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IDMA BULLETIN

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Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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IDMA BULLETIN

Vol. No. 53 **Issue No. 01** **01 to 07 January 2022**

Postponement of IDMA 60th Annual Day

Dear Member,

This refers to our IDMA 60th Year Celebrations which were scheduled to be held on **Friday 7th & Saturday 8th January 2022 at Hotel Sahara Star, Mumbai.**

We have been receiving several calls from our members and exhibitors with regards to the current Covid-19 and the Omicron variant situation and the uncertainty & anxiety it has created. Due to the rapid spreading of the Covid-19 and its variant Omicron throughout the city of Mumbai, our members have been requesting to postpone the gala celebrations.

As a responsible Pharmaceutical Association and keeping in mind the interest, health and safety of our members, the Organizing Committee in an emergency meeting held this evening i.e. Thursday, 30th December 2021 decided to postpone the IDMA 60th Year Deliberations and Celebrations till further notice.

Please be rest assured that the Annual Day Deliberations and Celebrations would be organized with great gusto and enthusiasm at a later date during 2022. We will ensure that members would receive the information at least 30 days prior to the new date.

Also, kindly be rest assured that the registration fees as well as the hotel booking charges paid by you will continue to remain valid till the new date which will be announced.

The inconvenience caused to our members and well-wishers specially the outstation members is sincerely regretted.

We sincerely thank all our members for their support, co-operation and understanding during these tough and trying times.

Wishing you, your family and all at your esteemed organization a safe, healthy, fruitful and a covid-19 variant free year 2022.

Thanking you,

Yours sincerely,
For Indian Drug Manufacturers' Association,

Bharat Shah
Chairman, Organizing Committee, IDMA
60th Year Celebrations

Dr Viranchi Shah
National President

Daara B Patel
Secretary - General

Exciting Times Ahead for the Indian Pharma Industry

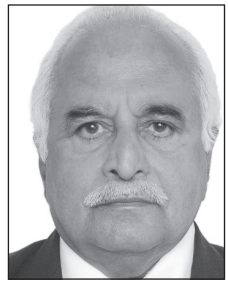
Dr Gopakumar G. Nair, *Editor, Indian Drugs*

Dear Reader,

Coinciding with the 60th Anniversary of IDMA, a true and vibrant transition phase is commencing for your association, its publications and allied activities. Dr. Viranchi Shah, the young and energetic Hon. President from "Vibrant Gujarat" is taking over the reigns of IDMA, with an equally young team of Executive committee members. We are confident that IDMA's flag will fly high globally, all the more, in the coming years. It is time that the young (and the long-experienced ones too) get ready for the new integrated and synergised challenges of the 2020's and 2030's to keep pace with the clarion call for intense pharma research and innovation to keep pace with the west and the rest.

As referred in earlier editorials, with the Indian pharma industry entering the proverbial 25-year circle of new IP/ Patent law regime (1995 to 2000+), it is time for IDMA and the Indian Pharma Industry to review and revamp its innovative research and patenting strategies. Let us admit and appreciate that the Indian Pharma Industry has come a long way and has established its rightful place in the global arena of generic pharma. Let us replicate this in the field of innovation and IPR protection too. Let us hope and take note that the recent meetings of IDMA under the emerging leadership of Dr. Viranchi Shah, both with USFDA-Country Director Dr. Sarah McMullen and the few representatives of US Pharma Industry, both at Ahmedabad, are only the beginning of a long standing, durable and mutually beneficial relationship with the US and Indian Pharma Industries and more importantly with the regulatory authority, USFDA.

The days of the Indian Pharma Industry pleading for waivers and exemptions must be left behind. Let India and South Africa seek waiver of patent rights in context of the larger public interest. IDMA and the Indian Pharma Industry has always worked for the best interests of the patients and the community at large, not only in India but across the world. This will continue with invigorated vision and mission under the new IDMA leadership. Requests for abolition of patent rights on Human Rights considerations and as a fundamental right of freedom to operate under the Constitution of India are passé. We have left behind such thoughts of the eighties and nineties and have marched forward with strong self-belief, self-respect and vigorous will and pursuit to achieve a global leadership position not only in the pharma bio-vaccine industry, but also in pharmaceutical innovation and building an out- licencing oriented patent portfolio along with high regulatory standards of new innovative molecules and dosage forms to meet the increasing expectations and needs of the Indian and third world country communities.



Dr. Gopakumar G. Nair is a Ph.D in Organic Chemistry (1966) from National Chemical Laboratory, Pune (Pune University). He was a Post-Doctoral fellow at IIT Bombay, Powai (1967) before joining the Pharma Industry. He was Director of Bombay Drug House P. Ltd., later Chairman of BDH Industries Ltd. as well as CMD of Bombay Drugs & Pharma Ltd., which was merged with Strides Arcolab Ltd. in 2001. Dr. Nair served IDMA as office bearer for many years from 1972 onwards and was Chairman of various Committees for nearly 4 decades. He was the President of IDMA in 1999/2000. Currently, Dr. Nair is the Chairman of the IPR Committee in IDMA.

Having moved into the Intellectual Property field, he was the Dean of IIPS (Institute of Intellectual Property Studies) at Hyderabad in 2001/2002. Later, he set up his own boutique IP firm, Gopakumar Nair Associates, as well as Gnanlex Hermeneutics Pvt. Ltd., having done his L. L. B. from Mumbai University. He is also CEO of Patent Gurukul and President of Bharat Education Society, Kurla, Mumbai, managing many educational institutions in and around Mumbai.

Courtesy: Indian Drugs, Editorial, 58 (11), November 2021

Report on "An Interactive Meeting with US Delegation" At Courtyard by Marriot SBR, Ahmedabad on 12th December 2021

An interactive Session was organised with IDMA-GSB Members at Courtyard by Marriot SBR, Ahmedabad with the delegation from the US led by Mr. Harinder S. Panaser - President, Global Indian Trade & Cultural council USA, in presence of Dr. H. G. Koshia, Commissioner, FDCA Gujarat State. Mr. Anand Krishnamurthy, CEO, Coolsoft LLC, USA and Mr. Pankaj Kumar, Chief Technology Officer were present.

IDMA was represented by Sr. Vice President Dr. Viranchi Shah & IDMA GSB Chairman, Mr. Milan Patel, office bearers Dr. Shrenik shah, Mr Sumit Agrawal, Mr. Rajiv Shah and EC members Dr. Milan Satia and Mr. Maulik Shah.

Programme started with a welcome speech delivered by Dr. Shrenik Shah, Sr. Vice Chairman, IDMA GSB. Dr. Viranchi Shah Sr. Vice President IDMA Presented flower bouquet to Mr. Harinder S. Panaser - President, Global Indian Trade & Cultural council USA & Mr. Milan Patel, Chairman IDMA GSB presented flower bouquet to Dr. H. G. Koshia, Commissioner, FDCA Gujarat State.

A small video presentation on "Opportunities in Healthtech and IT" waspresented by Mr. Pankaj Kumar Chief Technology Officer Coolsoft LLC.

The meeting ended with vote of thanks speech delivered by Mr. Sumit Agrawal Hon. Secretary, IDMA GSB and followed by lunch.

It was a very successful meeting wherein the discussion was centered around pathways for Indian Pharma and Healthcare companies to explore US markets for OTC and Rx products and Opportunities in Healthtech and IT.

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Have you renewed your **Membership** for the years

2020-2021 & 2021-2022

If not, please do so; kindly contact IDMA Secretariat at:
Email: actadm@idmaindia.com / accounts@idmaindia.com
Tel.: 022 - 2494 4624 / 2497 4308 /Fax: 022 - 2495 0723

IDMA representation to CBIC on Extension of Existing Concessional GST rates on certain COVID-19 treatment drugs for a further period of 6 Months - reg.

IDMA have submitted the following representation on 07th January, 2022 to Mr. Vivek Johri, IRS , Chairman, Central Board of Indirect Taxes and Customs, Ministry of Finance, North Block, New Delhi with the copies to Ms. S. Aparna, IAS, Secretary, Department of Pharmaceuticals and Shri Kamlesh Kumar Pant, IAS, Chairperson, National Pharmaceutical Pricing Authority on the above subject:

Respected Sir,

Greetings from Indian Drug Manufacturers' Association (IDMA)!

We refer to IDMA's Representation / Submissions dated 25th May 2021 on Goods and Service Tax – Key issues and concerns of Pharmaceutical industry for GST Council Meeting (copy attached) and the OM File No. 19(175)/2019/DP/NPPA/Div.II dated 15th June, 2021 issued by NPPA in reference to the Lower GST announced for COVID drugs. We thank the 44th GST Council and the 45th GST Council under the Chairmanship of Union Finance & Corporate Affairs Minister Smt Nirmala Sitharaman for deciding to reduce the GST rates on the specified items being used in Covid-19 relief and management till 30th September, 2021 and then considering it apt to further extend the Existing Concessional GST Rates till 31st December 2021.

As you are aware, the third wave of Covid-19 along with the Omicron variant has created a situation of uncertainty & anxiety through our country. Due to the rapid spreading of the Covid-19 and its variant Omicron throughout the country, IDMA as a responsible Pharmaceutical Association and keeping in mind the interest, health and safety of our patients humbly request you to kindly give us an Extension for the Existing Concessional GST rates on certain COVID-19 treatment drugs for a further period of 6 Months.

Looking forward to your positive response.

Thanking you.

Yours faithfully,

Dr. Viranchi Shah
National President, IDMA

B G Barve
Chairman, Excise & Taxation Committee, IDMA

Note: *IDMA representation to CBIC published in IDMA Bulletin-Volume No. 52, Issue No. 20, 22 to 30 May 2021 GST Council Meeting published in IDMA Bulletin - Volume No. 52. Issue No. 35,15 to 21 September 2021*

Online Applications for EODC/closure under Advance Authorisation Scheme (AAS) — Option to file manual applications

Trade Notice No. 28/2021-2022, dated 31st December 2021

To,
1. All Regional Authorities of DGFT,
2. All members of Trade and Industry.

1. Kindly Refer to Trade Notice 49/2020-21 dated 29.03.2021 issued on the above subject.

2. In view of difficulties expressed by Advance Authorization (AA) holders in their representations and also to ease process of filing of applications for closure of Advance authorizations, it has been decided to give an option to file manual/physical EODC applications for all such AAs, which have been issued prior to 1.12.2020.

3. In cases where the application for EODC/closure has been received in manual/physical mode, RAs on approval of such physical files are required to upload closure letters in the online system & update the status of the AA suitably.

4. It is further seen that in some cases of AA, the EODC/closure issued manually in earlier periods is not reflected correctly in the online system. Option is therefore provided on the DGFT website where the status of the past AA Authorizations can be seen by concerned exporters. In case it is found that Authorization has been closed/redeemed and the status is not reflected correctly, the exporter is required to upload online the copy of the closure letter/ redemption letter against the said Authorization. RA may verify the request submitted by exporter for EODC updation against available office records and process it suitably. RA may also choose to update the status of the said cases suo-motu after verification from its

5. The exporters may follow the steps for EODC status updation as follows —

i. "Go to DGFT Website under Services → AA/DFIA → 'Manual EODC Status Update"

ii. Scanned copy of EODC/Closure letter(s) is required to be uploaded at the time of

iii. Accordingly All AA Holders are requested to verify the status of the AA issued earlier and submit the online request for updation of status(where required), not later than 31.03.2022. In the absence of updated online status, RA may take necessary action, as deemed fit for non-fulfilment of export obligation.

6. This issues with the approval of the competent authority.

Effect: Manual/physical filing of EODC/closure applications under AA scheme is allowed for AAs issued before 1.12.2020. Exporters are also requested to update EODC/Closure status of earlier issued AAs in the online system by 31.3.2022.

File No. 01/94/180/018/AM21/PC-4)/194

Vijay Kumar, Additional Director General of Foreign Trade, Directorate General of Foreign Trade, Ministry of Commerce & Industry, Department of Commerce, Government of India, Udyog Bhawan.

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Continuation of operations of the DGFT 'COVID-19 Helpdesk' for International Trade related Issues'

Trade Notice No. 29/2021-2022, dated 06th January 2022

To,
All Exporters/Members of Trade,
All Export Promotion Councils/Commodity Boards.

1. Department of Commerce and DGFT have undertaken to monitor the status of export and imports and difficulties being faced by trade stakeholders in

view of the surge of COVID-19 cases. DGFT has operationalised a 'COVID-19 Helpdesk' to support and seek suitable resolutions to issues arising in respect of International Trade.

2. The 'COVID-19 Helpdesk' would look into issues relating to Department of Commerce/DGFT, Import and Export Licensing Issues, Customs clearance delays and complexities arising thereon, Import/ Export documentation issues, Banking matters etc. Helpdesk would also collect and collate trade related issues concerning other Ministries/ Departments/Agencies of Central Government and State Governments and will co-ordinate to seek their support and provide possible resolution(s).

3. Export-Import community may submit information on the DGFT website and submit information relating to their issues on which support is required using the following steps--

i. Navigate to the DGFT Website (https://dgft.gov.in) -- > Services -- > DGFT Helpdesk Service

ii. 'Create New Request' and select the Category as 'Covid-19'

iii. Select the suitable sub-category, enter the other relevant details and submit.

Alternatively, you may send your issues to email id: dgftedi@nic.in with the subject header: Covid-19 Helpdesk, or call the Toll-Free No at 1800-111-550

4. The status of resolutions and feedback may be tracked using the Status tracker under the DGFT Helpdesk Services. Email and SMS would also be sent as and when the status of these tickets are updated. Trade Community is requested to kindly make use of the given facilities suitably.

This issues with the approval of the competent authority.

File No. 01/02/08/AM22/EG&TF[E-27797]

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

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INDIAN PHARMACOPOEIA COMMISSION

Amendement List 09 to IP 2018 - reg.

F.No.T.11013/02/2018-AR&D, dated 30th December 2021

To,

1. *The Drugs Controller General (India)*
2. *CDSCO Zonal Offices*
3. *All State Drug Controllers*
4. *Members of the Scientific Body of IPC*
5. *Members of Sub-Committees of the Scientific Body of IPC*
6. *Directors of Drugs Testing Laboratories*
7. *Government Analysts*
8. *IDMA/OPPI/BDMA/FOPE/FSSAI/Small Scale Industry Associations.*

The 8th Edition of Indian Pharmacopoeia (IP) 2018 has become effective from 1st January, 2018. Based on scientific inputs, some IP monographs needed up-gradation and accordingly Amendment List 09 to IP 2018 is issued containing such amendments. The same shall be effective from **31st December 2021.**

This is for notice and compliance with the IP 2018.

Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director, Ministry of Health & Family Welfare, Sector 23, Raj Nagar, Ghaziabad, India

Note: *Interested Member can visit IPC website http://www.ipc.gov.in/ to get details on Amendment List 09 to IP- 2018*

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Anti-dumping Duty on Imports of 1,1,1,2-Tetrafluoroethane or R-134a from China PR - reg.

Notification No.01/2022-Customs (ADD), dated 06th January 2022

In exercise of the powers conferred by sub-sections (1) and (5) of section 9A of the Customs Tariff Act, 1975 (51 of 1975), the Central Government revokes the anti-dumping duty imposed on "1,1,1,2-Tetrafluoroethane or R-134a", originating in or exported from China PR, and imported into India and hereby rescinds the notification of the Government of India in the Ministry of Finance (Department of Revenue) No.30/2016-Customs (ADD), dated the 11th July, 2016, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.675(E), dated the 11th July, 2016, except as respect things done or omitted to be done before such rescission.

F.No.CBIC-190354/294/2021–TRU-CBEC

Rajeev Ranjan, Under Secretary, Ministry of Finance, Department of Revenue, New Delhi.

Note: *The principal notification No.30/2016-Customs (ADD), dated the 11th July, 2016 was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.675(E), dated the 11th July, 2016 and last amended vide notification No.30/2021-Customs, dated the 24th day of May, 2021 published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), vide number G.S.R.339(E)., dated the 24th day of May, 2021.*

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Preventive measures to contain the spread of COVID-19 - Setting up of a Control Room for Internal Trade and e-Commerce related issues - reg.

No.F-12016/1/2021-Estt. NG, dated 4th January, 2022

To
All Industry & Trade Associations.

1. I am directed to inform that due to the surge in the COVID cases across the country, DPIIT has taken cognizance of the steps taken by various State Governments/UTs to control the spread of COVID cases. Therefore, as a measure of precaution and for supporting our business ecosystem, DPIIT will monitor the status and issues arising (if any) during transportation and delivery of goods and essential commodities due to the restrictions (if any) imposed by various State Governments/UTs.

2. In the event of any manufacturing, transportation, distribution, wholesale or e-commerce companies facing difficulties in transportation and distribution of goods or mobilization of resources, the same may be informed to this Department at the following telephone number/email:

Telephone: +91 11 23063554, 23060625
Email: dpiit-controlroom@gov.in

3. The above telephone numbers will remain functional from 9 AM to 9 PM w.e.f. 05.01.2022. The issues reported by various stakeholders through this control room shall be taken up with the concerned State/ UT Governments. The stakeholders are, therefore, requested to report the issues affecting the above stated services to the control room.

Shambhu Datt Sati, Under Secretary, Ministry of Commerce and Industry, Department for Promotion of Industry and Internal Trade, Udyog Bhawan, New Delhi.

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Evaluation of certain pre 1988 permitted Fixed Dose Combinations (FDCs) de novo for manufacture for sale in the country without due approval from Central Licensing Authority - reg.

File No. 4-01/2013-DC (Misc. 13 PSC Part II), dated 06 January 2022

Dear Member,

IDMA has received below communication from CDSCO office regarding Evaluation of certain pre 1988 permitted Fixed Dose Combinations (FDCs) de novo for manufacture for sale in the country without due approval from Central Licensing Authority.

The meeting of the Expert Committee which was scheduled to be held on 29th & 30th Dec 2021 was postponed.

Now, the expert committee again invites the concerned stakeholders for hearing through WebEx (Video Conference) on 27th & 28th Jan 2022 w.r.t. FDCs mentioned under Annexure A. Date & time of hearing is also mentioned under Annexure A.

Members are requested to make it convenient to give a presentation through WebEx (Video Conference) before the Expert Committee on these FDCs.

Kindly confirm your participation through e-mail at fdc@cdsco.nic.in by 24.01.2022 with a copy to us at idma2@idmaindia.com.

Please find below the Notice dated 06th Jan 2022 on the subject mentioned.

Thanks and regards,

Daara Patel

Secretary - General

This is in continuation to this office notice dated 27.12.2021 whereby the meeting of the Expert Committee was postponed which was scheduled to be held on 29th & 30th December 2021.

Now, the expert committee again invites the concerned stakeholders for hearing through WebEx (Video Conference) on 27th & 28th January 2022 w.r.t. FDCs mentioned under Annexure A. Date and time of hearing is also mentioned under **Annexure A.**

It is requested that the concerned stakeholders may kindly make it convenient to give a presentation through WebEx (Video Conference) before the Expert Committee on these FDCs. In the event that the Stakeholders does not attend the hearing, the Committee reserves the right to make its decision on the basis of information available before it.

You are requested to kindly confirm your participation through e-mail at fdc@cdsco.nic.in by 24.01.2022 and also submit Power Point presentation (PPT) alongwith the presenter details, Mobile number, email ID, s. No. of FDC as per **Annexure-A.**

This is for information of all the concerned.

Sanjeev Kumar , Deputy Drugs Controller (India), Directorate General of Health Services, Central Drugs Standard Control Organization , (FDC Division), New Delhi

Annexure-A

S.No.	FDC Name	Date & Time of Hearing
1	Nimesulide +Paracetamol dispersible tablets	27.01.2022 11:30 AM to 06:00 PM
2	Paracetamol + Phenylephrine + Caffeine	
3	Amoxicillin + Bromhexine	
4	Pholcodine + Promethazine	
5	Imipramine + Diazepam	
6	Chlorpheniramine maleate+ Dextromethorphan+ Dextromethorphan + Guaifenesin + Ammonium chloride + Menthol	
7	Chlorpheniramine Maleate +Codeine syrup	
8	Ammonium Chloride + Bromhexine + Dextromethorphan	
9	Bromhexine +Dextromethorphan +Ammonium Chloride +Menthol	
10	Dextromethorphan +Chlorpheniramine + Guaifenesin +Ammonium Chloride	
11	Caffeine +Paracetamol +Phenylephrine + Chlorpheniramine	28.01.2022 11:30 AM to 06:00 PM
12	Paracetamol + Bromhexine +Phenylephrine +Chlorpheniramine + Guaifenesin	
13	Salbutamol + Bromhexine	
14	Chlorpheniramine +Codeine phosphate +Menthol syrup	
15	Phenytoin + Phenobarbitone sodium	
16	Paracetamol + Propyphenazone + Caffeine	
17	Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol	
18	Salbutamol + Hydroxyethyltheophylline (Etofylline) + Bromhexine	
19	Chlorpheniramine Maleate + Ammonium Chloride + Sodium Citrate	

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In Lok Sabha & In Rajya Sabha

In Rajya Sabha

Consolidation of trading relationship with USA

Rajya Sabha Question No. 687

Shri K.C. Ramamurthy

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

(a) whether it is a fact that USA is becoming the largest trading partner with India;

(b) how the Ministry looks at this positive outcome since China cannot be relied upon, be it relating to supplies or quality or price;

(c) the efforts being made to consolidate this relationship with USA;

(d) whether it is also a fact that trade with Australia, UAE and Belgium has also gone up in the first nine months of this year; and

(e) if so, the details thereof?

Answered on 03rd December 2021

A. (a) USA has been the largest trading partner of India with respect to merchandise trade since the FY 201849, except 2020-21 when trade with the U.S. declined marginally on account of the Covid-19 pandemic. In the current FY 2021-22 (April- October), USA has once again become the largest trading partner with bilateral merchandise trade of US$ 67.41 billion, accounting for 11.98% of India's total merchandise trade. (as per DGCIS figures)

(b) and (e): India and United States enjoy a comprehensive strategic partnership covering a broad range of areas, underpinned by shared democratic values and vibrant people-to-people contacts.

Trade and commercial ties form an important component of this multi-faceted partnership. India and the U.S. are continuously engaged in strengthening these ties through bilateral dialogue mechanisms at Ministerial level including the Trade Policy Forum and Commercial Dialogue.

The 12th India-U.S. Trade Policy Forum meeting co-chaired by the Commerce and Industry Minister of India and the U.S. Trade Representative was held recently in November, 2021 at New Delhi, in which both the Ministers discussed various outstanding trade issues for early resolution on mutual basis, and also reached convergence on certain market access issues.

(d) & (e): Yes, the bilateral trade with Australia, UAE and Belgium has gone up in the first nine months (Jan-Sept) of Calendar Year 2021. During this period, India's bilateral trade with Australia has increased to US$ 13.88 billion in 2021 from US$ 7.48 billion in the corresponding period of 2020. The bilateral trade with UAE has grown to US$ 49.06 billion in 2021 from US$ 29.48 billion in 2020 for the same period. The bilateral trade with Belgium has also grown to US$ 13.70 in 2021 from US$ 7.63 billion in 2020 for the same period. (as per DGCIS figures).

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

Share of exports in annual GDP

Rajya Sabha Question No. 686

Shri Deepender Singh Hooda

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

(a) the details of share of exports in the annual Gross Domestic Product (GDP) for the last five years including the current year;

(b) whether the share of exports in GDP is witnessing a declining trend;

(c) if so, the reasons therefor; and

(d) the details of the annual rate of growth of exports and the corresponding annual rate of growth of GDP for the last five years including the current year?

Answered on 03rd December 2021

A. (a) The details of exports of goods and services and Gross Domestic Product (GDP) at current prices, and percentage share of India's exports to the GDP for the last five years and current year are as follows:

S. No.	Year	India's exports of goods and services (in Rs. Crore)	GDP (in Rs. Crore)	% Share of exports of goods and services in GDP
1	2016-17	29,48,772	1,53,91,669	19.2
2	2017-18	32,11,521	1,70,90,042	18.8
3	2018-19 (2nd RE)	37,66,294	1,88,86,957	19.9
4	2019-20 (1st RE)	37,50,567	2,03,51,013	18.4
5	2020-21 (PE)	36,85,170	1,97,45,670	18.7
6	2020-21 (April-September)	16,69,646	86,14,840	19.4
7	2021-22 (April-September)	23,12,942	106,76,879	21.7

Source: National Accounts Division, CSO, MoSPI
Note: RE: Revised Estimate, PE : Provisional Estimate

The share of export of goods and services in GDP has increased to 18.7 % during 2020-21 over 18.4% in 2019-20 and 21.7% in 2021-22 (April-September) over 19.4% in 2020-21 (April-September).

(d): The details of the annual rate of growth of exports of goods and services and the corresponding annual rate of growth of GDP at current prices for the last five years and current year are as follows:

S. No.	Year	India's exports of goods and services (in Rs. Crore)	% Growth in exports	GDP (in Rs. Crore)	% Growth in GDP
1	2016-17	29,48,772	--	1,53,91,669	--
2	2017-18	32,11,521	8.9	1,70,90,042	11
3	2018-19 (2nd RE)	37,66,294	17.3	1,88,86,957	10.5
4	2019-20 (1st RE)	37,50,567	-0.4	2,03,51,013	7.8
5	2020-21 (PE)	36,85,170	-1.7	1,97,45,670	-3
6	2020-21 (April-September)	16,69,646	--	86,14,840	--
7	2021-22 (April-September)	23,12,942	38.5	106,76,879	23.9

Source: National Accounts Division, CSO, MoSPI

The Minister of State in the Ministry of Commerce and Industry (Smt. Anupriya Patel)

In Lok Sabha

Meeting of GST Council

Unstarred Question No.2375

Shri C. Lalrosanga:

Q. Will the **Minister of Finance** be pleased to state:

(a) the main focus areas of the meeting of next Goods and Services Tax (GST) Council;

(b) whether the Group of Ministers (GoM) is reviewing the current rate slab structure including special rates;

(c) if so, the time by which GoM is likely to submit its report;

(d) whether any roadmap has been framed by the GST Council to help the small businesses and consumers; and

(e) if so, the details thereof ?

Answered on 13th December 2021

A. (a) The date of the next meeting of the Goods and Services Tax (GST) Council has not been fixed.

(b) The terms of reference of the Group of Ministers (GoM) on Rate Rationalization constituted on 24th September, 2021 include, inter-alia,

(i) Review the current tax slab rates and recommend changes in the same as may be needed to garner required resources.

(ii) Review the current rate slab structure of GST, including special rates, and recommend rationalization measures, including merger of tax rate slabs, required for a simpler rate structure in GST.

(c) The GoM on Rate Rationalization have already held two meetings and would submit the report once it concludes its deliberations.

(d) & (e) The GST Council, in its meetings have deliberated and taken various measures for the benefit of small businesses and consumers. Details of the salient milestones are as follows:

i. A threshold exemption limit of Rs. 40 lakh for goods and Rs. 20 lakh for services has been prescribed.

ii. A composition levy scheme is operational under which assessees with turnover below a specified threshold can discharge their GST liabilities in a simple manner at reduced rates.

iii. Taxpayers having aggregate annual turnover less than Rs. two (2) crore are not required to file Annual Return in FORM GSTR-9 and FORM GSTR-9A for F.Y. 2017-18, 2018-19, 2019-20 and 2020-21. Further, taxpayers having

aggregate annual turnover less than Rs five (5) crore are not required to furnish Annual Reconciliation Statement in FORM GSTR-9C.

iv. Quarterly Return Monthly Payment Scheme (QRMP) has been introduced with effect from 01.01.2021 for registered persons having aggregate turnover up to Rs. five (5) crore, as per which taxpayers have been given facility to file GST returns on quarterly basis, instead of monthly basis.

v. Late fee imposed for delayed filing of returns has been rationalized to reduce the burden of late fee on smaller taxpayers.

Minister of State in the Ministry of Finance
Sh. Pankaj Choudhary

CSR ACTIVITIES

Lok Sabha Unstarred Question No. 2451

Shri Hemant Tukaram Godse

Q. Will the Minister of **CORPORATE AFFAIRS** be pleased to state:

(a) whether the Government maintains the records of private/Government companies/organisations participating in CSR activities in various States including Maharashtra;

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

(c) whether the Government would help the public representatives to identify the companies/ organisations involve/invest in any particular constituency; and

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

Answered On 13th December, 2021

A. (a) & (b): The broad framework for Corporate Social Responsibility (CSR) has been provided under Section 135 of the Companies Act, 2013 ('Act'), Schedule VII of the Act and Companies (CSR Policy) Rules, 2014. The CSR framework is disclosure based and CSR mandated companies are required to file details of CSR activities annually in the MCA21 registry. On the basis of the filings made by the private/government companies in the MCA 21 registry, details of CSR funds spent by Public Sector Undertakings (PSUs) and Non-PSUs in various States/Union Territories (UTs) (including Maharashtra) for the financial years 2018-19, 2019-20 and 2020-21 are given below:

Nature of Company	FY 2018-19		FY 2019-20		FY 2020-21	
	No. of Companies	Total Amount Spent (in Rs. Cr.)	No. of Companies	Total Amount Spent (in Rs. Cr.)	No. of Companies	Total Amount Spent (in Rs. Cr.)
PSUs	615	4,206.30	452	5,241.57	20	561.18
Non-PSUs	24484	15,943.97	22079	19,447.09	1599	8,266.93
Grand Total	25099	20,150.27	22531	24,688.66	1619	8,828.11

(Data upto 30.09.2021) [Source: National CSR Data Portal]

Regarding CSR data for financial year 2020-21, it is informed that the companies are required to hold Annual General Meeting (AGM) within six months from the end of financial year. Thereafter, financial statements and board reports containing disclosures about CSR, are to be filed in MCA21 within 30 days of the AGM. In view of the disruption caused by COVID-19 pandemic, Registrars of Companies have accorded extension of time till 30th November, 2021 for conduct of AGMs by companies. The Ministry vide General Circular No. 17/2021 dated 29.10.2021 has relaxed the levy of additional fees till 31.12.2021 for filing of financial statement in respect of the financial year 2020-21.

(c) & (d): The Ministry had launched a National CSR Data Portal in 2018 for greater transparency and wider dissemination of information on CSR to the public at large. All data related to CSR filed by companies, including the list of eligible CSR companies, in MCA21 registry is available on said portal at www.csr.gov.in. Further, CSR is a Board driven process and the Board of the company is empowered to plan, decide, execute and monitor CSR activities based on the recommendations of its CSR Committee. The Government does not issue any specific direction in this regard.

Minister of State (Independent Charge) of the Ministry of Statistics and Programme Implementation; Minister of State (Independent Charge) of the Ministry of Planning and Minister of State in the Ministry of Corporate Affairs [Rao Inderjit Singh]

Investigations by CCI

Lok Sabha Unstarred Question No. 2466

Shri Kesineni Srinivas:

Q. Will the Minister of **CORPORATE AFFAIRS** be pleased to state:

(a) the details of the number of investigations undertaken by the Competition Commission of India (CCI) during each of the three years;

(b) the reasons for the declining trend if any, in the number of investigations undertaken by the CCI each year;

(c) whether the Government is aware of the drastically declining budgetary allocation to CCI and if so, the reasons therefor;

(d) whether the Government is aware of the recent revelations of large scale anti-competitive practices undertaken by firms in the alcohol beverage industry, if so, the measures being planned by the Government to strengthen the capacity of the CCI to thwart such anti-competitive practices in business; and

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

Answered On 13th December, 2021

A. (a) & (b): The details of the number of investigations undertaken by the Competition Commission of India ('Commission') during each of the three years are as follows:

Year	Number of Investigations ordered by the Commission in respect of anti-competitive agreements & abuse of dominant position	Number of Inquiries undertaken and disposed of, by the Commission in Combination Notices
2018-19	22	89
2019-20	20	81
2020-21	17	90

Since the Commission became functional, it has taken various proactive measures from time to time to ensure effective competition and fair play in the market. These, inter-alia, include conducting market studies on relevant sectors of the economy, undertaking competition assessment of the Model Concession Agreements in the public service delivery sectors, extensive and intensive advocacy outreach initiatives such as conducting workshops /conferences/webinars/roadshows on competition laws & practices etc. These have resulted in greater sensitization and understanding of different stakeholders including end-consumers as to the purport and import of competition law regime and accordingly, pure consumer disputes having no competition concerns, have declined. Further, with the enactment of the Real Estate (Regulation and Development) Act 2016, filings before the Commission in respect of pure consumer disputes related to real estate sector have also declined. Furthermore, the Commission has sought to imbibe a culture of competition compliance and self-regulation amongst the market participants. Thus, such initiatives and advocacy measures have supplemented and complemented the enforcement functions of the Commission, resulting in fostering competition in the markets ex-ante and thereby lessening the need for enforcement actions.

(c): The details of the budgetary allocation to the Commission during the financial years 2016-17 to 2020-21 is given below: -

Amount in Rs. crore

Financial Year	2016-17	2017-18	2018-19	2019-20	2020-21
Grant-in-Aid to CCI	92.10	119.27	151.56	55.49	46.15

The increase in Grants-in-Aid to the Commission during the Financial Years 2017-18 to 2018-19 was due to requirement of funds for a new office complex of the Commission, which the Commission has already occupied.

(d) & (e): The Commission has received cases alleging anti-competitive practices by firms in alcohol beverages industry and has issued appropriate orders, including imposition of monetary penalties.

In order to strengthen the capacity of the Commission to address anti-competitive practices by firms, the Commission has a dedicated in-house Capacity Building Division which undertakes capacity building

initiatives on regular basis by organising trainings/ workshops, etc. These programs are conducted with the help of international experts from overseas multilateral agencies and competition authorities as well as domestic experts and organisations specialising in the field of law, economics, finance etc. In addition, the Commission conducts in-house trainings as well as Peer-to-Peer sessions, where inter-divisional sharing of knowledge and information takes place. Also, the Commission deputes its officers for training by way of secondments with counterpart anti-trust agencies.

The Minister of State (Independent Charge) of the Ministry of Statistics and Programme Implementation; Minister of State (Independent Charge) of the Ministry of Planning; and Minister of State in the Ministry of Corporate Affairs.
(Rao Inderjit Singh)

Amendment to the NDPS Act, 1985

Lok Sabha Unstarred Question No.2530

Shrimati Sajda Ahmed:

Shri Shanmuga Sundram K:

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

(a) whether the Government has proposed to revamp the Narcotic Drugs and Psychotropic Substances (NDPS) Act, 1985 and if so, the details thereof;

(b) whether the Government is aware of the Tripura High Court judgment regarding the amendment to NDPS Act, 1985 with reference to Section 27A of the NDPS Act and if so, the details thereof;

(c) whether the Section 2(viiia) sub-clause i-v which decides the catalog of offences, does not exist after the 2014 amendment and if so, the details thereof; and

(d) whether the Government is taking steps to rectify the error pointed out by the Tripura High Court and if so, the details thereof?

Answered On 13th December, 2021

A. a) The Government has introduced a Narcotic Drug and Psychotropic Substances Amendment Bill, 2021 in the Lok Sabha on 6.12.2021.

b) Yes, the Hon'ble court had directed to take appropriate steps for amendment as required in Section 27A to rectify the anomaly.

c) The provisions of Narcotic Drugs and Psychotropic Substances Amendment Act, 2014 came in to effect from 01.05.2014. Prior to the amendment, clause (viiia) of section 2 of the said Act, contained sub-clauses (i) to (v), wherein the term 'illicit traffic' has been defined. This clause was re-lettered as clause (viiib) by the NDPS (Amendment) Act, 2014 as a new clause (viiia) in Section 2 defining 'essential narcotic drugs' was inserted. However, inadvertently, consequential change was not carried out in Section 27A of the NDPS Act, which cause an anomaly. Though in the matter of Julie Singh Vs Union of India in the High Court of Bombay at Goa the hon'ble court with regard to Section 27A of the NDPS Act had held that object behind the legislation and the purpose for enacting the same is clearly discernible. Therefore, the legislative intent of the statute, has always been to read clause: (viiib) in section 27A, and already stood therein

d) The Hon'ble President has already promulgated the Narcotic Drugs and Psychotropic Substances (Amendment) Ordinance, 2021 (8 of 2021) on 30.09.2021 to rectify the aforesaid anomaly and to carry out the legislative intent of the statute. The Government has introduced a Narcotic Drug and Psychotropic Substances Amendment Bill, 2021 in the Lok Sabha on 6.12.2021.

Minister of State in the Ministry of Finance
(Shri Pankaj Choudhary)

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Pharmaceuticals Export Promotion Council of India

(Set Up by Ministry of Commerce & Industry, Government of India)

PXL/HO/Cir-120/2021-22 **Date: 03.01.2022**

Hyderabad

IDMA (Indian Drug Manufacturer's Association)

Dear Sir/Madam,

Subject: 2nd International AYUSH Conference & Exhibition from 28-31.Jan.2022 at Sharjah, UAE

We are glad to inform member companies that 2nd International AYUSH Conference is taking place at Expo Centre Sharjah, UAE during 28-31 January 2022. The event is being jointly organized by **Science India Forum, Dubai & World Ayurveda Foundation, India**, and supported by **Consul General of India, Dubai & Ministry of AYUSH, Govt. of India and Pharmexcil.**

This event is a golden opportunity to make a Footprint of AYUSH organizations on the promising lands of **UAE** that is a **Global HUB for product display, inquiries, & trade.** Moreover, the Ongoing **Dubai World Expo 2020** has accelerated the footfall in the UAE region, and **Sharjah** being a residential hub for UAE & other Citizens assures maximum footfall to the Expo.

India's export of AYUSH and Herbal Products have touched Usd 539.27 mn with a growth rate of 35% over previous year indicates significant potential for exports in this region. This is a never-before opportunity to propagate and present AYUSH systems of medicine in their true element at this time of resurgence that we all are experiencing in India & abroad, especially during & after the pandemic.

Please note that 2nd IACE is a supported event by the Ministry of AYUSH under the International Cooperation Scheme. AYUSH stakeholders, with prior approval from the Ministry of AYUSH are entitled to reimbursement up to 75% of expenditure (whichever is less) up to a ceiling of Rs. 3 Lakhs, on air- travel (economy class), accommodation and product-display arrangement including hiring of stalls, on submission of application in prescribed format along with relevant documents as specified.Pl refer to the Ministry of AYUSH website for the updates & details. (Application forms attached)

Members are kindly requested to take advantage of the support from the Ministry of AYUSH.

World's Largest AYUSH Conference & Exhibition **with active support from the Ministry of AYUSH, Govt. of India**

- International AYUSH Exhibition Fair
- Participation from over 20+ countries
- Proposed International B2B Meet organsied by Pharmexcil (on adequate participation)

We are pleased to inform that there is a special discount of 10% on the Stall tariff for members of Pharmexcil. **The Stand cost for a 3 x 3 booth costs AED 12500 plus 5% VAT and for Pharmexcil members the stand cost is AED 11,250 plus 5% VAT. The floor plan is shared for your ready reference and booking the stands.**

Member companies are requested to kindly confirm your participation directly to Dr.Tanuja, Trustee, World Ayurveda Foundation at arogya@ayurworld.org');" target=_blank >arogya@ayurworld.org

We look forward to your active support & participation.

Thanking you,

with regards,

Uday Bhaskar
Director General


Organiser
WORLD AYURVEDA FOUNDATION
Supported by
Consulate General of India, Dubai
Ministry of AYUSH Govt of India
INTERNATIONAL AYUSH CONFERENCE & EXHIBITION UAE
2nd International
AYUSH Conference & Exhibition 2022
28-31 JANUARY 2022 SHARJAH EXPO CENTER
Patron
buimerc
Partner
pharmexcil
Co-organiser
NASYA
GHF
EAGA
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Appendix-II

Application Form for seeking reimbursement under the Scheme for Promotion of International Cooperation in AYUSH

"Incentive to drug manufacturers, entrepreneurs, AYUSH institutions and Hospitals etc. for international propagation of AYUSH" by participating in international exhibitions, trade fairs, road shows etc.

1. Name of the Organization:
2. Name and details of the event for which prior approval/ grant is being sought:
3. Address of the company/organization for which prior approval/grant is being sought
4. Status (Govt./Semi govt./Autonomous/Private)
5. Nature of organization and Standing in profession
6. Details of GMP certificate (For AYUSH Drug Industry only) or registration certificate for other AYUSH organizations.
7. Import Export Certificate (IEC)
8. List of products to be displayed/ displayed
9. Total annual turnover of last 3 years (in attached format)

Year	Total Turnover	Turnover related to AYUSH Products	Export Related to AYUSH Products
2000			

10. Whether Grant in aid has been received from Ministry of AYUSH earlier under IC Scheme, if so details thereon
11. Undertaking for not seeking/ taking any Grant in aid/ Incentive from Central Govt/ State Govt for the same purpose.
12. Total expenditure involved in participation of event.
13. Amount sought/ requested from the Central Govt. along with details of contribution by the Organization
14. Name of the authority to whom the draft is prepared for re-imbursement or grant is to be released:
15. Any other relevant information
16. In case of hospitals, No of Beds, OPD daily, IPD, ICU facility, Their Turnover details certified by CA, functioning since how long and in which stream (A,Y,U,S,H), whether the fair is related to the hospitals if yes then how, no. of staff person, if any specialized treatment is given/ Recognised by state or /Central govt./ NABH Accreditation or any other related Certificate.

Signature of the Head of Pharmaceutical Industry/MD/ Organization

Dated :

Documents at the time of reimbursement required within three months after the event is over:

1. Statement of the expenditure of participation in event attested by Chartered Accountant along with original vouchers/ receipts etc. on completion of the event;
2. Certificate of participation along with photographs of stall in the fair etc on completion of the event.
3. Copy of Pan Card and Aadhaar Card
4. ECS mandate form (Appendix-VII)

APPENDIX-VII

MANDATE FORM

ELECTRONIC CLEARING SERVICE (CREDIT CLEARING/REAL TIME GROSS SETTLEMENT (RTGS) FACILITY FOR RECEIVING PAYMENTS.

A. DETAIL OF ACCOUNT HOLDER:-

NAME OF ACCOUNT HOLDER	
COMPLETE CONTACT ADDRESS	
TELEPHONE NUMBER/ FAX/EMAIL	

B. BANK ACCOUNT DETAILS:

BANK NAME	
BRANCH NAME WITH COMPLETE ADDRESS, TELEPHONE NUMBER AND EMAIL	
WHETHER THE BRANCH IS COMPUTERISED	
WHETHER THE BRANCH is RTGS ENABLED? IF YES, THEN WHAT IS THE BRANCH'S IFCS CODE	
IS THE BRANCH ALSO NEFT ENABLED?	
TYPE OF BANK ACCOUNT (SB/ CURRENT/CASH CREDIT)	
COMPLETE BANK ACCOUNT NUMBER (LATEST)	
MICR CODE OF BANK	

DATE OF EFFECT:-

I hereby declare that the particulars given above are correct and complete. If the transaction is delayed or not effected at all for reasons of incomplete or incorrect information I would not hold the user Institution responsible. I have read the option invitation letter and agree to discharge responsibility expected of me as a participant under the scheme.

(.....)

Date: Signature of Customer

Certified that the particulars furnished above are correct as per our records.

(Bank's Stamp) (.....)

Date: Signature of Customer

1. Please attach a photocopy of cheque along with the verification obtained from the bank.

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'AI usage in Indian pharma still at a nascent stage': Mr. Ganesh Ramachandran

Mr. Ganesh Ramachandran, global chief information officer, Alkem Laboratories

The pharmaceutical industry has witnessed myriad changes over the last couple of years, be it in demand variation, input pricing pressure or the need to accelerate new product pipelines. However, Ganesh Ramachandran, Global Chief Information Officer (CIO), Alkem Laboratories, said the industry is still at a nascent stage when it comes to implementing advanced technologies such as artificial intelligence (AI), the Internet of Things (IoT) and blockchain. In an interview, Ramachandran discussed the role of emerging tech in the pharma sector, and the way forward in terms of collecting the right data while allaying privacy concerns. Edited excerpts:

What kind of emerging technologies are being deployed in the pharmaceutical industry today?

If we refer to the pharmaceutical industry, one sees many newer age technologies being adopted across the value chain globally, with research and development (R&D) at one end and front office at the other, though Indian pharma majors are rapidly looking to scale adoption. A lot of tracking on the whole R&D pipeline is ensuing to reduce the product launch time. Technology is also being leveraged to ensure there are fewer rejections and give the right kind of requirements from an entire project management perspective across different stages of filing.

Which are the places where tech such as AI, blockchain or IoT are implemented?

Multinationals overseas use a substantial amount of AI, while in the Indian context it is still at a nascent stage. In the global context, they are in a phase of discovering use cases in various business operations, in various current manual processes to eradicate manual intervention and make the processes more accurate.

In India, a lot of focus has gone on developing the right data models and ensuring data quality over the last few years, which is a key requirement to drive the usage of AI. Cost-sensitivity needs to be assessed as well, with labour costs not being as high as what one sees overseas. Having said that, one is beginning to see business teams looking to leverage the power of AI and machine learning

(ML), though these are more in a proof of concept (PoC) stage currently.

Quality is an area where immense tech is being used. While blockchain is being used for transparent data sharing between contractors or supply manufacturers, the adoption is just gaining momentum in India. I see blockchain use cases emerging between pharma majors and contract manufacturers to ensure that the quality levels are fine from inputs through to the finished product.

We have seen some major pharmaceutical companies being breached lately, how is the security issue addressed?

Although we talk about the IoT as one of the main pillars of industry 4.0, to link the information technology (IT) and operational technology (OT) is being seen as a potential area for a security breach. Some of these concerns are holding back organizations from going full swing on IoT implementation. One thing can be the IoT implementation for local areas, but again, it does not justify the kind of investments required. Thus, many organizations which had started out the implementation of industry 4.0 prior to the lockdowns have slowed down due to concerns around security, especially during the pandemic. Many of the organizations have looked at strengthening their cyber security posture, we are seeing zero trust, AI/ML coming into play, along with analytics for automated responses to threats.

What do you think is the way forward for pharma companies?

Unlike in consumer-packaged goods (CPG), where manufacturers have a good idea of the demand generated at retail, movement of stock at the stockists and consumer behaviour, pharmaceutical manufacturers in India have a limited view of the stockists, chemists, doctors and patients' needs and behaviours. To add to this a pharmaceutical organization typically has multiple divisions within an organization, with each division addressing a particular therapy.

The challenge comes when multiple divisions address the same doctor, leading to the doctor being duplicated at an organization level. This makes it challenging to get accurate details of the doctor in the customer relationship management (CRM) platform, and to ensure that organizations can personalize communication that would be relevant for doctors.

Pharma manufacturers are also looking to gain insights from doctors on whether the product is solving the requirements that doctors have or how products are faring against competitors, or which are the products that are not moving, to ensure availability of the right stocks at the right place at the right time. This is a classical big data problem where you have a bundle of data coming from all sources.

The way forward is to start by collecting the right data, keeping in mind privacy concerns and pooling in the different data sources.

Source: Moumita Deb Choudhury, Mint, 04.01.2022

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NATIONAL NEWS

Covid cases on the rise, experts call for newer drugs, faster approvals

The government should speed up approvals to, and ensure the availability of, new antiviral drugs and monoclonal antibodies that appear to work against Omicron and other variants of Covid-19, say doctors and hospitals as the number of new cases escalates.

The Drug Controller General of India had last week approved Merck and Ridgeback's antiviral molnupiravir for the treatment of mild-to-moderate Covid-19 at high risk of developing into severe disease.

However, the All India Institute of Medical Sciences and the Indian Council of Medical Research have not yet issued clinical guidance for the drug, even as states like Maharashtra that are seeing a surge in cases are keen on procuring the antiviral.

Molnupiravir works by introducing errors to the genetic code of the virus, preventing it from replicating further. Healthcare experts say some of the latest treatment are not yet available in India. "We have experience, manpower, ventilators, oxygen; what we are short of is access to Covid specific antivirals and monoclonal antibodies that work against both Omicron and Delta, and if taken early will prevent people from developing severe disease," said Alok Roy, chair of the Ficci Health Services Committee and chairman of the Kolkata-based Medica Group of Hospitals.

"The government should ensure availability of these therapies," Roy said.

Most Covid cases are mild that would require isolation, rest and medications such as paracetamol and cough suppressants, depending on symptoms.

However, for people above 60 years of age, and those having cardiovascular disease, hypertension, diabetes, obesity and other immunocompromised patients, Covid-19 may lead to severe disease, hospitalisation and death if not treated early. There is a wave of new antivirals and monoclonal antibodies cocktails such as Pfizer's Paxlovid, GSK's sotrovimab, Regeneron-Roche's casirivimab-imdevimab, Eli Lilly's bamlanivimab-etesevimab and AstraZeneca's tixagevimab and cilgavimab to treat Covid.

These can significantly cut severe disease and mortality and may prevent severe symptoms from developing in those who are at high risk.

However, the casirivimab-imdevimab and bamlanivimab-etesevimab cocktails that emerged towards the receding phase of the Covid second wave are not seen as effective in neutralising the Omicron variant. Besides, these are not without risks or side effects and need to be administered taking into consideration the cost-benefit.

"Oral antiviral pills such as molnupiravir and Paxlovid, have generated lot of excitement, as they are scalable, convenient ... and affordable against monoclonal antibodies which come in parenteral form, are expensive and need to be taken in a hospitalised setting with limited capacities," said Mandar Kubal, director, Infectious Diseases & Pulmonary Care, a Mumbai-based healthcare company that offers care against Covid and other respiratory diseases.

Pfize told ET that it is committed to making Paxlovid that appears to be effective against the Omicron variant available in India, but it didn't provide a timeframe.

Source: Viswanath Pilla, ET Bureau, 02.01.2022

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Take the third wave very seriously

The rapid rise in Covid cases is indication that India is experiencing a third wave. Lessons learnt, GoI has been vigilant, alerting states and stepping up genome sequencing of samples. Yet, caution has been thrown to the winds since Omicron is less virulent than Delta. Political parties see holding pre-election rallies as harmless. Some states are delaying action and others are still deploying ineffective interventions. Avoiding a repeat of the second wave requires individual members of the citizenry to take responsibility and governments to match those efforts.

In the US, Britain and Europe, more people are being infected by Omicron but fewer need hospitalisation, the latter being mostly requirements of a lower order. But even at lower rates, India's healthcare system could be overwhelmed. A fragile healthcare system augmented on the run may be pushed to the brink in an 'Omicron-plus' wave. Prevention must be the name of the game. Here, individuals have a critical role. They must strictly adhere to measures such as avoiding crowding, cutting down non-essential gatherings and masking. After two years, this should not be the hardship many make it out to be. This must be matched by sensible government response. Governments have the task of preventing transmission without disrupting the economy.

Even with low levels of virulence, Omicron can exact a huge economic cost. Some 3,000 flights had to be cancelled on a single day in the US due to Omicron cases in the aviation industry. Reducing the ridership capacity in public buses and metro leads to crowding. Suspending suburban train services disrupts livelihoods. Governments must take measures that facilitate economic activity while minimising transmission, using tech-enabled proactive options such as home delivery and restrictive ones such as WFH.

In democracy, people and institutions make up the system, each aware of their rights and duties. If India is to avoid being overwhelmed, then people and institutions must work in tandem. It would protect both lives and livelihoods. And the economy.

Source: ET, 03.01.2022

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Price war rages as pharma firms despatch Covid-19 antiviral pill

Competitive pricing among firms keeps rates at Rs 1,400-2,490 for full treatment

Oral Covid pill Molnupiravir will hit retail stores this week as companies have started despatching the drug all over the country.

Meanwhile, a price war is on among several companies launching Merck's antiviral drug.

After Mankind Pharma said it would price its Molnupiravir brand Molulife at Rs 35 per capsule, or Rs 1,400 for the full course of 40 capsules (eight capsules a day for five days), as the most "affordable brand" in the market, Hyderabad-based Dr Reddy's Laboratories (DRL) on Tuesday launched the drug at the same price.

R C Juneja, chairman of Mankind Pharma, said for some drugs affordability, not profit, was the key.

"We wanted our drug to be affordable. When the chances of hospitalisation reduce, the burden of such expenditure goes down for the needy," Juneja told Business Standard, adding that Molulife would be dispatched first to cities like Delhi and Mumbai, where the cases of Covid were high. It will go to smaller centres thereafter.

A DRL spokesperson said the company would launch the "most affordably priced molnupiravir" capsule (200 mg) under the Molflu brand.

The country's largest drug maker, Sun Pharma, has launched its brand Molxvir at Rs 38 per capsule, taking the treatment cost to Rs 1,520.

"We are launching a toll-free helpline to ensure the availability of Molxvir to doctors and patients," a Sun Pharma spokesperson said.

Pune-based Emcure Group is launching molnupiravir capsules under the name Lizuvira, which will be marketed by its subsidiary Zuventus Pharma. Lizuvira will be priced at Rs 1,750 for the full course. Cipla has priced its brand Cipmolnu at Rs 2,000 per course.

Hyderabad-based Hetero has launched its brand Movfor at Rs 2,490 for the 40-capsule course. Sources among those stocking the medicine said Aurobindo had done so at Rs 2,000.

While some brands like Molflu are expected to be available from early next week in pharmacies, stockists say they have started receiving dispatches of several brands.

"At the level of cost and freight agents, stocks arrived in the past few days. Several hundred packs have been forwarded to districts. For example, almost 40 of the 56 districts in Madhya Pradesh will receive stocks of molnupiravir in the next few days," said Rajiv Singhal, general secretary of the All India Organization of Chemists and Druggists (AIOCD), an umbrella association of more than 650,000 retail chemists in the country.

Singhal said more than 600 districts in the country would receive stocks within this week.

A senior executive at a Mumbai-based pharma firm said any brand priced below Rs 1,500 might have thin margins, but the huge volumes expected during the third wave were anticipated to more than make up for it.

Analysts say prices will go down once the third wave subsides.

Kunal Randeria, analyst with Edelweiss, said: "Favipiravir is no longer standard of care. Molnupiravir prices will not fall much from Rs 2,000 immediately as the demand is high. Once the demand recedes, there will be a price war. So it should remain at this level for now. Obviously government procurement will be at lower rates."

Companies are ready to scale up production if demand rises. Juneja said his firm was getting the brand contract-manufactured, but was ready to meet high demand quickly. Thirteen Indian companies got the nod from the drug regulator (Drug Controller General of India) on December 28 to manufacture and market oral antiviral drug Molnupiravir, developed by Merck and Ridgeback, for restricted use under emergency situations for those in the high-risk category.

The approval for Molnupiravir is significant because it can give affordable oral treatment for Covid. The drug targets the part of the virus called ribonucleic acid polymerase, which has not changed much even after mutations in the Omicron variant. The drug inhibits a replication of the Sars-CoV-2 virus and has been approved in the UK and the US, and it has been recommended for adult patients who have at least one risk factor in developing a severe illness.

Earlier this year, DRL entered into a non-exclusive voluntary licensing agreement with Merck to manufacture Molnupiravir and supply it to India and more than 100 low- and middle-income countries. In a first-of-its-kind collaboration in the Indian pharmaceutical industry, a DRL-led consortium, including Torrent Pharmaceuticals, Emcure Pharmaceuticals, Sun Pharma, and Cipla, has collaborated to sponsor, supervise, and monitor the phase III clinical trial in India, and presented its findings to the Subject Expert Committee.

Between March and April, these five companies had individually entered into non-exclusive voluntary licensing agreements with Merck Sharp Dohme (MSD) to manufacture and supply molnupiravir.

Source: Business Standard, 05.01.2022

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Commerce Ministry to launch Brand India Campaign to boost exports

Commerce and Industry Minister Piyush Goyal has recently reviewed the status of Brand India Campaign of India Brand Equity Foundation

With the country's outbound shipments all set to cross $400 billion this fiscal year, the Commerce Ministry is planning to launch Brand India Campaign to give momentum to exports of both services and products in new markets, an official said.

This campaign would serve as an "umbrella campaign" for promoting goods and services exported by India, the official said.

In the initial stage, the campaign would focus on Indian exports in specific sectors such as gems and jewellery, textiles, plantation products (tea, coffee, spices), education, healthcare, pharma, and engineering.

It would essentially focus on quality, heritage, technology, value, and innovation.

Commerce and Industry Minister Piyush Goyal has recently reviewed the status of Brand India Campaign of India Brand Equity Foundation (IBEF).

IBEF is a trust established by Department of Commerce with the primary objective of promoting and creating international awareness of the 'Made in India' label in markets overseas and to facilitate dissemination of knowledge of Indian products and services.

"The need for such a uniform campaign is necessary because at present, different sectors have been promoted with individual identities in different ways,"the official added.

The campaign approach would include focused export-oriented messaging to both buyers and consumers; new potential markets; Indian talent, tradition and modernity; and promotional events through digital channels and international events.

An agency will be selected and a Branding Steering Committee will be formed for the purpose besides creation of uniform logo identity, development of branding creatives (films, TVCs, print ads, digital banners).

Source: Business Line, 05.01.2022

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The uneven nature of India's export growth

Boosting export infra, striking beneficial trade deals, and focussing on tech-intensive exports is the way forward

International trade posted a strong recovery in 2021 on the back of relaxation in pandemic associated restrictions, economic stimulus from governments and rising commodity prices.

Globally, trade in goods is expected to reach record levels of $22 trillion in 2021, an increase of 23 per cent as compared to the levels in 2020, and 11 per cent as compared to the pre-Covid levels in 2019. The buoyant global demand also boded well for exports from India. Merchandise exports from India posted a strong recovery in 2021, reaching nearly $354.4 billion during January to November 2021. This was a 104.5 per cent increase over the corresponding period of 2020.

The increase was not simply due to a low base-effect as merchandise exports were also an impressive 19.3 per cent higher than the pre-Covid levels in the corresponding period of 2019.

During the first three quarters of 2021, merchandise exports far outpaced the pre-Covid levels, and the trend is likely to have continued in Q4 of 2021. Forecast by Exim Bank's Export Leading Index indicates a likely growth of 39.6 per cent during Q4 2021.

Diverse growth patterns

Notwithstanding the encouraging trends in global exports, the growth remained largely uneven across sectors. While sectors such as petroleum products, and industrial commodities were buoyed by increasing global demand and rising commodity prices, trade in sectors like automotive and electronics were disrupted by global shortage of semiconductors.

Growth in India's merchandise exports also mirrored this trend, with exports increasing in several traditional areas of competence like petroleum products, engineering goods, drug formulations, gems and jewellery, and textile and garments, but remaining far below pre-Covid levels in the sectors affected by semiconductor shortage such as cars and certain electronic components and electronic instruments.

The rising food security concerns in regions such as the Middle East and North Africa also led India to emerge as a reliable supplier of food products. Technology-intensive exports such as two- and three-wheelers, auto components and telecom instruments also recorded remarkable double-digit growth during the year.

Unresolved trade tensions

Several long-standing issues for India such as negotiations on fisheries subsidies, the highly ambiguous future of the Doha Round and persistent disagreements over reform of the multilateral trading system continued to pose challenges to rule-based trading regime.

Moreover, several of India's trade disputes, both as a complainant and as respondent, remained unresolved due

to the failure to reach a decision on appointments to the Appellate Body of WTO for the second consecutive year. Delay in reaching an effective outcome poses a potential threat of backlash against globalisation.

Growing regionalism

Promoting trade resilience through regional integration has been a noticeable trend in 2021. The African Continental Free Trade Area became effective from January 2021, and the RCEP also comes into effect from January 2022.

While these are likely to boost intra-regional trade, experts have time and again highlighted that the benefits of trade diversion and trade creation will most likely remain skewed in favour of a few, rather powerful member countries.

India finds itself in a dichotomy between the urgent need to foster trade relations in an era of growing regionalism and treading cautiously on account of its prior experiences with trade agreements. Driven by both these considerations, India is engaging in negotiations with partner countries for enhancing market access. India has recently entered into an agreement with Mauritius, which is its first trade agreement with an African economy.

Besides, negotiations are also underway for an India-EU trade agreement and India-GCC trade agreement, as also for bilateral trade agreements with Israel and Thailand, among others. Going forward, trade deals with top markets such as the UK and the UAE, among others, are also expected to materialise. Trade agreements are therefore expected to increasingly gain salience in India's trade relations.

Logistics and export infra

Notwithstanding the remarkable recovery in global demand, logistics cost and container shortages marked a severe dent on the ability to cater to the demand and led to backlogs in supply. While several short-term measures have been taken by the government to alleviate the challenges associated with container shortage, a long-term priority would be to boost the manufacturing of containers in the country.

Currently, container manufacturing is dominated by Chinese and Korean suppliers and building domestic capacities in this area would be crucial for achieving self-reliance.

The much-awaited logistics policy could also be a game-changer for Indian exporters, as reduced logistics cost could improve their export competitiveness. The policy needs to be complemented by efforts from State governments to strengthen export infrastructure. States need to enhance the utilisation of support provided under the Centre's Trade Infrastructure for Export Scheme (TIES) for strengthening export infrastructure.

As on March 12, 2021, only 18 States/UTs had projects approved under TIES. The States/UTs that have not availed support under the scheme account for more than one-third of India's merchandise exports. With improvement in export infrastructure, these States/UTs can further boost their exports.

The way ahead

With production likely to outpace consumption growth, commodity prices are expected to gradually ease during 2022. Consequently, exports of petroleum products, metals, and agri-products are likely to moderate, if the scale of exports volumes does not increase substantially to offset the decline in prices.

The growth momentum in exports from technology-intensive sectors is likely to be bolstered through the implementation of schemes such as the Production-linked incentive scheme. The likely extension of the Interest Equalisation Scheme for export credit would be a further boost to exporters.

Going forward, strengthening export infrastructure through State-level participation, striking mutually beneficial trade agreements, and diversification of exports basket towards technology-intensive sectors would be the core motifs of India's export growth strategy.

The writers are economists with the Export-Import Bank of India. Views expressed are personal

Source: Jahanwi Singh/Neha Raman,
The Hindu Business Line, 04.01.2022

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Over 100 cr Covishield doses given in India, abroad testimony of its safety, efficacy, says SII

Over 100 crore Covishield doses have been given in India and abroad which is a testimony of its safety and efficacy, Serum Institute has informed the DCGI which had

sought more data for granting full marketing approval to the Covid vaccine, official sources said on Tuesday.

Covishield is currently authorized for emergency use in the country. Serum Institute of India (SII), on October 25, had applied to the Drugs Controller General of India (DCGI) seeking regular market authorization for the vaccine.

The drug regulator in December sought more data and documents for it. Following this, Prakash Kumar Singh, the Director, Government and Regulatory Affairs at SII, recently submitted a response along with more data and information. In addition to the successful completion of phase 2/3 clinical study in India, till now, more than 100 crore doses of Covishield vaccine have been administered to the people in this country and worldwide, Singh is learnt to have stated in the response. Such a large-scale vaccination with Covishield and containment of COVID-19 infection is in itself a testimony of the safety and efficacy of the vaccine, he said.

Serum Institute of India sought approval for Covishield as a booster dose from India's drugs regulator citing adequate stock of the vaccine in the country and a demand for a booster shot due to the emergence of new coronavirus variants. (HT)

"It is a matter of pride for us that we have been a part of the world's largest vaccination drive under the dynamic and visionary leadership of our Prime Minister Narendra Modi.

"Under the kind guidance of Union Health Minister Mansukh Mandaviya, Team Government of India and leadership of our CEO Adar C Poonawalla, Team SII has been working relentlessly to manufacture and supply Covishield for making the world's largest COVID-19 vaccination drive successful," Singh is learnt to have stated in the reply.

Source: Financial Express, 05.01.2022

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Serum's Covidshield Technologies to merge with Biocon Biologics

CTPL is in the business of commercialisation of vaccines. BBL is engaged in the business of development, manufacturing, and commercialisation of biosimilars and other biologics. Vaccines were a natural adjacency to BBL's existing platform.

The board of Biocon Biologics (BBL) has approved the merger of Covidshield Technologies (CTPL), a wholly-owned subsidiary of Serum Institute Life Sciences Private (SILS) with Biocon Biologics, a subsidiary of Biocon.

Under the terms of the agreement, BBL will offer 15% stake to SILS. There is no cash consideration involved in this deal.

Covidshield Technologies is a private company and a wholly-owned subsidiary of Serum Institute Life Sciences, which has the rights to commercialise SILS vaccines.

CTPL is in the business of commercialisation of vaccines. BBL is engaged in the business of development, manufacturing, and commercialisation of biosimilars and other biologics. Vaccines were a natural adjacency to BBL's existing platform.

The merger with CTPL would allow BBL to enter the vaccine space. Post-merger of CTPL, BBL will get committed access to a 100 million doses per annum for 15 years, primarily from SILS's upcoming vaccine facility in Pune with commercialisation rights of the SILS vaccine portfolio, including Covid-19 vaccines for global markets.

BBL will generate a committed revenue stream and related margins, commencing H2FY23. Adar Poonawalla will have a board seat in BBL. Under the terms of the agreement, BBL will offer 15% stake to SILS. There is no cash consideration involved in this deal.

Source: FE Bureau, 05.01.2022

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Eyeing agri market, Australia offers tariff sops on 99% Indian imports

Australia has offered to give tariff concessions to 99% of its traded goods with India under the proposed bilateral free trade agreement in lieu of opening up of India's dairy and agriculture sectors through low or zero tariffs. Canberra is keen to export dairy products, grains, oilseeds and processed food to India. The two sides intend to complete the talks for an interim deal, called early harvest in trade parlance, by the end of this month.

"Australia has indicated to make their import duties zero on 99% goods at the time of entry into force of the agreement," said an official.

In FY21, India's exports to Australia- comprising refined petroleum, medicaments, railway vehicles including hovertrains, pearls and gems, jewellery, and made-up textile articles- were $4.04 billion, while imports were $8.24 billion.

Imports included coal, copper ores and concentrates, gold, vegetables, wool, fruits and nuts and lentils. India's exports of chemicals, fabrics, apparel, footwear and machine tools, among others could get zero-duty benefits. "Dairy and agriculture are sticking points. An interim package can include products where there is mutual consensus while the contentious issues can be taken up later," the official said.

Commerce and industry minister Piyush Goyal on Monday said that the interim agreement with Australia will cover "large areas of interest particularly our labour oriented sectors like textiles, pharma, footwear, leather products and agricultural products".

The two sides have agreed to conclude a long-pending FTA called a comprehensive economic cooperation agreement by the end of 2022.

However, industry experts cautioned about opening sensitive sectors like dairy and agriculture as they are huge employers. "Once sensitive sectors like dairy and agriculture are opened for Australia, others like the EU and the UK too will seek market access and make our products uncompetitive," said an industry representative.

Source: Kirtika Suneja, ET Bureau, 05.01.2022

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Preparing for 2022: Lessons and Strategies

As we enter into a new year, pharma industry's stakeholders talk about various strategies to implement the lessons learnt from the COVID-19 pandemic as India Pharmalnc embarks on the next phase of growth

Pace of vaccine development holds great potential for future of drug development

For the clinical research industry, the pandemic brought to the fore the need for expedited approvals and how a combination of innovative and tech-enabled solutions could fast track the process without compromising on patient safety and confidentiality.

The pace of vaccine development across the globe is testimony to the possibilities of expedited trials and holds great potential for the future of drug development. For emerging biopharma reliant on quick and nimble processes to progress their drug development aspirations, such developments hold much promise. The approach, however, requires the collaborative efforts of multiple stakeholders, amongst whom regulators play a vital role in creating an enabling environment.

India has been on the path of regulatory changes for the last few years. With the introduction of the New Drugs and Clinical Trial Rules in 2019, several regulatory concerns were addressed, resulting in a more balanced and robust regulatory environment. However, despite the progress made to date, there is a need to take stock, review how much we have gained and what more needs to be done to further strengthen the regulatory environment, particularly as we incorporate learnings and the best practices from the pandemic that can become the norm in the future.

The key enablers that will encourage research and innovation from a regulatory perspective are quicker approval and response time (regulatory approvals in some innovator countries like the US, EU and Israel take 20 to 40 per cent less time than India), simplification in the clinical trial submission and review process, inclusion of more technology/subject matter experts in the review and approval committees, and a more collaborative approach with sponsors. A key opportunity, and much needed by the industry is more digital enablement across various touchpoints in the clinical trial lifecycle and creating a robust technology backbone.

"While the pandemic saw the introduction of digital approval processes for clinical trial protocol review by ethics committees, more needs to be done and the regulators need to incorporate more tech-enabled options, such as decentralised trials (DCTs), which are becoming more pervasive world over."

Jinu Jose
Vice President, Head – Sales and Clinical Operations, R&D Solutions India

While the pandemic saw the introduction of digital approval processes for clinical trial protocol review by ethics committees, more needs to be done and the regulators need to incorporate more tech-enabled options, such as decentralised trials (DCTs), which are becoming more pervasive world over. These remote-based trials with patients participating from the comfort of their homes would be a significant advantage in a country like India which has such a diverse and geographically spread-out population. Tech innovations in DCTs include telemedicine, electronic clinical outcome assessments, e-consent and integrated digital health platforms such as participant reminders and other engagement tools.

Strengthening India's research and innovation ecosystem requires consistent and strong collaborative efforts of all stakeholder groups from big and emerging biopharma companies, startups and entrepreneurs, academia and clinical researchers. These stakeholder groups' efforts further need to be supported by growth enablers like infrastructure, financing, and supporting policies and regulations.

All of these developments hold promise for emerging biopharma companies that are flexible and eager to embrace new and innovative processes, be it for DCTs, remote monitoring, patient enrollment and more. There is no doubt that India is a significant market with untapped potential in the biopharma industry. As we come out of the pandemic, we need to take lessons from the last couple of years and work closely with regulators to build an ecosystem that is predictive and precise, and drives better patient outcomes in a country that has the second-highest patient population and the world's largest disease burden.

Technological trends are sure to transform pharma industry

In India, the pharma market is projected to reach $65 billion by 2024 and grow to $120-130 billion by 2030. Recent initiatives like the National Digital Health Mission (NDHM) and government attempts to unify the pharma sector are providing opportunities for innovation from within the pharma sector in different forms of technology. This includes AI and Machine Learning (ML) capabilities being used more extensively now than ever before.

"Precision medicine is coming from new technology that has allowed researchers to better understand and apply the differences in the way people respond to drugs"

Vinay K Mayer
Director, Market Research and Consulting, Asia Research Partners LLP

The use of AI and ML is propelling the drug discovery and development processes. Startups are employing these technologies to address the numerous challenges in the healthcare industry, including automation of manufacturing processes as well as designing effective post-launch strategies. Eligibility criteria identification is an essential step in the drug discovery and development process, which makes it vital for conducting clinical trials. AI simplifies patients' identification by making it fast and affordable, thus saving time for this key step.

The large volume of data available throughout the drug discovery and development process requires high-performance systems to properly analyse data and derive value from it. Therefore, pharma companies are looking to open up their data to third parties who can leverage those numbers for applications like modeling, thus making data management a crucial aspect of the innovation ecosystem. Moreover, the analytical techniques are used on almost all types of medical data from patient records, medical imaging, hospital data, etc.

Blockchain technology is being explored to track the sale of counterfeit drugs and substandard medicine that enter into the pharma supply chain and kill thousands of patients every year. The ability to share transactions makes blockchain a promising solution for securing transactions in the pharma supply chain ecosystem.

Mixed reality, virtual reality and augmented reality are making the visualisation of data a more meaningful reality than ever before, in several ways related to the biomedical sector. With tools like HoloLens, enterprises can cost-effectively design holographic augmented-reality applications that facilitate better interactivity with live-data samples and construction blueprints for example. Because

of this, there has been more exploration for potential human augmentation of pharma products in the manufacturing spheres.

The concept of precision medicine relies on the idea that each patient is an individual. Precision medicine is coming from new technology that has allowed researchers to better understand and apply the differences in the way people respond to drugs.

With advanced manufacturing methods like 3D printing and other innovations, precision medical manufacturing is helping shape how we, as a society, approach healthcare by focussing on making drugs more effective and less dangerous for individual patients.

Pharma technology has advanced to the point where we can now predict patients' behaviour and outcomes. Predictive models like this certainly help match patients with the most effective treatment plans.

The more we know about how each patient will respond to specific treatment plans, the better we are able to prevent adverse events and develop individualised plans for those who show signs of illness earlier in their healthcare experience. However, since their high costs prevent most businesses from adopting them, these technological trends are sure to transform the pharma industry.

Source: Express Pharma, 07.01.2022

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Doctors tread carefully on anti-viral Molnupiravir

Though 13 companies have approval to make the drug, safety concerns persist

Over 20 companies had approached the Indian drug regulatory authority for approval to make and market Molnupiravir, the newest antiviral in town to treat Covid-19. Thirteen received the go-ahead.

Molnupiravir is for treatment of adult patients with Covid-19

Despite multiple options of this capsule soon to be available to doctors, many in the fraternity are treading with caution to prevent a repeat of what the country witnessed during the second wave, where medicines were "overused".

Molnupiravir needs to be prescribed "conservatively" and long-term data maintained, given the safety concerns raised in different scientific quarters, they said. In fact, the Indian Council of Medical Research's Chief Dr Balram Bhargava further stirred the pot recently, admitting to certain safety concerns, including a condition that could affect women planning a pregnancy.

Genome mutations

Virologist Dr Gagandeep Kang explained, "The drug induces mutations in the virus so that it does not replicate. And the worry is whether it persists and alters the genome of the host, just as it did the virus."

The drug is not advised for pregnant women and those planning pregnancy. Those who are prescribed Molnupiravir need to be monitored and long term data maintained, said Kang, professor with The Wellcome Trust Research Laboratory, Christian Medical College (Vellore).

Clinical trials

Molnupiravir is from Merck and Ridgeback Biotherapeutics and their clinical trials have sought to address these safety concerns and indicated that this was not the case, said a doctor. But others worry about the dozen-odd companies vying with each other to sell this drug at different price points.

Dr Suranjit Chatterjee said that Molnupiravir must be given only to people whose condition could worsen and not to young people who are seen to be improving.

"I fear it's indiscriminate use, as seen with drugs like Remdesivir (an anti-viral) and steroids," he said, adding that Remdesivir and steroids had their benefits when prescribed at the right point of a person's infection.

The situation deteriorated when people started hoarding medicines during the second wave. And that is a concern with the surging Covid-19 cases and Omicron as a newer drug enters the market, explained Chatterjee, a senior internal medicine consultant with Delhi's Indraprastha Apollo Hospital. Given the mutagenicity concern, he said,

physicians need to use their judgement and refrain from giving Molnupiravir to young patients.

'Placed rightly'

Dr Emmanuel Bhaskar, professor of medicine with Chennai's Sri Ramachandra Medical College, urges caution with all antivirals, whether in treating Covid-19 or HIV.

With many companies bringing out the product, he cautions against "rampant" use, as that would cause resistance against the drug. Referring to the claim that the drug reduced hospitalisation by 30 per cent, he said there was a difference between absolute risk reduction and relative reduction, and from that standpoint, he did not see a benefit.

He expressed concern over the drug's "tolerability and side-effects where patients showed acute gastritis, vomiting and "confusion" (side effects involving the central nervous system)."

With eight pills to be given a day, he said, most patients were unable to finish their Molnupiravir course of five days.

Pointing to contraindications and interactions with other drugs, including some chemotherapy medicines, Dr Neha Mishra, Consultant (Infectious Diseases) at Bengaluru's Manipal Hospital, said Molnupiravir had to be "placed rightly" and given only to the profile where it can benefit a patient.

Source: PT Jyothi Datta , The Hindu Business Line, 07.01.2022

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No paracetamol, painkillers needed after getting Covaxin jab: Bharat Biotech

No paracetamol or painkiller is recommended after being vaccinated with COVID-19 vaccine Covaxin, Bharat Biotech said on Wednesday.

"We have received feedback that certain immunisation centres are recommending taking three paracetamol 500 mg tablets along with Covaxin for children. No paracetamol or painkillers are recommended after being vaccinated with Covaxin," Bharat Biotech said in a Twitter post.

Through the clinical trials spanning about 30,000 individuals, approximately 10 to 20 percent have reported side effects and most of them were mild, resolved within one or two days, and did not require any medication, the company further said.

Medication is recommended only after consultation with a physician, the vaccine maker said. Paracetamol was recommended along with other COVID-19 vaccines only and is not prescribed for Covaxin, it added.

Source: Pioneer, 06.01.2022

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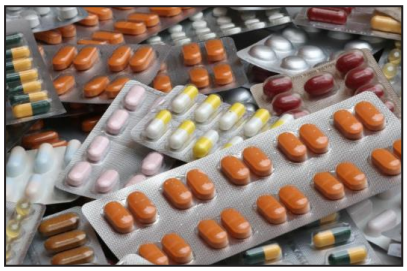
Kolkata: Medicine retailers sound shortfall alert, stock up paracetamol, antibiotics

KOLKATA: A sudden spike in the number of Covid-19 cases has prompted medicine retailers to stock up on medicines like paracetamol, cough syrup, azithromycin and ivermectin. The pharmacy associations have also asked the retailers to keep enough stock for paracetamol and

azithromycin suspension required to treat kids.

On Monday night, the All India Organisation of Chemists and Druggists (AIOCD) issued a letter to members of all states to keep sufficient stock of at least six medicines. The list of the medicines included all types of cough syrup, paracetamol tablets, vitamin C, zinc tablets, azithromycin and ivermectin.

"We have asked our members to prepare for the challenges in the time to come. The government is concerned that cases arising due to Omicron and Delta variants of the virus may increase. We have asked our members to



inform us immediately if there is any shortage of medicine," said Rajiv Singhal, General Secretary of the AIOCD.

Sajal Ganguly, secretary of the Bengal Chemists and Druggists Association said that no shortfall has so far been reported by the retailers. "Some medicines like paracetamol and azithromycin are going off the shelves fast. We have also asked retailers to keep enough stock of the two medicines required for children," he said.

According to Rajendra Khandelwal of Dhanwantary Pharma, there is no shortage of medicines so far. "People have started buying more immunity boosters like chyawanprash and multivitamins. Sales for Antihistamines and Montelukast are also on the rise. But sales of such medicines and health supplements go up during the winter," said Khandelwal.

In some pockets of Kolkata, retailers on Tuesday reported a very high demand of paracetamol and azithromycin. Retailers have also started to stock up antiviral molunopiravir which has received an emergency use nod from the Drugs Control General of India.

"There is also a high demand for zinc supplements and doxycyline. We have also stocked up molunopiravir as well but the demand is yet to pick up," said Somnath Ghosh of Metro Pharma.

But doctors cautioned against using any antibiotic without proper medical advice.

Source: TNN , 05.01.2022

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Rising Covid-19 tide lifts all pharma boats

Covid-19 has been a bane to many patients and their families, but nothing short of a huge boon to pharma companies.

The pandemic, which is now in its third year, has boosted the prospects of pharma industry goliaths and their smaller rivals alike, a closer look at their moving annual turnover (MAT) numbers showed by AWACS Pharmasofttech Pvt. Ltd's data.

While big-wigs such as Sun Pharma, Zydus Cadila and Cipla gained by selling Covid-related drugs, smaller companies such as Aristo Pharmaceuticals and Alkem Laboratories benefitted from strong demand for immunity boosters and gastrointestinal medicines, analysts said.

"Alkem and Aristo did not launch any direct Covid drug but were into the allied drugs space which benefitted them," Adbulkader Puranwala, Vice President at Elara Capital, said.

"Zincovit (which helps to prevent vitamin and zinc deficiencies) has become a Rs 650 crore brand during Covid but prior to Covid, it was a Rs 200 crore brand. Even for Alkem, their Vitamin brand A to Z was aRs 150 crore brand which turned out tobe Rs 260 crore brand during the pandemic," Puranwala pointed out.

Covid-19 was initially considered a respiratory disease, but the virus behind it can cause other issues in the human body and affect major organs including those that aid in digestion.

"Covid is definitely becoming a chronic disease and there is definitely a market, but in the long run, companies that look at the margin will benefit. There is a sizable opportunity in Covid which is why all these companies are benefitting," said Amit Khurana, Head of Equities and Research at Dolat Capital.

Aristo, Alkem, Abbott, Sun Pharma, Cipla, Macleods all figure in the list of the top 10 companies in the Covid and Covid-related space, as per AWACS Pharmasofttech Pvt. Ltd's MAT numbers.

Source: Veena Mani, Deccan Herald, 05.01.2022

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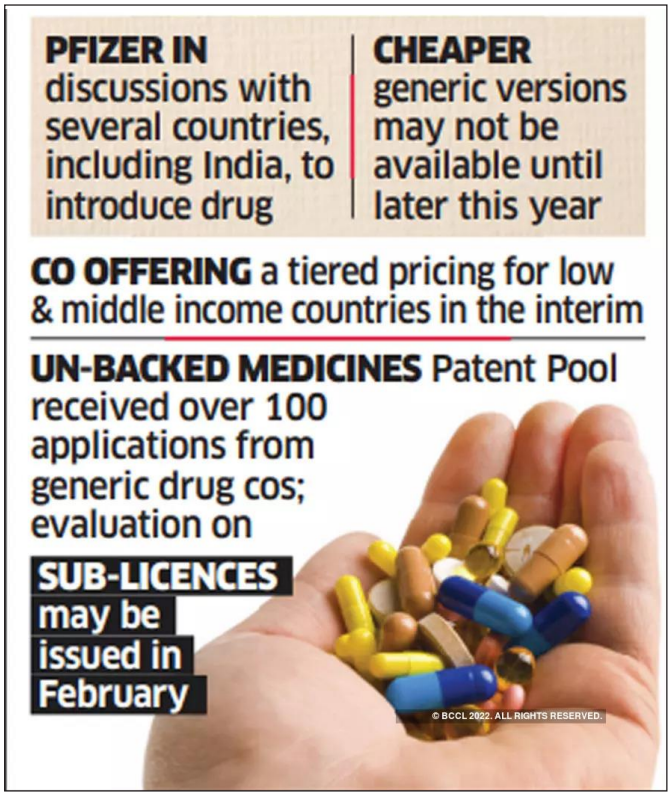
Pfizer may offer Covid antiviral drug to India at lower price for now

Pfizer may offer its Covid antiviral drug Paxlovid at lower prices for low and middle income countries (LMICs), including India, as an interim measure as the cheaper generic versions may not be available until later this year.



The company on Wednesday said it is in discussions with several nations, including India, to introduce Paxlovid. Pfizer has entered into advance purchase agreements with multiple countries. Sources told ET that Pfizer is yet to apply for emergency use authorisation in India.

The country is seeing a surge in Covid cases fuelled by the Omicron variant, and Pfizer's Paxlovid - a combination of nirmatrelvir and ritonavir - appears to be effective across variants. The antiviral has been approved in the US, the UK and other countries for emergency use.

The UN-backed Medicines Patent Pool (MPP) signed a voluntary licensing agreement with Pfizer in November, allowing the US-based drugmaker to grant sub-licences of Paxlovid to qualified generic drugmakers for supplying in 95 LMICs including India.

"We have received well over 100 applications and the process is currently ongoing. Once the (deadline for submitting) EoIs (expressions of interest) closed in December, the applications are blinded and the evaluation starts. We check each company through a number of criteria to ensure quality of production, this is then shared with Pfizer," said an MPP spokesperson.

'Vigorous Process' "With the checks ongoing, the current timeline for Pfizer sub-grantees to have signed a licence with us is February," the spokesperson added. MPP said those who sign will then be in a position to move to the next process that entails showing their product works as well as the original drug and getting quality approval from a regulator in an advanced country such as the US FDA, Emergency Medicines Agency (EMA) - the EU drug regulator - or secure WHO prequalification.

WHO prequalification determines the capacity of a manufacturer to produce a product of consistent quality as per international standards.

"Realistically these generic versions will not be available until later this year," the spokesperson said. "Pfizer is aware of this and is offering a tiered pricing for low and middle income countries in the interim," the spokesperson added.

MPP said the process is taking time because of the "vigorous process" that has to be adhered to. "It is true that the process may seem slow from the outside, but we are talking about life-saving medicines that need to be equivalent to the originator product. Therefore there is a vigorous process that has to be adhered to.

We have shortened these times as much as possible; the demand has been very high and we want to make sure that the best are selected," MPP said.

Executives of drug companies in India that have applied for a sub-licence of Pfizer's antiviral drug said the process of developing the drug is underway.

"We will be able to launch the Paxlovid generic in two months if the sub-licence is given at the earliest and the Indian drug regulator clears the application for emergency use," said a top executive of a pharma company who didn't want to be named.

Executives said the nirmatrelvir in Paxlovid is a novel and complex molecule to manufacture, and currently the key starting materials for the drug are sourced from a few manufacturers in China, and getting a reference product to establish bioequivalence would be challenging. "This will make even the generic version of Paxlovid at least 10 times more expensive than molnupiravir," another executive said.

India last week approved generic versions of Merck Sharp Dohme (MSD) and Ridgeback Biotherapeutics' Covid antiviral drug molnupiravir. The most affordable version

costs Rs 1,400 for the full course. Reuters had reported that the US government is paying around $530 per course (Rs 39,500) as part of its agreement to buy 10 million doses of Paxlovid from Pfizer.

Source: Viswanath Pilla & Teena Thacker, ET Bureau, 06.01.2022

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Indian pharma industry estimated to grow 9-11% in 2021-22: Icra

The Indian pharma industry is estimated to grow at 9-11% in 2021-22 and in the next few quarters, it will be driven by domestic and emerging markets, according to ratings agency ICRA. In a sample of 21 Indian pharmaceutical companies, ICRA said revenue growth was moderate at 6.4 per cent in the second quarter of FY22, down from 16 per cent in the first quarter of 2021-22.

The normalisation of the base and pricing pressures in the US market were the major reasons for slowing growth momentum in Q2 FY22, even as growth under domestic and emerging markets remained healthy, ICRA said in a statement. "Revenue growth for ICRA sample set is estimated at 9-11 per cent in FY2022 and in FY2023, supported by gradual recovery post the impact of COVID-19," ICRA Assistant Vice-President and Sector Head Mythri Macherla said.

In FY22, the sample set is estimated to have witnessed growth of 13-15 per cent in the domestic market, 14-16 per cent in the emerging markets and 9-11 per cent in the European business, she added.

Macherla said growth under the US business is expected to remain muted given the pricing pressure. In the domestic market, ICRA said a combination of steady normalisation in hospital footfalls and field force operations, given the relatively lower restrictions on account of Covid-19, continued traction in acute therapies and better pricing supported healthy revenue growth across companies.

Going forward, the ratings agency said sustenance of trend in doctor visits and elective surgeries given the news around the Omicron variant, and performance of new launches in addition to revenue growth momentum in the acute segment will remain key monitorables. ICRA said the emerging markets were the star performers clocking a robust 30.6 per cent year-on-year growth in Q2 FY2022.

It added that growth for the sample set was primarily led by new launches, low base, strong demand and rupee depreciation. As for the US market, the revenue growth for the sample set remained muted at 1.9 per cent during the second quarter owing to high single-digit to low teens price erosion and past inventory liquidation given the Covid-19-related uncertainties, it added. The outlook for the pharma sector remains stable led by healthy revenue growth and margins, ICRA said.

It added that it expects the sample set's capital structure and coverage indicators to remain comfortable despite higher capex and R&D (research and development) expenses given the robust cash levels.

This story has been published from a wire agency feed without modifications to the text. Only the headline has been changed.

Source: ET, 04.01.2022

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S.M.A.R.T Pharmaceuticals 2021-2030

Dr Ajaz Hussain, PhD and independent adviser, explains how to make common sense a SMARTfactory as the political and regulatory push for Industry 4.0 intensifies and take steps to understand options to align natural (i.e., within) and emerging artificial SMARTs - Self-Monitoring,Analysis and Reporting Technology in how we manage systems with Specific, Measurable, Achievable,Relevant, and Timely (or Time-bound) objectives

At the end of 2021, experiencing the surging uncertainty of Omicron as possibly a fifth coronavirus wave threatening a "Dark Winter" in the US and other countries, and anticipating advancing SMART factories making medicines called S.M.A.R.T Pharmaceuticals, this report spirals above the efforts on the ground supercharging the Industry 4.0 revolution to begin a professional journey to 2030.

Like some migratory birds navigate in the darkness using an internal "magnetic compass," this migration to the next stage of development utilises feelings (experience) to guide progress in uncertainty and complements vision 2020, naturally corrected SMARTly.

To prepare for this journey, let us recall some lessons in process understanding as defined in the "PAT Guidance" (2004) to make sense of anticipated chaos and pandemonium in this decade of the 21st century and know what it will take to be a "good practitioner." To be objective and evidence-based in our journey, let us select a predicated point of reference, the letter and spirit of the US Food, Drug, and Cosmetic Act of 1938, as amended in 1962.

Acknowledging that nothing is perfect, errors can occur but not repeat as mistakes. When necessary, course-correcting should be based on good and non-theory laden observations. Efforts to improve continually, based on continuing "scientific training and experience" is needed to *"fairly and responsibly"* deliver "substantial evidence of effectiveness." Let us begin to explore how to make common sense of SMART as Industry 4.0 advances and take steps to understand options to align our

natural and emerging artificial SMART - Self-Monitoring Analysis and Reporting Technology in how we manage systems with Specific, Measurable, Achievable, Relevant, and Timely (or Timebound) objectives.

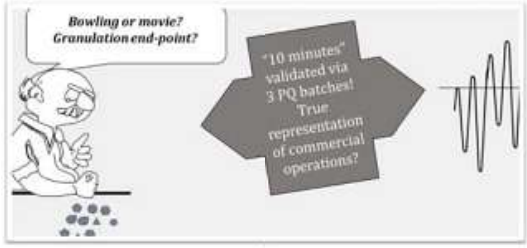

Figure 1 memorialises a point of initiation of the PAT initiative at FDA; it is included to invoke some thoughts and emphasise the importance of contemporaneous notes. In this case, a contemporary record; a presentation slide in 2000. It memorialises how the PAT/QbD journey began in 2000. Few presentation slides can still be found on the internet of the talk entitled "Advanced Quality Control of Pharmaceuticals: In-line Process Controls" at the FIP Millennium Conference, San Francisco (2000), by the author and his collaborator Dr Tom Layloff then at the USP. A related video message recorded in 2004 is available on YouTube; those interested can let their fingers go walking to locate it

"SMART Pharmaceuticals" invokes the notion of digital therapeutics and pills with embedded sensors that digitally track behaviours and medical surveillance and, broadly any pharmaceuticals made in a "SMART factory." Pharmaceuticals manufactured in standard and a "SMART factory" are the subjects of this report. Continued professional development is essential to remain "current" in pharmaceutical product development and manufacturing. The suitability and capability needed to do so in this decade will increasingly be gauged in the context of managing *fairly and responsibly,* locally and broadly, across sociotechnical systems we live and work.

The ensuing narrative intends to objectively empower individuals to progress in their efforts to develop to their next stage of maturity via attention to and proficiency in a valid experiential learning process.

What does it mean to learn from the experience? Do we do so with an SOP or broadly when allowed to experience different viewpoints and encouraged to innovate? What if such opportunities are not offered - how to self-empower are some questions explored implicitly in this report. The exploration itself is an experiential journey in practicing to take a migratory bird's-eye view to observe events in the real world from different viewpoints including insights. Within our worldview or scope is the experiential learning at the initiation and evolution of PAT initiative[1] at the US FDA, some twenty years ago and described in a journey from 2013 to 2020. How can this help to anticipate progress of the Industry 4.0 revolution in manifesting SMART factories by 2030 is considered.

We experience unfairness in life and at work (in new drug development, manufacturing, and all functions) as negative emotions such as anger and hate. To consider the relevance of *"fairly and responsibly"* in the regulatory context, this report reminds of practices such as *"file [ANDA] first and figure it out later,"* incentivised in the FD&C Act and habitually mandated in parts of the sector. Regulatory approval is often a reason to celebrate and grant bonuses to the development and regulatory departments. However, if or when the manufacturing and quality department struggle to reproducibly manufacture an "FDA approved" product with a process claimed to have been "validated," the finger is pointed at who?

The Subject of this Report is Experience

The word *"experience,* derived from Latin experientia," "means a trial, experiment knowledge gained by repeated trials", and as a verb, it means having first-hand knowledge of states, situations, emotions and sensations.

In the regulated CGMP environment, processes are expected to be "validated," and validity provides a high level of assurance of repeatability and reproducibility of predicted results. Hence, to be considered good, personnel must follow "valid" procedures, no matter the outcome.

Experiments to ensure repeatability are for the development phase exhibit batches. When transferring technology from development to operations, reproducibility by representative operators is

verified as the process qualification, part of process validation as described, for instance, the FDA guidance. Adequacy of qualification, which is supposed to include the representative experience of the operators who will manufacture routinely. However, it is often difficult to assess the state of validation without continued process verification. Therefore, it is not uncommon to note lagging indicators of control and reactive events resulting in regulatory warning letters.

Such events can induce fear, and negative emotions are not conducive to learning. So, what does it mean to learn from experience in a CGMP facility and broadly when one must comply with Standard Operating Procedures (SOPs)?

As a good practitioner, responsibility, in part, is trustworthiness. With the "validation" of our professional development and maturity, *albeit* a subjective judgement, others should fairly and responsibly recognise individual "suitability" (for instance -to be fair) and "capability" to be responsible and, in the context of promotion, take on increasing responsibility. Can Artificial Intelligence (AI) as a SMART supervisor be more objective than a human supervisor?

What does 'exploration narrated is an experiential' noted above mean? It means an objective process is followed to account for feelings (experience). Such a process guides the ensuing discussion. It emphasises unbiased, non-theory laden observations, as illustrated in *Figure 2*.

Being wedded to our theories and plans can be comforting. Actively being aware of exceptions to expected results can take us outside our comfort zones, egos and self-interest. When we do not acknowledge unexpected results, as often also observed with adverse reports and phase-IV commitment, it represents a conflict of interest. It takes away from our commitment to being *fair and responsible*.

In committing to being open to new data that may not be what we expected and practising to be a good observer, we test and challenge our plans, theories, and practices and go beyond our education and training to continuously experience and empower our development. So, then what is it that helps us to be SMART within, naturally?

Figure 2. The need to go beyond the theory and practice of industrial pharmacy to be vigilant has never been so acute as it is today. This report expands awareness of the need to validate a personal experiential learning process

Naturally, SMART within

In most corporations, it is a typical course of business for management to instruct how to set objectives for annual performance review. A SMART process of establishing and implementing performance objectives involves aspects of SMART as in self-monitoring progress, analysing deviations per plan, course corrections, remediation, and achievements, and providing periodic reports using accepted techniques such as reports, emails, etc.

In *Table 1*, the Specific, Measurable, Achievable, Relevant, and Timely (or Timebound) management objectives with Self-Monitoring Analysis and Reporting Technology in *Column 2* as an interaction or an interrelationship(⋈)and *Column 1* a reminder to introspect on the previous performance (2021) and *Column 3* performance considerations for learning from experience going forward (2022-).

The elements outlined in *Table 1* are deceptively simple.

Table 1. Mind matters, naturally. SMARTs within to consider introspecting on 2021 performance, engage SMART interaction, and interrelationship(⋈)between objectives and experience in 2022 and know-how to empower and enhance experiential learning in 2022

Performance 2021	Objective Experience 2022	Learning from Experience 2022
Objectives 2021	Specific(⋈)Self	Self-authored and self-assured
Measure/monitor?	Measurable(⋈)Monitor	Observe, feel, think and intend
Achived or not able?	Achievable(⋈)Analysis	Recognize (patterns), reproduce, repeat
Reported relevant?	Relevant(⋈) Reporting	Note insights contemporaneously
On-time or not?	Timely(⋈)Technology	Texts, blog, report writing

What does it take to be SMART within, naturally in ways that ensure our commitment to the stated mission, vision, policies, and objectives we document? Sometimes or often as the case may be, it is hard to set SMART goals and be smart about these objectives and be committed? What "life experiences" are foundational to adult development and maturation? Some adults continue to mature, but at different rates; many do not. What are experiences relevant to professional development? How do these relate to experience as a mode of qualifying requirement for CGMP operations as in the US regulations at 21 CFR 211.25, education, training, and experience"? We can extend this question to other functions, for instance, experience as a qualifying criterion for new drug development in the context of the US Food, Drug and Cosmetic Act of 1938 as amended in 1962, the Kefauver Harris Amendment, or "Drug Efficacy Amendment." This amendment is considered to have revolutionised new drug development, and among other things, stipulates *"scientific training and experience"* to *"fairly and responsibly"* evaluate *"substantial evidence of effectiveness."*

Seeking experiential, not theoretical, insights to these and other questions, I embarked on a journey to 2020 (why 2020 is explained later) in 2013. As the core purpose, I sought answers on how experience interrelates and interacts with quality culture, management systems and good practices before the WHO declared the novel coronavirus (COVID-19) outbreak a global pandemic.

After providing an overview of this journey, the relevance of the insights collected is discussed in the context of SMART Pharmaceuticals 2021-2030.

The journey to 2020: "I can see clearly now."

Serendipitously in mid-2012, I returned to the pharma sector when the attention of the US FDA was sharpening on BAD-I, a topic familiar since when I had moved to the US FDA, leaving behind the comfort of a tenured academic career. I chose the word serendipitously because I had not expected return to the pharma sector, given that I had crossed its boundaries to venture into the tobacco sector. Venturing into the tobacco sector and working on tobacco harm reduction had expanded my awareness of human behaviour, development, and behavioural economics, which informed my journey to 2020.

After a year with Wockhardt, I launched my consulting practice 'Insight, Advice, and Solutions' in July 2013. Soon, two topics - 'Human Factors in GMPs' and 'Culture of Quality' - dominated my teaching and public speaking engagements as a growing cluster of GMP deviations specifically breaches in the assurance of data integrity or BAD-I dominated the sector. Given the opportunity to interact with-pharma professionals up and down and across an organisational hierarchy of several companies, it was an opportunity to explore how experience interrelates and interacts with quality culture, management systems and good practices. The commitment to do so until the 2020 calendar year is my journey to 2020 literally and metaphorically - "I Can See More Clearly Now," and it reconnected me to the launch of the Process Analytica Technology (PAT) Initiative at FDA, where in November 2001, I wrote a few statements to describe a vision of pharmaceutical quality in the context of the, and I titled it 'Vision 2020'- "I can see clearly now."

On this journey, I sought to take a development stance via adaptive and experiential learning focusing my attention on insight as a symbolic "internal magnetic compass" to notice patterns of interactions and inter-relationships between observations, feelings, thoughts and intention to make sense of experience, what it meant, an insight, which I recorded contemporaneously and my learning shared with my network on social media such as *LinkedIn* (e.g., blog posts and articles) and broadly with the community of pharmaceutical practice and knowledge via industry news and update media such as *Express Pharma* and *Biopharm Asia*, industry experts panels such as CPhI community, publication of professional associations such as Indian Pharmaceutical Association's (IPA) Pharma Times, and the American Association of Pharmaceutical Scientists Journal AAPS PharmSciTech and also a public-private partnership with US FDA - the National Institute for Pharmaceutical Technology and Education (NIPTE). *Table 2* lists the dates and titles of some of these reports to provide a glimpse of

Table 2. Timely, relevant insights reporting helped gauge and monitor progress and provided a means to take a development stance to leverage natural intelligence via SMART within to self-assess progress in self-authorship

Outlets	Date	Title
LinkedIn	23.12.2014	Schrödinger's Cat & My Journey From 2015 to 2020
	29.12.2015	Six Blind Men, Regulatory Science, "Bob's Big Idea" and Gandhi's "a way out of hell": Goodbye 2015
	30.12.2016	"New Prior Knowledge": Roadmap 2017
	30.12.2017	Will Remember 2017 As the Year of Confirming an Amazing Juxtaposition. Message for 2018 - Jump Frog Jump, While You Can!
	31.12.2018	Moving forward with 2020 Vision
	25.12.2019	Vision 2020+: End of a Journey
	22.12.2020	A journey without traveling
Express Pharma	16.11.2013	Strategies for making high pharmaceutical quality affordable
	15.05.2016	Pharma quality assurance in 21st Century: Sharper focus needed on education, training, and experience
	20.05.2017	Strategies for making high pharmaceutical quality affordable: Part II
Biopharm Asia	09/10. 2015	The culture of Pharmaceutical Quality: Connecting the Dots
	11/12. 2015	The culture of Pharmaceutical Quality Management System
	03/04. 2016	The culture of Pharmaceutical Quality: Personnel Development
CPhI Annual Industry Report	10. 2016 (Barcelona)	Adherence to the Current Good Manufacturing Practice (CGMP) Regulations in the 21st Century (also published as Compliance or Adherence? How To Approach cGMP Regulations In The 21st Century? Pharmaceutical Online. Guest Column | 22 September 2016.)
	10. 2017 (Frankfurt)	Self-authorship of Performance Standards is Necessary to Break the Pharmaceutical 2-3 Sigma Barrier (also published as How to Break the Pharmaceutical 2-3 Sigma Barrier (Like Amgen). Pharmaceutical Online. 18 September 2017.
	11. 2019 (Frankfurt)	Chaos to Continual Improvement: Path to Harmonization
Pharma Times	06. 2014	Guest Editorial: Pharma Times Special issue on QbD in Pharma Development
	06. 2020	Pharmaceuticals Beyond 2020: Professionals and Artificial Intelligence. Indian Pharmaceutical Association
	12. 2020	Digitization in Pharma and Digital Therapeutics: A Migratory Birds Eye View for Charting a Path Forward
	Several	Mean Meaning Making and Manufacturing Maturity | A Column
AAPS PharmSciTech	02.01.2019	Shah, H.S., Chaturvedi, K., Hamad, M. et al. New Insights on Solid-State Changes in the Levothyroxine Sodium Pentahydrate during Dehydration and its Relationship to Chemical Instability. AAPS PharmSciTech 20, 39 (2019). https://doi.org/10.1208/s12249-018-1264-0
	12.03.2019	Hussain, A.S., Gurvich, V.J. & Morris, K. Pharmaceutical "New Prior Knowledge": Twenty-First Century Assurance of Therapeutic Equivalence. AAPS PharmSciTech 20, 140 (2019). https://doi.org/10.1208/s12249-019-1347-6
	24.05.2020	Gurvich, V.J., Hussain, A.S. In, and Beyond COVID-19: US Academic Pharmaceutical Science and Engineering Community Must Engage to Meet Critical National Needs. AAPS PharmSciTech 21, 153 (2020). https://doi.org/10.1208/s12249-020-01718-9
	04.03.2021	Hussain, A.S., Morris, K. & Gurvich, V.J. Pharmaceutical Quality, Team Science, and Education Themes: Observations and Commentary on a Remarkable AAPS PharmSciTech Theme Issue. AAPS PharmSciTech 22, 88 (2021). https://doi.org/10.1208/s12249-021-01970-7
NIPTE related	18.12.2016	NIPTE 2016: from roadblocks to roadmap-2017, with a 2020 vision. President's report. 2016. https://nipte.org/wp-content/uploads/2018/10/Roadblocks-to-Roadmap-2017-with-A-2020-Vision-12182016-Final-Version.pdf.
	16.06.2016	The National Institute for Pharmaceutical Technology and Education, Inc. (NIPTE) recommended topics for inclusion in the FY 2017 Regulatory Science Plan. 16 June 2016. Docket ID: FDA-2013-N-0402. Generic Drug User Fee Amendments of 2012; Regulatory Science Initiatives Part 15 Public Meeting, 2016.
	10.04.2017	How Trump and the FDA Can Create a Pharmaceutical Manufacturing Renaissance. Opinion | Morning Consult. https://morningconsult.com/opinions/trump-fda-can-create-pharmaceutical-manufacturing-renaissance/
	24.06.2018	The National Institute for Pharmaceutical Technology and Education, Inc. (NIPTE) recommends planning FY 2019 GDUFA regulatory science initiatives. Submitted 24 June 2018, to Federal Register Docket FDA-2017-N-6644.
	08.12.2020	Industrial Policy and NIPTE: Goodbye NIPTE. 2020 NIPTE Research Conference. https://www2.slideshare.net/a2zpharmsci/industrial-policy-and-nipte-goodbye-nipte

how the journey progressed. Beyond daily posts, over 45 articles are posted on *LinkedIn;* only the "end of the year" articles are listed. In December 2014, when insight into the value of social media posts to experiential learning was noted, the journey from 2015 to 2020 was named- *'Schrödinger's Cat & My Journey From 2015 to 2020.'* Further, not listed in *Table 2* are recordings and posted slides of conference presentations (if in-terested, see: YouTube *https://www.youtube.com/chan-nel/UCRkXTgz4kZ7WQdYO1uf9RyQ* and SlideShare *https://www2.slideshare.net/a2zpharmsci/).*

It is beyond the scope of this report to summarise all insights collected. So, in this section, a few topics are elaborated.

What is a good quality culture? A sentiment (force) permeating the environment to help us expand our awareness and simultaneously empowers all to continue their development and maturity from their current capability and suitability. The commitment and message credibility of founders, promoters, corporate board and officers to generate quality culture is a social force, as is fairness and responsibility to pursue the stated mission and vision per formulated quality policies and incentives. These forces permeate horizontally and vertically with "peer involvement" and "employee empowerment" via formalised and informal interrelationships and interactions we call reporting and meetings. Intentionally becoming aware of and leveraging this force, horizontally and vertically, in any hierarchy is how the enablers interact and interrelate to share their source code openly so that others can assess and, when convinced, use it to build their executable continuous development programmes - stand-alone or aligned with an enterprise-wide system.

We sustain and build a quality culture in moments that can be gauged in the choices of words to report minutes of meetings. A pledge of commitment can be a reinforcing interaction to understand a quality policy that typically hangs on a wall.

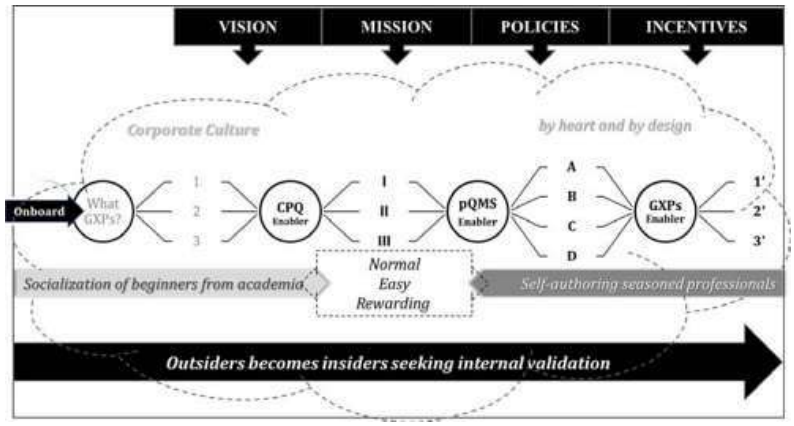

Figure 3. A simple "connect the dot" framework to visualise makes sense of cultures as a network of modulating interactions and interrelationships as in a neural network between people, systems and the sentiment (social force) in an environment that makes good practice normal, easy and rewarding

Recruitment and onboarding (- IQ) and orientation (-OQ) are socialisation processes that should carefully transform outsiders into insiders to build teams and prevent "groupthink" by actively remover fear, expanding awareness and empowering mastery to be internally validated to self-author procedures and plans to be selfassured in their responsibilities and demonstrate suitability and capability of taking on increasing responsibility. To give others assurance with integrity, we first must be self-assured. The relevant interactions and interrelationships to achieve these objectives should formally be a part of the pQMS such that metaphorically anybody can dance - ABCD. We recognise knowledge and risk management as key enablers of pQMS; ABCD calls for a formal, systemic effort to acknowledge and manage uncertainty and expectations on deviations, OOS, CAPA, continual improvement and continuous professional development. In the letter and spirit of the FD&C Act, theory to practice takes us to commercial operations, commitment to being vigilant, good observers, and experience is essential to sustain credibility and develop professionally.

The PAT initiative, which opened the door to FDA's Pharmaceutical CGMPs for the 21st Century: A Risk-based Approach and to Pharmaceutical Quality for the 21st Century at the International Conference for Harmonisation, ICH - which now is the International Council for Harmonisation, resulted in several "guidance documents" and this process continues to spiral with a draft ICH guidance on continuous manufacturing and a concept paper to spiral back to update ICH Q2 in the framework of analytical quality by design to facilitate real-time control and product release. In a highly heterogeneous sector spread across developed and emerging economies, converting this information to knowledge in practice remains a perpetual challenge. Efforts to educate and train need to be complemented with experiential learning to overcome this challenge. To facilitate experiential learing, we must change how we feel and think, and act synchronously. A quality culture needs to simplify interactions and interrelationships between management systems and practitioners to make it normal, easy, and rewarding.

The pharmaceutical sector is a heterogeneous collection of small and large corporations. Recruiting, onboarding and orientation programmes vary considerably - from "walk-in hiring" to elaborate orientation with programmes for continuous professional development. At most, the notion of system and systems thinking and quality culture can be amorphous and "brand" identity at few corporations. The frequency at which the US FDA CGMP inspections are the only objective assessment of quality system effectiveness can be unacceptably high. Therefore, this journey aimed to collect insights to facilitate individual empowerment of continuous professional development and maturity. Facilitation means removing barriers, blind spots, sharing know-how and acknowledging that - *"You have to do your own growing no matter how tall your grandfather was."* -**Abraham Lincoln**. The opportunity to take a development stance while interacting and interrelating within (novice, seasoned professional, and at the board level) and across systems (multi-university collaboration, regulatory and political systems), i.e., taking a "system of systems" (review articles an reports in *Table 2*) perspective was indeed an experience worth wring and learning. The process of experiencing in practice remains similar; the challenge we confront varies, and what we experience, changes. For instance, we worry that we will look bad (to others), seek validation of our opinions, proposals, etc., or we seek to belong to a group, we feel self-assured (internally validated), or we can see the potential to do good in others despite their failures. Although our development and maturity occur in many dimensions - the emotion in seeking to look good (to others) to be (considered) good by others point to a development stance in which we are seeking external validation, whereas "do good" and "see good" in others point to internal validation.

The following observations on human experience in interaction with smartphones are worth mentioning here. SMART's addictive, enslaving power is troubling in trend and scope. "Aiyo! my SMART phone is developing more efficiently than I, a phrase I wrote in 2020 in an article entitled "Pharmaceuticals Beyond 2020: Professionals and Artificial Intelligence."

Given that artificial SMART is a human invention, it should be obvious that it is manifested from within; obviously. Far from it, it seems to be hidden in plain sight, and for a large sement of the population, far from being obvious. Our dependence on SMARTs can retard our ability to feel in ways to empathise.

The feeling (experience) can be a inner compass, and learning using it objectively is essential to development and maturity. Like a migratory bird, the ability to simultaneously attend to details and panorama during planned introspection and integrate feelings helps to make good sense in uncertainty; this is "Vision 2020+" elaborated in the article (see *Table 2*) "Digitization in Pharma and Digital Therapeutics: A Migratory Birds Eye View for Charting a Path Forward." Such a journey can be transformative, expanded awareness and appreciation of the need to emphasise professional development, which we will discuss further in the current (2021) context and look forward to 2030.

Journey for 2021 to 2030: S.M.A.R.T Pharmaceuticals

A key lesson learned is that vision 2020 was necessary, but not sufficient; Vision 2020+, analogous to the bird's eye view with left-right lateralisation and a built-in magnetic com-

pass to migrate in darkness, is needed to be suitable and capable in chaos - an unpredictable system showing extreme sensitivity to initial or starting conditions.

Amidst the chaos and pandemonium in multiple systems, which are disrupting our supply chains, we must become aware of the S.W.O.T (strength, weakness, opportunities, and threat) of [our] development and maturity in today's realities to prepare to plan and keep these current in being ready to modify the our plans smartly. Concerted effort to "reset" the financial and economic systems and political "build back better" mandates intending to accelerate the revolution we refer to as Industry 4.0 can pose threats and present opportunities which we miss out with lingering weakness and leverage in our maturity, which is now a key strength. To begin such an analysis, we need to know our current state, the leading edge of competition, and the time it takes to be competitive per corporate mission and vision.

The stages in the adult development and maturity model for a SMART factory are illustrated in *Figure 4*. The leading edge of a digital plant is stage III- the Connected Plant. It is anticipated that several plants will be at maturity stage V - end-to-end automation, machine-to-machine communication and

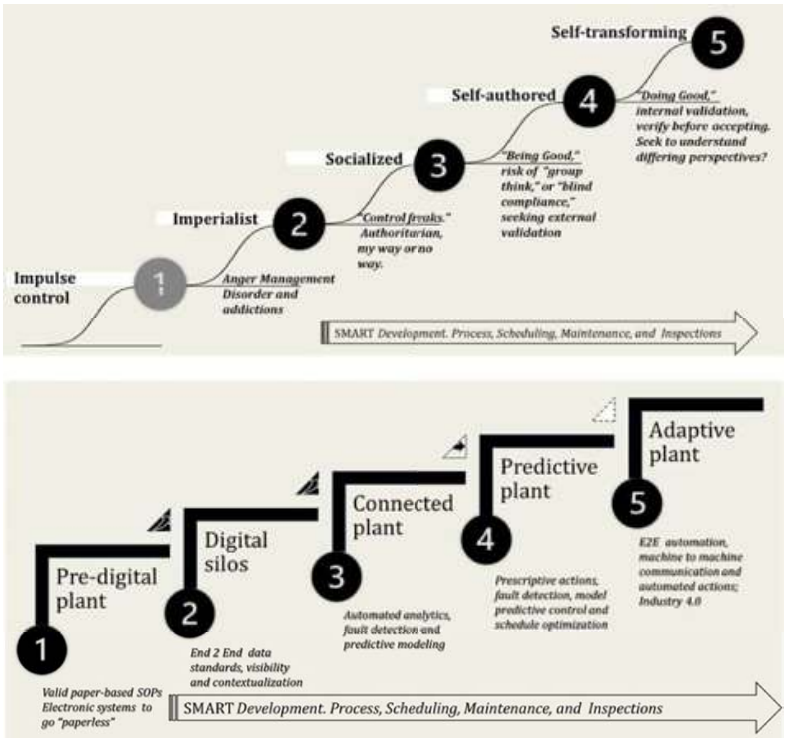

Figure 4. Staged adult development based on Robert Kegan's In Over Our Heads: The Mental Demands of Modern Life, Harvard University Press (Publication Date: 21/07/1998) and BioPhorum Digital Plant Maturity Model (*https://www.biophorum.com/resource/digital-plant-maturity-model/*)

automated actions.; i.e., "humanfree" and "carbon-neutral," etc. Regulators in the US, EU and others are politically charged to promote and accelerate the Industry 4.0 revolution; perhaps at disadvantage to traditional manufacturing,. it seems that challenges to regulatory inspections, given the lockdowns, social distancing and travel restrictions, are here to stay in to the future.

Do not underestimate the exponential growth of AI technology; beyond machine learning, natural language processing, a third-generation emotion chip can understand 64 trillion possible emotional states every 1/10th of a second at any moment. We are in an epoch of unprecedented changes in working and living. In the emerging new world, technologies will dominate more the markets and business; many (humans) engaged today in manufacturing will need to mature quickly or risk becoming victims to the "mean meaning-making" by profiteers and AI.

We need to smartly go beyond our education an training to continuously learn from experience and empower our development in moments. Note that we sustain and build a quality culture in moments and feelings and intentions are in the words we choos to think and report as in meeting minutes. Learn what you can do to be SMART within, naturally. Prepare for an unprecedented journey to 2030; this is your journey. I wish my journey to 2020 makes a contribution to expanding your awareness to articulate your Vision 2030. Remember - "*You have to do your own growing no matter how tall your grandfather was.*" **-Abraham Lincoln.**

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