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LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970
REGN NO. MCW/95/2021-23

IDMA BULLETIN

VOL. NO. 52 | ISSUE NO. 02 (PAGES: 40) | 08 TO 14 JANUARY 2021 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
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Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
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IDMA BULLETIN

Vol. No. 52 **Issue No. 02** **08 to 14 January 2021**

INDIAN DRUG MANUFACTURERS' ASSOCIATION

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ATTENTION MEMBERS

Invitation to participate in 'IDMA MARGI MEMORIAL BEST PATENT AWARDS 2019-20'

As you will be aware, the **IDMA Margi Memorial Best Patent Awards** recognize the **'Best Patent of the Year'**, both national and international. We request you to kindly send us details of your **patent/s granted in the last 12 months period (01.04.2019 to 31.03.2020)**. An Expert Panel will examine and evaluate the applications received and recommend their selection for the Award. A copy of the Patent granted should also be enclosed to enable the Panel to evaluate the Patent for the Award.

Applications should be forwarded in a closed and sealed envelope marked **'IDMA Margi Memorial Best Patent Awards 2019-20'** along with an ENTRY FEE of ₹10,000/- + GST @18% (Total ₹11,800/-) per Member Company immediately to reach us **latest by 18th January 2021.**

For the convenience of the panelists, soft copies of the application along with relevant supporting patent documents may also be sent separately.

Applications for the Award will need to comply with certain criteria as enumerated in the Guidelines (Do's and Don'ts) for IDMA Margi Memorial Best Patent Awards 2019-20 (as mentioned below). Kindly peruse the same before applying for the Award.

The winners will be notified by email after the Expert Panel finalizes selection of Award Winners. The Awards will be presented at the **IDMA 59th Annual Day Celebrations to be organized by end of February 2021 at Online Web.**

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GUIDELINES FOR SUBMISSION OF APPLICATIONS FOR PATENT AWARDS

The Expert Panel, constituted to scrutinise the Applications, has set the following **DOs and DON'Ts** for consideration for Awards as below:

DOs:

1. Applications must include Patents granted only during the financial year 2019-20 (1st April 2019 to 31st March 2020) for evaluation.
2. A Member-Company can apply for more than one Patent. Multiple Patents can be listed in a single application.
3. The Application is to be submitted both as Soft Copy as well as Hard Copies with Summary of the Patents. However, details of Patents may please be sent preferably only in Soft copy.
4. All Family Patents belonging to same invention will be considered as one patent. Country-wise validations for EU or ARIPO patents will not be considered as independent patents. Divisional patents granted with similar inventions will be considered along with parent patent.
5. Different inventions having same title with common priority document will be identified and considered as One Patent.
6. Group companies (including Research Centres) applying independently may indicate if they wish to be considered together or separately. If patent is granted to other than the applicant, the documents justifying the inclusion of such patents (group status) need to be attached.
7. Applications for Awards for Patents granted to individuals will be considered with documentary support of rights transferred to the Applicant (Member Company)
8. Applicants are requested to self-certify the authenticity of information submitted to minimise the review and verification work by IDMA.
9. The Application must be forwarded under a covering letter/or by email duly signed by an authorised signatory along with name, designation and contact details.
10. The covering letter should carry a declaration that *"We have read 'The Guidelines and Criteria for Evaluation of Patents submitted for IDMA Margi Memorial Patent Awards 2019-20 and abide by the same"*.

DON'Ts:

1. Please do not apply for Patents granted earlier than 1st April 2019 or after 31st March 2020. It will not be considered for this year's Awards.
2. Please do not apply for a pending patent. It will not be considered and will be disqualified.
3. Please do not apply for Patents which are already withdrawn, abandoned, not maintained or revoked will obviously not be considered.
4. An Application of a patent of the same family (of an invention which has already qualified for award in earlier years), even if granted in another country in the relevant year will not be considered.
5. If the data submitted is found to be not correct or factual, the applications will be disqualified.

(Note: The Decision of the Expert Panel will be Final).

IDMA-West Bengal State Board Committee for 2020-2021

Mr Mahesh H Doshi, National President and Members of IDMA Executive Committee congratulate and welcome the Members of IDMA-West Bengal State Board Committee for 2020-2021 elected and formalised at the VC Meeting held on 6th January 2021 as below:

1.	CHAIRMAN	:	**Shri Shiv Sagar Tewari**, Burnet Pharmaceuticals Pvt Ltd.
2.	HON SECRETARY	:	**Shri Siddhartha Paul,** Palsons Derma Pvt Ltd.
3.	HON JOINT SECRETARY	:	**Shri Probhas Bondhu Chakraborty**, Mendine Pharmaceuticals Pvt Ltd.
4.	HON TREASURER	:	**Shri Mriganka Sarkar,** Jupiter Pharmaceuticals Ltd.

COMMITTEE MEMBERS:

1. **Shri Utpal Moitra**, Emcee Pharmaceuticals Pvt Ltd.
2. **Shri Ranajit Dey**, Dey's Medical Stores Mfg Ltd.
3. **Shri Debarshi Duttagupta**, East India Pharmaceuticals Works Ltd.
4. **Shri Bharat Vora,** Vulcan Laboratories
5. **Shri Manab Bakshi**, Cradel Pharmaceuticals Pvt Ltd.
6. **Shri R G Mittal**, Siscon (I) Pvt Ltd.
7. **Shri Manoj Gupta**, Pharma Impex Laboratories Pvt Ltd.
8. **Shri Partha Paul**, Palsons Derma Pvt Ltd.
9. **Shri Tony Parmar,** Albert David Ltd.

SPECIAL INVITEE MEMBERS:

1. **Shri Deepnath Roy Chowdhury**, Strassenburg Pharmaceuticals Ltd.
2. **Shri Asheesh Roy**, Stadmed Pvt Ltd.

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DoP Constitutes Committee for suggesting ways for reducing the compliance burden faced by the Industry – reg.

DoP Communication Ref.No.31026/83/2020-Pricing, dated 6th January 2021

1. The Government is committed to minimize the compliance burden for the citizens and business activities. In this regard, the National Pharmaceutical Pricing Authority (NPPA) at its level has already initiated few measures.

2. Being a priority area for the Government, it has been decided to engage with the industry and other stakeholders for ascertaining the specific areas which require intervention.

3. As such, a Committee with composition, as under, is constituted to look into the issue and give its recommendations in a time bound manner:

Sr. No.	Name Designation	
1	Joint Secretary (Pricing), DoP	In Chair
2	Advisor (Cost), NPPA	Member
3.	Joint DCG(I), CDSCO	Member
4	Representative of FICCI	Member
5	Representative of IDMA	Member
6	Representative of BDMA	Member
7	Representative of IPA	Member
8	Representative of AIMED	Member
9	Joint Director (Pricing)	Convenor

4. The terms of reference of the Committee includes:

(a). Reducing Compliance Burden across areas related to renewals of licenses/permissions, inspections, return filings, registers, records and display requirements; and

(b). De-criminalization, identification of redundant laws and rules, regulatory impact assessment and use of technology.

5. Invest India team in DoP Investment Desk to provide support to the Committee.

6. The Committee may submit its report within a month.

Pawan Kumar, Joint Director, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, New Delhi.

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Video Conference by Additional DGFT, Mumbai Office for redressal of Exporter's grievances on every Working Day – reg.

Joint DGFT Trade Notice No.01/2020-21, dated 29th December, 2020

To,
All concerned Trade Members and Notice Board of this Office.

To promote the ease of business and to provide institutional mechanism for the redressal of exporter's grievances, members of the Trade may contact O/o Addl. DGFT, Mumbai via Video Conferencing (VC) from 05.00PM to 06.00PM on every working day.

The VC will be hosted for limited slots and on first come first served basis. All the members of Trade & Industry are requested to avail this opportunity.

Those exporters, members of Trade & Industry who wish to avail this facility may email to this Office on Email ID **dgft-mumbai@nic.in**, one day in advance in order to intimate the VC link and other details.

File No.34/1/20/HRD

Satya Raja Sekhar G, Deputy Director General of Foreign Trade, For Addl Director General of Foreign Trade, Office of the Addl Director General of Foreign Trade, Ministry of Commerce & Industry, Mumbai.

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Electronic Issuance of Preferential Certificate of Origin (CoO) for India's Exports to UK under Generalized Scheme of Preferences (GSP) - reg.

DGFT Trade Notice No.37/2020-2021, dated 11th January, 2021

To,
1. All Exporters/Members of Trade;
2. All Designated Issuing Agencies under FTAs/PTAs.

1. In continuation to earlier Trade Notice(s) 30/2020-21 dated 13.10.2020, it is informed that the United Kingdom (UK) is being added as a country of Export on the e-COO Platform under Generalised Scheme of Preferences (GSP).

2. The details provided by the UK on the Generalised Scheme of Preferences may be seen at **URL - https://www.gov.uk/government/publications/trading-with-developing-nations**. Goods that meet the UK GSP rules of origin requirements are eligible to claim a GSP rate of import duty on the basis of a valid proof of origin. A valid proof of origin must be either of the following:

i. GSP Form-A - which does not need to be stamped and signed by an authority designated by the GSP country.

ii. An origin declaration - which must include information to enable the identification of an originating good.

3. Reference 2 (i) above, the GSP Form-A is available electronically on the e-CoO Platform. Further, no physical pre-printed stationery of Form-A shall be issued. The exporters to UK planning to avail GSP benefits may submit the given form on the e-Platform. While the stamp and sign of the issuing authority is

not mandatory as per the instructions provided by UK authorities, the GSP certificate when submitted electronically on the e-CoO platform will be made available through the existing online approval process with the image sign and signature.

4. For guidance on registration and application submission on the e-CoO Platform, the Help manual & FAQs may be accessed on the landing page at **https://coo.dgft.gov.in.** For any further assistance you may utilize any of the following channels.

i. Raise a service request/suggestion ticket through the DGFT Helpdesk service link on the e-platform home page.

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

iii. Send an email to **coo-dgft@gov.in**

This issues with the approval of the competent authority.

File No.01/02/82/AM-19/EDI

Md Moin Afaque,
Deputy Director General of Foreign Trade,
Directorate General of Foreign Trade,
Department of Commerce,
Ministry of Commerce and Industry,
New Delhi.

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NPPA MATTERS

Updating the provisional list of Overcharging Cases (OC) under litigation relating to DPCO, 1979, 1987, 1995 and 2013 - reg.

NPPA Office Memorandum dated 11th January 2021

To,
IDMA, BDMA, OPPI, IPA, AIMED, MTAI, FICCI, CII.

1. The undersigned is directed to refer to the subject cited above and to state that NPPA has taken up an exercise to update the database in respect of OC cases under litigation relating to DPCO, 1979, 1987, 1995 and 2013. The data available in respect of such OC cases has been updated.

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

3. Feedback from companies, seeking any modifications in the provisional list, should be appropriately backed by supporting documents. The interest amount in respect of cases included in the provisional list have been updated, wherever possible, upto 30.11.2020. Any payment/part-payment made has been adjusted from Overcharged amount while updating the interest, due to which in some cases the date of updation of interest may vary.

4. The concerned companies may provide their feedback, within 15 days from the date of publication of this provisional list on the website of NPPA.

F.No.28 (01)/2020/Div-IV/NPPA

Rakesh Pandey,
Joint Director (OC),
National Pharmaceutical Pricing Authority,
Department of Pharmaceuticals,
Ministry of Chemicals & Fertilizers,
New Delhi.

(List not reproduced here. Concerned Members may access the list on NPPA website with the link provided below:

Provisional-List-of-OC-cases-under-litigation.pdf (nppaindia.nic.in)

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Government notifes Unique Health Identifier Rules, 2021

MoH&FW Notification G.S.R.3(E), dated 1st January, 2021

Whereas, the use of Aadhaar authentication in the interest of good governance and enabling access to services enables beneficiaries to get the service directly in a convenient and seamless manner and the voluntary use of Aadhaar provides a convenient way to prove one's identity to obtain services provided by the Central, State or Union territory Governments;

And whereas, the Ministry of Health and Family Welfare (hereinafter referred to as the Ministry) in the Government of India intends to create Unique Health Identifier (UHID) for identification and authentication of beneficiaries in various health IT applications implemented by the Ministry;

And whereas, UHID will facilitate integration of health data across various applications and create longitudinal Electronic Health Record (EHR) for citizens besides allowing de-duplication in various health services provided by Ministry;

And whereas, the creation of UHID will be voluntary;

And whereas, sub-clause (ii) of clause (b) of sub-section (4) of section 4 of the Aadhaar (Targeted Delivery of Financial and Other Subsidies, Benefits and Services) Act, 2016 (18 of 2016) (hereinafter referred to as the Aadhaar Act, 2016) allows an entity to perform authentication, if the Authority is satisfied that the requesting entity is permitted to offer authentication services under the provisions of any other law made by Parliament or seeking authentication for such purpose, as the Central Government in consultation with the Authority may provide by rules.

Now, Therefore, in exercise of the powers conferred by clause (aa) of sub-section (2) of section 53 of the Aadhaar Act, 2016, the Central Government in consultation with the Authority makes the following rules, namely:-

1. Short title and Commencement:

(1) These rules may be called as the **Unique Health Identifier Rules, 2021.**

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

2. Purpose: Aadhaar authentication shall be used on voluntary basis, for establishing Unique Health Identifier for identification and authentication of beneficiaries in various Health IT applications under Aadhaar Authentication for Good Governance (Social Welfare, Innovation, Knowledge) Rules, 2020 read with sub clause (ii) of clause (b) of sub-section (4) of section 4 of the Aadhaar Act, 2016.

3. Entities allowed for Aadhaar authentication: Entities which are desirous of allowing voluntary Aadhaar authentication as one of the options for users to create health ID, share health information under various Health IT applications shall be permitted to do so and the extant regulations in this regard shall be applicable to all entities and transactions.

4. Authentication User Agency (AUA) or KYC User Agency (KUA)- The Ministry will be the AUA or KUA for the purpose of providing Aadhaar authentication services to all health IT application to create UHID for identification and authentication of beneficiaries in various health IT applications. Instructions for the entities may be issued separately through an administrative order or circular.

5. No denial of health service: Since use of Aadhaar authentication service for creation of UHID is voluntary, no denial of health service provisioning in default shall be allowed.

6. Documents permitted for creation of UHID: The Ministry may by an order in writing allow additional identified documents for creation of UHID and health service delivery.

F.No.T-21016/311/2020-eHealth

Lav Agarwal, Joint Secretary,
Ministry of Health and Family Welfare,
(E-Health Section),
New Delhi.

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Ethylene Glycol (Quality Control) Order, 2020 amended (2nd Amendment of 2020) - reg.

Chemicals & Fertilizers Notification No.S.O.4781(E), dated 24th December, 2020

(Published in the Gazette of India on 31st December, 2020)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary so to do in the public interest, hereby makes the following order to amend the Ethylene Glycol (Quality Control) Order, 2020, namely:-

1. (1) Short title and commencement:

(1) This order may be called the **Ethylene Glycol (Quality Control) Amendment Order, 2020.**

(2) It shall come in the force on the date of its publication in the Official Gazette.

2. In the Ethylene Glycol (Quality Control) Order, 2020, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette.

F.No.PC-II-46016/6/2020-Tech.CPC

Kashi Nath Jha, Joint Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note : *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification number S.O.2184(E), dated the 29th June, 2020 and subsequent amend vide number S.O.2402(E), dated the 15th July, 2020.*

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Ether (Quality Control) Order, 2020 amended (1st Amendment of 2020) - reg.

Chemicals & Fertilizers Notification No.S.O.4782(E), dated 24th December, 2020

(Published in the Gazette of India on 31st December, 2020)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary so to do in the public interest, hereby makes the following order to amend the Ether (Quality Control) Order, 2020, namely:-

1. (1) Short title and commencement

(1) This order may be called the **Ether (Quality Control) Amendment Order, 2020.**

(2) It shall come in the force on the date of its publication in the Official Gazette.

2. In the Ether (Quality Control) Order, 2020, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette.

F.No.PC-II-46016/6/2020-Tech.CPC

Kashi Nath Jha, Joint Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note : *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification number S.O.2183(E), dated the 29th June, 2020.*

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Toluene (Quality Control) Order, 2020 amended (1st Amendment of 2020) - reg.

Chemicals & Fertilizers Notification No.S.O.4784(E), dated 24th December, 2020

(Published in the Gazette of India on 31st December, 2020)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary so to do in the public interest, hereby makes the following order to amend the Toluene (Quality Control) Order, 2020, namely:-

1. (1) Short title and commencement:

(1) This order may be called the **Toluene (Quality Control) Amendment Order, 2020.**

(2) It shall come in the force on the date of its publication in the Official Gazette.

2. In the Toluene (Quality Control) Order, 2020, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette.

F.No.PC-II-46016/6/2020-Tech.CPC

Kashi Nath Jha, Joint Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note : *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification number S.O.2186(E), dated the 29th June, 2020.*

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Terephthalic Acid (Quality Control) Order, 2020 amended (1st Amendment of 2020) - reg.

Chemicals & Fertilizers Notification No.S.O.4785(E), dated 24th December, 2020

(Published in the Gazette of India on 31st December, 2020)

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary so to do in the public interest, hereby makes the following order to amend the Terephthalic Acid (Quality Control) Order, 2020, namely:-

1. (1) Short title and commencement:

(1) This order may be called the **Terephthalic Acid (Quality Control) Amendment Order, 2020.**

(2) It shall come in the force on the date of its publication in the Official Gazette.

2. In the Terephthalic Acid (Quality Control) Order, 2020, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette.

F.No.PC-II-46016/6/2020-Tech.CPC

Kashi Nath Jha, Joint Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note : *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification number S.O.2185(E), dated the 29th June, 2020*

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Phthalic Anhydride (Quality Control) Order, 2020 amended (1st Amendment of 2020) - reg.

Chemicals & Fertilizers Notification No.S.O.4792(E), dated 24th December, 2020

(Published in the Gazette of India on 31st December, 2020)

In exercise of the powers conferred by section 16 and section 17 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government, after consulting the Bureau of Indian Standards, is of the opinion that it is necessary so to do in the public interest, hereby makes the following order to amend the Phthalic Anhydride (Quality Control) Order, 2020, namely:-

1. (1) Short title and commencement:

(1) This order may be called the **Phthalic Anhydride (Quality Control) Amendment Order, 2020.**

(2) It shall come in the force on the date of its publication in the Official Gazette.

2. In the Phthalic Anhydride (Quality Control) Order, 2020, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the expiry of one hundred and eighty days from the date of its publication in the Official Gazette.

F.No.PC-II-46016/15/2018-PC-II

Kashi Nath Jha, Joint Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note : *The Principal Order was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide Notification number S.O.1402(E), dated the 23rd April, 2020.*

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PARLIAMENT NEWS

In Lok Sabha & In Rajya Sabha

In Lok Sabha

Promotion and Guidance on Health Research

Lok Sabha Unstarred Question No. 2186

Dr Pritam Gopinath Munde:

Shri Chandra Sekhar Sahu:

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

(a): whether the Government has implemented 'Grant-in-aid scheme for Inter-sectoral convergence and co-ordination for promotion and guidance on health research as a flagship programme;

(b): if so, the details thereof;

(c): the priority area identified for research under this flagship programme;

(d): the financial assistance for carrying out research studies in identified areas for each State/UT since its inception; and

(e): the extent to which the research studies are beneficial to the public health?

Answered on 23rd September 2020

A. (a) & (b): Yes. Department of Health Research provides support for research projects in the form of Grant-in-aid under 'Grant-in-Aid (GIA) Scheme for Inter-Sectoral Convergence and Coordination for Promotion and Guidance on Health Research' for carrying out research studies across the country to identify the existing knowledge gap and to translate the existing health leads into deliverable products.

(c): Some of the priorities areas identified for research under the said scheme are as follows:

1. Research Studies in areas relevant to Public Health:

2. Programme for Translational Research:

3. Programme for Inter-sectoral Co-ordination including funding of joint projects:

4. Programme for Comparative/cost effectiveness analysis for public health choice.

5. Additional priorities areas include the following:

   (i): Innovation in Health Technologies.

   (ii): Health Technology.

   (iii): Environment and Health.

   (iv): Studies on emerging pathogens: outbreak/ epidemics potential including COVID-19.

   (v): GIS based disease mapping/ surveillance.

(d): A statement containing State/UT-wise details of financial assistance approved to research studies since inception of the scheme is laid on the Table of the House. *(Not reproduced here).*

(e): Under the scheme, research projects having public health relevance were given priority for support. Many products/kit/assays/technologies were developed under the project to whom financial assistance was provided. A statement containing the outcomes of GIA Scheme in brief is laid on the Table of the House.

The Minister of State in the Ministry of Health And Family Welfare (Shri Ashwini Kumar Choubey)

CSIR Reports in Public Domain

Lok Sabha Unstarred Question No.2211

Shri Vellalath Kochukrishnan Nair:

Shri V K Sreekandan:

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

(a): whether the annual reports of the Council of Scientific and Industrial Research (CSIR) have not been made available in public domain during the last five years; and

(b): if so, the reasons therefor and the time by which these reports are likely to be made available for public scrutiny?

Answered on 23rd September 2020

A. (a) & (b): Yes, Sir. As per Rule-68 and 69 of the CSIR Rules & Regulations, draft of the Annual Report thereon shall be placed before the CSIR Society for its consideration and approval before the same are placed on the Table of House of the Parliament. The Annual Reports and Annual Accounts of the CSIR for the financial years 2014-15; 2015-16; 2016-17 and 2017-18 (four years) had been approved by the Governing Body (GB), CSIR in its 187th; 189th; 190th and 191st meetings held on 01.06.2016; 21.11.2017; 20.12.2018 and 26.04.2019 respectively. The CSIR Society which was reconstituted and notified vide OM No.01.01.2016/2019-PD dated 07.11.2019 in its meeting held on 14.02.2020 had approved the Annual Reports of CSIR for the years 2014-15; 2015-16; 2016-17 and 2017-18 which will be placed on the Table of House of the Parliament in the ongoing monsoon session of the parliament. After the laying on the Table of the House of the parliament, the Annual Reports of CSIR for the years 2014-15; 2015-16; 2016-17 and 2017-18 will be made available in the public domain.

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

Vaccine for COVID-19

Lok Sabha Unstarred Question No: 2235

Shri T N Prathapan:

Shri Y S Avinash Reddy:

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

(a): whether the Government has taken note that many organizations are claiming that a vaccine has been invented/developed to control Corona Virus in the country;

(b): if so, the details thereof;

(c): whether the Government has examined their claims, if so, the details thereof;

(d): if not, the steps being taken by the Government to produce vaccine at the earliest?

Answered on 23rd September 2020

A. (a) to (d): Central Drugs Standard Control Organisation (CDSCO) has informed that as on date no COVID-19 vaccine has been approved for manufacture/import and marketing in the country.

CDSCO has granted test license permission for manufacture of COVID-19 Vaccine for preclinical test, examination and analysis to the following manufacturers in India:

1. M/s Serum Institute of India Pvt Ltd., Pune.
2. Ms Cadila Healthcare Ltd., Ahmadabad.
3. M/s Bharat Biotech International Ltd., Hyderabad.
4. Biological E Ltd., Hyderabad.
5. M/s Reliance Life Sciences Pvt Ltd., Mumbai.
6. M/s Aurbindo Pharma Limited, Hyderabad.
7. M/s Gennova Biopharmaceuticals Limited, Pune.

The Indian Council of Medical Research (ICMR), an autonomous organisation under the Department of Health Research, has informed that it is facilitating the following studies related to COVID-19 vaccines:

(i): An inactivated whole virion candidate vaccine (BBV152) for SARS-CoV-2 has been developed by Bharat Biotech International Ltd (BBIL) using the virus isolate (NIV-2020-770) provided by ICMR-National Institute of Virology (NIV), Pune. Characterization of the vaccine candidate has been undertaken at ICMR-NIV followed by safety and tolerability studies in small animals like rats, mice and rabbits. Status of Clinical Trials is as follows:

- Phase I Clinical Trials alongwith parallel studies in hamsters and rhesus macaques have been completed. The trial has revealed excellent safety of the candidate vaccine. Immunogenicity testing is in progress.
- Phase II Clinical Trials are ongoing.

(ii): A DNA vaccine (ZyCov-D) has been developed by Cadila Healthcare Ltd. Pre- clincial toxicity studies were conducted in small animals: mice, rats, rabbits and guinea pigs. The vaccine has been found to be safe and immunogenic. Cadila has partnered with ICMR for conduct of parallel pre-clinical studies in rhesus macaques. Status of Clinical Trialsis as follows:

- Phase I Clinical Trialshave been completed. The trial has revealed excellent safety of the candidate vaccine. Immunogenicity testing is in progress.
- Phase II Clinical Trials are ongoing.

(iii): Serum Institute of India (SII) and ICMR have partnered for clinical development of two global vaccine candidates:

- ChAdOx1-S, which is a non-replicating viral vector vaccine developed by University of Oxford/AstraZeneca. This vaccine is undergoing phase III Clinical Trials in Brazil. Phase II/III bridging studies have been initiated by ICMR at 14 Clinical Trial sites. ICMR-National Institute for Research in Tuberculosis (NIRT), Chennai is the lead institution.

ICMR and SII have also partnered for clinical development of a glycoprotein subunit nanoparticle adjuvanted vaccine developed by Novavax from USA. The trial will be initiated in second half of October after the vaccine is manufactured by SII. The trial is led by ICMR-National AIDS Research Institute (NARI), Pune.

As per details provided by Department of Biotechnology (DBT)/Department of Science and Technology (DST), more than 30 vaccine candidates have been supported which are in different stages of development. While the Government and Industry are trying their best to make available a safe and effective vaccine for COVID-19 at the earliest, it is difficult to comment on the exact timelines in view of various complex pathways involved in vaccine development.

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

National Biopharma Mission

Lok Sabha Unstarred Question No.2268

Shri Ravindra Shyamnarayan alias Ravi Kishan Shukla:

Shri Nayab Singh:

Shri John Barla:

Shri Gajendra Singh Patel:

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

(a): the details of the aims and objectives and the goals set by the Government under National Biopharma Mission (NBM);

(b): the details of the efforts being made by the Government under NBM for promoting entrepreneurship and indigenous manufacturing;

(c): the manner in which the Government is boosting innovation in the country to attain inclusivity; and

(d): whether any projects/activities are also being undertaken under NBM in Haryana, if so, the details thereof?

Answered on 23rd September 2020

A: (a) :The National Biopharma Mission was approved by the Cabinet in 2017 with an aim to transform the health standards of the country through affordable product development and bring 5-7 biopharmaceutical products closer to market. Objectives and goals of the Mission are a. Specific Product development under vaccines, biosimilars and medical devices b. Building shared infrastructure for product testing, characterization and manufacturing c. Promoting scientific research through establishment of translational research consortia and development of novel biopharmaceuticals and devices d. skill development though trainings e. creating and enhancing technology transfer and intellectual property management.

(b): The Mission is supporting small and medium enterprises for biopharmaceutical product development, enhancing industry academia interlink ages and providing opportunities to translate knowledge into products/technologies for vaccines, biotherapeutics, devices and diagnostics. The indigenous manufacturing is promoted through the supported shared facilities for process optimization, clinical grade manufacturing of Biologics, Analytical testing labs, cell line repository, prototyping facilities, large animal testing facilities and medTech zone for manufacturing devices and diagnostics at large scale. These high capital facilities provide easy access to equipment and infrastructure thus encouraging indigenous manufacturing. Technology transfer offices have been established to support technology transfer and support entrepreneurship.

(c): Financial and mentorship support has been provided to industry and academia for indigenous product development. This includes projects on development of components of upstream and downstream biologics manufacturing, such as engineered cell lines, media, resins and bioreactors which are currently in-licensed, requiring huge capital. To boost innovation, Mission is also supporting development of novel biologics, novel vaccines and medical devices like MRI, ventilators, diagnostic probes and Medical grade camera.

(d): Five projects are being supported in Haryana, 3 projects in Faridabad district (for Medical Device and Translational Research Consortia) and 2 in Gurgaon district (for Medical device and Clinical Trial network).

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

In Rajya Sabha

Assistance to Bulk Drug Industry for Common Facility Centre Scheme

Rajya Sabha Question No.1468

Shri V Vijayasai Reddy:

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state;

(a): whether it is a fact that Government has given final approval for setting up of common facility Centre under "Assistance to Bulk Drug Industry for Common Facility Centre" scheme to Medical Device Industry in the State of Andhra Pradesh;

(b): whether is it also a fact that an amount of Rs.25 crore has been finally approved for Andhra Pradesh; and

(c): if not, the reasons for the delay in releasing the money and by when Government is going to release the same?

Answered on 23rd September 2020

A. (a): Yes Sir.

(b): Yes Sir.

(c): An amount of Rs. 7.49 crore has been released to AMTZ as 1st instalment (30% of total) of the central assistance.

Minister In The Ministry Of Chemicals & Fertilizers (Shri D V Sadananda Gowda)

Engaging Essential Medicines under Price Control Regime

Rajya Sabha Question No.1472 :

Lt Gen (Dr) Devender Paul Vats:

Shri Vijay Pal Singh Tomar:

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state;-

(a): the details of the total number of Essential Medicines which are so far covered under the price control mechanism;

(b): whether Government has any proposal to bring in all the Essential Medicines under the price control regime to protect the interests of the patients; and

(c): if so, the details thereof, and if not, the reasons therefor?

Answered on 23rd September 2020

A. (a): The National Pharmaceutical Pricing Authority (NPPA) fixes the ceiling prices of Scheduled medicines which are specified in the National List of Essential Medicines (NLEM) and are included in Scheduled of the Drugs (Prices Control) Order, 2013 (DPCO, 2013).There were 348 medicines in the NLEM, 2011 which were included in the Scheduled of the DPCO, 2013. The NPPA fixed the ceiling prices of 530 scheduled formulations of such medicines based on market based pricing methodology.

Schedule-I of the DPCO, 2013 was amended by adopting NLEM, 2015 consisting of 377 medicines. The NPPA has fixed the ceiling prices of 871 scheduled formulations of medicines under NLEM, 2015. The fixation of Ceiling price includes ceiling price of Cardiac Stents under Para 19 of the DPCO, 2013 resulting in price reduction for Coronary Stents worked out up to 85% for Bare Metal Stents and 74% for Drug Eluting Stents.

Besides Cardiac Stents, Knee Implants, 106 anti-diabetic and cardiovascular medicines and 42 non-scheduled anti-cancer medicines have also been brought under price rationalisation in public interest by exercising extra-ordinary powers under the DPCO, 2013.

(b) & (c): The fixation of the ceiling prices by the NPPA is an on-going process. As and when the formulations are included in the National List of Essential Medicines (NLEM), their prices are fixed by the NPPA.

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

Bulk drug parks

Rajya Sabha Question No.1478

Shri B Lingaiah Yadav:

Q. Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a): whether Government has proposed norms for location of bulk drug parks in the county; and

(b): if so, the details thereof and the progress made therein?

Answered on 23rd September 2020

A. (a) & (b): The guidelines of the "Promotion of Bulk Drug Parks" scheme were released on 27th July, 2020. Under this scheme, financial assistance will be provided to the State implementing agencies for creation of common infrastructure facilities in Bulk Drug Parks to be developed by State Governments. Three Bulk Drug parks will be financed under the scheme. As per scheme guidelines, the State Government before submitting a proposal under this scheme, should identify a suitable location for the park keeping in mind various factors viz, environmental pollution, assured availability of power, assured availability of water, transport connectivity with railways, national highway, port, airport, etc. The identified location should be well away from eco-sensitive zone of protected areas. Further, the States will also be evaluated on few parameters of location norms as mentioned in point 5 & 7 of Appendix-1 of the guidelines. The scheme guidelines are available on the website of the department under the tab titled 'schemes'.

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

Import of Active Pharmaceutical Ingredients (APIs)

Rajya Sabha Question No.1481

Shri Anand Sharma:

Q. Will the Minister **of CHEMICALS AND FERTILIZERS** be pleased to state;

(a): whether it is a fact that Indian Pharma industry has been dependent on China for imports of Active Pharmaceutcal Ingredients (APIs) from China;

(b): if so, the details and percentage of imported APIs used for production of life saving medicines and injectables; and

(c): the steps taken by Government to ensure that Indian pharma industry is not deprived of supply of essential ingredients for the production of critical medicines and injectables?

Answered on 23rd September 2020

A. (a) & (b): Many raw materials are imported from China, for manufacturing of medicine. As per available data from the various Port Offices of the Central Drugs Standard Control Organization (CDSCO), the details of the percentage of raw materials imported from China are as under:-

Year	Percentage (in terms of value)
2017-18	68.62%
2018-19	66.53%
2019-20	72.40%

(c): With a view to attain self-reliance and reduce import dependence in APIs/Bulk drugs, the Department of Pharmaceuticals has rolled out two schemes viz (i) "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India" and (ii) "Promotion of Bulk Drug Parks". The guidelines of both the schemes were released on 27th July, 2020. These Guidelines are available on the website of the department.

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

Export Promotion Councils

Rajya Sabha Question No. 1484

Dr Vinay P Sahasrabuddhe:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state :-

(a): the number of Export Promotion Councils (EPCs) that have been created by the Ministry, the details thereof;

(b): the kind of work that has been done by these EPCs during the last five years; and

(c): whether there has ever been any audit of their performance, the details thereof?

Answered on 23rd September 2020

A. (a) to (c): Export Promotion Councils (EPCs) are organizations of exporters, set up under the Societies Registration Act/ Companies Act, with the objective of promoting Indian exports. The councils are responsible for promotion of a particular group of products/ projects/services as given in Appendix 2T of the Foreign Trade Policy (FTP) 2015-2020. The list of 14 such EPCs affiliated to the Department of Commerce is at Annexure. Regular joint meetings with the councils to facilitate interactions with exporters and assess performance of the councils are held. The accounts of the councils are subject to mandatory audit. The review reports of performance of the councils are laid in the Parliament along with Annual Report each year.

Annexure

LIST OF EXPORT PROMOTION COUNCILS AFFILIATED TO DEPARTMENT OF COMMERCE

1. Basic Chemicals, Cosmetics & Dyes Export Promotion Council (Chemexcil). Mumbai
2. Cashew Export Promotion Council of India (CEPCI), Kollam, Kerala
3. Chemical and Allied Products Export Promotion Council (Capexil), Kolkata
4. Council for Leather Exports (CLE), Chennai
5. EEPC India, Kolkata

6. Export Promotion Council for EoUs and SEZs (EPCES), New Delhi
7. Gem & Jewellery Export Promotion Council (GJEPC), Mumbai
8. Indian Oilseeds & Produce Export Promotion Council (IOPEPC), Mumbai
9. Pharmaceuticals Export Promotion Council (Pharmexcil), Hyderabad
10. Plastics Export Promotion Council (Plexconcil), Mumbai
11. Project Export Promotion Council (PEPC), New Delhi
12. Services Export Promotion Council (SEPC), New Delhi
13. Shellac & Forest Products Export Promotion Council (Shefexil), Kolkata
14. Sports Goods Export Promotion Council (SGEPC), New Delhi

The Minister of Commerce and Industry
(Shri Piyush Goyal)

Incentives to industries to Boost Economic Growth

Rajya Sabha Question No. 1487

Shri T G Venkatesh:

Q. Will the Minister of **COMMERCE AND INDUSTRY** be pleased to state;

(a): whether measures are being undertaken by the Ministry to instil confidence in the industries, considering the slow pace of economic growth in the country;

(b): if so, the details thereof, if not, the reasons therefor; and

(c): whether the Ministry has studied the impact of recent economic slowdown that has been reported and is prevalent in other parts of the world?

Answered on 23rd September 2020

A. (a) & (b): Promotion of industries is a continuous and ongoing effort of the Government. Various steps in addition to ongoing schemes to boost domestic and foreign investment in India have been taken to instil confidence in the industries. These include the National Infrastructure Pipeline, Reduction in Corporate Tax, easing liquidity problems of NBFCs and Banks, policy measures to boost domestic manufacturing. Government of India has also promoted domestic manufacturing of goods through public procurement orders, Phased Manufacturing Programme (PMP), Schemes for Production Linked Incentives of various Ministries. Also, Atmanirbhar Package to boost Industrial growth has been announced by the Government for Rs. 20.97 lakh crore with bold reforms in a number of sectors.

With a view to support, facilitate and provide investor friendly ecosystem to investors investing in India, an Empowered Group of Secretaries (EGoS) and Project Development Cells (PDCs) have set up in all concerned Ministries/Departments to fast track investment in coordination between the Central Government and State Governments and thereby grow the pipeline of investible projects in India to increase domestic investment and FDI inflow. A centralized Investment Clearance Cell is being created, which would provide end-to-end facilitation support. GIS mapping of available land banks has been developed and several steps taken to improve Ease of Doing Business including simplification and rationalization of existing processes.

(c): As per IMF's World Economic Outlook (WEO) (June 2020), in the year 2020, global economic growth is projected to contract by 4.9 percent. Most economies in the group are forecasted to contract this year, including the United States (— 8.0 percent), Japan (-5.8 percent), the United Kingdom (-10.2 percent), Germany (-7.8 percent), France (-12.5 percent), Italy (-12.8 percent), and Spain (-12.8 percent).

As per the Global Economic Prospects Report (June 2020) of the World Bank, global GDP is expected to contract by 5.2 percent in 2020, the deepest global recession in eight decades, despite unprecedented policy support.

The Minister of Commerce & Industry
(Shri Piyush Goyal)

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CBIC notifies New Exchange Rates w.e.f. 08th January 2021 - reg.

Notification No.03/2021-Customs (N.T.), dated 07th January, 2021

In exercise of the powers conferred by section 14 of the Customs Act, 1962 (52 of 1962), and in supersession of the Notification No.113/2020-Customs(N.T.), dated 17th December, 2020 except as respects things done or omitted to be done before such supersession, the Central Board of Indirect Taxes and Customs hereby determines that the rate of exchange of conversion of each of the foreign currencies specified in column (2) of each of **Schedule I** and **Schedule II** annexed hereto, into Indian currency or vice versa, shall, **with effect from 8th January, 2021,** be the rate mentioned against it in the corresponding entry in column (3) thereof, for the purpose of the said section, relating to imported and export goods.

SCHEDULE-I

Sr. No.	Foreign Currency	Rate of exchange of one unit of foreign currency equivalent to Indian Rupees	
(1)	(2)	(3)	
		(a)	(b)
		(For Imported Goods)	(For Exported Goods)
1.	Australian Dollar	58.30	55.90
2.	Bahraini Dinar	200.35	188.05
3.	Canadian Dollar	58.75	56.70
4.	Chinese Yuan	11.50	11.15
5.	Danish Kroner	12.35	11.90
6.	EURO	91.80	88.60
7.	Hong Kong Dollar	9.60	9.25
8.	Kuwaiti Dinar	249.20	233.60
9.	New Zealand Dollar	54.75	52.35
10.	Norwegian Kroner	8.85	8.55
11.	Pound Sterling	101.20	97.80
12.	Qatari Riyal	20.75	19.45
13.	Saudi Arabian Riyal	20.15	18.90
14.	Singapore Dollar	56.45	54.55
15.	South African Rand	5.00	4.70
16.	Swedish Kroner	9.15	8.80
17.	Swiss Franc	85.00	81.50
18.	Turkish Lira	10.30	9.70
19.	UAE Dirham	20.55	19.30
20.	US Dollar	74.00	72.30

SCHEDULE-II

Sr. No.	Foreign Currency	Rate of exchange of 100 units of foreign currency equivalent to Indian Rupees	
1.	Japanese Yen	72.30	69.60
2.	Korean Won	6.95	6.50

F.No.468/01/2021-Cus.V

Rathakrishnan Ananth, Under Secretary, Central Board of Indirect Taxes and Customs, Department of Revenue, Ministry of Finance, New Delhi.

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We help our customers create future-ready Pharma Manufacturing and Biotech facilities

__Sanjay Sudhakaran,__ VP, Digital Energy, Schneider Electric India expands on the value proposition of digital energy systems for the Pharma sector, giving some examples of how companies achieved RoI on this investment, in an interaction with __Viveka Roychowdhury__

The Pharmaceutical sector was one of the sectors which had to work through lockdowns, with less staff and sometimes more production. This has spurred many companies to think of the contactless way to maintenance, i.e. remote maintenance. What is the value proposition of digital energy systems for the Pharma sector?

While many Pharma companies had already started to build their digital capabilities, the Government imposed lockdown because of the COVID-19 pandemic has further spurred the adoption of digital technology in the sector. Many companies see this as an opportunity as they are going contactless to manage operations such as maintenance, supply chain management, production etc. For Plant Managers in the Pharma industry achieving energy efficiency is a strategic goal. Achieving energy efficiency reduces manufacturing costs as well as its environmental emissions.

At Schneider Electric, we provide the best conditions for manufacturing operations in Pharma companies through our environmental management system.

With this, we help our customers create future-ready Pharma manufacturing and biotech facilities while making the production environment comply with requirements and regulations.

We also enable guided remote maintenance using our solution that helps our customer to automate operation and progress toward predictive maintenance.

Besides, this system records data in a tamper-resistant, high-integrity format with store-and-forward functionality, for reliable regulatory auditing.

What are the Costs and Timelines to Deployment?

We offer our clients future-ready life sciences solutions to help them design a strategy, deliver efficiency in their facilities and sustain results over time through l ong-term partnerships. We offer adaptable architecture to our customers allowing them to select segregated or integrated BMS and EMS architectures dependent on-site requirements.

Our flexible architecture optimises OpEx costs with straight forward accessibility to the BMS segment compared to integrated architecture. Our customers can achieve reduced risks and costs in a stringent and evolving regulatory framework.

What are the levels of services and engagement with companies?

The vendor-agnostic services provided by our skilled professionals protect our customer's entire critical infrastructure, helping to assess risk, implement cyber-specific solutions and maintain onsite defence over time. Availing these services our customers can avoid costly regulatory fines and actions and secondly, apply cyber security solutions from operations perspective while integrating appropriate IT policies and requirements.

Can you give some use case examples of the ROI of some of these systems deployed?

Definitely, one of our most successful customer stories is of Boston Scientific, a worldwide developer, manufacturer, and marketer of medical devices. They opened a new corporate headquarters and integrated Eco Struxure Building Advisor as part of a strategic initiative to reduce energy waste and work towards creating a more sustainable corporate campus. Boston Scientific has achieved a 40 percent reduction in avoidable cost related to faults. Our solution points issues, trends and averages.

It also prioritises issues and suggests actions which have resulted in a 51 percent reduction in the energy-related faults at Boston Scientific.

Another story is about Xcellerex, a revolutionary biopharma products and vaccines manufacturer, faced with the greatest challenge of integrating complex technology with ultra-high levels of functionality. With our Eco Struxure solution, they have achieved a higher level of efficiency in their plant in terms of capital investment reduction exceeding 60 percent and lower overall cost of finished products by 32 percent.

Source: Express Pharma, 31.12.2020 (Excerpts)

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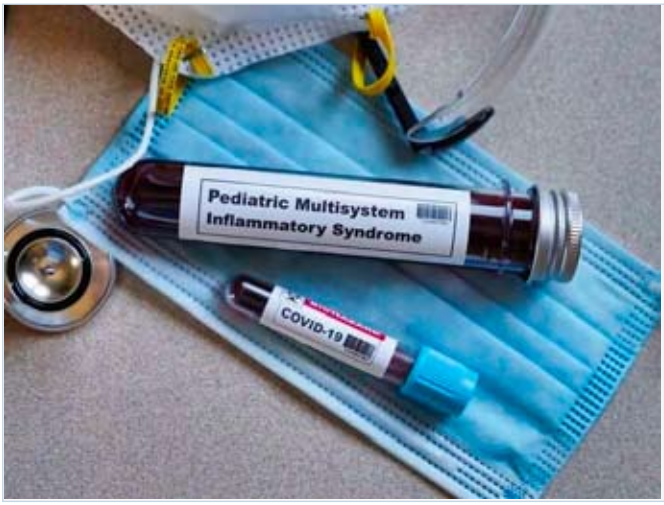
NEW DEVELOPMENTS

Coronavirus: Children with COVID-19 Reporting Multisystem Inflammatory Syndrome; Here's what we know

According to doctors at the Rady Children's Hospital, San Diego, there has been a huge surge in the number of MIS-C inflicted cases in children suffering from COVID-19. While the number of Coronavirus cases continue to rise, the number of COVID cases in children have also increased over time. Doctors, researchers and medical experts are working tirelessly to treat the young patients. However, it is important for us to know the early signs and symptoms of Multisystem Inflammatory Syndrome.

02/4 What is Multisystem Inflammatory Syndrome (MIS-C)?



The novel coronavirus has been quite forbearing towards the kids, considering the fact that children are less vulnerable to the deadly pathogen. However, recent reports have suggested an increase in the number of MIS-C cases in children infected with COVID-19. As per the research, COVID-19 can cause a serious condition called multisystem inflammatory syndrome in children (MIS-C).

While most children who have been affected by COVID-19 have only experienced mild symptoms, children who develop MIS-C condition have come up with severe inflammation in various organs of the body, including heart, lungs, blood vessels, kidneys, digestive system, brain, skin or eyes.

03/4 Symptoms associated with MIS-C in children

A COVID-positive child who has developed multisystem inflammatory syndrome (MIS-C) may show various symptoms other than the most common signs of COVID-19. Here are some of the symptoms to watch out for.

- Fever that won't go away for more than two days.
- Abdominal pain
- Diarrhea or vomiting

- A rash or changes in skin color
- Trouble in breathing

04/4What do the authorities say?

According to the CDC, since May there have been more than 1200 cases of MIS-C nationwide, and 23 deaths.

Given the hike in the number of cases at Rady Children's Hospital, Dr Jane Burns, the Director of the Kawasaki Disease Clinic at Rady's, said, "We're seeing a steady trickle of cases coming in." "It's many more than what we saw in September and in August," she added.

Source: The Times of India.Com, 06.01.2021

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New virtual screening strategy identifies existing drug that inhibits COVID-19 Virus

A novel computational drug screening strategy combined with lab experiments suggest that pralatrexate, a chemotherapy medication originally developed to treat lymphoma, could potentially be repurposed to treat COVID-19. Haiping Zhang of the Shenzhen Institutes of Advanced Technology in Shenzhen, China, and colleagues present these findings in the open-access journal PLOS Computational Biology.

With the COVID-19 pandemic causing illness and death worldwide, better treatments are urgently needed. One shortcut could be to repurpose existing drugs that were originally developed to treat other conditions. Computational methods can help identify such drugs by simulating how different drugs would interact with SARS-CoV-2, the virus that causes COVID-19.

To aid virtual screening of existing drugs, Zhang and colleagues combined multiple computational techniques that simulate drug-virus interactions from different, complimentary perspectives. They used this hybrid approach to screen 1,906 existing drugs for their potential ability to inhibit replication of SARS-CoV-2 by targeting a viral protein called RNA-dependent RNA polymerase (RdRP).

The novel screening approach identified four promising drugs, which were then tested against SARS-CoV-2 in lab experiments. Two of the drugs, pralatrexate and azithromycin, successfully inhibited replication of the virus. Further lab experiments showed that pralatrexate more strongly inhibited viral replication than did remdesivir, a drug that is currently used to treat some COVID-19 patients.

These findings suggest that pralatrexate could potentially be repurposed to treat COVID-19. However, this chemotherapy drug can prompt significant side effects and is used for people with terminal lymphoma, so immediate use for COVID-19 patients is not guaranteed. Still, the findings support the use of the new screening strategy to identify drugs that could be repurposed.

"We have demonstrated the value of our novel hybrid approach that combines deep-learning technologies with more traditional simulations of molecular dynamics," Zhang says. He and his colleagues are now developing additional computational methods for generating novel molecular structures that could be developed into new drugs to treat COVID-19.

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

Source: PLOS, Science Daily, 31.12.2020 (Excerpts)

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Hemant Kumar Pandey wins DRDO's Scientist of the Year Award

Indian scientist Hemant Kumar Pandey has been awarded DRDO's ***"Scientist of the Year Award"*** for his contribution in developing several herbal medicines, including the popular drug Lukoskin.

The citation accompanying the award stated that the award recognises his invaluable contribution to herbal medicine Research and Development. It stated that Dr Hemant Kumar Pandey has significantly contributed to the development of five herbal products and filed seven patents, one of which included the anti-leucoderma product.

The award was conferred to Dr Pandey by Union Defence Minister Rajnath Singh at an event in New Delhi. The award comprises a certificate and cash prize worth Rs.2 lakh.

Key Highlights:

- Dr Pandey has received several prestigious awards in the past as well for his outstanding contribution in the field of herbal medicine.
- He has been undertaking research at the Defence Research and Development Organisation's (DRDO) lab and Defence Institute of Bio-Energy Research (DIBER) at Pithoragarh in Uttarakhand for the past 25 years.
- Though he has developed six herbal drugs so far, Lukoskin has been most widely appreciated and found huge acceptance in the market.
- Besides Lukoskin, Pandey has also developed drugs for the treatment of eczema and toothache as well as an anti-radiation cream.
- Most of these products are being sold in the market following the Transfer of Technology (ToT).

What is Lukoskin?

Lukoskin is a formulation of around eight herbs found in the Himalayan region. The drug helps in treating of white patches. It is marketed by the Delhi-based Aimil Pharmaceuticals.

Usage:

Lukoskin is used for treating Leucoderma or Vitiligo, a condition in which white patches get developed on the skin. Leucoderma is an auto-immune disorder and it affects over 5 crore people in India. The disorder is not contagious or life-threatening. The disorder is present in 1-2 percent of the population worldwide.

Source: Jagran Josh, Defence News India, 04.01.2021

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Labour Ministry issues draft standing orders on work from home under new Industrial Relations Code: Report

The Labour Ministry on January 1 published its draft standing orders on work from home for the mining, manufacturing and service sectors, under the new Industrial Relations Code. It is aimed at formalising service-related matters in an amicable manner, as per a Ministry statement.

"Pursuant to Section 29 of the Industrial Relations Code (IRC), 2020, the Central Government has published the draft model standing orders for the manufacturing sector, mining sector and service sector," it said.

Under the model standing orders drafted for the services sector, decision on work hours for employees in the Information Technology (IT) space has been left up to employers, The Economic Times reported.

However, safeguards for the IT industry have been included in the services sector model in relation to employer computer system, unauthorised access of IT systems and customer or client misconduct, the news report noted. Money control could not independently verify the report. "Keeping in view the needs of the services sector, a separate model standing orders for the services sector has been prepared for the first time," the Ministry said.

All three models are uniform, but provide flexibility for sector-specific requirements. In the mining sector, rail travel facility has been extended to all workers – something that was earlier only allowed for coal miners, it also defines what would constitute a "habitual offender" in regards to indiscipline as employees found guilty of misconduct three or more times in preceding 12 months.

Source: Money Control, 02.01.2021

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Include Pharma workforce in Priority List for COVID-19 vaccination: Pharma Associations

Pharma Industry Associations, Indian Drug Manufacturers' Association (IDMA) and the Indian Pharmaceutical Alliance (IPA), have written individual letters to Dr Vinod Paul, Member of Niti Aayog and have requested the Government of India to include Pharma workforce in the Priority L List of COVID-19 vaccinations.

The letters highlight that COVID-19 vaccination will protect around two million workforce against the disease and will not only be a recognition for them but also ensure uninterrupted manufacture and supply of medicines in the country. "The industry will be ready to support the Government for distributing and dispensing of the vaccines. We once again assure you of the commitment of the Pharma industry to support the Government in this critical juncture," stated one of the letter.

Sudarshan Jain, Secretary-General, IPA, said, "The request to include the Pharma workforce in the Priority List of COVID-19 vaccination is to ensure that all our workforce from each segment of the industry continues their services in ensuring uninterrupted supply of medicines in the country.

The industry is already classified as an essential goods and services industry wherein the employees and all stakeholders have been committed to ensuring the consistent availability of medicines during the COVID-19 pandemic, therefore, we have requested the Government to consider our workforce also in the Priority List of COVID-19 vaccination."

Addressing a query on isn't it too late to make such a request, Shri Daara Patel, Secretary General, IDMA said, "The Government has announced that initially the COVID-19 vaccine will be given to frontline healthcare workers, which will take minimum 20- 30 days for a nationwide vaccination on them. Then, people who are above the age group of 50 with comorbidities have been added in the Priority List, our people can also be considered at the same time. It will have dual benefits, as it will be a recognition to our people who continued working in difficult times of COVID pandemic and ensure uninterrupted supply of medicines across the country. And their protection from the disease will further ensure that the supply of medicines remains uninterrupted."

Commenting on the probability of the Government not including the Pharma workforce in the Priority List, Jain responded, "In such a situation, the industry will wait for the vaccines' availability in the open market and then, individually Pharma companies will strategise their course of action for COVID vaccination of their employees."

Source: Usha Sharma, Express Pharma, 07.01.2021

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Indian Pharma Market registers 8.5% Growth in December 2020

The Indian Pharmaceutical Market (IPM) has registered a growth of 8.5 percent for the month of December 2020, as against growth of one per cent in November 2020. According to AIOCD-AWACS report, the IPM has recorded sales of Rs.1,45,354 crore for Moving Annual Total (MAT) basis during December 2020. Amongst the top 10 Corporates, Cipla exhibited the highest growth of 8.9 percent, followed by Torrent Pharma at 7.0 percent. Amongst the 11 to 25 ranked Corporates, Glenmark Pharma exhibited highest growth of 16.3 percent followed by Himalaya at 14.1 percent.

Amongst the 26 to 50 ranked Corporates, Apex Lab registered the highest growth of 20.1 percent followed by Boehringer Ingelheim at 14.4 percent. Amongst the 51 to 75 ranked Corporates, Danone registered the highest growth of 33.5 percent. Amongst the 76 to 100 ranked Corporates, Reckitt Benckiser exhibited the highest growth at 23.6 percent, followed by Llyod Hc at 14.4 percent.

Some therapies continue the trend of revival in December 2020. Cardiac registered a monthly growth of 14.9% as compared to 8.7% in November 2020, while anti-diabetic registered growth of 9.9% in December 2020 as compared to 1.9% in November 2020. While respiratory medicines growth slumps to -8.7% in December 2020 as compared to -6.9% in November 2020.

Post unlockdown since June 2020 the struggle for anti-infectives at 0.2% in November 2020 continues 5.2% in December 2020 and its associated therapy like gastro

exhibits growth of 16.2% in December 2020 as against 3.1% in November 2020. Vitamins have bounced back has growth of 14.0% in December 2020 as compared to 6.6% in November 2020 and pain and analgesics are at 6.0% in December 2020 as against -5.2% in November 2020.

Source: Yash Ved, Pharmabiz, 08.01.2021

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Medicinal plants in India require strategic approach of conservation: Dr Brindavanam

Medicinal plants in India require a more strategic approach of conservation. There is a need to consolidate and this certainly requires a strategy like Medicinal Plants Conservation Area (MPCA), said Dr N B Brindavanam, Consultant, National Resource Management, Biodiversity-Medicinal Plants.

Now preservation and conservation of medicinal plants are on in a traditional way across India and across the wild life sanctuaries/other protective areas under the Wild Life Protection Act. But these are incidental and we require a more strategic approach like MPCAs. This is by focusing on systematic surveys, geo referencing of existing natural population of medicinal and native aromatic species having medicinal use. Although this concept has been experimented for the last 30 years, unfortunately we did not consolidate the experiences well so it is important to revisit the MPCA model and bring it into the mainstream by making it robust in its presentation, he added.

Conservation of medicinal plants can be augmented through in-situ and ex-situ resource augmentation and artificial re-generation of local populations. The area of cultivation can be expanded under medicinal plants species with creation of nurseries to maintain good quality propagation material.

At wild life sanctuaries, considerable data of medicinal plants is captured. This area being a protected zone is seen to be more or less undisturbed as preservation happens efficiently. However, there is a need to bring in a mechanism to identify, incentivize, characterize the sites, earmark them and convert them into conservational centres. This task should be given not to the wild life authority but to the medicinal plant or biodiversity boards in the respective states. The process of preservation needs to be streamlined and we need to bring in the FTCs (Farmer Training Centres) too, said Dr Brindavanam told.

In order to ensure a systematic approach to plant accessibility there is a need for sustainable preservation of flora. Here a dedicated plant forum with a tailor-made mechanism for different resources is much desired. It might also need alternative strategies to bring in scientifically designed robust processes for its traceability. Although sale of medicinal plants is an ancient trading practice, it now sees the need for clear cut system in place. Today medicinal plants are marketed pan-India and come in from different parts of the country to particular aggregating points. It is here we need a platform to be able to trace the source of the medicinal plant.

Since the entire value chain of sourcing is driven by the collectors we need a platform to display transparency and traceability, said Dr Brindavanam who was also the former head, Bio Resources Development Group, Dabur Research & Development Centre, Ghaziabad. Commenting on the National Medicinal Plant Board's Seed-to-Shelf programme as a laudable move, he said that while the effort is to carry out its job in all earnestness, it should ensure continuity while establishing the linkage between the farmers and manufacturers.

Source: Nandita Vijay, Pharmabiz, 08.01.2021

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India's Pharma export shoots up amid Coronavirus pandemic; 'China plus one' policy helps

A spike in demand for Pharma products, induced by the Covid-19 pandemic, and hoarding of supplies by some nations in the wake of production disruptions have boosted the exports

India's pharmaceutical industry significantly increased exporting drugs when the world was suffering from the Coronavirus pandemic in the first half of the current fiscal

year. The country's formulation surged 18 percent while the bulk drug exports raised 9 percent on-year during H1 FY21, said a report by Crisil. During the full previous fiscal, the exports of formulation rose 11 percent and that of bulk drug contracted by 1 percent. A spike in demand for Pharma products, induced by the Covid-19 pandemic, and hoarding of supplies by some nations in the wake of production disruptions have boosted the exports, the report added.

Another reason for the increased demand for Active Pharmaceutical Ingredients (APIs) from India is the increasing customer diversification away from China and some countries adopting a 'China plus one' policy. The bigger markets such as the US and Europe have led to export growth due to increased demand for drugs. Furthermore, several Indian players have also inked agreements with Gilead Sciences to manufacture and export Remdesivir.

Why global de-risking of supply chain is good for Indian bulk drug exports:

The research stated that Chinese supply disruptions in early 2020 and persistent quality issues provide opportunities for Indian players as customers look at India as an alternative supplier of bulk drugs. Further, Indian API exporters have been able to garner good realisations on their exports during H1 FY21. Exporters of both formulations and bulk drugs are likely to help players maintain 7-8 percent on-year growth this fiscal.

Meanwhile, the gradual easing of lockdown restrictions, coupled with demand for Pharma products and bulk drugs in both exports and domestic markets, is expected to aid revenue growth. In addition, a ramp-up in specialty products and biosimilar exports, along with strong domestic sales will likely aid revenue growth in the next fiscal too.

Source: Samrat Sharma, Financial Express, 05.01.2021

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COVID vaccines to boost Indian Pharma exports, says Pharmexcil

The Indian pharmaceutical industry is likely to touch nearly 20 percent growth in exports. Despite recording growth in single digits after the months following the lockdown, the outlook for 2021-2022 is expected to be robust on the back of vaccines.

Uday Bhaskar, Director General of Pharmaceuticals Export Promotion Council (Pharmexcil), an outfit of the Ministry of Commerce, told *Business Standard* that India's exports may grow at 11-12 percent with the opportunity for a potential COVID-19 vaccine. "As India has large capacities to manufacture vaccines, it may have around 15 percent share by the number of doses of the COVID vaccine market globally," he said. Bhaskar also touched upon the likelihood of the European Union ramping up their production and increasing their portfolio to reduce the need to import.

"India had adequate stocks of both bulk drugs and formulations to meet most of the sudden rise in demand after April. It could also quickly locate alternate bulk drug supplies (some from Europe) as well as step-up local production," Bhaskar said.

- Panacea Biotec Consolidated September 2020 Net Sales at Rs.182.02 crore, up 45.41% Y-o-Y.
- Panacea Biotec Standalone September 2020 Net Sales at Rs.118.20 crore, up 463.39% Y-o-Y.
- As of April-October 2020, India's pharma exports stood at $13.88 billion and is growing at 15 percent.

"We expect FY21 to close with exports around $25 billion," he said. This would be a 20 percent jump over last year.

The overall growth rate has dropped to 2.2 percent in 2020. The Indian Pharmaceutical Market stood at Rs 1.44 lakh crore as per Moving Annual Turnover (MAT) in November 2020. The drop in sales in acute-therapies such as anti-infective drugs, gastrointestinal, gynaecological and pain and fever medications continues to exert pressure on growth while growth in select chronic therapies such as cardiac and diabetes has made a good recovery. The new launches were mostly related to COVID-19 related drugs and the price growth has remained in the region of 4-5 percent. The volume growth remains tepid at about 6.9 percent in November 2020.

The pharmaceutical industry is now hoping for **the sales to normalise by the second half of 2021**, with the availability of vaccines and COVID-19 receding. While the industry has performed better than many other sectors, given the

essential nature of medicines, it is also pinning its hopes on the end of the pandemic.

Source: Money Control, 05.01.2021 (Excerpts)

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Bharat Biotech CMD Dr Ella claims Covaxin safest; hails DCGI decision

Claiming that the Covid-19 vaccine, Covaxin, developed and manufactured by Bharat Biotech is safest, Dr Krishna Ella, Chairman and Managing Director of Bharat Biotech, hailed the decision of Indian drug regulator, Drug Controller General of India (DCGI) as historic, as it has approved Covaxin for emergency restricted use in India.

While addressing media virtually recently, Dr Ella said that Bharat Biotech has already conducted Clinical Trials on Covaxin at 18 locations across the world and it has been observed as the most safest vaccine having no major complications or side effects. "We are one of the leading vaccine manufacturers in the world among the developing countries. Our vaccine is on par with any of the major leading vaccine manufacturers in the world. We are happy that the DCGI has approved Covaxin for the emergency restricted use in India. This is a giant leap for innovation and novel product development in India," observed the CMD.

Expressing concern over a few people trying to target the abilities of Indian companies and the Indian scientists, Dr Ella lashed out against them and said that some elements are trying to lower and degrade the capabilities and abilities of Indian companies and the Indian scientists. He said they are doing this only because they have their own self interest. However, the CMD assured that Bharat Biotech's products are no way inferior to leading Pharma companies like Pfizer and others in the world.

"Bharat Biotech is the only company that has published 5 articles on Covid-19 vaccine process. Many are alleging we are not transparent with regard to data submission. But I would suggest them to first of all read the articles clearly and they will have all the data relating to the in-depth research we had taken up. More than 70 articles have been published in various International journals. Only thing is people should have patients to read these articles, only then they should comment," said Dr Ella.

Adding further Dr Ella sited some examples how the Indian companies are being targeted, and said that Merck's Ebola vaccine had never completed a human Clinical Trial but the World Health Organization (WHO) had given permission for emergency authorization for Liberia and Guinea. But for Covaxin, human Clinical Trials in first and second phases have successfully proved its safety and efficacy and even the third Clinical Trials are fast going to be concluded very soon. However in the meanwhile he expressed satisfaction over the DCGI decision to approve Covaxin for emergency restricted use and hailed it as a historic decision that would go a long way in encouraging the domestic companies to take up more innovative developments in the coming days.

Source: A Raju, Pharmabiz, 07.01.2021

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Covaxin marks important milestone in indigenous novel vaccinology: Karnataka Health Minister

Karnataka Government sees that approval of Covid-19 vaccine 'Covaxin' marks a significant milestone in indigenous manufacture of novel vaccinology in India. Amidst the controversy regarding the approval of two Covid vaccines, Karnataka Minister of Health & Family Welfare and Medical Education Dr K Sudhakar has urged people to refrain from unwarranted criticism which will discredit the handwork of the scientists.

Bharat Biotech has the credibility and experience of developing 16 vaccines including for influenza H1N1, Rotavirus, Japanese Encephalitis, Rabies, Chikungunya, Zika and the world's first tetanus-toxoid conjugated vaccine for Typhoid, said Dr Sudhakar in his series of tweets. While appealing to refrain from unwarranted criticism on vaccines, the State Health Minister said that the Hyderabad-based company has the credibility of delivering over 4 billion vaccine doses to under privileged people in more than 150 developing countries through UNICEF and other channels.

Covaxin's phase-3 Clinical Trial involves 24,000 volunteers and its data will be available soon. We need to refrain from unwarranted criticism which discredits the hard work of our scientists, he added. India is at the forefront of scientific innovation to combat Covid-19 pandemic. In line with our philosophy of *'Sarve Jana Sukhino Bhavantu'* and *'Vasudaiva Kutumbakam'* India will play a significant role in healing the humanity, he said.

On the status of the new variant, he said that 37 people out of 75 UK returnees have been tested positive. Only 11

among them are confirmed for new mutant virus. There is no increase in the number of infections. The vaccination roll out is set to start next week and the state is gearing up for the much awaited vaccination drive against the Corona Virus disease. Hence no criticism what so ever of vaccine, the vaccine should be made and we need to look at it as an important milestone in indigenous novel vaccinology, he said.

Source: Nandita Vijay, Pharmabiz, 07.01.2021

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CCMB scientists stress on strengthening Covid-19 preventive Guidelines for Public

The Scientists from Center for Cellular and Molecular Biology (CCMB) have stressed on the need for further strengthening the Covid-19 preventive Guidelines particularly in wards and hospitals treating Covid patients. The CCMB scientists revealed this at the backdrop of a recent study carried out by a team of scientists from CCMB in Hyderabad and from Institute of Microbial Technology, Chandigarh, which revealed that Coronavirus can stay in the air for longer period than expected particularly in the areas where there is a larger presence of Covid-19 patients.

"To further confirm and consolidate how far can Coronavirus sustain in air, a team of scientists from CCMB Hyderabad and IMTech Chandigarh had collected air samples of Covid wards in 3 hospitals each in Hyderabad and Chandigarh and found that the virus can sustain longer in the air and may cause infection to those who inhale the viral contaminated air in hospitals. With this finding we stressed on the need to strengthen all the existing Guidelines of Covid-19 prevention so that there should not be any kind of laxity in hospitals ignoring which may lead to unabated spread of the virus through air," said Dr Rakesh Mishra, Director of CCMB.

While releasing the research study data on the air-born nature of SARS-CoV-2, the scientists suggested that new Guidelines should be adopted such as demarcation of hospital zones, which could be an effective strategy to make sure the people in the surrounding areas of the hospital, can be kept at a safer distance from being infected through viral air contamination.

The scientists collected the air samples from 6 hospitals in all to find out the virus particles in the air from the hospital wards treating Corona patients and from those non-treating patients. They used an air sampler to collect the virus particles and then looked for their presence using RT-PCR, based on the study the scientists could find presence of Coronavirus in air samples all wards treating Covid-19 patients and non from non-treating Covid wards. It is also revealed that the chance of picking up SARS-CoV-2 through air is directly related to the number of Covid positive cases in the room, their symptomatic status and the duration of the exposure.

"When Covid positive individuals spend longer hours in a room, the virus is found in air for more than two hours and it can span up to two meters distance from the place of the infected patient. However for those patients who are asymptomatic, it showed that the virus does not spread farther from them when they are seated in a room without perceived air flow," revealed the researchers. In view of this, the scientists suggested that until the vaccine is available, it is important to follow the available social preventive measures like wearing of masks, maintaining social distance and regular hand sanitization, which is best preventive, measure to keep the deadly Coronavirus away.

Source: A Raju, Pharmabiz, 07.01.2021

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BIRAC invites research proposals from start-up Biotech companies for igniting new ideas in Biotechnology

The Biotechnology Industry Research Assistance Council (BIRAC) under its Biotechnology Ignition Grant (BIG) scheme has invited research proposals from potential entrepreneurs from biotechnology start-ups, or academicians, scientists, researchers, and medical degree holders, biomedical engineering graduates to pursue a promising technology idea and establish and validate Proof-of-Concept (PoC) for the idea.

This is the 18th call for proposals from BIRAC since the BIG scheme was launched in 2012 for igniting new ideas in biotechnology. The last date for submission of proposal is February 15, 2021. The purpose of the BIG scheme is to foster generation of ideas with commercialization potential; upscale and validate of proof of concept; encourage researchers to take technology closer to market through a start up; and to stimulate enterprise formation. As part of this scheme, successful BIG Innovators receive up to Rs.50 lakh for research projects with commercialization

potential with duration of up to 18 months. The scheme is for innovations under healthcare, life science, diagnostics, medical device, drugs, vaccines, drug formulations and delivery systems, etc.

The BIG scheme was launched by BIRAC as it is of the view that the "bio-innovation capital" of the nation would come from novel ideas which have a commercialization potential and that evolve out from start-ups or academic spin-offs. BIRAC's strategy was to support the numerous exciting ideas which have an unmet need for funding and mentorship. This strategy is fulfilled through a grant funding scheme called BIG which is available to scientist entrepreneurs from research institutes, academia and start ups.

The scheme is designed to stimulate commercialization of research discoveries by providing very early stage grants to help bridge the gap between discovery and invention. The BIG Scheme is currently managed through 8 BIG Partners across the country who works with the Ignition grantees (BIG Innovators) to provide mentoring, monitoring, networking and other business development related activities.

Source: Neethikrishna, Pharmabiz, 06.01.2021

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Government soon to share draft of UCMDMP with stakeholders for suggestions

Even as the Deprtment of Pharmaceuticals (DoP) has been seeking compliance reports from industry regarding implementation of the Uniform Code of Pharmaceutical Marketing Practices (UCPMP), the Union Ministry of Chemicals and Fertilizers is likely to soon share draft on Uniform Code for Medical Devices Marketing Practices (UCMDMP) with stakeholders for their suggestions towards a Uniform Code on Medical Device Marketing Practices in the country.

Like UCPMP, UCMDMP would be a self-regulatory framework for the industry and voluntarily in nature that aims to curb practices such as offering gifts to healthcare professionals to push a certain product. Similarly, Government has been mulling over to issue UCMDMP which will stipulate and prescribe limit to the incentives which can be provided to the doctors for recommending or using the medical device for the sake of patient safety and healthy competition. As per the draft, UCMDMP, a medical device must not be promoted prior to receipt of the product registration (wherever applicable) by the Competent Authority, authorizing its sale or supply as per Medical Device Rules (MDR-2017).

The promotion of a medical device must be consistent with the terms of documents submitted by the companies for obtaining product registration or licenses to manufacture, import and sell these medical devices in India; and specifically the Instructions For Use (IFU) or Directions For Use (DFU) of the relevant product. Product Information about Medical Devices must be up-to-date, verifiable and accurately reflect current knowledge or responsible opinion. Product Information about medical devices must be accurate, balanced, fair, objective, and must not mislead either directly or by implication. Product information about medical devices must be capable of substantiation.

UCMDMP draft stipulates that there are certain limits which need to be prescribed on a voluntary basis to start with so that such inductive mechanisms to distort markets are eliminated or removed. UCMDMP has been drafted to ensure high ethical standards for the medical device industry much in the similar manner as has been done in the case of Pharmaceutical industry by introducing Uniform Code for Pharma Marketing Practices (UCPMP) in 2011.

As per the UCPMP, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply drugs, by a Pharmaceutical Company or any of its agents i.e. distributors, wholesalers, retailers, etc. Gifts for the personal benefit of healthcare professionals and family members (both immediate and extended) (such as tickets to entertainment events) also are not to be offered or provided.

According to a Senior Health Ministry official which drafted the UCMDMP, all such technologies which are closed systems like the Glucometer for which you have to buy the reagents of a particular brand can be given or considered as induced in turn incentive to the physician. If a company gifts the doctor a Glucometer, he will be forced to buy and then recommend the strips of the same Glucometer although the Glucometer was free. So in a way you are distorting the market." The Medical Council of India (MCI) also prescribes the maximum number of incentives for a doctor. There are limits set in regulation which prohibit the manufacturer or trader to induce demand through incentivising the doctor but in case of medical devices the situation is very complex considering the cases mentioned above. The UCPMP, a voluntary code was issued by the DoP in 2011 and its amended version came out in

2015. The marketing code lacks penal provisions to deter wrongdoers.

Source: Shardul Nautiyal, Pharmabiz, 08.01.2021

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All Covid-19 vaccines being developed in India can be stored at 2-8 degrees Celsius: DBT Secretary

All vaccines being developed in the country against Covid-19 can be stored at 2-8 degrees Celsius as the logistics have been worked out considering temperature as a factor, according to Renu Swarup, Secretary, Department of Biotechnology (DBT). Bharat Biotech's Covid-19 vaccine Covaxin and Oxford-AstraZeneca's Covishield have robustly undergone immunoassay lab tests, Swarup said.

Both the DNA vaccine candidate being developed by Zydus Cadila, and the Biological E's mRNA vaccine will work at storage temperatures of 2-8 degrees Celsius. Unlike the Pfizer and Moderna which requires a minus 70 degree Celsius (cold) chain, this (the Biological E's vaccine candidate) is basically at the 2-8 degree Celsius, said Swarup. Zydus Cadila candidate has been granted approval to conduct the phase-3 trial while the Biological E candidate is in its phase-1 Clinical Trial stage, and Dr Reddy's Laboratories had partnered with Russia's Gamaleya Institute and a vaccine was being developed for India targeting storage at 2-8 degrees Celsius.

Seeking to ally apprehensions on this, Swarup said, these two vaccines which have been spoken about right now, we have had the robust immunoassays which have been studied through within the laboratories. Referring to the Translational Health Science and Technology Institute (THSTI), Faridabad, an institute under the DBT, Swarup said the lab has sets of immunoassays – which are biochemical tests – that run all these vaccines through them. So anything that comes out of this immunoassay lab gives you the confidence that it has gone through the robust assay system which gives you the immunogenicity and the safety data as we move forward. There are 30 vaccine candidates in India at different stages. The country's drugs regulator granted emergency use approval to Oxford-AstraZeneca's Covishield and also to the indigenously developed Covaxin even though not enough data on the latter's efficacy and safety was available, which has triggered a debate.

Source: Pharmabiz, 08.01.2021

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Indian Pharma sees regulatory submissions in electronic format to ease risk assessment and allow speedy Approvals

Indian Pharma sees that the US FDA norms on the format requirements for the electronic submission of the content of a Risk Evaluation and Mitigation Strategy (REMS) document as part of submissions under New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), and certain Biologics License Applications (BLAs) will make simpler the assessment and allow speedy clearances of applications. The REMS documents need to be submitted to FDA in the Structured Product Labeling (SPL) format which is approved by Health Level Seven (HL7) and adopted by FDA as a mechanism to exchange product and facility information.

The key advantages of SPL format are effortless information exchange. This is in sync with the current technology adoptions to ease inspection operations. The use of standard terminology and coding across the content, like for instance the package types and routes of administration will be delivered in a lucid form, noted industry experts. For the regulatory authority, this is part of the Good Guidance Practice (GGP) regulation covering design, production, labeling, promotion, manufacturing, and testing of regulated products; besides evaluation of submissions and enforcement policies. Moreover the regulatory authority had engaged stakeholders over a 3-year time frame and analyzed their feedback regarding REMS standardization. These findings were published as a report: Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS).

The industry had expressed concern about the clarity and consistency on information about REMS materials and requirements. They communicated that it may be difficult to locate and expressed the need to have better ways to integrate REMS materials and procedures into their existing health information systems and health care delivery processes. They also requested to avoid spending excessive time trying to locate, understand, and comply with different REMS requirements while ensuring safe use of drugs with REMS.

In order to address these concerns, applicants of NDAs, ANDAs, and certain BLAs are now required to submit the content of their REMS documents in SPL format. This can be used to capture and present REMS information in a

format that is easily shared with stakeholders and readily incorporated into health information technology.

Accordingly, because the Guidance issued on December 28, 2020, all REMS documents submitted to FDA on or after December 28, 2022 should be in SPL format. This includes REMS documents associated with new REMS as well as REMS documents submitted as part of REMS modifications. In addition, beginning December 28, 2022, REMS revision submissions that include REMS documents that are already in SPL format must remain in SPL format, while REMS revision submissions that include REMS documents that have not yet been converted to SPL format are not needed to be converted to SPL format until their next modification is submitted, said the regulatory authority.

Source: Nandita Vijay, Pharmabiz, 05.01.2021

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FPME urges Government to maintain rational rates for Pharma industry under RoDTEP scheme

The Federation of Pharmaceutical Merchant Exporters and Allied Products (FPME) has urged the Government to maintain rational rates for the pharmaceutical industry under Remission of Duties and Taxes on Exported Products (RoDTEP) scheme. "The implementation of the scheme for RoDTEP to all export goods is a welcome move, but still transition is not easy. Many shipping bills were generated on 31st December, 2020 but has not cleared been yet," stated Jaynesh Patel, Gujarat Chapter co-ordinator, FPME.

Government stated that the RoDTEP scheme would refund to exporters the embedded Central, State and local duties/taxes that were so far not being rebated/refunded and were, therefore, placing our exports at a disadvantage. The refund would be credited in an exporter's ledger account with Customs and used to pay basic customs duty on imported goods. The credits can also be transferred to other importers.

The RoDTEP rates would be notified shortly by the Department of Commerce, based on the recommendation of a Committee chaired by Dr G K Pillai, former Commerce and Home Secretary. An exporter desirous of availing the benefit of the RoDTEP scheme shall be required to declare his intention for each export item in the shipping bill or bill of export. The RoDTEP shall be allowed, subject to specified conditions and exclusions.

RoDTEP is a new scheme to replace the existing MEIS scheme for exports of goods. The aim of the RoDTEP scheme is to reimburse the taxes and duties incurred by exporters such as local taxes, coal cess, mandi tax, electricity duties and fuel used for transportation, which are not getting exempted or refunded under any other existing scheme such as Duty Drawback, GST refunds, central/state Government exemptions, subsidy, etc.

Incorporated on March 30, 2019, FPME today has 150 members in a span of just one year and is planning to add 500 members this year. As per Pharmexcil data, there are approximately 2,000 merchant exporters in the country. The main objective of FPME Association is to represent pharmaceutical and allied product merchant exporters in Government, semi-government, regulatory, legislative and other trade and industry bodies for policy development and interventions.

Source: Yash Ved, Pharmabiz, 05.01.2021

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A Game Changer

For making the country self-reliant in the Pharma sector, the Department of Pharmaceuticals in July, 2020 had come out with a Notification for Rs.3,000 crore bulk drug parks' promotion scheme and Rs.6,940 crore Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of critical key starting materials (KSMs)/drug intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India. Though the country has, over the years, adorned the epithet of 'the pharmacy of the world' as it has been exporting life-saving medicines to the entire world, including developed nations, India has been critically dependent on Chinese imports for basic raw materials that are used to produce some of the essential medicines. By introducing the PLI scheme, the Indian Government wanted to end this scenario. Earlier, a committee on drug security constituted by the DoP had identified 53 APIs for which the country is heavily dependent on Chinese imports. The list of 41 products contained in the scheme Guidelines will enable domestic production of these 53 bulk drugs. Under the scheme, financial incentives will be given to a maximum of 136 manufacturers selected under the scheme as a fixed percentage of their domestic sales of these 41 products manufactured locally with the required level of domestic value addition. However, there were protests from the MSMEs who felt that they were deprived of the benefits under the PLI scheme because of the threshold investment criterion. As per the scheme, the selected manufacturers

will have to make a threshold investment mandated for each product and achieve a prescribed minimum installed capacity before they are eligible to receive incentives. As per the scheme Guidelines, threshold investment was Rs.400 crore for four fermentation based products and Rs.50 crore for ten fermentation based products. Similarly, threshold investment was Rs.50 crore for four chemically synthesised products, and Rs.20 crore for 23 chemically synthesised products. There are more than 2,000 MSMEs involved in API and drug intermediate manufacturing in the country. Due to the threshold investment limit, these MSMEs have not been able to participate in the PLI scheme.

Now, in a welcome step to ensure effective participation of the industry, the Government has introduced revised PLI scheme, removing minimum investment criteria and incorporating export and sale-based production criteria following an appeal by drug and medical device industries. As per the revised guidelines of PLI scheme, for boosting indigenous production of 41 products which cover all the identified 53 APIs for which India is critically dependent on China, the criteria of 'minimum threshold' investment has been replaced by 'committed investment' by the selected applicant. The change has been made to encourage efficient use of productive capital as the amount of investment required to achieve a particular level of production depends upon choice of technology and it also varies from product to product. Indeed, the removal of minimum investment criteria is a right step to ensure the participation of the MSMEs in the scheme. It will encourage MSME manufacturers to participate in the PLI scheme in large numbers. This will make the country self-reliant in the production of APIs in the long run. By making the amendment, the Government has rightly acknowledged the contribution of the MSMEs which played a crucial role in ensuring affordable drugs to the consumers over the last four decades of the pharmaceutical industry's pompous march in the country. Now, it is sure they can also play a significant role in making India self-reliant in bulk drug production also. The threshold investment requirement was a constraint for the manufacturers who can make minimum investment to produce identified products considering they already have common surplus utilities available to them. The replacement of the criteria of threshold investment with committed investment will definitely prove to be a game changer in the long run as it has the potential to make India a world leader in APIs also.

Source: Ramesh Shankar, Pharmabiz-Editorial, 30.12.2020

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SMEs need to move up from generics to oral dosage forms: Harish Jain

The Indian Pharma's Small and Medium scale Enterprises (SMEs) need to progress from generics to oral dosage forms and move up the value chain into exports and innovation, said Harish K Jain, Director, Embiotic Labs. At a webinar organized recently by the Small and Medium Pharmaceutical Centre (SMPIC), the National Institute of Pharmaceutical Education and Research (NIPER), Mohali, Jain deliberated on the topic 'Development of Oral Solid Dosage Forms in a SME Setup–Need of the Hour'.

Stressing that the potential of the SMEs could not be ignored, he said that the Pharma companies in the small sector need handholding in a structured and focused manner. This is because they lack confidence in facing regulatory audits and are ignorant or lack awareness on documentation management and submission. Besides, they also have no robust processes in place, he added.

SMEs depend heavily on traditional generics driven by low cost of production, price controls and not-of-standard quality due to absence of organized product development. In most small pharma companies, vendor validation is almost impossible or absent while only a handful of companies do process validation. There is also an absence of validated analytical methods and BA/BE (bioanalytical/ bioequivalence) data at least for BCS (Biopharmaceutics Classification System) Class and Class IV drugs, said Jain. In order to move up from generics to oral dosage forms, we do not require big capital investment but a change of management mindset and vision for a sustainable business model, he said.

Organized development brings in new business opportunities and continuous access to new products that will command a higher price. The development of any product is always guided with the aim of ensuring that it complies with high quality standards during the entire shelf life. Solid oral dosage forms and especially tablets for oral administration are the most common pharmaceutical dosage forms. These are ubiquitous across all systems of medicine, despite apparent simplicity but they demand a careful research and development process, he said.

The key challenges of the sector are lack of dedicated and trained professionals for product development, dearth of investment resources on basic equipment and dedicated

areas even for lab scale trials to demonstrate even proof of concept. There is lack of consistent approach and vision, he said. In order to offset the lack of infrastructure and equipment, outsourcing of these services would give the SMEs a wide access to partner and produce the products. This would probably be a platform for Indian pharma SMEs to be able to move up from generics to oral dosage forms, said Jain.

Source: Nandita Vijay, Pharmabiz, 11.01.2021 (Excerpts)

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INTERNATIONAL NEWS

European Commission authorizes COVID-19 vaccine Moderna in Europe

Moderna, Inc (Nasdaq: MRNA), a biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines, announced that the European Commission has granted a Conditional Marketing Authorization (CMA) for COVID-19 Vaccine Moderna, allowing vaccination programs using the Moderna vaccine to be rolled out across the European Union. The authorization is based upon the recommendation of the European Medicines Agency (EMA) for use of the COVID-19 Vaccine Moderna for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus in individuals 18 years of age and older.

"I want to thank the European Commission for its engagement and endorsement and the EMA for its recommendation, which is another significant moment in our company's history," said Stéphane Bancel, Chief Executive Officer of Moderna. "The EMA and the Committee for Medicinal Products for Human Use reviewers, working over the holidays, provided a thorough review and comprehensive Guidance as we worked together to achieve this authorization. I am proud of the role Moderna has been able to play globally in helping to address this pandemic."

The European Union is the fourth jurisdiction to authorize Moderna's COVID-19 vaccine, following the United States on December 18, 2020, Canada on December 23, 2020 and Israel on January 4, 2021. Additional authorizations are currently under review in Singapore, Switzerland and the United Kingdom. On December 18, the EMA exercised its option to increase its confirmed order commitment by 80 million doses of Moderna's vaccine against COVID-19, bringing its confirmed order commitment to 160 million doses. The first deliveries of COVID-19 Vaccine Moderna to European countries from Moderna's dedicated non-US supply chain are expected to begin next week.

The EMA's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for COVID-19 Vaccine Moderna based on the totality of scientific evidence shared by the Company, including a data analysis from the pivotal Phase 3 clinical study announced on November 30.

About the COVID-19 Vaccine Moderna:

The COVID-19 Vaccine Moderna (referred to in the US as the Moderna COVID-19 Vaccine) is an mRNA vaccine against COVID-19 encoding for a prefusion stabilized form of the Spike (S) protein, which was co-developed by Moderna and investigators from NIAID's Vaccine Research Center. The first clinical batch, which was funded by the Coalition for Epidemic Preparedness Innovations, was completed on February 7, 2020 and underwent analytical testing; it was shipped to the NIH on February 24, 42 days from sequence selection. The first participant in the NIAID-led Phase 1 study of the Moderna COVID-19 Vaccine was dosed on March 16, 63 days from sequence selection to Phase 1 study dosing. On May 12, the US Food and Drug Administration granted the Moderna COVID-19 Vaccine Fast Track designation. On May 29, the first participants in each age cohort: adults ages 18-55 years (n=300) and older adults ages 55 years and above (n=300) were dosed in the Phase 2 study of the vaccine. On July 8, the Phase 2 study completed enrolment.

Results from the second interim analysis of the NIH-led Phase 1 study of the Moderna COVID-19 Vaccine in the 56-70 and 71+ age groups were published on September 29 in *The New England Journal of Medicine*. On July 28, results from a non-human primate preclinical viral challenge study evaluating the vaccine were published in *The New England Journal of Medicine*. On July 14, an interim analysis of the original cohorts in the NIH-led Phase 1 study of the vaccine was published in *The New England Journal of Medicine*. On November 30, Moderna announced the primary efficacy analysis of the Phase 3 study of the vaccine conducted on 196 cases. On

November 30, the Company also announced that it filed for Emergency Use Authorization with the US FDA and a Conditional Marketing Authorization (CMA) application with the European Medicines Agency. On December 3, a letter to the editor was published in *The New England Journal of Medicine* reporting that participants in the Phase 1 study of the Moderna COVID-19 Vaccine retained high levels of neutralizing antibodies through 119 days following first vaccination (90 days following second vaccination). On December 18, 2020, the US FDA authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age or older. On December 23, 2020, Health Canada authorized Moderna's vaccine against COVID-19 for the immunization of people 18 years of age and older under an Interim Order. On January 4, 2021, Israel's Ministry of Health (MOH) authorized the importation of the COVID-19 Vaccine Moderna in Israel.

Authorized use:

The COVID-19 Vaccine Moderna has been granted a Conditional Marketing Authorization by the European Commission, based upon the recommendation of the European Medicines Agency, which authorizes the COVID-19 Vaccine Moderna for active immunization to prevent COVID-19 caused by SARS-CoV-2 virus in individuals 18 years of age and older.

Source: World Pharma News, 07.01.2021 (Excerpts)

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FEATURE

Boost in Pharma exports as Countries look beyond China

Abhinav Singh

Increase in demand for Pharma Products, induced by the COVID-19 Pandemic

The Indian Pharmaceutical sector saw a boost in exports thanks to a spike in demand for Pharma products induced by the Covid-19 pandemic and countries adopting a 'China plus one' policy. India's formulation and bulk drug exports improved by 18 and 9 percent on-year (in constant currency) during the first half of the current fiscal compared to 11 percent and -1 percent, respectively (in constant currency) for the whole fiscal.

As per a recent report by CRISIL, there has been an increase in demand for Pharma products, induced by the Covid-19 pandemic, and hoarding of supplies by some nations in the wake of production disruptions, have boosted exports. Besides that, increasing customer diversification away from China with respect to bulk drug policy, coupled with some countries adopting a 'China plus one' policy, has led to increased demand for Active Pharmaceutical Ingredients (APIs) from India.

CRISIL report points out that a robust demand from most economies boosted India's exports in the first half of the current fiscal and major regions such as the US and Europe brought good exports growth due to increased demand for drugs, especially anti-virals and anti-biotics for treatment of Covid-19. In addition to this, global de-risking of the supply chain has boded well for the Indian bulk drug exports. Chinese supply disruptions in early 2020 and persistent quality issues provided an opportunity for the Indian Pharma players as many global customers started looking at India as an alternative supplier of bulk drugs. Further, Indian API exporters have been able to garner good realizations on their exports during the first half of this fiscal.

However, as per the CRISIL report, the Indian domestic market fell by 2.5 percent in the first half of the current year. Given the lockdown in April and May, the Domestic Pharma Market logged a 6 percent decline in growth in the first quarter of this fiscal. Closure of smaller clinics and hospital OPDs and postponement of surgeries resulted in slower sales of drugs in the domestic market, although some support was provided by an increase in sales of chronic therapies such as cardiac and anti-diabetes medicines. This continued for some more time as the growth in the

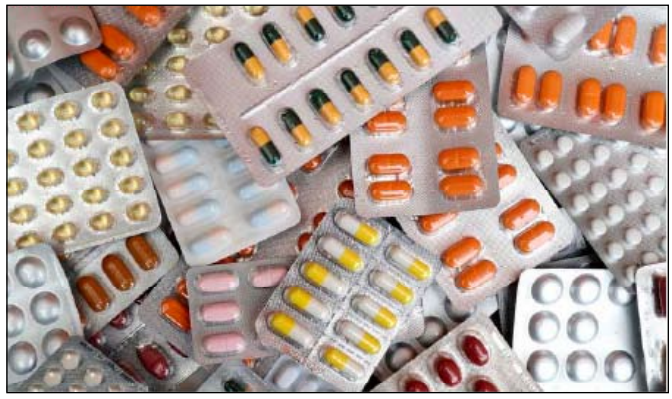
domestic market remained muted in the second quarter as well, leading to an overall decline of 2.4 percent for the first half.

It is expected that the domestic market will bounce back in the later half of the current fiscal as demand disruptions ease. Revenues of Pharma companies will show an uptrend this fiscal driven by the exports growth in both formulations and bulk drugs and the players are expected to have 7-8 percent (in rupee terms) on-year growth this fiscal. The CRISIL report further observes that the gradual easing of lockdown restrictions, coupled with demand for Pharma products and bulk drugs in both exports and domestic markets, will aid this revenue growth.

The report pointed out that a ramp up in specialty drugs and biosimilar exports, along with strong domestic sales, will aid revenue growth for Pharma companies in the next fiscal, too. Lower travel and marketing costs on account of the lockdown, along with a favourable business mix had led to an improvement in margins for formulation and bulk drug players in the first half of this fiscal. Operating expenses for Pharma firms had reduced due to a fall in movement of medical representatives and other cost cuts, along with rationalisation of manpower.

The CRISIL report further observes that the withdrawal of the Merchandise Exports from India Scheme (MEIS) will have some impact on the margins of the export-oriented pharma players. The Government has announced the withdrawal of the MEIS scheme by December 31, 2020 and will be replaced by the Remission of Duty or Taxes on Export Products (RoDTEP) scheme. Further, incentives under MEIS have been capped at Rs.20 million per exporter.

A report by Emkay Global Financial Services has observed that Global Pharma companies, especially those based in the US and Europe, are actively looking to de-risk their supply chain from China and may exercise different options. They may try to produce APIs in-house or outsource manufacturing to other US or Europe-based companies or they may choose a supplier from a developing country ex-China. The report points out that the first two options are not viable for their entire portfolio, leaving the third



option open. It is here that the Indian Pharma companies have an edge, given their long history of supplying APIs and formulations globally plus offering better quality and regulatory compliance and better supply reliability. The report says that while the discussions around adding new suppliers have started, the financial impact will take time as adding an API supplier will take 6-18 months, depending on the regulatory pathway.

Source: The Week, 05.01.2021 (Excerpts)

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Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 14.01.2021

Edited, Printed and Published by **Dr.Gopakumar G. Nair** on behalf of **Indian Drug Manufacturers' Association**, Printed at **Ebenezer Printing House**, Unit No. 5 & 11, 2nd Floor, Hind Services Industries, Veer Savarkar Marg, Dadar (West), Mumbai 400 028 and Published from 102-B, Poonam Chambers, "A" Wing, 1st Floor, Dr. A. B. Road, Worli, Mumbai 400 018. Editor: **Dr.Gopakumar G. Nair.**