a landmark move, India and South Africa sought a waiver from World Trade Organization (WTO) on 2 October 2020 (reproduced below) to allow all countries to choose to neither grant nor enforce patents and other intellectual property (IP) related to COVID-19 drugs, vaccines, diagnostics and other technologies for the duration of the pandemic, until widespread vaccination is in place globally, and the majority of the world's population has developed immunity. This bold step, if approved, could be a historic turning point in the countries' response to the pandemic.

In a recent interaction organized by Dr K M Gopakumar under the TWN (Third World Network), Dr Gopakumar G Nair, Past President, IDMA and Chairman of IDMA IPR Committee, had appealed to the Government of India to move on a positive note to balance Healthcare concerns vis-a-vis IP Rights, especially in light of the current pandemic background.

In the meantime it is relevant to mention here that Moderna, the manufacturer and patent owner of the 'messenger RNA (mRNA) Vaccine', has declared that Moderna will not enforce their Patents on their vaccines intended to combat the pandemic. They have proposed to offer voluntary licensing to others on request. The proposed Resolution is coming up at WTO for voting at the session on 16th October, 2020. (The Moderna Press Release is also reproduced in the following Pages):

WTO Ref. No.IP/C/W/669, (20-6725), dated 2nd October 2020

(Council for Trade-Related Aspects of Intellectual Property Rights)

WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19

Communication from India and South Africa

1. On 11 March 2020, the World Health Organization (WHO) declared the Coronavirus Disease 2019 (COVID-19) to be a global pandemic, after having announced a related Public Health E-emergency of International Concern (PHEIC) on 30 January 2020.

2. The World Trade Organization (WTO) has cautioned that the "Pandemic represents an unprecedented disruption to the global economy and world trade, as production and consumption are scaled back across the globe"[1]. We have witnessed a break down in global supply chains coupled with growing supply demand gaps.

3. Given this present context of global emergency, it is important for WTO Members to work together to ensure that Intellectual Property Rights such as patents, industrial designs, copyright and protection of undisclosed information do not create barriers to the timely access to affordable medical products including vaccines and medicines or to scaling-up of Research, Development, manufacturing and supply of medical products essential to combat COVID-19.

4. The COVID-19 pandemic is now widespread, affecting most WTO Members. As at 1 October 2020, there were about 333,722,075 confirmed cases Globally with 1,009,270 confirmed deaths[2]. To date, there is no vaccine or medicine to effectively prevent or treat COVID-19. All WTO Members are struggling to contain the spread of the pandemic and provide health care services to those affected. Many developed, developing and least developed countries have declared a national emergency with the aim to curb the growing outbreak, and as advised by the WHO implemented social distancing measures with significant consequences for society and the economy. Notably, developing countries and least developed countries are especially disproportionately impacted.

5. An effective response to COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need.

6. The outbreak has led to a swift increase in global demand with many countries facing acute shortages, constraining the ability to effectively respond to the outbreak. Shortages of these products has put the lives of health and other essential workers at risk and led to many avoidable deaths. It is also threatening to prolong the COVID-19 pandemic. The longer the current global crisis persist, the greater the socio-economic fallout, making it imperative and urgent to collaborate internationally to rapidly contain the outbreak.

7. As new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities and at affordable price to meet global demand. Critical shortages in medical products have also put at grave risk patients suffering from other communicable and non-communicable diseases.

8. To meet the growing supply-demand gap, several countries have initiated domestic production of medical products and/or are modifying existing medical products for the treatment of COVID-19 patients. The rapid scaling up of manufacturing globally is an obvious crucial solution to address the timely availability and affordability of medical products to all countries in need.

9. There are several reports about Intellectual Property Rights hindering or potentially hindering timely provisioning of affordable medical products to the patients[3]. It is also reported that some WTO Members have carried out urgent legal amendments to their national patent laws to expedite the process of issuing compulsory/government use licenses.

10. Beyond patents, other Intellectual Property Rights may also pose a barrier, with limited options to overcome those barriers. In addition, many countries especially developing countries may face institutional and legal difficulties when using flexibilities available in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). A particular concern for countries with insufficient or no manufacturing capacity are the requirements of Article 31 *bis* and consequently the cumbersome and lengthy process for the import and export of pharmaceutical products.

11. Internationally, there is an urgent call for global solidarity, and the unhindered global sharing of technology and know-how in order that rapid responses for the handling of COVID-19 can be put in place on a real time basis.

12. In these exceptional circumstances, we request that the Council for TRIPS recommends, as early as possible, to the General Council a waiver from the implementation, application and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19.

13. The waiver should continue until widespread vaccination is in place globally, and the majority of the world's population has developed immunity hence we propose an initial duration of [x] years from the date of the adoption of the waiver.

14. We request that the Council for TRIPS urgently recommends to the General Council adoption of the annexed decision text.

1. https://www.wto.org/english/tratop_e/covid19_e/covid19_e.htm.
2. https://covid19.who.int.
3. See e.g. https://www.bloomberg.com/news/articles/2020-03-20/world-war-ii-style-production-maycarry-legal-risks-for-patriots; https://eu.courier-journal.com/story/news/2020/04/03/beshear-calls-3-mrelease-patent-n-95-respirator-amid-pandemic/5112729002/

ANNEXURE

DRAFT DECISION TEXT

WAIVER FROM CERTAIN PROVISIONS OF THE TRIPS AGREEMENT FOR THE PREVENTION, CONTAINMENT AND TREATMENT OF COVID-19

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting that the Coronavirus Disease 2019 (COVID-19) is a new infectious disease caused by Severec Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2);

Recalling that on 11 March 2020, the World Health Organization (WHO) declared the 2019–20 Coronavirus outbreak to be a pandemic, and it continues to be a very high risk across the globe in all WTO Members;

Noting with concern the threat to human health, safety and well-being caused by the COVID-19 pandemic, which has spread all around the globe, as well as the unprecedented and multifaceted effects of the pandemic, including the severe disruption to societies, economies, global trade and travel and the devastating impact on the livelihoods of people;

Recognising the need for unimpeded and timely access to affordable medical products including diagnostic kits, vaccines, medicines, personal protective equipment and ventilators for a rapid and effective response to the COVID-19 pandemic;

Recognizing also that the COVID-19 Global pandemic requires a global response based on unity, solidarity and multilateral cooperation;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement);

Decides as follows:

1. The obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to prevention, containment or treatment of COVID-19, for [X] years from the decision of the General Council.

2. The waiver in paragraph 1 shall not apply to the protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations under Article 14 of the TRIPS Agreement.

3. This decision is without prejudice to the right of least developed country Members under paragraph 1 of Article 66 of the TRIPS Agreement.

4. This waiver shall be reviewed by the General Council not later than one year after it is granted, and thereafter annually until the waiver terminates, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement.

5. Members shall not challenge any measures taken in conformity with the provision of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, or through the WTO's Dispute Settlement Mechanism.

Statement by Moderna on Intellectual Property Matters During the COVID-19 Pandemic

Moderna is a pioneer in the development of messenger RNA (mRNA) vaccines and therapeutics. From its inception in 2010, Moderna saw the potential of this new class of medicines to make a significant difference in patients' lives. With the support of our investors we have invested billions of dollars into research and development to make mRNA medicines a reality. One of the exciting discoveries advanced by Moderna was the combination of mRNA and lipid nanoparticles (LNPs) to make vaccines, and the demonstration of this potential in human clinical trials for eleven different infectious disease vaccines since 2015. Those discoveries and the expertise we developed have uniquely positioned Moderna to respond to the COVID-19 pandemic quickly.

As a company committed to innovation, Moderna recognizes that intellectual property rights play an important role in encouraging investment in research. Our portfolio of intellectual property is an important asset that will protect and enhance our ability to continue to invest in innovative medicines.

Beyond Moderna's vaccine, there are other COVID-19 vaccines in development that may use Moderna-patented technologies. We feel a special obligation under the current circumstances to use our resources to bring this pandemic to an end as quickly as possible. Accordingly, while the pandemic continues, Moderna will not enforce our COVID-19 related patents against those making vaccines intended to combat the pandemic. Further, to eliminate any perceived IP barriers to vaccine development during the pandemic period, upon request we are also willing to license our intellectual property for COVID-19 vaccines to others for the post pandemic period.

Moderna is proud that its mRNA technology is poised to be used to help end the current pandemic.

moderna

Source: Moderna Press Release

CGTMSE launches UDAAN Portal - a possible gamechanger

UDAAN Communication Ref No.Indl Assoc/210, dated 21st Sepember 2020

To
The National President, IDMA.

As you are aware that Credit Guarantee Fund Trust for Micro and Small Enterprises (CGTMSE) has been set up with joint initiative of GoI (through Ministry of MSME) and Small Industries Development Bank of India (SIDBI) to catalyse flow of institutional credit to Micro & Small Enterprises (MSES). Over the past 20 years, CGTMSE has been instrumental in providing guarantee cover to collateral/third party guarantee free credit facilities extended by eligible Member Lending Institutions [MLEs] to Micro and Small Enterprises (MSES) and thus is promoting collateral-free credit and bringing a paradigm shift from collateral based lending to project based lending. Credit Guarantee Scheme is considered as a vehicle of inclusive growth by reaching out to the disadvantaged sections of society particularly women and those belonging to the weaker segments. CGTMSE has crossed an important milestone in FY 2020 by recording cumulative guarantee approvals of over 43 lakhs with an aggregate loan amount of over 2.22 lakh crore. For further details, you may please access **www.cgtmse.in.**

CGTMSE has always been responsive and pro-active organization to enhance the ease of access to credit by MSEs. In this effort, CGTMSE has recently launched **UDAAN Portal - a possible gamechanger by providing comfort of provisional guarantee certificate even before sanction of loan.** It is a tool which provides provisional guarantee certificate to entrepreneurs for availing collateral free loans from lending institutions.

We are sanguine that the UDAAN Portal introduced by the Trust would greatly enhance the effectiveness of the credit guarantee scheme leading to enhanced flow of institutional credit to the MSE sector.

In this connection, keeping in view the important role played by your Association, inter alia, in dissemination of information to your member Micro and Small Enterprises, we would request you to advise your members to visit the portal - **www.udaanformse.in** to avail Provisional Guarantee Certificate and approach the bank/financial institution as selected by them on the portal of their choice to avail the benefit of Credit Guarantee Scheme for their bankable and viable proposals. Please feel free to contact us for any further information/clarification.

Jigar Shah, Chief Operating Officer, Credit Guarantee Fund Trust for Micro and Small Enterprises (Set up by Government of India & SIDBI) SIDBI, Bandra Kurla Complex, Bandra (E), Mumbai.

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OBITUARY

Mr Subharthee Dey

Dey's Medical Stores Ltd/Dey's Medical Stores (Mfg) Ltd/Dey's Medical Stores (UP) Pvt Ltd

Mr Subharthee Dey was a Whole Time Director at Dey's Medical, a manufacturing unit started in 1957 in the city of Calcutta with its own indigenous know-how. Today, Dey's has 3 State of the Art GMP compliant Nation's Best Manufacturing Units & may well be considered as a national pride. Mr Subharthee Dey left for his heavenly abode on Monday, 12th October 2020 due to cardiac arrest.

Mr Subharthee Dey was a very active senior member of IDMA for more than 3 decades where he rose to the rank of Vice President (Eastern Region). We, at IDMA, can proudly state that because of Mr Dey's efforts and active participation in IDMA Activities mainly the West Bengal State Board, the Pharmaceutical Industry in the Eastern Region grew immensely.

The Indian Pharmaceutical Industry has not only lost a stalwart in Mr Subharthee Dey but also, a friend and guide. May God grant his departed soul eternal peace and provide strength to his family and all at Dey's Medical to bear this irreparable loss.

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Dr Parthajyoti Gogoi

Dr Parthajyoti Gogoi, Regional Director, Regional Office of Ministry of Health and Family Welfare and Director of Regional Drug Testing Laboratory (RDTL), Guwahati, left for his heavenly abode after being diagnosed with COVID-19 related complications at a private hospital in New Delhi on October 9. He was 56. Born in Chabua, Dibrugarh district to Ganesh Chandra Gogoi and former Congress legislator of Duliajan LAC, Amiya Gogoi. He was a pioneer regulator, administrator and leader of the Pharmaceutical Profession in Northeast India.

Dr Gogoi was a member of the Editorial board of Indian Drugs. He used to actively participate in the Pharmaceutical Analyst Convention (PAC) organised by IDMA. In his passing away, the Indian Pharmaceutical Industry has lost a friend, philosopher and guide. May God grant his departed Soul eternal peace and provide strength to his wife and son to bear this irreparable loss. A noble soul and pious person, he was loved and admired by all for his amicable nature.

In Lok Sabha & In Rajya Sabha

In Lok Sabha

Ban on Freebies to Doctors by Pharmaceutical Companies

Lok Sabha Unstarred Question No: 2134

P Velusamy:

Q. Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state;

(a): whether the Government has banned doling out freebies, cruise tickets, paid vacations and sponsorships for educational conferences and seminars to doctors by Pharmaceutical companies from January 1, 2014, if so, the details thereof;

(b): whether the Government is aware that Mumbai branch of the Income Tax Appellate Tribunal has disallowed an allowance of Rs.76.55 lakhs paid by a leading Pharma company, if so, the details thereof;

(c): the steps taken by the Government to prevent such kind of unethical practices followed by the Pharma companies hitherto; and

(d): whether the Government is having any proposal to bring out specific comprehensive law in this regard, if so, the details thereof?

Answered on 23rd September 2020

A. (a): The Department of Pharmaceuticals has informed that the Government had prepared and announced in year 2014 a Uniform Code for Pharmaceutical Marketing Practices (UCPMP) for stopping unethical practices employed by Pharma Companies for promoting sales of their medical products, on 12th December, 2014. It was sent to all the Pharma associations for voluntary implementation with effect from 01.01.2015.

Further, as per clause 6.8.1 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, a Registered Medical Practitioner is not allowed to receive gifts, travel facilities, hospitality and cash/monetary grants.

(b): No.

(c): The Department of Pharmaceuticals has informed that the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) is voluntary in nature and under UCPMP, there is no provision for Department of Pharmaceuticals to directly deal with complaints received regarding unethical practices. As per UCPMP, any complaint received against a Pharmaceutical company is dealt by an Ethical Committee for Pharma Marketing Practices (ECPMP) constituted in the Pharmaceutical associations.

The Minister of State In the Ministry of Health and Family Welfare
(Shri Ashwini Kumar Choubey)

In Rajya Sabha

Uniform Code for Pharmaceutical Marketing Practices (UCPMP)

Rajya Sabha Unstarred Question No. 702

Shri Jyotiraditya M Scindia:

Q. Will the Minister of **Chemicals and Fertilizers** be pleased to state;

(a): whether Government had decided to make a Uniform Code for Pharmaceutical Marketing Practices (UCPMP) mandatory;

(b): if so, the present status of the UCPMP;

(c): whether the implementation of voluntary code has not shown any results and unethical practices have increased; and

(d): if so, the corrective steps that Government proposes to take in this regard?

Answered on 18th September 2020

A. (a): No Sir.

(b): In view of reply to (a) above, the question does not arise.

(c) & (d): The Uniform Code for Pharmaceutical Marketing Practices (UCPMP) is voluntary in nature and under UCPMP, there is no provision for Department of Pharmaceuticals to directly deal with complaints received regarding unethical practices. As per UCPMP, any complaint received against a Pharmaceutical company is to be handled by an Ethical Committee for Pharma Marketing Practices

(ECPMP) that is to be constituted in each of the Pharmaceutical associations. Department has been following up with the Pharma associations to implement the code effectively. In this regard, this department has also taken multiple meetings with the Pharmaceuticals associations and most of the associations have put UCPMP on their websites and constituted the Committees for handling complaints regarding breach of UCPMP.

Minister in The Ministry of Chemicals & Fertilizers (Shri D V Sadananda Gowda)

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OBITUARY

Shri Ram Vilas Paswan

Shri Ram Vilas Paswan, Union Minister of Consumer Affairs, Food and Public Distribution in the Prime Minister Narendra Modi led Government, passed away on 8 October 2020. He was 74 years old.

Shri Paswan was undergoing heart surgery at a Delhi hospital and had been hospitalised for the past few weeks.

Shri Paswan was also the President of the Lok Janshakti Party, nine-time Lok Sabha member and Rajya Sabha MP. He was a Minister in the Narendra Modi Government, the UPA Government as well as the Atal Bihari Vajpayee-led NDA Government.

As the Minister of Chemicals and Fertilizers during 2004 to 2009 in the Manmohan Singh led UPA Government, he interacted with IDMA stalwarts and Pharma industry leaders regularly.

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

CONDOLENCE MESSAGE

IDMA has sent the following Condolence Message on 11th October 2020 to Hon'ble Shri Chirag Paswan, Member of Parliament & President, Lok Jan Shakti Party, 12, Janpath, New Delhi.

Shri Chirag Paswan ji,

We, at Indian Drug Manufacturers' Association (IDMA) are saddened with the sudden demise of Hon'ble Shri Ram Vilas Paswan ji.

We have lost a leader with vision and wisdom. He always championed the cause of the oppressed.

It is a void in Indian polity which cannot be filled.

We pray to Almighty God to give you and the family members strength to bear this irreparable loss and continue to tread the paths followed by Shri Ram Vilas Paswan ji.

With heartfelt Condolences, Mahesh Doshi, National President, IDMA.

Scientists trace severe COVID-19 to faulty genes and an autoimmune condition

More than 10 percent of young and healthy people who develop severe COVID-19 have misguided antibodies that attack not the virus, but the immune system itself, new research shows. Another 3.5 percent, at least, carry a specific kind of genetic mutation. In both groups, the upshot is basically the same: The patients lack type I interferon, a set of 17 proteins crucial for protecting cells and the body from viruses. Whether the proteins have been neutralized by so-called auto-antibodies, or were not produced in sufficient amounts in the first place due to a faulty gene, their missing-in-action appears to be a common theme among a subgroup of COVID-19 sufferers whose disease has thus far been a mystery.

Published in two papers in Science, the findings help explain why some people develop a disease much more severe than others in their age group--including, for example, individuals who required admission to the ICU despite being in their 20s and free of underlying conditions. They may also provide the first molecular explanation for why more men than women die from the disease. "These findings provide compelling evidence that the disruption of type I interferon is often the cause of life-threatening COVID-19," says Jean-Laurent Casanova, head of the St Giles Laboratory of Human Genetics of Infectious Diseases at The Rockefeller University and a Howard Hughes Medical Institute investigator. "And at least in theory, such interferon problems could be treated with existing medications and interventions."

The findings are the first results being published out of the COVID Human Genetic Effort, an ongoing international project spanning over 50 sequencing hubs and hundreds of hospitals around the world, co-led by Casanova and Helen Su at the National Institute of Allergy and Infectious Diseases. The study participants included various nationalities from Asia, Europe, Latin America, and the Middle East. "COVID-19 may now be the best understood acute infectious disease in terms of having a molecular and genetic explanation for nearly 15% of critical cases across diverse ancestries," Casanova says.

Genetics of COVID-19 outliers:

The way SARS-CoV-2 affects people differently has been puzzling. The virus can cause a symptom-free infection and go away quietly, or it can kill in a few days. Casanova's research over the past two decades has shown that unusual susceptibility to certain infectious diseases can be traced to single-gene mutations that affect an individual's immune response. Since February, his team and their collaborators have been enrolling thousands of COVID-19 patients to find out whether something in their genetic make-up drives the disparate clinical outcomes the disease produces.

In one study, the researchers genetically analyzed blood samples from more than 650 patients who had been hospitalized for life-threatening pneumonia due to SARS-CoV-2, 14 percent of whom had died. They also included samples from another group of over 530 people with asymptomatic or benign infection. They initially searched for differences between the two groups across 13 genes known to be critical for the body's defense against the influenza virus. These genes govern type I interferons.

It soon became obvious that a significant number of people with severe disease carried rare variants in these 13 genes, and more than 3 percent of them were in fact missing a functioning gene. Further experiments showed that immune cells from these patients did not produce any detectable type I interferons in response to SARS-CoV-2.

Interferons are part of the intrinsic and innate immunity, kicking in before the adaptive immune system mounts an antibody response. They are known to play an important role in immediately heightening the cells' defenses in response to several viruses. Follow up experiments led by Rockefeller's Charles M Rice showed that this is also the case for SARS-CoV-2: Human fibroblast cells with mutations affecting the interferon type I pathway were more vulnerable to the virus, and died in higher numbers -- and faster -- than cells without those mutations.

A mysterious autoimmune condition:

Three other infectious diseases caused by mutations affecting an immune signaling protein can also be caused by auto-antibodies against that protein. So next, the team checked for the possibility of a similar scenario. Examining 987 patients with life-threatening COVID-19 pneumonia, they found that more than 10 percent had auto-antibodies against interferons at the onset of their infection. The majority of them, 95%, were men.

Biochemical experiments confirmed these auto-antibodies can effectively curb the activity of interferon

type I. In some cases, they could be detected in blood samples taken before patients became infected; in others, they were found in the early stages of the infection, before the immune system had the time to mount a response. These auto-antibodies seem to be rare in the general population. Out of 1,227 randomly selected healthy people, only four were found to have them.

"All of these findings strongly indicate that these auto-antibodies are actually the underlying reason some people get very sick, and not the consequence of the infection," Casanova says. The findings point to certain medical interventions to consider for further investigation, Casanova says. For example, there are already two types of interferons available as drugs and approved for use to treat certain conditions such as chronic viral hepatitis.

The team continues to look for genetic variations that may affect other types of interferons or additional aspects of the immune response in COVID-19 outliers.

Source: World Pharma News, 24.09.2020 (Excerpts)

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NATIONAL NEWS

Cadila Pharma offers new hope to Cardiac Patients

Ticagrelor can be used for the primary prevention of stroke in patients with coronary artery disease as approved by the US FDA. Cadila Pharmaceuticals launches Tikacad® in India, an antiplatelet drug-containing Ticagrelor, a P2Y12 platelet inhibitor indicated to reduce the rate of cardiovascular death, myocardial infarction, and stroke in patients with Acute Coronary Syndrome (ACS) or a history of Myocardial Infarction (MI).

One in 4 deaths in India are because of CVDs where ischemic heart disease and stroke is responsible for >80% of this burden. Acute Coronary Syndrome (ACS) is a syndrome (set of signs and symptoms) due to decreased blood flow in the coronary arteries such that part of the heart muscle is unable to function properly or later results into fatality. To reduce this burden, Ahmedabad based Cadila Pharmaceuticals launched Tikacad® which has shown to reduce stroke incidence by 19% and ischemic stroke by 20%. For at least the first 12 months following ACS, it superior to has shown better results compared to Clopidogrel.

"With the launch of Tikacad®, we want to give quality care and medications to heart patients. Tikacad® is the next in the long line of Cardiac specialty drugs produced by Cadila Pharmaceuticals such as Nodon and Teli AM. We are on a mission to keep serving the community" said Mr Ravikiran Numburi, Vice-President, Sales and Marketing.

"Tikacad® is a ray of hope for patients of Cardiovascular diseases. With Tikacad® we aim to reduce the suffering of these patients and help them lead a long and happy life. We are committed to our promise of quality care and are constantly working towards finding the next innovative drug for our patients" said Mr O P Singh, President-Sales and Marketing, Cadila Pharmaceuticals Limited.

Tikacad is available in the form of 90mg tablets. Tikacad® containing Ticagrelor reduces the rate of stent thrombosis in patients who have been stented for treatment of ACS. Ticagrelor can also be used for the primary prevention of stroke in patients with coronary artery disease as approved by the US FDA.

Source: biospectrumindia.com, 10.10.2020

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IDMA urges CDSCO to amend definition and responsibilities of Marketer for Quality in D&C Rules

The Indian Drug Manufacturers' Association (IDMA) has appealed to the Central Drugs Standard Control Organisation (CDSCO) to amend the definition of the term "Marketer" to remove the words 'agent' or 'person in any other capacity' in the Notification G.S.R.101(E) dated February 11, 2020 since these words are not specific and have a wider meaning.

The Notification has amended the Drugs and Cosmetics Rules to include a definition of Marketer that places certain responsibilities for quality and regulatory compliance on the marketer for the products marketed by him. The Rule comes into force from March 1, 2021. Besides, this definition in the Rules contradicts the section 19(3) of Drugs and Cosmetics Act, 1940 that provides certain safeguards to the person not being either a manufacturer or an agent of the drug.

Any Rule contrary to the provisions under the Act or having an overriding effect will not withstand a judicial scrutiny. The IDMA has requested above amendments to remove lacuna in Gazette Notification issued by Union Health and Family Welfare Ministry on February 11, 2020 on implementation of Drugs and Cosmetics (Amendment) Rules, 2020 holding marketers along with the manufacturers responsible for ensuring quality and regulatory compliances of the marketed drugs in the country. The Rule will come into force from March 1, 2021.

The newly inserted Rule 84E in D&C Rules comprising responsibility of Marketer of the drugs said any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these Rules. The industry body affirmed that the responsibility for quality and regulatory compliance cannot be placed on the marketer grossly and has to be specified clearly, particularly in view of the fact that the outsourcing of products is done in two different manners - loan license arrangement and P2P arrangement that has different set of responsibilities on the marketing company.

In the loan license arrangement, where the technology/ product know-how is provided by marketer, the D&C Rules provide the responsibilities in the form of conditions for grant of a loan license. In P-to-P arrangement, two P-to-P parties, one having manufacturing skills and capabilities and the other having marketing skills and capabilities work synergistically using their respective skills and resources.

Under this arrangement, the Marketer accepts the product developed and manufactured by the manufacturer under a drug license.Under the marketing arrangement, it is practically not possible for a marketer to exercise a control on the manufacturing and testing of the drugs that is governed by the conditions of the license issued to the manufacturing company. Further, the words "responsible for other regulatory compliance", are vague, non-specific and wide in meaning.

The expected regulatory compliances to be complied by the marketer needs to be provided in clear terms, it added. In fact, since the marketer is neither a manufacturer, nor a loan licensee, the provisions of Chapter VII governing conditions of manufacturing license would not apply to him. The applicable requirements for storage and distribution of drugs are specified in Part VI. Thus, providing for the responsibility of a marketer under Part VII would be out of place, context and scope of part VII.

The IDMA has suggested the introduction of a separate Part in the D&C Rules, since Part VII applies to license holders for manufacturing- own license/loan license and not to marketers. The newly inserted Rule 84D in D&C Rules requires that before marketing of the product the marketer should have an agreement with the manufacturer. Pointing out lacuna in provision of Rule 80D, IDMA stated that the key contents of the agreement are not specified.

The shared responsibilities for quality and regulatory compliance between the manufacturer and marketer have to be consistent with the legal requirements and hence have to be specified, it said. As per the Gazette Notification, in Rule 2 of D&C Rules, existing clause (ea) shall be re-lettered as clause (eb) containing definition of "marketer" which means a person who as an agent or in any other capacity adopts any drug manufactured by another manufacturer under an agreement for marketing of such drug by labeling or affixing his name on the label of the drug with a view for its sale and distribution.

The IDMA suggested that the term 'agent or in any other capacity' in the definition of 'marketer' has wider meaning and is not specific. Hence the definition of the term 'marketer' has to be modified to remove the words 'agent' or 'person in any other capacity'. Marketer cannot be considered as an agent of the manufacturer since he works on a P-to-P contract basis. This Gazette Notification, if implemented without amendments suggested by the industry body, may interrupt supply of medicines that would be against the interest of the patients, particularly in the current pandemic period.

The disruption caused by the pandemic is predicted to last for at least two years and any interruption to the supply has to be prevented.This Notification, in its current form, may not provide any additional benefit in terms of ensuring product quality but may act as an impediment in Government's thrust on 'ease of doing business'. Until the suggested amendments are notified, the implementation of the Rules may be deferred, it opined.

Source: Laxmi Yadav, Pharmabiz, 05.10.2020

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Indian Pharma Market registers 4.5% Growth in September 2020

The Indian Pharmaceutical Market (IPM) has registered a growth of 4.5% for the month of September 2020, after five months of COVID-19 crisis. According to AIOCD AWACS report, the IPM has recorded sales of Rs.1,42,868 crore for

Moving Annual Total (MAT) basis during September 2020. Amongst the top 10 Corporates, Mankind exhibited the highest growth of 8.4 percent, followed by Torrent Pharma at 7.1 percent. Amongst the 11 to 25 ranked Corporates, Aristo exhibited highest growth of 13 percent followed by Glenmark Pharmaceuticals at 15.4 percent.

Amongst the 26 to 50 ranked Corporates, Boehringer Ingelheim registered the highest growth of 22.3 percent followed by JB Chemicals at 15.8 percent. Amongst the 51 to 75 ranked Corporates, Danone registered the highest growth 29.7 percent followed by Merck at 16.9 percent. Amongst the 76 to 100 ranked Corporates, Reckitt Benckiser exhibited the highest growth at 30 percent, followed by Llyod Hc at 23.7 percent.

Cardiac has registered a monthly growth of 17.1% in September 2020 as compared to 11.5% in August 2020, while anti-diabetic registered growth of 6.5% as compared to 1.6% in August 2020. Respiratory medicines growth slumped to -10.5% as compared to -12.4% in August 2020. Post lock-down, the struggle for anti-infectives stood at -11.0% in August 2020 shows some revival, but still it is at 1.4% in September 2020. While associated therapy like gastro further dips to 5.5% as against -3.1% in August 2020. Vitamins have bounced back, with growth of 16.3% in September as against 6.2% in August 2020. Pain and analgesics are at -4.3 % in September 2020 as against -9.8% in August 2020. The NLEM 2013 containing molecules market showed growth at 8.7 per cent, whereas the non NLEM market registered growth of 4 percent.

Source: Yash Ved, Pharmabiz, 09.10.2020

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COVID-19: ICMR receives Clinical Trial approval for animal-derived antibodies treatment

ICMR Director General Dr Balram Bhargava addresses a Press Conference in New Delhi. (File Photo)

The plasma therapy may not have shown any benefits during recent trials, but the Indian Council of Medical Research (ICMR), the country's biological research regulator, has received the National Drugs Controller's approval to conduct a Clinical Trial on animal derived antibodies against SARS-COV-2, the virus that causes Coronavirus Disease (Covid-19), for the treatment of patients.

The antibodies from animals, or animal-derived sera, are also called antisera. The ICMR will be conducting Clinical Trials on antibodies derived from horses. ICMR along with Hyderabad-based Biological E Limited have developed highly purified antisera to treat Covid-19 patients.

"We have developed equine sera and developed a horse sera with Biological E, which may also be considered. We have completed some studies on horse sera, where we have a predictive dose of antibodies in an ampoule, which is a small sealed glass capsule containing the dosage that can be injected. We are awaiting a clearance for a Clinical Trial with the horse sera," said Dr Balram Bhargava, Director-General, ICMR, at the Union Ministry of Health and Family Welfare's (MoH&FW) Covid-19 briefing on Tuesday, 06.10.2020.

Earlier, equine sera was tried to treat several viral and bacterial infections such as rabies, Hepatitis B, vaccinia virus, tetanus, botulism and diphtheria. "Although, plasma recovered from Covid-19 patients could serve a similar purpose, the profile of antibodies, their efficacy and concentration keep varying from a patient to another. As a result, it makes an unreliable Clinical Tool for Covid-19 patient management," ICMR had earlier said in a statement.

"Standardisation achievable through equine sera-based treatment modality stands out as yet another remarkable public health initiative supported by the ICMR in the time of Covid-19," it added. ICMR's study on determining efficacy of plasma therapy in treating Covid-19 patients was conducted on 464 patients across 39 hospitals in India, with at least 350 doctors participating in the study. "…and it clearly demonstrated no benefit in reducing mortality in moderate to severe cases of Covid-19. It also did not arrest the progression of disease from moderate to severe.

This was well established. This publication has been reviewed and has been accepted as a full paper in the British Medical Journal, one of the most prestigious journals in the world. At the moment, a pre-print has been

published, but the entire article will be published soon," said Dr Bhargava. "However, following the cue from that we have developed the equine sera to be used in Covid-19 treatment," he added.

Source: Rhythma Kaul, Hindustan Times, 08.10.2020

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Pharmastart-ups & MSMEs work out effective IP strategies to bolster Innovation & Market edge

The Indian Pharma start-ups and MSMEs (Micro Small and Medium Enterprises) and Medical Technology companies are now devising effective Intellectual Property (IP) strategies to reinforce their innovation and strengthen their market edge in the competitive global and domestic arena. At a time when India is facing multiple challenges including the COVID-19 pandemic, IP creation is the only valuable asset for any Research and Innovation-driven company, said Bindu Sharma, Patent Attorney and Chief Executive Officer, Origiin IP Solutions LLP.

"But IP requires investment in terms of money, time and intellect. However, it is extremely important for the companies to claim legal rights on IP and prevent others from using the same. Hence it is now extremely important for startups and MSMEs to not only realize the importance of innovation & IP but also to devise correct and effective strategies, processes and policies at the inception stage of ideas to make sure their innovation is well protected, enforced and eventually commercialized," Sharma told.

The most effective IP strategy is the one that is aligned with the business objectives of a company. Success of IP strategy is dependent on its formulation & implementation of practices, processes and policies within the organization, she added. Noting that there are five components to an IP strategy, she said that the first would be to reduce the R&D cycle especially in product development. Early entry of these innovative products into the market will result in a competitive edge.

While protection of IP with trademarks, patents, designs, copyrights is the second critical aspect for a business, the third would be infringement risk analysis. Here Sharma sees the need for any product company to ensure Freedom to Operate (FTO) to be an integral part of the company's IP Policy and would save companies from litigations.

Monetization of IP which is the fourth component is the mainstay for companies as it helps revenue generation from licensing or transfer technology. For instance, Sree Chitra Tirunal Institute of Medical Sciences & Technology, Thiruvananthapuram developed a technology to manufacture blood bags conforming to international standards. It identified Peninsula Polymers to set indigenously manufacture the blood bags.

This enabled to locally produce blood bags three decades ago. Subsequently, the Institute transferred the technology to many other companies enabling access to high quality blood bags at affordable prices which was also exported globally.

Further in a competitive business environment, companies will need to enforce IP which is the fifth component to prevent patent infringement cases .Therefore, only an effective IP strategy, aligned with business game-plan would accelerate growth prospects for start-ups and MSMEs providing the much-needed market edge, said Sharma.

Source: Nandita Vijay, Pharmabiz, 07.10.2020

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Panel for self-reliance in cancer drugs

Observing that the country is not investing much on research that has resulted in overwhelming dependence on raw materials from China, particularly those for cancer treatments, Judge N Kirubakaran ordered for the constitution of a committee comprising Joint Secretary-level officers from the Union Ministries of Pharmaceuticals and Finance to ensure self-reliance of India in cancer drugs.

The HC made the observations while hearing a plea moved by M Perumal, MD of Vinkem Labs Limited. The Chennai-based Pharmaceutical company had complained about the lack of impetus from the Centre in carrying out generic research especially on manufacturing Active Pharmaceutical Ingredients (API). The judge in his 226-page order observed, "Our country's reliance on one single nation for key ingredients of all life-saving medicines remains at very high proportions posing grave security and other concerns.

Source: The New India Express, 09.10.2020 (Excerpts)

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Bharat Biotech to supply Covaxin to the World soon as Trials will be completed by 2020 end: Krishna Ella

With the first phase and second phase of Clinical Trials for Corona Vaccine, Covaxin, almost coming to an end and the lead research institutes are preparing for the conduct of third phase of Clinical Trials soon, there is optimism that the vaccine will be ready for supply by the end of this year.

Krishna Ella, Chairman and Managing Director of Bharat Biotech International, expressed confidence that by the end of 2020 all the 3 phases of Clinical Trials will be completed successfully. The entire team of Bharat Biotech including the lead research institutes like Indian Council of Medical Research (ICMR) and various lead hospitals conducting Clinical Trials are working day and night to make sure that all the 3 phases of Clinical Trials are completed successfully by the end of the year, he said.

"So far the results of Clinical Trials in the first and second phase for Covaxin have shown positive results. Across India, more than 20 hospitals have been selected for conducting the Clinical Trials for Covaxin. The results for the first and second trials have been successful; we are in the process of preparation for conducting 3rd phase of Clinical Trials, which will be done on a larger scale compared to the previous two trials. Hopefully, we will complete all these trials by end of this year and expecting nod from the Indian regulatory body for the manufacture of mass scale production of the vaccine," said the Bharat Biotech CMD.

Recently, the Telangana Governor Tamilsai Soundaryarajan visited the Bharat Biotech Company located in Genome valley at Shamirpet on the outskirts of Hyderabad and enquired about the status of the Clinical Trials on the Vaccine developed by the Bharat Biotech Company. While giving a detailed presentation, Krishna Ella along with the lead scientists from the company explained the various steps and measures being taken to bring the vaccine at the earliest for the public.

In his presentation, Krishna Ella said that the scientists at Bharat Biotech are working tirelessly to make sure they come up with a most effective and affordable vaccine for the man kind to get rid of the deadly virus. "I thank all those scientists and people involved in the development of Covaxin. I came here to learn about the development status of Covaxin. I am satisfied and appreciate the efforts of these scientists who are working to bring out a most effective and affordable vaccine. Not just people Telangana and India, but the entire world is looking at Bharat Biotech for its vaccine," observed the Telangana Governor.

The Governor expressed hope that very soon Bharat Biotech will provide the much needed Covaxin to the world and eradicate the deadly virus and save mankind from its killer impact. At present, Bharat Biotech is manufacturing various types of vaccines and has supplied more than 300 crore doses of different vaccines to the entire world. Very soon Bharat Biotech is expected to take a lead in the supply of Covaxin to the entire world. Telangana Governor congratulated and praised the efforts of Suchitra Ella, Joint Managing Director of Bharat Biotech, who is playing a vital role in leading the research and manufacturing of Covaxin. The Governor also personated a Thanking Badge to the JMD for her efforts to bring out the vaccine at a speedier pace.

Source: A Raju, Pharmabiz, 08.10.2020

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CSIR-IICT Scientist bags CSIR award for innovative work to mitigate fluorosis related health problems

The innovative work of a team of scientists led by Dr S Sridhar, Senior Principal Scientists at Council for Scientific and Industrial Research and Indian Institute of Chemical Technology (CSIR-IICT) has bagged the prestigious CSIR award for their scientific and technological (S&T) innovations, which has been effective in mitigating the fluorosis disease across various states in the country.

Dr M Chandrasekharam, Senior Principal Scientist at IICT informed that the team of scientists led by Dr Sridhar from Process Engineering and Technology Transfer Department had designed and deployed a highly compact, low-cost nanofiltration and reverse osmosis membrane system of 100-1000 liter/hour capacities for ground and surface water purification.

"As we all know, lakhs of people have been suffering due to the fluorosis problem causing severe healthcare problems because of high level of fluoride in the drinking water. For instance, take the example of a number of villages in Nalgonda district where lakhs of poor people in the villages have been adversely impacted with the fluoride problem. To mitigate the fluoride problem, the innovation of the CSIR-IICT scientists has come handy and today this

new water purification system has been installed in various villages across Telangana, Andhra Pradesh, Karnataka and Tamil Nadu," informed the Senior Principal Scientist.

In fact, the CSIR national award under the Rural Development (CAIRD) category for the year 2017 was announced during the 79th CSIR foundation day celebrations held on 26th September, 2020 in Hyderabad. Dr Sridhar had received special appreciation for the work done in the mitigation of fluorosis in rural India as he was the first to initiate drinking water purification in rural India through the installation of the first model defluoridation plant in 2005 and has continued to promote societal welfare with many such installations including ultrafiltration based systems for flood water purification during the recent Amphan cyclone in 2020.

Dr Sridhar has also developed innovative technologies including an import substitute for production of ultrapure medical grade water for haemodialysis patients as well as biochemical applications to replace expensive systems from MNCs, design of indigenous atmospheric water generator for water scarce regions besides a low cost device for healthy alkaline ionized water. He has contributed to industrial development through membrane-based effluent treatment, solvent recovery by electro dialysis, as well as gaseous separations. He has also designed and distributed multilayered masks and face shields for the common man during COVID-19.

Dr Sridhar has excelled in basic research by publishing 150 papers in reputed journals with a high h-index of 44. He holds 12 patents, published 2 books and 40 book chapters, and guided 10 Ph.Ds and 350 dissertation students. For his outstanding services to society, industry and academia, Dr Sridhar has previously been honored with 42 awards including CSIR Young Scientist 2007, NASI-Scopus Young Scientist 2011, NASI-Reliance Platinum Jubilee Award 2013, VNMM Award from IIT-Roorkee 2015, Nina saxena Award from IIT-Kharagpur 2017 besides several awards from IIChE, Kolkata.

Source: A Raju, Pharmabiz, 06.10.2020

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India declines proposal to test Sputnik-V Covid vaccine in large study

India's drug regulator has knocked back a proposal from Dr Reddy's Laboratories Ltd to conduct a large study in the country to evaluate Russia's Sputnik-V Covid-19 vaccine and has asked it to first test the vaccine in a smaller trial. The recommendations by an expert panel of the Central Drugs Standard Control Organisation (CDSCO) noted that safety and immunogenicity data from early-stage studies being conducted overseas is small, with no inputs available on Indian participants.

India's move comes as a setback for Russia's plan to roll-out the vaccine even before full trials show how well it works, while pushing back its efforts to win approval for the vaccine in the country that leads the world on average number of new infections. India is expected to overtake the United States over the next several weeks as the country with the world's largest number of cases. The Russian Direct Investment Fund (RDIF), which is marketing the Sputnik V, and Dr Reddy's Laboratories last month announced their partnership to run Clinical Trials and distribute the vaccine in India.

Russia was the first country to grant regulatory approval for a novel Coronavirus vaccine, and did so before --large-scale trials were complete, stirring concerns among scientists and doctors about the safety and efficacy of the shot. RDIF and Dr Reddy's did not immediately reply to *Reuters'* requests for comment outside business hours.

Source: Reuters/ET-Health World, 09.10.2020

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New US FDA Guidance on ANDA to benefit Indian Companies to get faster generic drug approvals

Indian Pharma industry is of the view that the recent US FDA Guidance on ANDA (Abbreviated New Drug Application) submissions, amendments and requests for its final approval is expected to provide a big push for faster generic drug clearances. The new guidance is intended to assist applicants in preparing and submitting amendments to tentatively approved ANDAs, including requests for final approval.

The Guidance provides recommendations on the timing and content of amendments to facilitate submission in a timely manner that can result in final approval on the earliest approval date. "Going forward, it is the ANDA approvals which would accelerate further growth of Indian Pharma too," said the Pharma companies. According to Umesh Baikunje, founder & Director, Baikunje Consultancy, this Guideline is very useful since it gives necessary recommendations to applicant avoid any further delays

in getting the final approvals. India being very efficient in producing cost-effective or affordable quality product in shortest time, this will help to speed up and get more approvals. Only rider is any delay in submitting the amendments or updates will miss the bus.

The regulatory note also stated that the process for obtaining approval to market a drug product approved under a New Drug Application (NDA) differs from that for obtaining approval to market a generic drug under an ANDA. A sponsor of an innovator drug must submit an NDA, which should contain among other things, a demonstration of the safety and effectiveness of the drug for the conditions of use for which approval is sought. Commenting on the Guidance, Prema Desai, Pharma consultant noted that a request for final approval should clearly identify, in its cover letter, all changes to the ANDA that have been made. The applicant also needs to monitor for updates related to the drug product like changes in bioequivalence recommendations, the RLD labelling changes and ensure that amendments are submitted on time and clearly identified before a request for final approval from the FDA.

In the last few years, Indian companies have been grabbing a fair share of the ANDA approvals from the global regulatory authority, estimated to be over 35 percent and by far the largest by any country. An ANDA is submitted for the approval of a generic drug. It is only after US FDA's consent, an applicant can manufacture and market the low cost generic product ensuring its safety and efficacy that is referenced with a branded version.

Indian companies including Sun Pharma, Aurobindo, Alembic, Biocon , Cipla, Dr Reddys, Glenmark, Granules India, Ind-Swift Labs, Indoco Remedies, Jubilant Lifesciences, Strides Pharma and Zydus Cadila have been submitting ANDA applications and receiving the approvals. It is reported that last year Indian Pharma manufacturers secured 40 percent of total final ANDA approvals and 49 percent of total tentative approvals.

In the last decade, alone, US FDA approved 5,768 ANDAs and 1,351 tentative approvals. Indian companies continued to hold leadership to garner over 35 percent approvals. However an ANDA applicant is not required to provide independent evidence of the safety and effectiveness of that generic drug. Instead, the applicant may rely on FDA's finding that the Reference Listed Drug (RLD) relied upon by the ANDA applicant is safe and effective. Therefore, an ANDA must also include sufficient information to demonstrate that the proposed product is bioequivalent to the RLD. It should also ensure the product's identity, strength, quality, and purity.

Source: Nandita Vijay, Pharmabiz, 05.10.2020

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Health Ministry issues draft National List of Essential Assistive Products

The Union Health Ministry has released the draft National List of Essential Assistive Products (NLEAP). The list is aimed to provide Assistive Technologies (ATs) and devices for elderly, Persons with Disabilities (PwDs), patients with Non-Communicable Diseases (NCDs) such as stroke, diabetes, congenital birth defect associated disabilities and people in humanitarian crisis and disasters.

The Ministry has invited suggestions and comments on the list from the stakeholders by October 10, 2020. Earlier, the Indian Council of Medical Research (ICMR) had initiated steps to prepare a list of assistive products on the pattern of WHO's Priority Assistive Products List (WHO-APL). A total of 383 Assistive Products (APs) have been included in the NLEAP through a consultative process. As India already has a National List of Essential Medicines (NLEM), hence during various Expert Group meetings by ICMR, it was agreed that the list may be termed as NLEAP.

In January 2020, Director General (DG), ICMR, Balram Bhargava constituted a National Expert Committee (NEC) under the leadership of Dr R K Srivastava, Ex-DGHS, to assist in preparation of a list of assistive products. The NEC recommended creation of 4 sub-groups, each representing their specialties like public health, Physical Medicine & Rehabilitation (PMR), geriatrics and engineering. Each of the specialties had one leader with involvement of two more members.

These Sub-Groups were:

Public Health Specialists led by Dr Harshad Thakur, Director, National Institute of Health and Family Welfare (NIHFW), physical medicine and rehabilitation professionals led by Rajendra Sharma, Consultant, Dr Ram Manohar Lohia Hospital, Delhi, geriatric medicine experts led by Dr A B Dey and engineering professionals led by Dr PVM Rao, IIT-Delhi. Lead Expert of each sub-group was given liberty to include more members. Dr Sanjiv Kumar, Ex-National Health Systems Resource Centre (NHSRC); Dr Arvind Mathur, renowned geriatrician;

Dr S L Yadav, AIIMS; Dr Balakrishnan, IIT-Delhi; Dr Shipra Chaudhary, RML Hospital; Dr Shweta Bhandari, and Dr Suman Badhal, Safdarjang Hospital; Dr Monika Saini, Dr Rajni Bagga, Dr Manoj and Dr Niraj –NIHFW; contributed towards finalisation of the complete master list of assistive products. In addition to this Prakash Bachani, Scientist, Bureau of Indian Standards (BIS) and Dr Sangeeta Abrol, Ministry of Health & Family Welfare contributed by providing BIS-ISO standards and Health Ministry perspectives. Each sub-group met many times to discuss the assistive products from their specialty angles.

During its meetings, NEC and Sub-Groups felt the need to go beyond simple list to classify them age-wise (different requirements in different age groups), disability-wise (21 disabilities as per RPwD Act 2016 or Visual, Hearing, locomotor, Cognitive, Communication, Self-Care), system-wise (Primary, Secondary or Tertiary Health Care Systems), cost-wise (Low, Medium or High), provision-wise (Govedrnment, Private, Insurance, Welfare, NGO), Indigenous v/s Imported (available in India or to be imported), BIS-ISO Standards, and Technology-wise (Simple, complex, advanced including softwares).

Current list was prepared after Expert Group consultations and referring to Safdarjung list, CGHS list, ALIMCO list, Mobility India list, EU list, BIS-ISO list, textbooks, and National Trust (with a network of more than 700 NGOs). ICMR aims to deliberate, contribute and guide the way forward towards building a National list of Essential Assistive Products (NLEAP)-India, with focus on the principal themes of appropriateness, quality, affordability, accessibility and standardization of ATs and strategies for strengthening and service provision.

By 2022, existing 1,50,000 Sub Centres and Primary Health Centres will be converted to HWCs. Ministry of Social Justice and Empowerment (MoSJE), Government of India is the nodal agency for care of persons with disabilities. An overarching legal provision in form of Rights of Persons with Disabilities Act 2016 (RPwD Act, 2016) was enacted by MoSJE. RPwD Act has clearly delineated the steps for provision of assistive products. It directs every Ministry to develop their own systems for care of PwDs. Health and healthcare has been mentioned more than 25 times in the said act.

Subsequently, Union Health Ministry has included the assistive products under the list of health products vide notification dated February 11, 2020. The Assistance to Disabled Persons for Purchase/Fitting of Aids/Appliances (ADIP) Scheme under MoSJE is providing ATs to the PwDs. It was conceived in 1981 to provide "durable, sophisticated, scientifically manufactured modern, standard aids and appliances" to disabled persons. Since that period the ATs like sticks, walkers, spectacles, wheelchairs, tricycles, smart cane, cochlear implants are being extended to the needy people. The NLEAP will facilitate ADIP scheme to provide better products to those who need them.

Source: Shardul Nautiyal, Pharmabiz, 03.10.2020

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Interest subvention for MSMEs: Modi Government extends Scheme Validity to March 2021

SIDBI is the nodal implementation agency for the interest subvention scheme for MSMEs

Ease of Doing Business for MSMEs:

In order to further provide interest relief of 2 percent per annum to MSMEs, Modi Government has extended the validity of the Interest Subvention Scheme for MSMEs till March 31, 2021, the Reserve Bank of India (RBI) said in a Notification on Wednesday, 07.10.2020. "The validity of the scheme has been extended till March 31, 2021. Accordingly, fresh or incremental term loan/working capital limit extended by co-operative banks with effect from March 3, 2020, will be eligible for coverage under the scheme," the Notification read. The Government had announced the scheme on November 2, 2018, to offer interest relief on loans to the extent of Rs.1 crore and implemented for FY19 and FY20 and now up to FY21.

The announcement comes nearly 10 months after the Government had approved amendments in the scheme in December 2019. The Notification included modifications such as acceptance of claims in multiple lots for a given half-year by eligible institutions permitted, the requirement of *Udyog Aadhar* Number dispensed with for MSMEs eligible for GST instead of UAN GSTN numbers earlier mandatory; MSMEs, which are not required to obtain GST, allowed to either submit Income Tax Permanent Account Number or their loan account must be categorised as MSME by the concerned bank; and trading activities without UAN allowed to be covered. The Notification was addressed to heads of all Urban Cooperative Banks, state Cooperative Banks, and District Central Cooperative Banks.

The changes, however, were already part of the amendments approved in December that also included

"50 percent of the estimated claim amounts may be released to eligible institutions (at least to those belonging to Public Sector Banks), based on data/information to be furnished by them and the Utilisation Certificate duly certified by respective statutory auditor to submitted by June 2020," as per an MSME Ministry statement on December 16, 2019. According to an update by the MSME Ministry, out of the total corpus of Rs.975 crore, Rs.825 crore (including SIDBI administrative fee) was released to SIDBI for claim settlements as on September 30, 2020. SIDBI had received and settled the claims of Rs.825 crores from 57 banks/NBFCs. SIDBI is the nodal implementation agency for the interest subvention scheme for MSMEs.

Source: Sandeep Soni, The Financial Express, 08.10.2020

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BPPI issues Guidelines for opening new *Pradhan Mantri Bhartiya Jan Aushadhi Kendras*

Close on the heels of Union Chemicals Minister D V Sadananda Gowda's announcement last week that efforts are being made to increase the number of PMBJKs from the current 6,500 to 10,500 in the country by March 2025, the Bureau of Pharma PSUs of India (BPPI) has issued Guidelines for opening new *Pradhan Mantri Bhartiya Jan Aushadhi Kendra (PMBJK)* in the country. Since the Government intends a pan-India expansion, BPPI has noted that the PMBJK will be opened only in selected hospitals and medical colleges identified by the respective state Governments in the shortest possible time.

"The premises will be solely used for the purpose it has been allotted. It will not be allowed for sub-letting to undertake any other activity. The Kendra will need 120 sq ft area with sufficient furniture like racks to store the medicines, counter for issue of bill and medicines to the patients, besides computer table and chairs for the working staff," stated the Bureau in its guidance. For the proper implementation of the scheme, BPPI would render all possible assistance to the operating agency for running the PMBJK. It would also facilitate the supply of affordable generic medicines, surgical supplies and consumables through a supply chain against the payment of dispatched Goods.

The operating agency will be given 20 percent margin against the MRP excluding taxes. It will provide a one-time financial assistance of Rs.2.5 lakh of which Rs.1 lakh will be for furniture and fixtures, another Rs.1 lakh for free medicines in the beginning and Rs.50,000 towards reimbursement towards computer, internet, printer, scanner etc. The number of medicines to be sold at PMBJK will be increased to make the scheme viable, in addition, surgical supplies as per requirement would also be supplied. The Bureau pointed out that it would be the responsibility of the operating entity to obtain drug license in the name of PMBJ Kendra and other permissions to run a drug store.

Compliance to all statutory requirements for storage of drugs needs to be ensured by the operating agency. The norms also stated that the operating agency will run PMBJK according to the conditions in agreement to be signed with BPPI before start of operations. Now the Government has called on pharmacy entrepreneurs to take up the scheme among others. Here the Karnataka State Registered Pharmacists Organisation led by Ashok Swamy raised concerns that the operating agency should be a qualified pharmacist that even though to obtain drug license among others to run a PMBJK. Expressing apprehensions in a communication to the Union Government, KSRPO insisted that there is a need to amend Rule 64(1) of the Drugs and Cosmetics Rules, 1945, so as to grant a pharmacy shop license or a wholesale license, only to a firm where a Registered Pharmacist is the sole proprietor or a Managing Partner or a Managing Director. Replying to Heroor, Dr B P N Prasad, Joint Drugs Controller, CDSCO said that the KSRPO should now approach the state licensing authority and the state pharmacy council to ensure that only Registered Pharmacists are granted the license for opening a PMBJ Kendra.

Source: Nandita Vijay, Pharmabiz, 30.09.2020

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DCG(I) nod to Phase-1 Human Trials of 'antisera' with potential to treat COVID-19

The Drugs Controller General of India has given permission for conducting Phase-1 Human Clinical Trial for an "antisera" that was developed by injecting inactivated SARS-CoV-2 in horses and can be a potential treatment for COVID-19, ICMR officials said on Tuesday, 06.10.2020. The 'antisera' has been developed by the Indian Council of Medical Research (ICMR) in collaboration with a Hyderabad-based biopharmaceutical firm. "With Biological E Limited we have developed an horse 'antisera' and we have just got clearance for conducting Clinical Trials for that,"

Agencies
The 'antisera' is yet to undergo human clinical trials to establish safety and efficacy. (Representative Image)

ICMR Director General Dr Balram Bhargava said at press briefing on Tuesday, 06.10.2020. The 'antisera' is yet to undergo human Clinical Trials to establish safety and efficacy. Antisera are blood serum high in antibodies against specific antigens and are injected in humans to help kick-start the immune system to fight specific infections.

"The ICMR and Biological E Limited, Hyderabad, have developed highly purified antisera (raised in animals) for prophylaxis and treatment of COVID-19," the apex Health Research Body had earlier said in a tweet. The pre-print version of the study regarding the development of the equine antisera has been posted on the Research Square platform. "The study provides evidence of the potential of generating highly purified F(ab')2 from equines against SARS-CoV-2 that can demonstrate consistent and high neutralisation activity," the study paper said.

"Further, *in vivo* testing for efficacy of this indigenously developed, cost effective product will pave the way to clinical evaluation. Additionally, being a donor independent method, this may prove as an efficient alternative to convalescent plasma for treatment of COVID19 patients," it said. Earlier such measures were used for controlling several viral and bacterial infections. "Although, plasma recovered from patients experiencing COVID-19 could serve similar purpose, the profile of antibodies, their efficacy and concentration keep varying from one patient to another and therefore, make it an unreliable Clinical Tool for patient management," the ICMR had said in a tweet. "Standardisation achievable through equine sera based treatment modality thus stands out as yet another remarkable public health initiative supported by ICMR in the time of COVID-19," it said. As part of the study, 10 healthy horses were immunised with inactivated SARS-CoV-2 and after 21 days of immunisation, plasma samples were tested. The results of the plasma samples indicated presence of SARS-CoV-2 specific IgG antibodies as detected in ELISA with neutralising capacity.

Source: The Economic Times, 08.10.2020

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MDOA working on formation of a Parliamentarians Group to promote ISM

The Mahamana Declarations on Ayush (MDOA) is working on the formation of a group of Parliamentarians to promote Indian Systems Of Medicine (ISM) in the country. The nine-member group will have representatives from Lok Sabha and the Rajya Sabha who would be sensitized about the opportunities and challenges emerging within the MDOA.

"We are seriously considering and approaching members including Anurag Sharma, an MP from Madhya Pradesh who is also a leading manufacturer of Ayurveda products and Dr Sudhanshu Trivedi from BJP in the Rajya Sabha, who was recommending the National Commission of Indian Systems of Medicine Bill, among others. Our plan is to have four members each from the ruling and opposition parties as this would help promote Ayurveda in India and globally", Prof Bejon Kumar Misra, one of the founders of MDOA told Pharmabiz post the working group meeting held recently.

Besides, we have also planned to launch a platform HamaraAyush.org where every citizen can have access to credible information without falling prey to misleading advertisements. This is particularly crucial during the current times when immunity formulations in herbal medicine are vying for consumers' attention, said Prof Misra. The objective is to empower citizens to make an informed choice in the face of aggressive advertisements and publicity by herbal healthcare brands. This platform will explain in a simple, easy to understand language on scientific papers with evidences about the quality of all Ayush products. Further, HamaaraAyush.org will build a strong network of citizens who have benefited from Ayush and are prepared to endorse it to let others join the movement, he added.

According to Praful Sheth, working group member, MDOA, the game plan is to consolidate and develop a mechanism for a strong regulatory framework for Ayush. This should be a single-window regulatory channel for medicinal plants, raw material, herbs, final formulations, manufacturing unit approvals and Good distribution Practices (GDP). Further, our focus is also to improve the curriculum of Ayush not just in colleges but introduce it as a subject of study at the school level too. The course module at colleges will ensure that students achieve a policy of practice.

Noting that there is a need for a university body to evaluate Ayush, Anil Jauhri, Member, MDOA said that

it would be appropriate to appoint the Benares Hindu University which can be the certifying authority for a slew of courses. In order to sustain the system of Ayush Practice, courses are required to revive the practice of traditional healers. It will strengthen the practice of vaidyas and hakims that are currently difficult to access and even if they exist, their quality standards of medicines and their source should be known.

Source: Nandita Vijay, Pharmabiz, 29.09.2020

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3 mega drug bulk parks to be set up across India: Sadananda

Union Minister of Chemicals and Fertilisers D V Sadananda Gowda said that the Union Government has decided to set up three mega drug bulk parks in different states of the country at a total cost of Rs.13,600 crore, to counter China's monopoly in the Pharmaceuticals sector. He was speaking after inaugurating the Platinum Jubilee Celebrations of Sarada Vilas Educational Institutions and launching the skill development training courses at a function held at its centenary hall. He said that presently the country had been importing 70% of the Pharmaceuticals Ingredients.

"To counter this dominance, the Narendra Modi-led Government has initiated to set up such parks under the *Atma Nirbhar Bharat* scheme aimed at making India self-reliant, generate jobs and train local talents. The Centre will contribute Rs.1,500 crore and state government must spend Rs.2,000 crore to set up such a park," he said. As many as 92 lakh youths had been trained under the Union Government's flagship ambitious Skill India and *Koushalya Bharath* scheme. Of this, 80% of them were employed. The Centre has targeted the creation of 3 crore jobs, and to hone their skills at 25,000 skill development training centres across the nation.

In Karnataka, as many as 3,68,419 youths had been trained against the 3,85,534 registered under the scheme so far, and 50,151 youths were employed. Over 5 lakh PPE Kits and N-95 masks have been produced under the *Atma Nirbhar* scheme.

The Union Minister also highlighted the contributions of Sarada Vilas educational institutions, in which former Chief Minister Siddaramaiah, MP V Sreenivasa Prasad, and Infosys Mentor N R Narayana Murthy studied. District Minister S T Somashekhar promised to sanction civic amenities for the institution to continue its educational promotion activities.

Source: The Times of India, 09.10.2020

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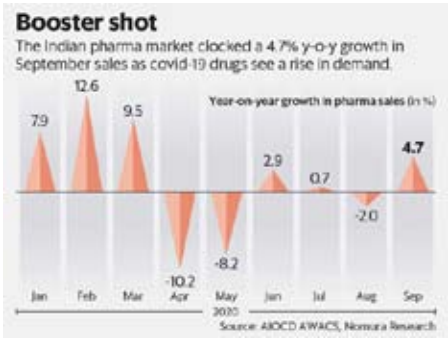
Covid-19 domestic drug sales may benefit Glenmark, Cipla

Glenmark's 37% y-o-y growth is the highest among Pharma firms, followed by Cipla with a 16% y-o-y Growth



The Indian Pharmaceutical market's 4.7% year-on-year (y-o-y) sales growth in September is a welcome relief. This is a considerable jump from the 2% contraction seen in August and is one of the best months for domestic Pharma sales since the outbreak of Coronavirus.

This has come against the backdrop of Covid-19 cases surging in the country, which has led to an increasing demand for drugs such as Favipiravir and Remdesivir. Consequently, new drug launches accounted for about 3.8% growth in sales. Companies that are into Covid-19 therapies have also clocked an improvement in sales in September. Glenmark's 37% y-o-y growth is the highest among Pharma companies, followed by Cipla with a 16% y-o-y growth.

Booster shot:

"We expect Covid-related drugs to be a key growth driver for Cipla and Glenmark during Q2FY21. Cipla is likely to benefit from higher sales of Remdesivir and Tocilizumab. Similarly, Glenmark is expected to benefit from Favipiravir. We also expect a marginal positive impact for Dr Reddy's and Cadila from Remdesivir sales during Q2FY21," said Nomura Financial Advisory Services Ltd analysts in a note to its clients. As has been the case over the past few months, price increases contributed about 4% to the sales growth on a y-o-y basis. Domestic Pharma sale volumes, though, have not been encouraging, dipping by about 4% in September. August's 9% decline in volumes was sharper, but the domestic Pharma market continues

to see a contraction in the acute category. With the flu season over, this segment could moderate further. "We expect acute therapies to continue to underperform the market owing to improvements in hygiene habits across the country due to covid-19," said the Nomura note. Chronic drug sales, such as cardiac, anti-diabetes, and neuro categories, however, continue to show improvement. Demand for vitamins and minerals also shot up by about 16.3% in volume in September. However, some of the heightened expectations from Coronavirus-related drug launches may already be reflecting in the stock prices of Pharmaceutical majors. The Nifty Pharma index dipped on Wednesday after rising 6% in the past month.

Source: Clifford Alvares, LiveMint, 08.10.2020

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INTERNATIONAL NEWS

COVID-19 vaccine may be ready by year-end, says WHO Chief

A 'safe and effective' vaccine against novel Coronavirus disease may be ready by year-end, the World Health Organization (WHO) said on Tuesday, 06.102020. "We will need vaccines and there is hope that by the end of this year we may have a vaccine. There is hope," WHO Director-General Tedros Adhanom Ghebreyesus said at the meeting of WHO's Executive Board.

WHO Director-General also called for solidarity and political commitment by all leaders to ensure equal distribution of vaccines when they become available. "We need each other, we need solidarity and we need to use all the energy we have to fight the virus," he said. Nine experimental vaccines are in the pipeline of the WHO-led COVAX global vaccine facility. "Especially for the vaccines and other products which are in the pipeline, the most important tool is political commitment from our leaders especially in the equitable distribution of the vaccines," Tedros said.

The COVAX facility, led by the WHO and the Public-Private Partnership GAVI vaccine alliance, gives access to COVID-19 vaccine candidates in development. Countries that sign on to COVAX will get access to a broad portfolio of new vaccine candidates to combat COVID-19. So far some 168 countries have joined the COVAX facility, but neither China, the United States nor Russia are among them. The GAVI vaccine alliance's board earlier approved up to $150 million to help 92 low-and-middle-income countries prepare for the delivery of future COVID-19 vaccines, including technical assistance and cold chain equipment.

All eyes on Pfizer COVID-19 vaccine:

Europe's drugs regulator on Tuesday, 06.10.2020 started an early review of an experimental COVID-19 vaccine from Pfizer Inc and BioNTech SE. Called a "rolling review," the process will allow the European Medicines Agency to look at how the vaccine is performing in real time as data emerges from trials, instead of waiting for the drug makers to submit everything at once. The US Food and Drug Administration on Tuesday, 06.10.2020 told Coronavirus vaccine developers that it would need at least two months of safety data after a full vaccination regime to review applications for emergency use authorization of an experimental vaccine. Pfizer earlier said that it will seek regulatory approval for its vaccine as early as October. The companies have been granted fast-track review in the US. "We believe US FDA's independence is today more important than ever as public trust in COVID19 vaccine development has been eroded by the politicization of the process," Pfizer Inc's Chief Executive Officer Albert Bourla said.

Source: Live Mint, 07.10.2020 (Excerpts)

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EU agency recommends AstraZeneca-Merck drug Lynparza for two cancers

The European Medicines Agency (EMA) has recommended approval for Lynparza in patients with a form of prostate cancer and as a first-line maintenance treatment for a form of advanced ovarian cancer, the British drug maker AstraZeneca said. Prostate cancer is the second-most common type of cancer in men worldwide, while ovarian cancer is the fifth most common cause of cancer death in Europe. The EMA recommendation follows positive regulatory updates for Lynparza, which AstraZeneca has developed with Merck & Co Inc as it faces competition from British rival GlaxoSmithKline on cancer drugs.

Lynparza became the first marketed PARP drug with a US approval for ovarian cancer in 2014. PARP inhibitors

are a growing focus for drug research, with potential for use in breast, lung and prostate cancers. Last week, GSK's cancer treatment Zejula, which is also a PARP inhibitor, won positive recommendation from the EU watch dog as a first option to keep advanced ovarian cancer at bay in women who have responded to chemotherapy. Zejula competes with rival PARP inhibitors, a class of treatments that work by block in genzymes involved in repairing damaged DNA, thereby helping kill cancer cells, from AstraZeneca and Clovis Oncology.

Monday's recommendation for approval from the EMA's Committee for Medicinal Products for Human Use (CMPH) comes after Lynparza won EU approval in July for treating a form of pancreatic cancer. While final approvals are up to the European Commission, it generally follows the CHMP's recommendation and endorses them within a couple of months. AstraZeneca also said it is exploring additional trials in metastatic prostate cancer for Lynparza, and expects to publish data on a separate late-stage trial in the second half of 2021.

(Reporting by Aakash Jagadeesh Babu and Pushkala Aripaka in Bengaluru; Editing by Saumyadeb Chakrabarty and Alexander Smith)

Source: ET-Healthworld /Reuters, 21.09.2020

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Explained: Nobel Prize in Chemistry for scissors to edit genes

First, researchers artificially create a guide RNA, which helps take the genetic scissors to the place in the genome where the cut will be made. To edit a gene, they specially design a small DNA template. When the cell repairs the cut, it will use this DNA template. This changes the code in the genome. (Johan Jarnestad/The Royal Swedish Academy of Sciences)

Its simplicity has often been compared to the 'Cut-Copy-Paste' mechanism in any Word Processor (or probably, the equally common 'Find-Replace' mechanism), while its use scan potentially transform human beings, and all other life forms. It can potentially eliminate genetic, and other, diseases, multiply agricultural production, correct deformities, and even open up the more contentious possibilities of producing 'designer babies', and bringing cosmetic perfection. In effect, anything that is linked with functioning of the genes can be corrected, or 'edited'.

The CRISPR (short for the rather inelegantly named Clustered Regularly Interspaced Short Palindromic Repeats) technology for gene-editing has been triggering tremendous excitement ever since it was developed in the year 2012, both for the promise that it holds in improving the quality of life, and the dangers of its misuse. Hundreds of scientists and laboratories have since started working on the technology for a variety of uses. In the last eight years, the technology has brought a string of awards and honours for its developers. On Wednesday, 07.10.2020 it culminated in the Nobel Prize for Chemistry for the two women who started it all, 52-year-old Emmanuelle Charpentier of France, and 56-year-old American Jennifer Doudna. It is possibly the only time in the history of Nobel Prize that two women have been declared the sole winners.

The Technology:

Editing, or modifying, gene sequences is nothing new. It has been happening for several decades now, particularly in the field of agriculture, where several crops have been genetically modified to provide particular traits. "But what CRISPR has done is make gene editing very easy and simple, and at the same time extremely efficient. And the possibilities are nearly endless," said Debojyoti Chakraborty who works with this technology at the New Delhi-based CSIR-Institute of Genomics and Integrative Biology.

In essence, the technology works in a simple way — it locates the specific area in the genetic sequence which has been diagnosed to be the cause of the problem, cuts it out, and replaces it with a new and correct sequence that no longer causes the problem.

The technology replicates a natural defence mechanism in some bacteria that uses a similar method to protect itself from virus attacks. An RNA molecule is programmed to locate the particular problematic sequence on the DNA strand, and a special protein called Cas9, which now is often described in popular literature as 'genetic scissor', is used to break and remove the problematic sequence. ADNA strand, when broken, has a natural tendency to repair itself. But the auto-repair mechanism can lead to the re-growth of a problematic sequence. Scientists intervene during this auto-repair process by supplying the desired sequence of genetic codes, which replaces the original sequence. It is like cutting a portion of a long zipper somewhere in between, and replacing that portion with a fresh segment.

Because the entire process is programmable, it has a remarkable efficiency, and has already brought almost miraculous results. There are a whole lot of diseases and disorders, including some forms of cancer, that are caused by an undesired genetic mutation. These can all be fixed with this technology. There are vast applications elsewhere

as well. Genetic sequences of disease-causing organisms can be altered to make them ineffective. Genes of plants can be edited to make them withstand pests, or improve their tolerance to drought or temperature. "In terms of its implications, this is possibly the most significant discovery in life sciences after the discovery of the double-helix structure of the DNA molecule in the 1950s," said Siddharth Tiwari of the Mohali-based National Agri-Food Biotechnology Institute who has been using the CRISPR technology on genes of banana plant.

The Winners:

Charpentier and Doudna were working independently when they stumbled upon different pieces of information that later came together to be developed into this technology. Charpentier, a biologist then working at a laboratory in Sweden, needed the expertise of a biochemist to process the new information she had got on the genetic sequences in a particular bacteria she had been working on called Streptococcus pyogenes.

She had heard of Doudna's work at the University of California, Berkeley, and the two happened to meet at a scientific conference in Puerto Rico in 2011, according to an account published on the website of the Nobel Prize. Chapentier proposed a collaboration, to which Doudna agreed. Their research groups then collaborated over long distance over the next year. Within a year they had been able to come out with a revolutionary technology of gene-editing.

Several other scientists and research groups also made vital contributions in the development of this technology. Someone like Virginijus Siksnys, a biochemist working at the Vilnius University in Lithuania, is widely recognised as a co-inventor of this technology. In fact, Siksnys shared the 2018 Kavli Prize in Nanoscience with Doudna and Chapentier for this technology. But the seminal contribution of the two women is undisputed. Their achievement has been recognised through several prestigious awards in the last few years, including the Breakthrough Prize in Life Sciences in 2015 and the Wolf Prize in Medicine earlier this year.

There has been some murmurs in the scientific community about the Chemistry Nobel having gone to biologists. But apparently this is not a new phenomenon. The central role of chemistry in life sciences — at the molecular level, biology is essentially chemistry — has ensured that increasing number of Nobel prizes have recently been awarded for work in the field of biochemistry. In fact, a research paper published earlier this year has pointed out this gradual shift in the nature of Chemistry prize. According to Chemistry World, a news magazine published by the Royal Society of Chemistry, of the 189 scientists awarded with the Chemistry Nobel so far, 59 had worked in the field of biochemistry. This was more than any other branch of chemistry.

Ethical Concerns:

In November 2018, a Chinese researcher in Shenzen created international sensation with his claim that he had altered the genes of a human embryo that eventually resulted in the birth of twin baby girls. This was the first documented case of a 'designer babies' being produced using the new gene-editing tools like CRISPR, and raised exactly the kind of ethical concerns that scientists like Doudna have been speaking about.

In the case of the Chinese twins, the genes were edited to ensure that they do not get infected with HIV, the virus that causes AIDS. This special trait would then be inherited by their subsequent generations as well. The concerns were not over the reason for which the technology was used as much as the ethics of producing babies with particular genetic traits. Scientists pointed out that the problem in this case, potential infection to HIV virus, already had other alternative solutions and treatments. What made matters worse was that the gene-editing was probably done without any regulatory permission or oversight. Others also pointed out that while CRISPR technology was incredibly precise, it wasn't 100 per cent accurate, and it is possible that some other genes could also get altered by mistake.

Doudna herself has been campaigning for the development of internationally rules and Guidelines for the use of CRISPR technology, and has advocated a general pause these kind of applications till such time.

Source: Amitabh Sinha, Indian Express, 09.10.2020 (Excerpts)

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