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IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 05 (PAGES: 40) | 01 TO 07 FEBRUARY 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

Indian APIs & Formulations for Global Healthcare

INDIAN DRUG MANUFACTURERS' ASSOCIATION

REGISTER NOW

IDMA & APTAR PHARMA - Eye Care Webinar

on

"Ocular Drug Delivery, A Therapeutic Area with an Interesting Past and a Fascinating Future": to be held on 17th February 2022

(Details on Page No. 4)

HIGHLIGHTS

A Publication of
Indian Drug Manufacturers' Association
102-B, 'A-Wing', Poonam Chambers,
Dr. A.B. Road, Worli, Mumbai - 400 018
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IDMA BULLETIN

Vol. No. 53 **Issue No. 05** **01 to 07 February 2022**

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

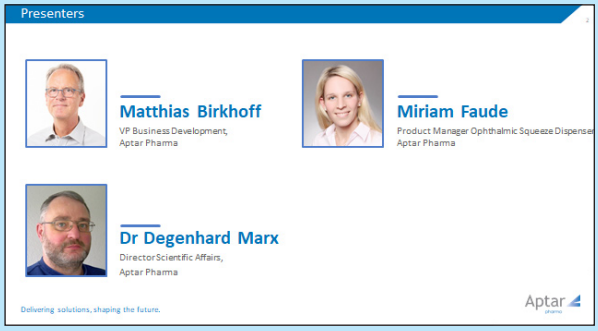
102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli, Mumbai - 400 018. Maharashtra, India.
Tel: +91-22-24974308 / 24944624 E-mail: actadm@idmaindia.com Website: www.idma-assn.org

Dear Member,

Aptar Pharma and Indian Drug Manufacturers Association (IDMA) is organizing an Eye Care Webinar on "Ocular Drug Delivery, A Therapeutic Area with an Interesting Past and a Fascinating Future" on the Thursday, 17th February 2022 from 4.00 pm to 5.30 p.m.

The Moderator of the Webinar : Mr. S R Vaidya, Chairman, MSME Committee, IDMA

The International Speakers for this webinar :



Abstract :

Ophthalmic diseases such as AMD and Glaucoma are potentially blinding chronic conditions, requiring life-long medical therapy. Failure to adhere to proper treatment may lead to disease progression and visual loss, not to speak of economic consequences.

Poor compliance is widespread. It is often a cocktail of many ingredients, including stinging drops and the difficulty of applying drops accurately, in particular for older patients. Preservatives play a prominent role in this unfavorable mixture.

However, nobody must accept any compromises when it comes to microbiological integrity.

This webinar presents available options and discusses future trends, in particular preservatives, debatable additives, but also novel ideas like "Connected Eye Care", an issue that gains even more attraction in the pandemic situation we are all in.

You will learn about strategies to address patient compliance in both clinical settings and in home care as well as limitations and regulatory hurdles.

Kindly note that there are no registration fees for this webinar but prior registration is compulsory.

REGISTRATION LINK : registration page

https://teams.microsoft.com/registration/PkrXX3rVDkGNfALE3wYiNA,M8Y2FUhaNEmpIW5AtPPojg,H699HZJvpke-twCuPK6LVQ,kS0JCOhubUGFfXDFqOhP7Q,06URgzC2y0mJE5u3A4NPtw,iJgaAMb71U2HM0vJSjBiLQ?mode=read&tenantId=5fd74a3e-d57a-410e-8d7c-02c4df062234&skipauthstrap=1

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

Thanks & regards,

Daara B Patel
Secretary – General,
IDMA

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Union Budget 2022-23 (List 3 and List 4 of Customs Notification No.02/2022, dt.1.2.2022)

Budget 2022-23

Compiled on 03.02.2022

Original Notification No.50/2017-Customs, dt.30.6.2017

Following items deleted vide Notification No. 02/2022-Customs, dated 1st February 2022

List 3 omitted : 35 items (S. No. 166 of Table of Notification No.50/2017-Customs, dt.30.6.2017)

i. Item Nos. 3, 7, 8, 12, 22, 25, 27, 28, 30, 33, 38, 39, 43, 44, 49, 50, 53, 54, 61, 62, 68, 70, 80, 86, 88, 93, 97, 99, 102, 107, 109, 110, 115, 117, 121 and the entries relating thereto shall be omitted.

Item No.	Item
3	Amrinone
7	Busulphan
8	BCG Vaccine, Iopromide, Iotrolan
12	Cyclophosphamide
22	Isoprenaline
25	Lomustine
27	Melphalan
28	Mesna
30	MMR (Measles, mumps and rubella) vaccine
33	Praziquantel
38	Somatostatin
39	Strontium Chloride (85 Sr.)
43	Typhoid Vaccines: (i) VI Antigen of Salmonella Typhi, and (ii) Ty 2la cells and attenuated non-pathogenic strains of S. Typhi
44	Tretinoin
49	Vasopresssin
50	Vecuronium Bromide
53	Pegulated Liposomal Doxorubicin Hydrochloride injection
54	Ketoanalogue preparation of essential amino acids
61	Haemophilus Influenzae Type b Vaccine
62	Mycophenolate Sodium
68	Muromonab CD3
70	Valganciclovir
80	Everolimus tablets/dispersible tablets

86	Injection Exenatide
88	Pneumococcal-7 Valent Conjugate Vaccine (Diphtheria CRM197 Protein)
93	Entacevir
97	Lapatinib
99	Suntinib Malate
102	Anidulafungin
107	Maraviroc
109	Sorafenib tosylate
110	Varenciline tartrate
115	Bevacizumab
117	Rotavirus Vaccine (Live Oral Pentavalent)
121	Octreotide

Item number 95 (Influenza Vaccine) and the entries relating thereto shall be omitted with effect from the **1st day of October 2023**;

After item number 122 and the entries relating thereto, the **following entries shall be inserted with effect from 2nd February, 2022, namely:-**

"(123) Diagnostic Agend for detection of Hepatitis B antigen

(124) Diagnostic kits for detection of HIV antibodies

(125) Enzyme linked immune absorbent assay kits Elisa Kits"

Budget 2022-23

Compiled on 03.02.2022

Original Notification No.50/2017-Customs, dt.30.6.2017

List 4 omitted : 39 items (S. No. 167 and 607 of Table of Notification No.50/2017-Customs, dt.30.6.2017) **– Fully exempted**

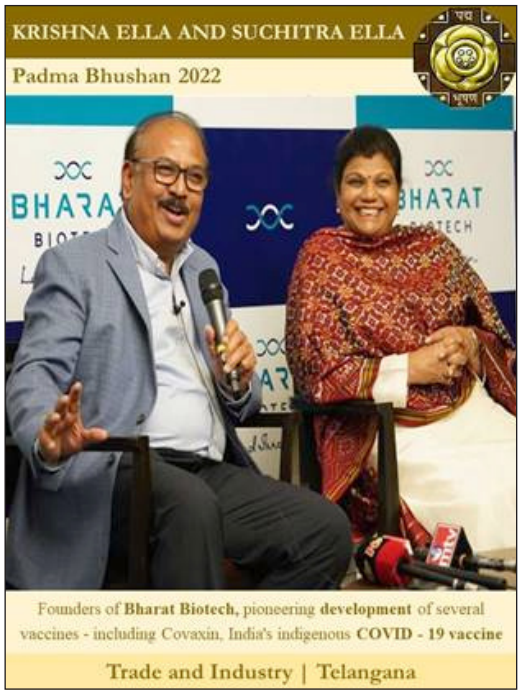
Item numbers 1, 3, 4 ,7, 8, 9, 13, 17, 18, 19, 26, 27, 28, 29, 30, 32, 37, 42, 45, 46, 50, 51, 58, 60, 61, 63, 71, 72, 73, 74, 76, 77, 78, 81, 89, 91, 98, 99, 110 and the entries relating thereto shall be omitted:

Item No.	Item
1	Aurothiomalate Sodium
3	Agglutinating Sera
4	Anti-Diphtheria Normal Human Immunoglobulin
7	Anti-Pertussis Normal Human Immunoglobulin
8	Anti-Plague serum
9	Anti-Pseudomonas Normal Human Immunoglobulin
13	Botulinum Toxin Type "A"

17	Bretyleum Tossylate
18	Calcium Disodium Edetate
19	Carmustine
26	Cyanamide
27	Diagnostic Agent for Detection of Hepatitis B Antigen
28	Diagnostic kits for detection of HIV antibodies
29	Diphtheria Antitoxin sera
30	Diazoxide
32	Enzyme linked Immunoabsorbent Assay kits FLISA KITS
37	Flecainide
42	Gasgangrene Anti-Toxin Serum
45	Hexamethylmelamine
46	Hydralazine
50	Inactivated rabies vaccine Human diploid cell
51	Inactivated rabies vaccine Vero-cell
58	Levodopa with benserazine
60	Meningococoal A and C combined vaccine with diluant solvent
61	Methicillin
63	Monocomponent insulins
71	Penicillinase
72	Poliomyelitis vaccine (inactivated and live)
73	Potassium Aminobenzoate
74	Porcine Insulin Zinc Suspension
76	Porcine and Bovine insulin
77	Purified Chick Embryo Cell Rabies Vaccine
78	Pyridostigmine
81	Radio-immunoassay kit for hormones (T3, T4, TSH Insulin, Glucogen, Growth Hormone Cortisol, L.H., FSH and Digoxin)
89	Freeze Dried Form of Human Follicle Stimulating and Luteinising Hormones
91	Specific Desensitizing Vaccine
98	Ticarcillin
99	Tranexamic Acid
110	Zoledronic Acid

● ● ●

Congratulations on being honoured with Padma Bhushan



Dear Dr. Krishna Ella & Mrs. Suchitra Ella,

We, at IDMA, take this opportunity to congratulate both of you on being honoured with the Padma Bhushan 2022, the country's third-highest civilian award, on our Republic Day, 26th January 2022.

The prestigious award has been bestowed upon you both for your stupendous work in pioneering the development of several vaccines including Covaxin – India's indigenous Covid –19 vaccine. We are indeed proud of your achievements and thank you for taking the Indian Pharmaceutical Industry to the next level of the Global Healthcare.

We were very keen to interact with you and listen to your address at our IDMA 60th Year Celebrations but unfortunately the celebrations had to be postponed to another date due to the disruption caused by covid-19 third wave.

The IDMA 60th Year Celebrations Committee would be taking the decision on the next dates within a month's time.

We would be informing you a month prior to the event and humbly request Mrs. Ella and you to grace the celebrations with your gracious presence and give us the pleasure of honouring you both.

Once again, congratulations to both of you and wishing you the best for your future endeavours.

Warm & regards,

Yours sincerely,
For Indian Drug Manufacturers' Association

Dr. Viranchi Shah
National President

Daara Patel
Secretary – General

Response By Dr. Krishna Ella

Dear Patel and Shah Saab,

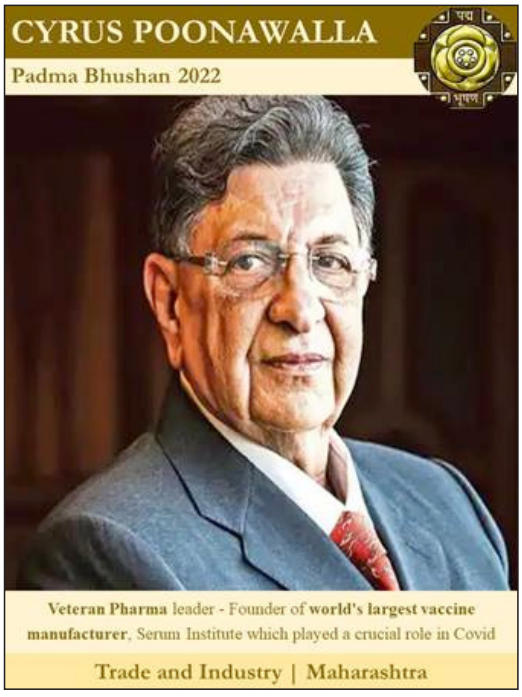
Honour to receive your wishes which I will take it as Blessings from both of you.

I consider this award is for recognition for Indian Science and Pharma. People like you worked selfless to Pharma industry of India. We are also grateful to you all.

Kind regards

Dr. Krishna Ella

Congratulations on being honoured with Padma Bhushan



Dear Dr Cyrus Poonawalla,

We, at IDMA, take this opportunity to congratulate you on being honoured with the Padma Bhushan 2022, the country's third-highest civilian award, on our Republic Day, 26th January 2022.

The prestigious award has been bestowed upon you for the stupendous work done by you, Mr. Adar Poonawalla and all at Serum Institute for manufacturing the COVID-19 vaccine in record time. Serum Institute of India played a crucial role during the covid-19 pandemic and saved many lives and families.

Sir, we are indeed proud of your achievements and thank you for taking the Indian Pharmaceutical Industry to the next level of the Global Healthcare. **We are extremely happy and fortunate to have you as our Prestigious Member.**

Once again, heartiest congratulations and we look forward to honouring you at our forthcoming IDMA 60th Year Celebrations.

Warm & regards,

Yours sincerely,
For Indian Drug Manufacturers' Association

Dr. Viranchi Shah
National President

Daara Patel
Secretary – General

Response by Dr Cyrus S. Poonawalla

Dear Dr. Viranchi Shah / Daara Patel,

Thank you very much for your felicitations, which I appreciate.

With best regards,

Dr. Cyrus S. Poonawalla

Amendment in Export Policy of Syringes - reg.

Notification No. 52/2015-2020, dated 31st January, 2022

1. In exercise of powers conferred by Section 3 read with Section 5 of the Foreign Trade (Development & Regulation) Act, 1992 (No. 22 of 1992), as amended, read with Para 1.02 and 2.01 of the Foreign Trade Policy, 2015-20, the Central Government hereby makes following amendment to the Notification No. 38/2015-2020 dated 14th October, 2021 pertaining to Chapter - 90 of Schedule — 2 of ITC (HS) Export Policy, 2018 related to export of Syringes:

S.No	ITC HS Code	Revised Description	Current Export Policy	Revised Export Policy
207AD	90183100	Syringes with or without Needles of the following denominations : - 0.5 ml/ lml AD syringes. - 0.5 ml/1 ml/2 ml/3 ml disposable syringes. - 1ml/2 ml/3 ml RUP Syringes.	Restricted	Free

2. **Effect of this Notification:**

The export policy of all kinds of syringes falling under HS code as mentioned above or falling under any other HS code has been made 'Free' with immediate effect.

F.No.01/91/180/005/AM22/EC/E-29234

Santosh Kumar Sarangi, Director General of Foreign Trade, Ex-Officio Additional Secretary, GoI, Ministry of Commerce & Industry, Department of Commerce, Directorate General of Foreign Trade, Udyog Bhawan, New Delhi

● ● ●

Capping the trade margin of five medical devices - reg

NPPA Order S.O.401(E), date 31st January 2022

1. The National Pharmaceutical Pricing Authority, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India vide S.O.2808(E) dated 13th July, 2021 issued notification under Para 19 of the DPCO, 2013 regarding capping the trade margin of five medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer at first point of sale of the product through Trade Margin Rationalization Approach. In continuation to the above notification, capping the trade margin of five medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer at first point of sale upto 31st January, 2022 is further extended upto 31st July, 2022.

2. The Notes (b) to (m) of the Notification S.O.2808(E) dated 13th July, 2021 shall remain in force during the currency of this order.

PN/227/95/2022/F/
F. No. 8(95)/2022/DP/NPPA/Div.II

Rajesh Kumar T, Deputy Director, National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, New Delhi.

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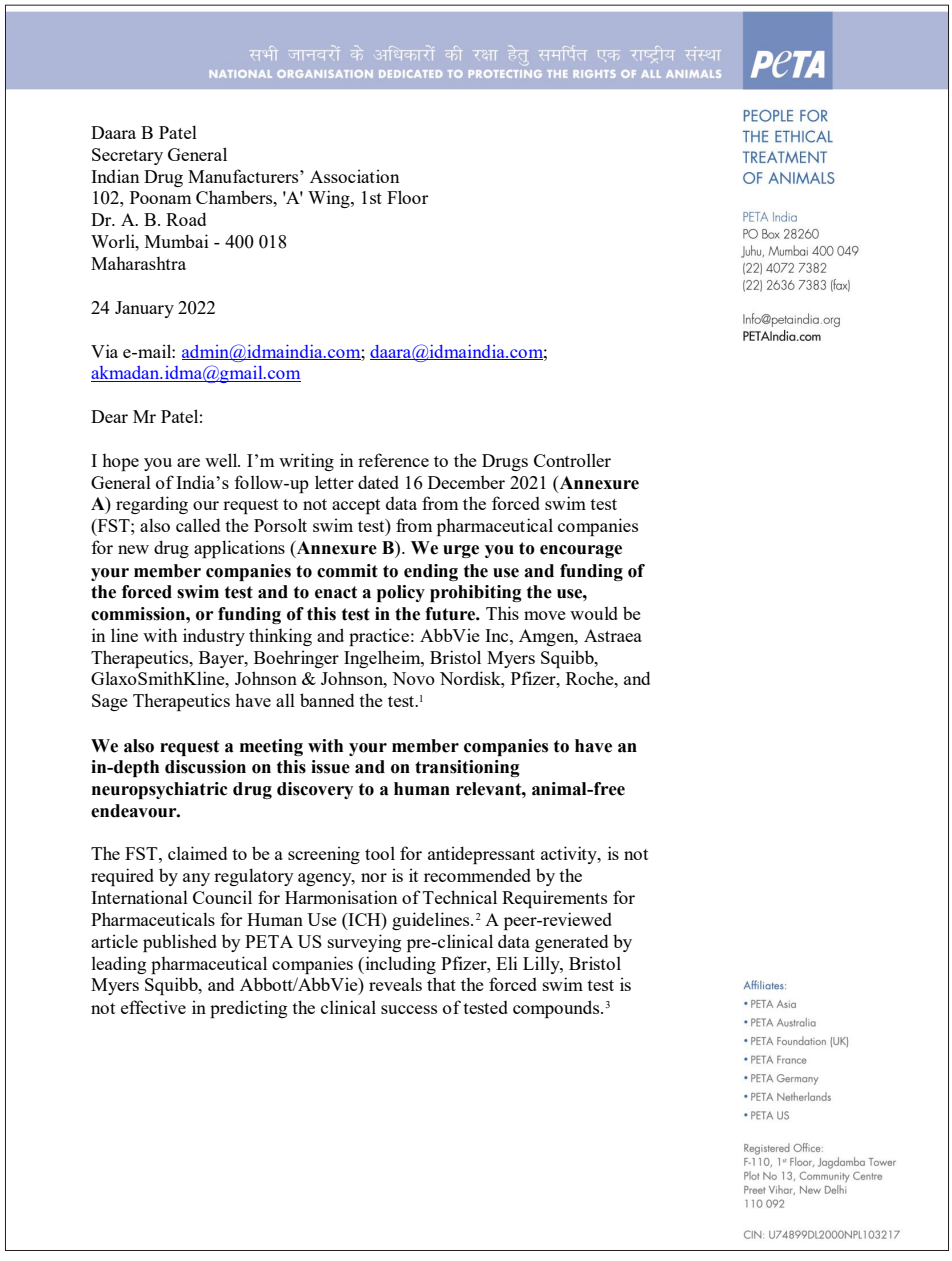
PETA-India and DCGI request on Forced Swim Test – reg.

Dear Member,

Our Association have received a communication from PETA –India (as reproduced below) dated 24th January 2022 from Dr. Ankita Pandey, PhD, Science Policy Advisor, PETA India requesting to inform our member companies for not using or funding the forced swim test (FST).

Members are requested to peruse the PETA communication.

Thanks & Regards,
Daara B Patel
Secretary – General,
IDMA



सभी जानवरों के अधिकारों की रक्षा हेतु समर्पित एक राष्ट्रीय संस्था
NATIONAL ORGANISATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

PETA

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

PETA India
PO Box 28260
Juhu, Mumbai 400 049
(22) 4072 7382
(22) 2636 7383 (fax)

Info@petaindia.org
PETAIndia.com

Daara B Patel
Secretary General
Indian Drug Manufacturers' Association
102, Poonam Chambers, 'A' Wing, 1st Floor
Dr. A. B. Road
Worli, Mumbai - 400 018
Maharashtra

24 January 2022

Via e-mail: admin@idmaindia.com; daara@idmaindia.com; akmadan.idma@gmail.com

Dear Mr Patel:

I hope you are well. I'm writing in reference to the Drugs Controller General of India's follow-up letter dated 16 December 2021 (**Annexure A**) regarding our request to not accept data from the forced swim test (FST; also called the Porsolt swim test) from pharmaceutical companies for new drug applications (**Annexure B**). **We urge you to encourage your member companies to commit to ending the use and funding of the forced swim test and to enact a policy prohibiting the use, commission, or funding of this test in the future.** This move would be in line with industry thinking and practice: AbbVie Inc, Amgen, Astraea Therapeutics, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Novo Nordisk, Pfizer, Roche, and Sage Therapeutics have all banned the test.[1]

We also request a meeting with your member companies to have an in-depth discussion on this issue and on transitioning neuropsychiatric drug discovery to a human relevant, animal-free endeavour.

The FST, claimed to be a screening tool for antidepressant activity, is not required by any regulatory agency, nor is it recommended by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines.[2] A peer-reviewed article published by PETA US surveying pre-clinical data generated by leading pharmaceutical companies (including Pfizer, Eli Lilly, Bristol Myers Squibb, and Abbott/AbbVie) reveals that the forced swim test is not effective in predicting the clinical success of tested compounds.[3]

Affiliates:
- PETA Asia
- PETA Australia
- PETA Foundation (UK)
- PETA France
- PETA Germany
- PETA Netherlands
- PETA US

Registered Office:
F-110, 1st Floor, Jagdamba Tower
Plot No 13, Community Centre
Preet Vihar, New Delhi
110 092

CIN: U74899DL2000NPL103217

Another recently published article by the UK's National Centre for the Replacement, Refinement and Reduction of Animals in Research and the UK's Medicines and Healthcare products Regulatory Agency concludes that "scientific concerns [over the use of forced swim test] relate to the lack of neurobiological correlation between the effects seen in humans and the behaviour in animals". It adds that "responses in the [forced swim test] are acute, and therefore do not model the observation that clinical effects of most [antidepressants] require chronic dosing".[4]

In summary, the FST does not reliably predict successful treatments for human depression – nullifying any scientific justification for conducting the test – and it causes acute suffering and distress to the animals who are used, presenting a compelling ethical argument against using the test.

In light of these scientific and ethical concerns, we request you recommend your member companies to take the forward-thinking step of committing to neither using nor funding the test and that you facilitate a meeting between our scientists and your member companies to discuss this issue further.

May I please hear from you regarding this important matter? I can be contacted on +91 9910317382 or at AnkitaP@petaindia.org. Thank you for your time and consideration.

Sincerely,

Ankita Pandey, PhD
Science Policy Advisor
PETA India

Enclosures:

Annexure A: DCGI letters to pharmaceutical associations
Annexure B: PETA India letters to DCGI

---

[1]People for the Ethical Treatment of Animals. Victories! PETA Is Ending Near-Drowning Experiments on Animals. https://www.peta.org/features/peta-ends-near-drowning-tests-small-animals. Accessed 12 January 2022.
[2]International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Safety Guidelines. https://www.ich.org/page/safety-guidelines. Accessed 10 September 2021.
[3]Trunnell E, Carvalho C. The forced swim test has poor accuracy for identifying novel antidepressants. *Drug Discov Today*. 2021;26(12):2898-2904. https://www.sciencedirect.com/science/article/abs/pii/S1359644621003615.
[4]Sewell F, Waterson I, Jones D, Tricklebank MD, Ragan I. Preclinical screening for antidepressant activity – shifting focus away from the forced swim test to the use of translational biomarkers. *Regul Toxicol Pharmacol*. 2021;125:105002. https://www.sciencedirect.com/science/article/pii/S0273230021001434.

Annexure A

Reminder- I

F. No. ECR/Misc/11/FST/2020
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(New Drugs Division)

FDA Bhawan, Kotla Road
New Delhi
Dated: 16 DEC 2021

To,

1. Indian Drug Manufacturers Association
   102, Poonam Chambers,'A' Wing, 1st Floor
   Dr. A. B. Road, Worli, Mumbai - 400 018

2. Organization of Pharmaceutical Producers of India,
   1st Floor, L-29, Outer Circle, Connaught Place,
   New Delhi – 110 001

3. Indian Pharmaceutical Alliance,
   A-205, Sangam Building, 14B, S V Road, Santacruz West
   Mumbai 400 054, India

Subject: Request of PETA-India to discontinue use of **Forced Swim Test** (or **Porsolt Swim Test**) by pharmaceutical companies- reg.

Sir,

Please refer this office letter of even number on the subject cited above (Copy enclosed) wherein you were requested to go through the representation from PETA and provide your comments on acceptance of data generated using FST in all the IND applications submitted by pharmaceutical firms for taking further necessary action in the matter. However, no response has been received yet by this office.

You are again requested to provide your comments on the matter at the earliest.

Yours faithfully

(Dr. V. G. Somani)
Drugs Controller General (India)

Copy to:

1. PS to DGHS, Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
2. People for the Ethical Treatment of Animal India, F-110, 1st Floor, Jagdamba Tower, Plot No. 13, Community Centre, Preet Vihar, New Delhi 110092.

Annexure B

सभी जानवरों के अधिकारों की रक्षा हेतु समर्पित एक राष्ट्रीय संस्था
NATIONAL ORGANISATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

PETA

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

PETA India
PO Box 28260
Juhu, Mumbai 400 049
(22) 4072 7382
(22) 2636 7383 (fax)

Info@petaindia.org
PETAIndia.com

VG Somani
Drugs Controller General of India
Central Drugs Standard Control Organization
Ministry of Health and Family Welfare
FDA Bhavan, ITO
Kotla Road
New Delhi 110 002

13 September 2021

Dear Dr Somani:

I hope you are well. On 13 January, you sent a letter to three pharmaceutical associations (the Indian Drug Manufacturers' Association, the Indian Pharmaceutical Alliance, and the Organisation of Pharmaceutical Producers of India), seeking their responses to PETA India's request to not accept data obtained by using the forced swim test (FST, aka "Porsolt swim test") for new drug applications (**Annexures A** and **B**). I'm writing to ask whether you have received any responses from these associations.

The forced swim test, claimed to be a screening tool for antidepressant activity, is not required by any regulatory agency, nor is it recommended by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines.[1] A peer-reviewed article published by PETA US surveying pre-clinical data generated by leading pharmaceutical companies (including Pfizer, Eli Lilly, Bristol Myers Squibb, and Abbott/AbbVie) reveals that the forced swim test isn't effective in predicting the clinical success of tested compounds.[2]

Another recently published article by the UK's National Centre for the Replacement, Refinement and Reduction of Animals in Research and the UK's Medicines and Healthcare Products Regulatory Agency concludes that "scientific concerns [with the use of FST] relate to the lack of neurobiological correlation between the effects seen in humans and the behaviour in animals". It adds that "responses in the FST are acute, and therefore do not model the observation that clinical effects of most ADs require chronic dosing".

Affiliates:
- PETA Asia
- PETA Australia
- PETA Foundation (UK)
- PETA France
- PETA Germany
- PETA Netherlands
- PETA US

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CIN: U74899DL2000NPL103217

[1]International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Guidelines. Safety Guidelines. https://www.ich.org/page/safety-guidelines. Accessed 10 September 2021.
[2]Trunnell E and Carvalho C. The forced swim test has poor accuracy for identifying novel antidepressants. *Drug Discov Today* (available online 12 August 2021) https://www.sciencedirect.com/science/article/abs/pii/S1359644621003615.

The paper also advises that "regulatory requirements have been incorrectly cited as a reason to support the use of the FST". **The paper confirms that FST is not a regulatory requirement:** "On occasions, claims have been made incorrectly that the FST is required by the medical regulators for applications for new Medicines Licences for the treatment of depression and anxiety, as part of the pharmacodynamic data submitted to demonstrate efficacy. Use of the FST in this context is not a regulatory requirement, because specific methodologies/models used to generate the primary pharmacodynamic data are not prescribed by regulations."[3]

A number of leading pharmaceutical companies – including AbbVie Inc, Johnson & Johnson, Roche Pharmaceuticals, Pfizer, Astraea Therapeutics, Boehringer Ingelheim, Bristol Myers Squibb, Sage Pharmaceuticals, Bayer, and Novo Nordisk A/S, GlaxoSmithKline – have banned the use of this cruel test.[4] Clearly, companies whose bottom line depends on conducting experiments that hold value for human conditions understand that the forced swim test does not add value when attempting to bring new products to market. In summary, the forced swim test does not reliably predict successful treatments for human depression – nullifying any scientific justification for conducting the test – and it causes acute suffering and distress to the animals who are used, presenting a compelling ethical argument against using the test.

If you haven't yet received responses from the pharmaceutical associations, would you please contact them again and request a response? Additionally, we respectfully request that you formally prohibit the inclusion of FST data in drug company submissions and encourage Indian pharmaceutical companies to employ more predictive, non-animal, human-relevant preclinical testing methods, which can help researchers gain reliable insights and expedite the drug discovery process.

May I please hear from you regarding this important matter? I can be contacted on +91 9910317382 or at AnkitaP@petaindia.org. Thank you for your time and consideration.

Sincerely,

Ankita Pandey, PhD
Science Policy Advisor
PETA India

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Pharmaceuticals Export Promotion Council of India

(Set up by Ministry of Commerce & Industry, Govt. of India)

PXL/HO/BEC-029/2021-22 Dt: 01.02.2022

Hyderabad

IDMA (Indian Drug Manufacturer'S Association)

Dear Sir/Madam,

Subject: Trade Enquiry from Denmark - Original Manufacturers of Vegan/ Chemical Vitamin D3

We take pleasure in informing you that Pharmexcil is in receipt of communication from the Royal Danish Embassy, New Delhi wherein a company from Denmark with Vit D3 product portfolio in Nordics intends to procure Vegan/ Chemical Vitamin D3 from original manufacturers in India.

It has been further conveyed that the Danish company will further assist shortlisted companies with respect to documentation in complying with EU requirements.

Interested member companies dealing in the product are requested to send their proposals directly to **Mr. Ashish Paliwal (Email: ashpal@um.dk ,Mobile: +91 92-05-982460)**, Sector Expert & Commercial Head - Agriculture and Food - Royal Danish Embassy, New Delhi.

With regards,

Uday Bhaskar
Director General

Disclaimer: Members may please note that the above information is circulated on the basis of information received from the Danish Company through the Royal Danish Embassy, New Delhi. Members are advised to make their own decisions before finalizing their business transactions.

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Acetic Acid (Quality Control) Order, 2019 published vide Notification Number S.O. 2791(E) dated the 5th August 2019 amended - reg.

Chemicals & Fertilizers Order S.O.396(E) S.O.399(E), dated 31st January 2022

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government hereby makes the following amendment in the Acetic Acid (Quality Control) Order, 2019 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

In the said order, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the 3rd August, 2022."

F.No.13012/3/2021-Chem.II

Samir Kumar Biswas, Additional Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note: *The principal order for Acetic Acid was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide notification number S.O.2791(E) dated the 5th August, 2019. Subsequently amended vide notification number S.O.344(E) dated the 24th January, 2020, S.O.2179(E) dated 1st July, 2020, S.O.3799(E) dated the 22nd October, 2020 and S.O.1676(E) dated 19th April, 2021*

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Aniline (Quality Control) Order, 2019 published vide Notification Number S.O. 2792(E) dated 05.08.2019 amended - reg.

Chemicals & Fertilizers Order S.O.397(E) S.O.399(E), dated 31st January 2022

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government hereby makes the following amendment in the Aniline (Quality Control) Order, 2019 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

In the said order, in paragraph 1, for sub-paragraph (2), the following subparagraph shall be substituted, namely:-

"(2) This order shall come into force on the 3rd August, 2022."

F.No.13012/3/2021-Chem.II

Samir Kumar Biswas, Additional Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note: *The principal order for Aniline was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide notification number S.O.2792(E) dated 05.08.2019. Subsequently amended vide notification number S.O.203(E) dated 15th January, 2020, S.O.2180(E) dated 1st July, 2020, S.O.3796(E) dated the 22nd October, 2020 and S.O.1677(E) dated 19.04.2021.*

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Methanol (Quality Control) Order, 2019 published vide Notification Number S.O. 2793(E) dated the 5th August 2019 amended - reg.

Chemicals & Fertilizers Order S.O.398(E) S.O.399(E), dated 31st January 2022

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government hereby makes the following amendment in the Methanol (Quality Control) Order, 2019 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

In the said order, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the 3rd August, 2022."

F.No.13012/3/2021-Chem.II

Samir Kumar Biswas, Additional Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note: *The principal order for Methanol was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide notification number S.O.2793(E) dated the 5th August, 2019. Subsequently amended vide notification number S.O.345(E) dated the 24th January, 2020, S.O.2181(E) dated 1st July, 2020, S.O.3795(E) dated the 22nd October, 2020 and S.O.1681(E) dated 19th April, 2021.*

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Morpholine (Quality Control) Order, 2020 published vide Notification Number S.O. 1893(E) dated the 16th June 2020 amended - reg.

Chemicals & Fertilizers Order S.O.399(E) S.O.399(E), dated 31st January 2022

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government hereby makes the following amendment in the Morpholine (Quality Control) Order, 2020 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

In the said order, in paragraph 1, for sub-paragraph (2), the following sub-paragraph shall be substituted, namely:-

"(2) This order shall come into force on the 1st August, 2022."

F.No.13012/3/2021-Chem.II

Samir Kumar Biswas, Additional Secretary, Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, New Delhi.

Note: *The principal order for Morpholine was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide notification number S.O.1893(E) dated the 16th June, 2020. Subsequently amended vide notification number S.O.2030(E) dated the 25th May, 2021.*

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Draft rules on Schedule H - reg.

Drugs & Cosmetics Notification G.S.R. 75(E), dated 1st February, 2022

The following draft of certain rules further to amend the Drugs Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by sub-section (1) of section 12 and subsection (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and in consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Gazette of India containing these draft rules are made available to public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 434, C Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. (1) These rules may be called the Drugs (..... Amendment) Rules, 2022.

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

2. In the Drugs Rules, 1945, in Schedule H, after serial number 551 and the entries relating thereto, the following shall be inserted, namely:—

"552. Acitretin".

F.No.X.11014/11/2021-DR

Dr. Mandeep K. Bhandari, Joint Secretary, Ministry of Health and Family Welfare, Department of Health and Family Welfare, New Delhi.

Note: The principal rules were published in the Gazette of India vide notification number F.28-10/45-H(1), dated the 21st December, 1945 and last amended vide notification number G.S.R. ……(E), dated the…

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OBITUARY

IDMA mourns the sudden demise of Dr. (Mrs.) Gopa Ghosh

Late Dr. (Mrs.) Gopa Ghosh
24.07.1951 –24.01.2022

Dr. Gopa Ghosh's sudden and sad demise will be an irreparable loss to the pharmaceutical industry and regulatory sector. Dr. Gopa Ghosh joined CDL-Kolkata, Government of India, Ministry of Health & family Welfare as Senior Scientific Officer (Microbiology) on 1st December 1980. Subsequently she was given the charge as Director i/c, CDTL-Mumbai on 26th September 2007 to 31st July 2011 up to her retirement. Simultaneously she was also given the additional charge as Nodal Officer for establishing CDTL at Hyderabad from 29.01.2010 till retirement. She spearheaded the shifting of CDTL laboratory from Thane premises to Zonal FDA Bhawan at Mumbai Central – Mumbai. She took all efforts to establish the state of art laboratory of CDTL-Mumbai. Dr. Gopa Ghosh was a dynamic personality and with her vast knowledge arena ensured compliance of the laboratory with applicable regulations. Her mission was to develop the laboratory to meet the world class requirement. She was one of the Indian Drugs Active reviewer and supported IDMA in various Seminars/workshops. She will always be remembered for her caring leadership, demonstration of passion for her work, preservance and a growth mindset. Dr. Gopa Ghosh will be held in highest regard by CDTL team and by others with whom she has worked in our industry. She set an example that will continue to be an inspiration to all of us.

OBITUARY

IDMA fondly remembers Dr. R. B. Smarta

IDMA mourns the sad demise of Dr. R. B. Smarta, Founder of Interlink Marketing Consultancy Pvt Ltd, on Tuesday, January 25, 2022.

Interlink Marketing Consultancy is an IDMA Member and hence, the loss of Dr Smarta is huge and irreplaceable as we have lost not only a doyen of the Pharmaceutical Industry but also a gem of a person.

Dr Smarta was a pioneer of Management Consulting and one of the best brains in strategic marketing. Dr Smarta was a brilliant trainer and influenced more than 10,000+ Healthcare industry professionals in more than 300 organizations on strategic issues & provided directions over the past 3 decades.

Dr Smarta was very enthusiastic and innovative in nature, he and his organization, Interlink, enabled launch of 50+ Pharma and Healthcare brands and divisions. A few are new concepts that were launched first time in India.

He was one of the finest Pharma Thought Leaders and he authored 10 Pharma, Nutra, and Wellness books and 2 more will be launched shortly. With the unique combinations of academics of science, management, and business practices, Dr. Smarta was associated with Institutes like Bombay college of pharmacy, SNDT, and various Associations like IDMA, CSIR, ITF, HADSA, IADSA, Bio valley, Nutrify today, Vitafoods and Canadian Embassy.

Dr Smarta's memorable quote, **"In Life, you have either Reasons or Results",** showed his crystal-clear perspective and dedication towards work.

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

RoDTEP

Lok Sabha Unstarred Question No. 2872

Shrimati Vanga Geetha Viswanath:

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

(a) whether the Ministry is seeking more funds from the Finance Ministry for the new tax refunds scheme for exporters - the Remission of Duties and Taxes on Export Products (RoDTEP) - after expressing its displeasure at the long delay in notifying the details of the scheme; and

(b) if so, the details thereof along with corrective steps being taken in this regard?

Answered on 15th December 2021

A. (a) The Scheme for Remission of Duties and Taxes on Export Products (RoDTEP) was notified on 17.08.2021 for implementation with effect from 01.01.2021. After the budgetary allocation of Rs 12,454 Crores for the Scheme for Financial Year 2021-22, additional funds have not been sought.

(b) Does not arise.

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

Regional Trade Agreements

Lok Sabha Unstarred Question No. 2899

Shri Sushil Kumar Singh:

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

(a) the list of countries with which India is planning to or negotiating an Regional Trade Agreements (RTA) currently;

(b) the list of quantifiable benefits (without any jargon) of each existing RTA for India in the last five years, RTA-wise;

(c) whether the RTAs have succeeded in investment creation;

(d) if so, the details thereof; and

(e) whether the Government is planning to renegotiate an existing RTA; and

(f) if so, the details thereof?

Answered on 15th December 2021

A. (a): India is actively negotiating Regional Trade Agreements (RTAs)/Free Trade Agreements (FTAs) with the following countries/regions :

Sr.	Countries/ Regions	Name of the Agreement
1	UAE	India-UAE CEPA
2	Australia	India - Australia Comprehensive Economic Cooperation Agreement (CECA)
3	Canada	India – Canada Comprehensive Economic Partnership Agreement
4	Israel	India – Israel Free Trade Agreement (FTA)
5	United Kingdom	India-UK Enhanced Trade Partnership (ETP)
6	Armenia, Belarus, Kazakhstan, Kyrgyzstan, and Russia	India-Eurasian Economic Union (EAEU) Free Trade Agreement (FTA)
7	European Union	India - EU Broad Based Trade and Investment Agreement (BTIA)
8	South Africa, Botswana, Lesotho, Swaziland and Namibia	India - SACU PTA

(b), (c) & (d): India has signed 11 RTAs/FTAs with various countries/regions namely, Japan, South Korea, Mauritius, countries of ASEAN region and countries of South Asian Association for Regional Cooperation. India's merchandise exports to these countries/regions have registered a growth of 20.75% in the last five years. As regards India-

Mauritius Comprehensive Economic Cooperation and Partnership Agreement (CECPA), as this has been implemented w.e.f. 01-04- 2021, it is too early to calculate quantifiable benefits. The following table gives country/region wise merchandise export details:

RTA partner countries/Region wise India's exports

Values in US$ billion

India RTA partner Countries / region	Names of RTAs	Export in FY 2016	Export in FY 2021
ASEAN	India-ASEAN FTA India-Singapore CECA India-Malaysia CECA India-Thailand FTA - Early Harvest Scheme (EHS)	25.13	31.49
Japan	India-Japan CEPA	4.66	4.43
South Korea	India-South Korea CEPA	3.52	4.68
SAFTA	Agreement on SAFTA India-Sri Lanka FTA India-Nepal Treaty of Trade India-Bhutan Agreement on Trade, Commerce and Transit	18.60	22.08
Mauritius	India-Mauritius Comprehensive Economic Cooperation and Partnership Agreement (CECPA)	It is too early to calculate quantifiable benefits for this RTA, as it was implemented only w.e.f. 10.04.2021.	

Source: Directorate General of Commercial Intelligence and Statistics (DGCI&S)

As per the FDI data maintained by the Department for Promotion of Industry and Internal Trade (DPIIT), the cumulative investment received from the above countries/regions in the last 5 years (between October 2016 and September 2021) is to the tune of US$ 89.46 Billion. However, it is not possible to ascertain if investment from a country has taken place due to signing of an RTA or any other reason(s).

(e) & (f): Review of RTAs/FTAs with South Korea, ASEAN and Singapore is under consideration.

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

In Rajya Sabha

Policy to Manage Expired Vaccines

Rajya Sabha Unstarred Question No. 1867

Shri Partap Singh Bajwa:

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

(a) the data on number of vaccines in public hospitals that have an expiry date in the month December, 2021, State-wise;

(b) the data on number of vaccines in private hospitals that have an expiry date in the month December, 2021, State-wise;

(c) the details on the Government policy to avoid wastage of vaccine because of expiry date; and

(d) the details on the Government policy to deal with vaccine beyond expiry date?

Answered on 14th December 2021

A. (a) to (d) As on 9th December 2021, there are 2,410 Covid-19 vaccine doses having an expiry date in the month of December 2021. The States-wise details of the same are attached at Annexure 1.

Data on expiry of COVID-19 vaccines at private hospitals is not maintained Centrally, however Government of India closely monitors COVID-19 vaccine stocks in States/UTs so as to ensure their optimal utilization. COVID-19 vaccine stock which has not been utilized in private hospitals and nearing expiry are usually taken up for redistribution by respective State Government, for its timely utilization. States/UTs have also been advised to review program coverage & vaccine wastage on a daily basis and redistribute the vaccine stock if required.

Annexure 1

State-wise details of COVID-19 vaccine doses with expiry date in December 2021 available in Government stores (as reported on eVIN on 9th December 2021)

Sr. No.	State/UT	Covaxin Doses	Covishield Doses	Total Doses
1	Rajasthan	100	-	100
2	Ladakh	-	400	400
3	Maharashtra	10	1,900	1,910
	Total	110	2,300	2,410

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

New Legislation for Regulation of Medicines, Cosmetics, E-Pharmacy and Medical Devices

Rajya Sabha Unstarred Question No.1866

Shri Sanjay Raut:

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

(a) whether it is a fact that the Ministry is seriously thinking of bringing new legislation to regulate medicines, cosmetics, e-pharmacy and medical devices;

(b) if so, the details thereof and shortcomings identified in the existing legislation;

(c) whether Government is also considering to curtail import dependency of medicines and devices in the country; and

(d) if so, the details thereof?

Answered on 14th December 2021

A. (a) to (d): The Ministry has constituted a committee for drafting "Drugs, Cosmetics & Medical Device Bill". The Department of Pharmaceuticals has launched three schemes for promoting domestic manufacturing of pharmaceutical drugs including Active Pharmaceuticals Ingredients (APIs) by attracting large investments in the sector to ensure their sustainable domestic supply and thereby reduce Indian's import dependence on other countries.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

Colour Coding of Geriatric Medicines

Rajya Sabha Unstarred Question No. 1873

Smt. Roopa Ganguly:

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

(a) whether the Ministry is aware of the problem that senior citizens are not able to read properly the instructions on the medication packaging;

(b) if so, the details of the measures that have been taken by the Ministry to make it more readable;

(c) whether the colour coding has been done for the geriatric medicines to make it more accessible; and

(d) if so, the details thereof?

Answered on 14th December 2021

A. (a) to (d): As per report received from Central Drugs Standard Control Organisation (CDSCO), no such representation that senior citizens are not able to properly read the instructions on the medication packaging has been received.

Rule 96 of the Drugs Rules 1945 prescribes the manner of labelling for the Drugs. The Rule was amended with effective from 13.09.2018 providing that the proper name of the drug or fixed dose combination (FDC) drugs other than FDCs of vitamins and other FDCs containing three or more drugs shall be printed or written in a conspicuous manner which shall be at least two font size larger than the brand name or trade name (if any) shall be written below or after the proper name on the drug label.

There are no specific provisions related to requirements of colour coding for Geriatric medicines under Drugs and Cosmetics Act 1940 and Rules thereunder.

The Minister of State in the Ministry of Health and Family Welfare (Dr. Bharati Pravin Pawar)

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Virtual Clinical Trials: A renaissance in the making

The shift towards virtual clinical trials, spurred by the pandemic, is ushering newer research models that are more convenient, transparent and patient-centric. India needs to invest in the right technologies, policies and people to be a leader in this space and leverage its huge potential

Since the onset of the COVID-19 pandemic, we have seen Austrian economist Joseph Schumpeter's concept of creative destruction come into play often. As the wily virus caused chaos and mayhem to social and economic activity globally and challenged existing models and current systems, it left no one with any option but to adapt and innovate. As a result, we have witnessed businesses and systems replace their long-standing and sometime obsolete practices, products and services with more effective and innovative approaches and offerings to survive and thrive during the pandemic. Decentralisation of clinical trials is a case in point.

Trials and tribulations

An article published online in *The Lancet* in December 2021 informs that the COVID-19 pandemic affected scientific research worldwide and over 2000 trials registered on ClinicalTrials.gov were stopped. Delays in regulatory approvals, hassles with site set-ups and delegation of responsibilities, limited scope for site visits, lack of participation by health units and clinicians, enrollment of patients for the study, etc were some of the challenges of doing clinical research during the pandemic.

Henry McNamara, Sr VP and GM, Oracle Health Sciences shares his views on this situation and explains, "The COVID-19 pandemic radically changed clinical operations forcing the clinical research community to re-evaluate how to manage clinical trials. In a flash, physical access to patients across the globe became infeasible, causing a significant impact on clinical data collection and patient monitoring."

KEY STEPS IN A VIRTUAL CLINICAL TRIAL (VCT)

Patient recruitment: In VCTs a combination of traditional patient recruitment and digital recruitment is used. When happening digitally, patients are targeted directly via web-based platforms. This allows faster recruitments without geographical limitations. Patients don't have to travel to sites to sign up for the study; instead, they could send in e-consent forms. Technology reaches patients who would be most suitable for the study, ensuring that they participated with minimal travel to the site, significantly increasing patient participation and retention during clinical research studies.
Phone-based visits: While some in-person office visits will always be required (e.g. to perform certain testing, and conduct physical examinations), the hybrid approach with replacing few in person visits with phone based visits can lead to increase patient retention as well as cost optimisation.
Remote electronic monitoring: As both the complexity of clinical trials and demand for remote site connectivity is increasing, research organisations are looking for solutions to lower cost and remove inefficient workflows. COVID-19 has further emphasised the need for remote clinical trial monitoring solutions.
Patient retention: VCTs are patient centered, meaning that they are based from the patient's home and connect with the patient's own smart phone. This increases the convenience for patients, especially for elderly and disabled.
Digital health data collection: After patients are recruited for a study, it is important to collect data during the clinical research study process. There are multiple ways to collect this data using digital tools. Demographic and medical health data, patient activity, and physiological parameters, patient-reported outcomes, along with images, can now be collected using electronic medical records, smartphones, or tablets.
Safety monitoring in virtual trials: The fast pace of digital technology movement into routine processes in a clinical trial has helped in significantly improving efficiency, reducing time and cost for sponsors. New tools are now being paired with traditional biomarker assessments to enhance safety and validation.
Data Security: To develop intelligent clinical trials that do not require constant human monitoring but are dependent on advancements in technology, certain challenges need to be addressed. There is an increased need to tighten data security during collection, transmission, and analysis. To overcome this, the FDA has put forward specific guidelines, like conveying information collected by the digital tools to all stakeholders. Medical device certification has been developed as a measure to control data breach.
Data analytics: Flexible, extensible, and scalable clinical trials can be carried out only with the support of effective data analysis. For example, an AI and ML powered platform enables study investigators to connect remotely and access data from clinical trials in near real-time. Such emerging technology helps automate processes and mapping data, with advanced analytic methods applied to manage multiple facets of clinical trials.
Optimising trial methods: There are multiple ways in which virtual resources support clinical trials optimisation. A method of intervention optimisation, called micro-randomised trials, involves identifying factors like dose and timing that can be managed better using reminders. Such engagement strategies are best suited for patient recruitment, enrolling and retention. The personalisation of the clinical trial process helps in enhanced patient participation in clinical trials.
Limited number of sites in VCTs: Number of sites in VCTs are limited. For the same principal investigator, a team of multiple sub investigators can ensure health and safety of participants via remote visits where patients contribute with data virtually via their smart phones.

- ***Sowmya Kaur**, EVP – Navitas Clinical Research and BU Head Clinical APAC*

"The biggest factor delaying clinical trials today – exacerbated by COVID-19 – is enrollment. It's difficult to find enough patients to participate in trials. The study found that more than half (51 per cent) of respondents identified longer enrolment timelines as one of the key ramifications of the pandemic. This is partly due to the inconvenience of trial participation for the patient. For instance, some patients may be living away from the site, so in-person visits can be a large inconvenience," he adds.

These circumstances have paved the way for accelerated adoption of virtual clinical trials (VCTs) worldwide, altering the traditional approaches to clinical trials, probably for ever.

The age of VCTs

A GlobalData report titled 'Virtual Clinical Trials – Thematic Research', states, "COVID-19 lockdowns and social distancing measures caused significant disruption to clinical trials and accelerated the use of virtual trials. Companies that had not considered this model before had no option but to rapidly implement new technologies and procedures to maintain business continuity, and many companies will continue to use virtual trials post-pandemic.

67 per cent of the participants cited COVID-19 as the reason they plan to use decentralised clinical trials in the future."

McNamara shares data from an Oracle-commissioned study by Informa Pharma Intelligence that reveals "76 per cent of respondents accelerated their adoption of decentralised clinical trial methods during the COVID-19 pandemic." Why? Well, as Sowmya Kaur EVP – Navitas Clinical Research and BU Head Clinical APAC explains, "A virtual clinical trial harnesses the power of technology to improve patient recruitment, retention, collection of data, and analysis. They support efficient trials as they tap into digital technologies, like apps, monitoring devices, and online social engagement platforms to conduct each stage of the clinical trial. This includes enhanced support for recruitment, informed consent, patient counseling, measuring clinical endpoints, and in determining adverse reactions."

"The advent of digital solutions in clinical trial management and conduct has improved transparency, with an onus on delivering better healthcare. Consumers or patients have access to a wide range of information, and, with this dissemination of information, there is increased expectancy. This has initiated a need for rethinking clinical trials to maximise benefits. There has been a significant shift towards embracing the incredible advantages of data analytics, along with digital models of engagement, to forge clinical trials that cater to the current demands," opines Kaur. *(Check Box: Key steps in a virtual clinical trial)*

"Virtual trials ease the patient burden of traveling to sites for multiple visits and tests, remove geographic and logistical constraints to participation, and leverage technology for real-time information access and communication between sites and patients. Investments in technology and remote trials were underway before COVID-19 due to cost and efficiency considerations and the pandemic will only catalyse these developments", points out Jinu Jose, VP, Head – Sales and Clinical Operations, R&D Solutions, IQVIA India.

Thus, the market outlook for virtual clinical trials is very bright. The global virtual clinical trials market is expected to grow from $ 2,092.67 million in 2020 to $5,521.67 million by the end of 2025, as per a report by ResearchandMarkets.com. Another recent report by ResearchandMarkets.com states that the global eClinical solutions market is expected to grow from $6,784.59 million in 2021 to $14,897.53 million by 2027at a CAGR of 14 per cent.

KEY AREAS FROM AN ETHICAL PERSPECTIVE AS VIRTUAL TRIAL ECOSYSTEM IN INDIA EVOLVES

Informed consent: Linguistic differences, literacy levels, therapeutic misconceptions, socio-cultural aspects, and perceptions about the medical system make informed consent an important focus area. The compliance issue of participants with digital tools needs to be considered throughout the ongoing trial, especially for trials involving certain vulnerable populations for whom the use of technology is an arduous task for them.
Vulnerable populations: Working with these populations requires careful consideration
Investigational Medicinal Product (IMP) management: Shipping, administering, and tracking the IMP poses certain challenges in terms of storage at the patient's residence, logistics and adherence.

*- **Jinu Jose,** VP, Head – Sales and Clinical Operations, R&D Solutions, IQVIA India*

Advantage India

Clearly, virtual clinical trials are set to increase, but what does this mean for India? Well, industry stakeholders seem to share a positive outlook about India's potential for growth in this sphere.

Jose informs, "The investments we have seen in building the decentralised trial infrastructure have been unprecedented. These developments, coupled with the introduction of the New Drugs and Clinical Trials Rules, 2019, which was a significant milestone, will encourage more global clinical studies to be conducted in India, thus improving access to treatment for patients."

He shares, "Given its large population and growing disease burden, unmet medical needs, highly trained, English-speaking healthcare professionals, clinical research professionals, leadership in information technology, advancements in mobile and internet accessibility and burgeoning patient population, India possesses immense potential for conducting global decentralised clinical trials."

"The growing number of pharma companies in developing Asian countries such as China, India, Taiwan, and Korea has also opened up growth opportunities for the eClinical solutions market in this region," states Kaur.

Preparing for progress

However, to leverage the advantage and optimise the growth potential, there is a need to put certain measures into place. So, what do the industry experts recommend?

Invest in the right technologies: GlobalData's report titled 'Virtual Clinical Trials – Thematic Research' highlights a considerable increase in deal-making activity in the virtual trials space over the past 18 months. Nine M&As linked

to virtual trials were witnessed in 2020, instead of one in 2018 and two in 2019, as per the report. In 2021, this segment has seen some major M&As including Thermo Fisher's acquisition of PPD for $17.4 billion in April 2021 and ICON's acquisition of PRA Health Sciences for $12 billion in February 2021.

India needs to learn from the global playbook and invest in existing and emerging technologies to build and fortify its position in the virtual clinical trials space.

Industry experts also under-score this fact and elaborate on the importance of emerging technology in this space. McNamara points out, "The ability to do home health, virtual visits, and telemedicine are key to making trials easier for patients, which lessens the enrolment barrier. Whilst the technology has existed, two key barriers have precluded its adoption: state/regulatory support and end-user (physician) acceptance. COVID-19 has broken down these barriers almost overnight, triggering mass relaxation of regulatory hurdles, and likewise immediate realisation by the medical community that video can work, and in many cases, is better than face-to-face interactions."

Jose adds, "Great advances have been made in AI and Machine Learning (ML), which can be applied to automate many data-heavy processes to lessen the pressure. AI and ML not only process data faster than humans, but they can also point to patterns and trends that humans can't see. This ideally leads to a more accurate and detailed view of how patients are responding in trials, which can lead to better patient experience, better therapies, and treatments in the long run."

Kaur weighs in, "The need to invest in digital tools like Artificial intelligence (AI) and Machine Learning (ML) tools is crucial. These tools help ensure clinical trial continuity during and post the pandemic era. Significant strides in incorporating digital health solutions began a few years ago, more as experimental solutions or as support for certain sections of clinical trials. Such investments have paved the way for hybrid clinical trials that are guiding forces for successful and efficiently run clinical trials."

Adequate regulatory support: Regulatory support and flexibility to accommodate novel approaches and interventions for disease management is crucial. Indian regulators should promote and encourage initiation and conduct of virtual clinical trials in an ethical manner with appropriate processes and policies. Fortunately, industry stakeholders inform that regulatory pathways in India for clinical trials are evolving to keep pace with changing demands.

MANAGING THE DELUGE OF DATA

The amount of data is far more information than humans can process or manage and outsourcing or throwing more people at the problem is no longer sustainable or effective. Not only is there more data, but it is also much more complex.
AI and ML are currently being incorporated into advanced, cloud-based life sciences technology platforms to support trial design, data monitoring, and safety case management. But this is only the beginning. Five years from now, a patient's clinical trial experience could be very different. Wearables combined with cloud technologies will enable continuous and instantaneous data collection and advanced analytics that is fed back to the study teams developing new treatments. Each enrolled patient could be creating millions of data points a week—or even per day. That could mean more accurate assessments as the data will reflect the patient's everyday experiences.
To support the move to decentralised clinical trials and the variety and volume of patient data that is going to come with it, organisations need a single platform where the data can be collected, harmonised, and analysed quickly and efficiently. In the past, sponsors and CROs may have used point solutions designed to improve specific processes in clinical trials, such as electronic data capture (EDC), and drug randomisation and supplies management (RTSM). But as these systems weren't built to work together, it causes process redundancy and data quality issues. The data streaming in from remote devices and patient apps further add to the complexity.

- ***Henry McNamara,*** *Sr VP and GM, Oracle Health Sciences*

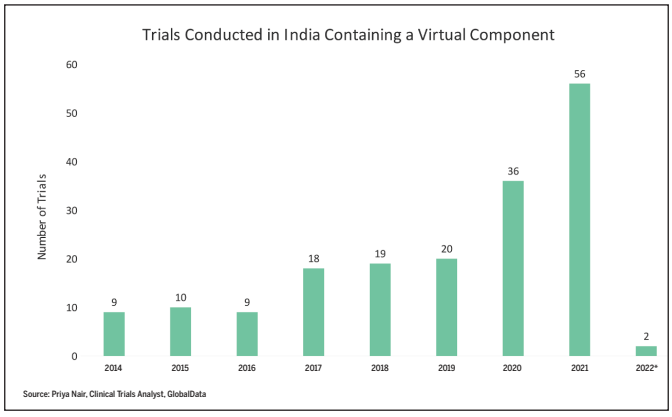
Jose updates, "Indian clinical trials regulations have evolved over the last few years and introduction of the New Drugs and Clinical Trials Rules, 2019 has been a significant milestone infusing significant interest and confidence in the clinical trials industry. During the pandemic, the clinical trial industry worked very closely with regulators on innovative trial designs, improvised pathways for approvals, and use of digital health platforms in various aspects of the clinical trial continuum. We hope that these will continue beyond the pandemic to sustain the momentum and fast track the clinical trial application review process."

He further opines, "While these were short-term measures, we are confident that this opens many possibilities to further improve the overall clinical trials process and leverage technology and automation to bring drugs to markets faster while reducing the overall cost of development. Some of the specific areas in virtual trials that require focus from a regulatory perspective include – IMP management, patient consent, use of digital platforms, documentation, and access to data. We also believe that there are significant opportunities for the industry to proactively partner with regulators to drive continued innovations and faster adoption of newer ways of working."

"In the context of the pandemic, the regulators have been willing and flexible to adopt new technologies and provide quicker approvals. As the pandemic situation spiraled, regulators moved with speed to issue guidance

enabling sponsors to introduce new approaches and protocols for clinical trials,' states Kaur.

Build better security management systems: Jose explains, "Cyber security, privacy and data protection are key tenets of managing a clinical trial. Any service delivery model that has a backbone of data and technology is prone to cyber-attacks and data thefts. The conventional clinical trial processes are largely automated (electronic data capture, trial management, document exchange, IMP management etc.) and while virtual trials introduce a layer of technology, the risk does not significantly rise."



"While continuing to invest in world-class technology, cyber security and digital capability can help mitigate the risks to a larger extent. We believe that investments in training, education, and increasing awareness of employees and the larger clinical research ecosystem we operate can significantly help better manage these risks," he adds.

Kaur enlightens, "As clinical trials take a digital approach the complexity grows along with the risk to data integrity. The challenge is the difficulty in securing a clinical trial ecosystem that may involve hundreds of data input points, trial sites, networks and applications, including patient's own devices like wearables, smart phone apps being on the constant rise."

She adds, "It is critical when designing a clinical study, to map the data flow, from where the data is generated, how it is stored and how many software systems it flows through. Clear controls need to be in place at the sponsor's site, at the sponsor's trial partners to scan for malware and incorporate patch applications as soon as patches become available, and train/inform personnel on how to protect data."

However, Kaur also informs that increased use of technology is being accompanied by the development of better security management systems. She says, "Industry as well as regulators understand the utmost importance of data protection. The importance of data protection increases as the amount of data created and stored continues to grow at unprecedented rates. There is also little tolerance for downtime that can make it impossible to access important information. There are many storage and management options that can help to restrict access, monitor activity, and respond to threats (e.g.,Data loss prevention, Storage with built-in data protection, Firewalls, Encryption, Endpoint protection etc.,)"

Create a tech-savvy, digitally-skilled workforce: A barrier to progress in virtual trial field is skill-shortage. GlobalData's State of the Biopharmaceutical Industry 2021 report cites lack of specific skills and talents as the key hurdle barrier to digital transformation initiatives. It is an imperative to recruit and train digital talent on priority to enable utilisation of remote technologies in clinical trials. The industry needs a workforce that is skilled in digital, advanced data analytics and AI/ML to leverage these tech solutions to generate and analyse datasets.

As Jose highlights, "The future of work in our industry will be at the intersection of strong clinical/medical expertise, use of data/analytics and digital platforms to achieve better outcomes for our patients. The foundation skill is and will continue to remain the ability to apply clinical and medical expertise in different contexts in a clinical trial. Data and analytics will be pervasive in our decision making and the use of new technology platforms will drive the future of our work. Therefore, we need to continue to invest in building skills in emerging areas including data, analytics and digital platforms.

He adds, "Remote working lends itself well to the decentralised trial model. Virtual trials will open new opportunities for professionals in the areas of information technology, logistics, patient care (home health nursing/ phlebotomy support) and training."

Kaur emphasises, "Virtual trials mandate the need for a digital-savvy workforce which is required to satisfy patient health and well-being demands, which will be frequently delivered through innovative technology-based applications. The focus for professionals in the industry should be on developing skills in technology like AI, ML, etc., data analytics, governance of data and more."

On an optimistic note, Kaur shares, "About 50 per cent of workers find themselves as digital natives, with the figure set to rise to 75 per cent by 2025. Within the next few decades, the entire workforce will have grown up

under the ubiquitous influence of the Internet and other technologies. Digital natives are already shaping the future of working life: as a new generation enters the workforce, business processes will continue to modernise in view of evolving skill sets."

VCTs are here to stay

Jose says, "The process, technology and infrastructure supporting virtual trials is evolving. Like with most emerging industry solutions, we do expect that over a period there will be consolidation, standardisation, and greater maturity of the ecosystem supporting virtual trials. In the future, we believe that this will pave the way for not only for reduced R&D costs but also better data quality, access to patients, better diversity, improved protocol adherence, reduce study dropout, faster patient recruitment and reduced cycle times for clinical trials."

McNamara opines, "Today's environment has helped push the industry from looking at decentralised trials as a series of pilots to accelerating adoption because they are simply a better way to operate. Organisations have adapted to decentralised trials quickly in the face of the global pandemic, but the industry needs to embrace this change not as situational, but as a permanent evolution. With the right processes and technologies in place, the shift can be advantageous to patients, sites, and sponsors moving forward. Ultimately, decentralised trials will change clinical research forever, driving patient centricity, richer real-world data, and faster development of life-enhancing therapies and treatments.

"Virtual clinical trials enable improving patient-centric experience, offers a cost-effective, and easy to manage solution. All these indicators provide a compelling insight for virtual trials to become the default in the post COVID era," asserts Kaur.

Thus, the outlook for VCTs is very positive given the myriad advantages they offer over traditional, site-based clinical trials. Therefore, as Kitty Whitney, Director of Thematic Analysis at GlobalData highlights, "While COVID-19 shone a spotlight on virtual trials, data show that the shift towards virtual trials was underway before the pandemic. Companies who are not already integrating virtual components into trials need to adapt their research models to become more patient-centric in order to recruit and retain more participants and improve trial efficiencies overall."

(https://www.expresspharma.in/virtual-clinical-trials-a-renaissance-in-the-making/)

Courtesy: Lakshmipriya Nair, Express Pharma, 03.02.2022

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Filling the gaps in India's pharma manufacturing supply chain

The lessons of the past – of spiralling API costs, over dependence on a shrinking list of API makers – have been well learnt

This Republic Day, the nation honoured the vaccine makers –Serum Institute of India's Dr Cyrus Poonawalla, and Bharat Biotech's Dr Krishna Ella and Suchitra Ella – with Padma Bhushans, the third highest civilian award. As we start the third year under the shadow of the COVID-19 pandemic, there is no greater acknowledgement of the importance of the sector, vital to India's future health, both at the citizen and corporate level. Will this sentiment also be reflected in Budget 2022 allocations? Will the Finance Minister have the fiscal space to do so? We will know this by 1st February, but as I write this on 27th January, it is anyone's guess.

However, even if Budget 2022 falls short of support, PE and VC players are stepping up to support key parts of the sector, most notably the much neglected API segment.

Most recently, on 24th January, Advent International acquired a controlling stake in Hyderabad-based Avra Labs, a contract manufacturing and research services (CRAMs) and speciality Active Pharmaceutical Ingredients (APIs) manufacturer. The PE player has reportedly invested in over 20 businesses in pharma R&D, production and distribution with the goal of "creating a top five merchant API Platform in India" – a goal, which presumably predates the pandemic by at least three decades. Since 1990, Advent has invested $10.5 billion in 52 companies in the sector worldwide. In addition to Avra Laboratories, recent pharma and healthcare investments by Advent include GS Capsule, BioDuro-Sundia, RxBenefits, RA Chem Pharma, ZCL Chemicals, Bharat Serums and Vaccines, Industria Chimica Emiliana, Vitaldent, Definitive Healthcare, Zentiva, AccentCare and Iodine Software.

Carlyle is another global PE player investing to create a global generics player based out of India. The group made significant investments last June and November in Viyash Life Sciences, which is already a leading manufacturer of APIs and intermediates. Viyash was set up by ex-Mylan veteran Dr Hari Babu in partnership with Dr Srihari Raju Kalidindi, with a strategy to 'consolidate other pharma intermediates, API and formulation assets to create an integrated offering for large generics customers', as per a release. With the acquisitions so far, Viyash already has ten manufacturing facilities in India with a combined capacity of ~2000 KL as well as one formulation facility in the US, and CEO Dr Hari Babu has indicated that the next phase will be about integration across these businesses.

In November 2020, Asia-focussed PE firm PAG, with consortium partners CX Partners and Samara Capital, acquired a controlling stake in Chennai-based API manufacturer Anjan Drugs. Again, this was of the consortium's strategy to 'create a best-in-class platform for the development and production of bulk drug ingredients.'

Clearly, the lessons of the past – of spiralling API costs, over-dependence on a shrinking list of API makers – have been well learnt. As larger pharma companies look to de-risk their supply chain, API and ingredient makers have seen PEs and VCs lining up to invest in their scale up.

Many pharma companies are implementing various strategies, like the Government of India's PLI scheme, to de-risk from dependency on China for key raw materials and fill the gaps in India's pharma manufacturing supply chain. In fact, the pharma segment, and APIs, in particular, could see much more investment as new sectors emerge as contenders for PE/VC investments in the years ahead.

The Drugs Controller General of India's (DCGI) nod for regular market sales of Covishield and Covaxin for adults, albeit under certain conditions, is another affirmation of the importance of the biopharma sector. Even though the vaccines will still not be available for sale at chemists, hospitals and clinics can now purchase the vaccines. Hospitals and clinics will have to submit vaccination data to DCGI every six months and related data will be updated on CoWIN app, as per news agency reports. As these are still relatively newer vaccines, the government has indicated that adverse events following immunisation will continue to be monitored.

All in all, as we enter the third year of the COVID-19 pandemic, the country seems better placed to ride out the Omicron-driven third wave. Let this year's Padma Bhushans be a reminder that hard work pays off but let us not wait for a pandemic to invest in pharma and healthcare infrastructure.

(https://www.expresspharma.in/filling-the-gaps-in-indias-pharma-manufacturing-supply-chain/)

Courtesy: Express Pharma, 31.01.2022

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Economic Survey: FDI in pharma sector shot up by 200% in 2020-21

The Indian pharmaceutical sector witnessed a 200% increase in foreign direct investment (FDI) in 2020-21, noted the Economic Survey 2021-22.

"FDI in the pharmaceutical sector has seen a sudden spurt in 2020-21 vis a vis the previous year showing a 200% increase," said the Economic survey tabled in Parliament by finance minister Nirmala Sitharaman. In 2021-22 (April-September) the FDI inflows continued to be buoyant at ₹4,413 crore, growing at the rate of 53% over the same period in 2020-21, it said.

According to the report, the extraordinary growth of foreign investments in pharma sector is mainly on account of investments to meet Covid related demands for therapeutics and vaccines. The Indian Pharmaceutical industry ranks third in the world in pharmaceutical production by volume. During 2020-21, total pharma exports stood at $24.4 billion against the total pharma import of $7.0 billion, thereby generating a rade surplus of $17.5 billion.

India is the largest supplier of generic medicines with a 20 percent share in the global supply. "Price competitiveness and good quality has enabled Indian medicines producers to be dominant players in the world market, thereby making the country the "Pharmacy of the world," the survey said. The survey said that although India is a prominent player in formulations, the country is significantly dependent on the import of bulk drugs that are used in the formulation of medicine. In certain cases, import dependence varies between 80-100%.

Source: Economic Times, 03.02.2022

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Freebies to doctors at your own cost, pharma companies told

The Finance Bill has pulled the plug on the practice adopted by pharmaceutical companies of claiming as a business deduction the cost of various freebies, including foreign trips provided to doctors. In other words, since such expenditure can no longer be claimed as a business deduction, it will jack up the taxable profits (or reduce the business loss) of a pharma company and is likely to make handing out of freebies less attractive.

Diving deep into various contrary judicial decisions, the Explanatory Memorandum to the Finance Bill states: "The legal position is clear that the claim of any expense incurred in providing various benefits in violation of the provisions of Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002, shall be inadmissible under section sub-section (1) of section 37 of Act being an expense prohibited by the law."

TOI, in its edition dated October 16, 2021, had covered a related decision of the Mumbai Income-tax Appellate Tribunal (ITAT). The tax tribunal in the case of Macleods Pharmaceuticals had observed that the freebies from pharma companies came with strings attached. Freebies cannot be lawfully accepted by medical professionals under the Medical Council Act and its rules. Therefore, expenditure on such freebies is for a purpose prohibited by law. An explanation to Section 37(1) of the I-T Act denies claim of any such expense if the same has been incurred for a purpose that is either an offence or prohibited by law. This explanation was inserted by the Finance Act, 1998, with retrospective effect from April 1, 1962.

The tax dispute related to two years and the cumulative sum of the freebie was Rs 248.7 crore. However, given a contrary ruling by a coordinate bench, where the cost of the freebie was allowed as a business deduction, it had referred the matter to a larger bench of ITAT.

The Finance Bill also nixes the claim as a deduction of expenses that are an offence under foreign law. The Explanatory Memorandum points out that, in some cases, the tax tribunals have accepted such a claim. The

exhaustive proposed legislative wording will now ensure that taxpayers cannot claim as a business deduction any expenditure incurred for any purpose that is an offence or is prohibited by any law, whether in India or overseas. They can also not claim as expenditure anything in the nature of a benefit provided to another person (say a doctor), where acceptance of such benefit was in violation of any law or rule governing his/her professional conduct.

Source: Times of India, 02.02.2022

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In the time of a pandemic, health sector gets a sugar pill

MUMBAI : India's annual budget left the healthcare industry disappointed. The two areas that received a boost from the finance minister Nirmala Sitharaman's budget were tele-mental health centres and the National Digital Health Ecosystem that is expected to digitize health records and create health identity for Indians. The measures, experts said, were inadequate to tackle the immensity of the country's crisis.

Allocation to the health ministry in the FY23 budget rose by ₹1,000 crore to ₹83,000 crore from this fiscal year's revised estimates of ₹82,000 crore. The department of health research was allocated ₹3,200 crore, an increase from the revised estimates of ₹3,080 crore of the current fiscal. The finance ministry allocated ₹690 crore for future pandemic preparedness as part of the Prime Minister's Ayushman Bharat Health Infrastructure Mission-BioSecurity Preparedness and strengthening pandemic research.

Experts said the focus on the mental health crisis in the budget is the most progressive step taken by the government this year. "The pandemic has accentuated mental health problems in people of all ages. To improve access to quality mental health counselling and care services, a 'National Tele-Mental Health Programme' will be launched," said Sitharaman in her budget speech. The pandemic has exacerbated mental health crises across the world, and India is no exception.

The budget proposes to set up 23 tele-mental health programmes with the help of Bengaluru-based NIMHANS and the Indian Institute of Information Technology with a budgetary allocation of ₹40 crore.

The second big allocation is to digitize health records through an open platform that will have digital registries of health providers and health facilities, unique health identity, consent framework, and universal access to health facilities. The budget allocated ₹200 crore for the National Digital Health mission.

These announcements were, however, too little to cheer the healthcare sector. "The budget did not provide the prominent focus, a long-term strategy, and a much higher allocation for healthcare as was expected," said Charu Sehgal, partner, life sciences and healthcare leader, Deloitte India. "It appears that the intent in this year's budget was not to make new major announcements but to consolidate and successfully implement some of the initiatives announced during the past 18 months of the pandemic."

Analysts have been expecting that there will be a fillip to the pharma sector in terms of concessions regarding the manufacturing of active pharmaceutical ingredients and regulatory pathways to speed up approvals. "While much more was expected on the pharma front, the inclusion of genomics and pharma as a sector for supportive policies, light-touch regulation and promotion of R&D are encouraging. However, the implementation of the details remain to be seen," Sehgal said in a statement.

The industry was hoping that the long-standing demand of making healthcare allocation to the GDP by over 2% would be met during the pandemic year. "Coming out of the shadows of the pandemic, it is most important to allocate at least 3% of the budget to healthcare," said Azad Moopen, chief executive officer of Aster DM Hospitals. Healthcare expenditure has been historically ignored during the annual budget despite the tall claims made by the government to strengthen health systems every year. The pandemic exposed the fault lines of the crumbling health infrastructure, especially in primary healthcare, that led the central government to take quick-fix measures such as setting up field hospitals, providing free covid-19 vaccines, and purchasing test kits to tackle the pandemic.

"The proposals made in Budget 22-23 should have made quality healthcare accessible and affordable. The government should have focused more on primary healthcare investment and given the healthcare system a 'National Priority' status, as was done for the IT sector", said Alok Roy, member of the industry lobby group Ficci's Health Services Committee.

Rajiv Nath, chairman of the All India Medical Device Industry, said he was disappointed that the budget did not include any measure that could boost the domestic medical device industry that could help the country end the 85% import dependence on medical devices. The Indian medical

device industry had expected a predictable tariff policy. Increase in customs duty for imported medical devices to 10-15% from the current rate of 0 to 7%, a move that could give domestic companies an advantage over their foreign counterparts. And the reduction in GST of certain medical devices that are currently considered luxury goods and taxed at 18%.

"Sadly, the Union budget 2022 speech has no stated strategic measures to boost the domestic manufacturing. These are the same domestic manufacturers; when imports got disrupted during the covid-19 crisis, the Govt. relied heavily on them to meet the rising demand of essential Covid items for the country, pushing the Indian medical devices sector to become self-reliant", Nath said. The only silver lining for suppliers of medical goods to the government is the revision in public procurement that now mandates 75% upfront payment to companies.

Source: Divya Rajagopal, HT Mint, 02.02.2022

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'Welcome acknowledgement of need for multi-stakeholder ecosystem for sunrise sectors such as pharma'

I would describe Union Budget 2022-23 as a growth-oriented one with infrastructure and digital as the key thrust areas.

On infrastructure, the Prime Minister's GatiShakti project seeks to encompass all modes of logistics in tandem with sustainability, clean energy and social infrastructure, in the process also creating massive livelihood opportunities. From a long-term perspective, I would say this project truly has transformative potential. On the digital front, what stood out for me was that not only has the Finance Ministry considered promotion of a digital economy and fintech, but it has also sought to harness the power of digital in skilling, financial and social inclusion.

Additionally, the Budget has recognised the privately-funded start-up ecosystem in India as one of the largest of its kind, and also recognises its potential as a growth driver. Overall, I would say that Budget 2022-23 maintained continuity with no major disruptions. For pharma, while there were no specific measures or initiatives announced, we do welcome the recognition of the need to build an enabling ecosystem with funding. On the healthcare front, as the Finance Minister observed in her opening remarks, the ongoing Covid-19 wave is dominated by the Omicron variant. The vaccination campaign has been and continues

to be the biggest focus for the country at present.

I would single out two announcements as highlights for the healthcare sector. The first one is a continuation of the thrust on digital – the roll-out of the Ayushman Bharat Digital Mission. The announcement of the open digital platform consisting of digital registries of health providers and health facilities, unique health identity, consent framework, and universal access to health facilities has been a long-awaited one. Such an open platform puts patient convenience and access at the centre of healthcare provision.

The other extreme announcement was on the launch of the 'National Tele Mental Health Programme' – a network of 23 tele-mental health centres, with NIMHANS as the nodal centre and the International Institute of Information Technology, Bangalore, providing technology support. This is a highly welcome and progressive move in view of the lack of open discussion and support systems when it comes to mental health. NIMHANS has for long rendered yeoman service in this area, and this is a recognition also of its contribution to this critical area of health.

From a pharma sector perspective, I am happy to note the Finance Minister's recognition of pharmaceuticals as among the sunrise sectors that have potential to contribute to sustainable development, modernisation, and making India competitive. As a pharma company, we see sustainable development as a core pillar of business strategy, along with the need for innovation to meet unmet patient needs.

The government proposes to take an approach comprised of supportive policies, light-touch regulations, facilitation of domestic capacities, and promotion of research & development. For R&D in these sunrise sectors, the Finance Minister has noted the need for collaboration among academia, industry and public institutions, along with government contribution. The government also proposes thematic funds for blended finance with it contributing up to 20 per cent and the funds being managed by private fund managers. These are conversations that the pharma industry has been having with the government in recent times.

We welcome the acknowledgement of the need for a multi-stakeholder ecosystem that enables and incentivises

R&D and innovation in pharma. We look forward to taking this further and working closely with the Government as we look to go from 'Make in India' to 'Discover and Make in India'.

The author Satish Reddy,is Chairman, Dr. Reddy's Laboratories Ltd.

Source: The Hindu Business Line, 01.02.2022

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GST collection up 15%, tops ₹1.38 lakh crore in January

India's goods and services tax collections in January stood at ₹1.38 lakh crore, a growth of 15 % over the year-ago period. January is the fourth straight month when GST collections crossed ₹1.30 lakh crore. The highest monthly GST collection has been ₹1,39,708crore in the month of April 2021. The finance Ministry, in a statement, said that 6.7 crore e-way bills were generated in the month of December 2021 which is 14% higher than 5.8 crore e-way bills generated in the month of November 2021. The government expects the positive trend in the revenues to will continue in the coming months as well. Other indicators are also suggesting that the growth momentum in tax collections will continue. Total number of GSTR-3B returns filed up to January 30, 2022 was 1.05 crore that includes 36 lakh quarterly returns, the finance ministry said. Of the gross GST revenue collected in the month of January 2022, CGST was ₹24,674 crore, SGST ₹32,016 crore, IGST ₹72,030 crore, including ₹35,181 crore collected on import of goods and cess was ₹9,674 crore, including ₹517 crore collected on import of goods.

The total revenue of the Centre and states in January after regular and ad-hoc settlements was ₹71,900 crore for CGST and ₹73,696 crore for SGST. The Centre also released GST compensation of ₹18,000 crore in January 2022 to states and UTs. During the month, revenues from import of goods was 26% higher and the revenues from domestic transaction are 12% higher than the same month last year.

Source: ET Bureau, 01.02.2022

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This Budget is an inclusive road map that prepares for India@100

The Union Budget of FY23 was announced in the backdrop of concerns over inflation, global supply chain

Ajay Piramal, The writer is chairman, Piramal Group

issues, income inequality, immense scope for improvement in private investment and risks from future waves of the pandemic. Measures outlined in the budget will set the stage for India to successfully navigate through these concerns.

The budget is focused on growth over fiscal consolidation, preparing for India @100. This is in sync with the vision outlined under Atmanirbhar Bharat, especially as we bring in the Amrit Kaal. In my view, it is critical to be self-sufficient in key areas of the economy to propel the country towards the next orbit of growth. Towards that, measures such as earmarking 68% of the capital procurement budget for defence for the domestic industry, PLI across segments and incentivising startups are positive steps.

Apart from Atmanirbharta, the budget focuses on supply-side measures with a lofty capex target. The ₹7.50-lakh-crore planned capex for FY23 is higher than the ₹5.40 lakh crore planned for FY22 and is more than double that in pre-pandemic times. This expenditure is likely to crowd in private investment and support economic growth. According to estimates, for every ₹1 crore of capex by the government, economic production grows by ₹2.45 crore.

Private investment is also likely to be incentivised through measures undertaken to improve infrastructure and simplify processes. The PM Gati Shakti envisages creating modern infrastructure and focuses on multimodal connectivity - roads, railways, airports, ports, mass transport, waterways and logistics. This will help in the efficient transport of goods and people, which are key inputs for all businesses. For instance, the latest Economic Survey demonstrates how the government e-marketplace made procurement of supplies by government contactless and paperless and resulted in substantial savings of as much 15-56%. Tax incentives for startups will help increase employment across districts. Simplification of processes will save time and money. Similarly, allocations of close to ₹48,000 crore under the Awas Yojana and even the ₹60,000 crore Har Ghar Nal Se Jal reflect the commitment towards building infrastructure and supporting economic growth through public expenditure.

The MSME sector is of paramount importance for the Indian economy - it accounts for 30% of GDP, 40% of exports and employs over 100 million people. The budget

rightly focuses on ways to ease and improve business conditions for MSMEs. Expansion and extension of ECLGS to March 2023 and revamping the CGTMSE scheme will ensure credit flows to the sector. The Raising and Accelerating MSME Performance (RAMP) programme will help MSMEs become more resilient. Push to MSMEs is imperative for inclusive growth and capex boost is necessary to crowd in private investment.

In the spirit of Atmanirbharta, the emphasis on reducing import dependence on oilseeds, export promotion and additional allocation under PLI for manufacturing solar PV modules augur well to guard against inflationary pressures. Plans to leverage digital infrastructure and real-time data will help India better position itself as an investment destination. There is a strong thrust on technology and digital. The announcement on centrally-backed digital currency by the RBI and on virtual digital assets shows that the government is cognisant of the changes happening in the digital space and taking appropriate measures accordingly. Further, the digital push in the form of bringing post offices under core banking and creating digital banking units augurs well for an inclusive growth.

The agenda of inclusive growth is also reflected in the expenditure allocation for social sectors. All in all, the budget laid out the medium-term road map to drive sustainable, durable growth, while keeping in mind the objective of fiscal consolidation.

Source: ET, 02.02.2022

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Budget 2022 is a catalyst for accelerated growth and a New India, says Yezdi Nagporewalla

The onset of 2022 has brought in its own set of challenges for the global economy. The ongoing pandemic, geo-political tensions, inflation, and tapering measures continue to keep conditions uncertain and risks aplenty. India, however, has shown signs of recovery during this tumultuous period with real GDP growth of 9.2% in FY22 and forex reserves at an all-time high of $634 billion. Fiscal deficit and inflation remain significant concerns though. Budget 2022 continues to provide impetus to growth with a focus on creating an inclusive, sustainable, and clean India.

Gati Shakti plan seeks to pull together in unison various infrastructure engines while data exchange between various operators through a common interface is proposed to facilitate seamless and efficient movement of goods. The budget also places thrust on energy transition and climate action, and measures such as clean and sustainable mobility, promoting energy efficiency and savings, increased allocation for solar power industry under the PLI scheme and issuance of green bonds are expected to help solidify India's commitment to be carbon-zero by 2070. Going with the philosophy of augmenting economic revival and consolidation through the 'multiplier effect', the government has sought to increase the outlay of effective capital expenditure to ₹10.68 lakh crore, which is approximately 4.1% of the GDP. Liquidity concerns in the MSME sector are sought to be eased through additional credit lines.

Increased allocation to capital expenditure would also spur consumerism. There is also a continued focus on affordable housing with an outlay of ₹48,000 crore, which augments the inclusiveness agenda of the government. The budget seeks to add impetus to the recent manufacturing surge by expanding the PLI scheme to 5G telecom infrastructure and extending the time limit for commencement of manufacturing by newly incorporated companies. The startup ecosystem has also been encouraged with extension of time to avail tax holiday concessions and reduction of surcharge on long-term capital gains. Crypto assets have been brought into the tax net. The government also seeks to shortly introduce a digital currency. While the construct is being formulated, it is expected that digital currency is unlikely to carry any underlying or intrinsic value. There have been certain misses, too. It would have been good to see changes on the personal tax front, as also measures like lowering input costs, especially on imports, which would have boosted consumption. Overall, it is a forward-looking budget with a long-term vision to consolidate the capital investment cycle, laying the foundation for a new India. Writer is CEO Designate, KPMG India

(Disclaimer: The opinions expressed in this column are that of the writer. The facts and opinions expressed here do not reflect the views of www.economictimes.com.)

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