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IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 47 (PAGES: 32) | 15 TO 21 DECEMBER 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

Block your Date

IDMA has pleasure in announcing the much awaited

22nd IDMA – APA Pharmaceutical Analysts' Convention (PAC) 2023
Along with EDQM (European Directorate for the Quality of Medicines & HealthCare)
On

Friday, 24th February and Saturday, 25th February, 2023

Venue: Hotel Four Seasons, Worli, Mumbai

Please await further details

HIGHLIGHTS

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40-50	425-300
40-45	425-355
35-40	500-425
30-35	600-500
25-30	710-600
20-25	850-710
18-20	1000-850
16-20	1180-850
16-18	1180-1000
14-16	1400-1180
12-14	1700-1400
10-12	2000-1700

Signet

The Complete Excipients Company

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Published on 7th, 14th, 21st and 30th of every month

Annual Subscription
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Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 53 **Issue No. 47** **15 to 21 December 2022**

IDMA ACTIVITIES:

GOVERNMENT COMMUNICATION:

NPPA MATTER:

PARLIAMENT NEWS:

NATIONAL NEWS:

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)
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Invitation For Pharma Conclave to be held on 8th January 2023 in association with BAPS, Swaminarayan Sanstha at Ahmedabad

Dear Member,

It gives us great pleasure to invite all members of "Pharma industry to participate" in "Pharma Conclave"- a special 1 day conference to be held in association with "BAPS" Swaminarayan Sanstha at Pramukh Swami Nagar on Sunday, 8th January, 2023. The conclave is organised in association with *GCCI, DMMA, GCA, GPA, FGSCDA, GAAMA, IPMMA, NDIA, Pharmexcil and other leading associations. BAPS Swaminarayan Sanstha is celebrating Pramukh Swami Maharaj's Centenary from 15th December 2022 to 15th January 2023 at Pramukh Swami Nagar, Sardar Patel Ring Road, Ahmedabad.

BAPS has invited IDMA to organize a one-day conference at the 600-acre Pramukh Swami Nagar festival site. The conference will feature talks and presentations by our leading members on most recent topics followed by enlightening talks from BAPS Sadhus.

A "personal guided" tour for all our esteemed members to the sprawling festival site has also been arranged. The Pramukh Swami Nagar comprises of several exhibition pavilions on life values, children's adventure land, light & sound show, thematic glow gardens, cultural gates, Pramukh Swami Maharaj's maha-murti, a replica of Swaminarayan Akshardham in New Delhi amongst other inspiring attractions.

Members are requested for their active participation.

Thanks & Regards,

Daara B. Patel
Secretary - General

IDMA

Indian Drugs Manufacturers' Association

Pramukh Swami Maharaj Centennial Celebrations

PHARMA CONCLAVE

8th Jan 2023

Pramukh Swami Maharaj Nagar, Nr. Ognaj Circle, SP Ring Rd, Ahmedabad

CONFERENCE THEME: NICHE-THE GROWTH STRATEGY

08:30 AM TO 9:15 AM	REGISTRATION & BREAKFAST
09:15 AM TO 09:45 AM	IDMA GSB AGM
09:45 AM TO 10:45 AM	INAUGURAL FUNCTION: KEY NOTE ADDRESS BY SHRI PANKAJBHAI PATEL, CHAIRMAN ZYDUS ADDRESS BY MINISTER
10:45 AM TO 11:15 AM	SHRI AMAN MEHTA- DIRECTOR TORRENT PHARMACEUTICALS LTD.
11:15 AM TO 11:45 AM	MS ADITI KARE - MD INDOCO REMEDIES LTD
11:45 AM TO 12:15 PM	TEA BREAK
12:15 PM TO 12:45 PM	DR. DUSHYANT PATEL- FOUNDER ASTRAL STERITECH PVT LTD
12:45 PM TO 01:00 PM	Q&A
01:00 PM TO 01:15 PM	VIDEO OF THE MAKING OF PRAMUKH SWAMI NAGAR
01:15 PM TO 02:00 PM	ADDRESS BY DR GYANVATSAL SWAMIJI ON "BEHIND THE SCENE- MANAGEMENT LEARNINGS"
02:00 PM TO 03:00 PM	LUNCH
03:00 PM TO 07:00 PM	GUIDED TOUR OF PRAMUKH SWAMI NAGAR BY BAPS VOLUNTEERS
07:00 PM ONWARDS	DINNER

SUPPORTING ASSOCIATIONS

- Gujarat Chamber of Commerce & Industry
- Federation of Gujarat State Chemist and Druggist Association
- Drugs Marketing & Manufacturing Association
- Gujarat Ayurvedic Aushadh Manufacturer's Association
- Gujarat Chemical Association
- Gujarat Pharmaceutical Association
- Pharmaceutical Export Promotion Council
- Indian Pharma Machinery Manufacturers Association
- Nutraceuticals & Dietary Supplements Industries Aid Association

Registration link will open soon

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www.pharmaliveexpo.com

IDMA
Indian Drugs Manufacturers' Association

Pramukh Swami Maharaj Centennial Celebrations

PHARMA CONCLAVE

8th Jan 2023

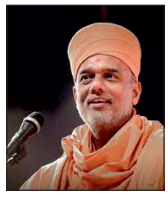
Pramukh Swami Maharaj Nagar, Nr. Ognaj Circle, SP Ring Rd, Ahmedabad

CONFERENCE THEME: NICHE-THE GROWTH STRATEGY

SPEAKERS


SHRI PANKAJBHAI PATEL


SHRI AMAN MEHTA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MS ADITI KARE


DR. DUSHYANT PATEL

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Registration link will open soon

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IDMA representation to Dr. Mandeep K Bhandari IAS, Joint Secretary to Government of India on the proposal to Amend Schedule-V of the Drugs and Cosmetics Rules, 1945 to revise the Limit of "Free Salicylic Acid Test" for medicines containing Aspirin

IDMA have submitted the following representation on 09th December 2022 to Dr. Mandeep K Bhandari IAS, Joint Secretary to Government of India, Ministry of Health & Family Welfare with a copy to Dr. V G Somani, Drugs Controller General of India on the above subject:

Greetings from Indian Drug Manufacturers' Association (IDMA).

In the deliberations at the 82nd meeting of Drugs Technical Advisory Board held on 02.04.2019 at DGHS, Nirman Bhawan, New Delhi Agenda 9,the Board was appraised of the proposal of revising the limit of "Free Salicylic Acid Test" for patent and proprietary medicines containing Aspirin .

The current provision under Schedule-V of the Drugs and Cosmetics Rules, 1945 is:

'All patent and proprietary medicines containing aspirin shall be subjected to "Free Salicylic Acid Test" and the limit of such acid shall be 0.75 per cent. Except in case of soluble type aspirin in which case the limit of such acid shall be 3 per cent.'

We would like to inform you that Aspirin and Aspirin containing FDCs are widely used formulations and covered under many different pharmacopeias.

Pharmacopoeia and the "Free Salicylic Acid" content limit specified in are as below:

Pharmacopoeia	"Free Salicylic Acid" content limit
IP 2018	Maximum 3 per cent
BP 2018	Maximum 3 per cent
USP 41	Not more than 3 per cent
USP 41	Not more than 8 per cent (for Aspirin Effervescent Tablets for Oral Solution)

The Drugs Technical Advisory Board (DTAB) deliberated upon the proposal and agreed to amend Schedule-V of the Drugs and Cosmetics Rules, 1945 to revise the limit of free salicylic acid content in medicines during the meeting.

However, the limits in the Schedule V have not been amended yet.

IDMA requests to revise the free salicylic acid limits under Schedule V of the Drugs and Cosmetics Rules, 1945 as proposed by the DTAB:

'All medicines containing aspirin shall be subjected to "Free Salicylic Acid Test", and the limit of "Free Salicylic Acid" content shall be not more than 3.0 per cent.'

This will harmonise the Limit mentioned under Schedule V of the Drugs and Cosmetics Rules, 1945 with all the pharmacopieas thus resulting in reducing the Regulatory Compliance issues.

We therefore request the Ministry of Health & Family Welfare and DCGI to kindly consider IDMA's request to revise the limit of Free Salicylic acid content and look forward to your positive response.

Thanking you.

Yours sincerely,

For Indian Drug Manufacturers' Association,

Dr Viranchi Shah
National President

S M Mudda
Chairman, Regulatory Affairs Committee

Trade Enquiry - Medicines Requirement by Republic of Belarus

PXL/HO/BEC-014/2022-23, date 15th December 2022

IDMA have a Communication from Mr. Udaya Bhaskar, Director General, Pharmexcil (Pharmaceuticals Export Promotion Council of India) (Set up by Ministry of Commerce & Industry, Government of India) dated 15th December 2022 on the above subject as reproduced below

Dear Sir/Madam,

Greetings from Pharmexcil!

Pharmexcil is in receipt of communication from the Embassy of Belarus in India, which seeks assistance in the procurement of select medicines. The following list of medicines as required by the Republic of Belarus.

1. Corglycone solution for injection 0.6mg/ml 1 ml (68 950 ampoules);
2. Strofantin solution for injection 0.25mg/ml lml (107 556 ampoules);
3. Neostigmine solution for injection 0.5mg/ml lml (162 020-);
4. Digoxin solution for injection 0.25mg/ml lml (22 744 -);
5. Hexamethonium benzosulfonate solution for injection 25mg/ml lml (54 190-);
6. Sodium oxybutyrate solution for injection 200mg/mi 10m 1(14 120-),
7. Valproic acid syrup 57.64mg/ml 150ml (3 566 bottles);
8. Buprenorphine solution for injection 0.3mg/ml lml (8 300 -);
9. Fluorescein solution for intravenous injection 100mg/ml 5ml (259-);
10. Vigabatrin tablets or sachet 500mg (24 000 tablets and more).

Interested member companies may kindly contact the following representative of the Embassy of Belarus in India.

Mr. Yaroslav Kolesnik

Second Secretary

Mob: +91 70420 01380

Tel : +91 11 405 29332

Email : india@mfa.gov.by

Member companies may take advantage of this unique opportunity for expansion of their business portfolio in the Republic of Belarus.

Important Note: *Members may please note that the above information is circulated on the basis of information received to us. Members are advised to make their own decisions before finalizing their business transactions.*

● ● ●

Minutes of the 237th(overall) and 105th meeting of the Authority under DPCO, 2013 held on 15.12.2022 at 03:30 PM

Proceeding No: 237/105/2022/F

I. The 237th meeting of the Authority (overall), which is the 105th meeting under the DPCO, 2013, was held on 15th December at 03:30 PM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

(i) Dr. Vinod Kotwal, Member Secretary, NPPA

(ii) Shri G. Venkatesh, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

(iii) Shri Saikat Sarkar, Economic Adviser, Department of Economic Affairs-joined through video-conferencing

Shri A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare also was present.

1.1 The following officers of NPPA attended the meeting and assisted the Authority in its deliberations:

(i) Shri Manmohan Sachdeva, Advisor (Cost-I)

(ii) Shri Sanjay Kumar, Advisor (Cost-II)

(iii) Shri G.L. Gupta, Director (M&E/A)

(iv) Ms. Rashmi Tahiliani, Join Director (Pricing)

(v) Shri Saurabh Bansal, DD (M&E)

(vi) Shri Mahaveer Saini, Deputy Director (Pricing)

(vii) Ms. Yuvika Panwar, Assistant Director (Overcharging/Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 104th Meeting held on 23.11.2022

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 - (a) Action Taken Report (ATR) on decisions taken by NPPA in its 104th Meeting held on 23.11.2022

2.1 Noted.

3. Agenda item no. 3 - Status of New Drug applications

3.1 Noted.

4. Agenda item no. 4 - New Drug applications for Price fixation under Para 5 and Para 15 of DPCO, 2013

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (1) to 4 (x) (total 10 Form I applications containing retail price fixation of 10 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 10(Ten) new drugs under Para 5 and 15 of the DPCO 2013, as detailed below:

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Amoxycillin and Potassium Clavulanate Oral Suspension IP	**Each Combipack contains:** (A) Amoxycillin and Potaassium Clavulanate Oral Suspension IP Composition: Each 5ml of Reconstituted suspension contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 600mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9mg (B) 2 Ampoule of Sterile Water for Reconstitution of Dry Syrup Each Ampoule Contains: Sterile Water for Injections IP 25ml	Combi Pack (50ml)	M/s Malik Lifesciences Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	168.43
2.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 1000mg (In Sustained Release form) Glimepiride IP 1mg Voglibose IP 0.2mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	11.60
3.	Metformin Hydrochloride (SR), Glimepiride and Voglibose Tablets	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 1000mg (In Sustained Release form) Glimepiride IP 2mg Voglibose IP 0.2mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	13.18
4.	Ceftazidime and Avibactam	**Each vial contains:** Ceftazidime	Per Vial	M/s Cipla Limited	

	powder for concentrate for solution for infusion	(pentahydrate) IP eq. to Ceftazidime 2mg Avibactam Sodium eq. to Avibactam 0.5gm Sodium content approx. 148mg (6.4meq)/vial			2500.00
5.	Moxifloxacin Hydrochloride and Loteprednol Ophthalmic Suspension	**Composition:** Moxifloxacin Hydrochloride IP eq. to Moxifloxacin 0.5% w/v Loteprednol Etabonate 0.5% w/v (Steril& Micronized) Sterile aqueous buffered vehicle q.s.	Per ml	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Limited	27.43
6.	Itraconazole Capsules 65mg (Supra-Bioavailable Formulation)	**Each hard gelatin capsule contains:** Itraconazole BP 65mg	1 Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	11.60
7.	Acetyleysteine& Acebrophylline Tablets	**Each film coated tablet contains:** Acetylcysteine BP 600mg Acebrophylline 100mg	1 Tablet	M/s Pure and Care Healthcare Pvt. Ltd. / M/s Cadila Pharmaceuticals Limited	14.91
8.	Paracetamol, Phenylephrine Hydrochloride, Caffeine & Dipphenhydramine Hydrochloride Tablets	**Each uncoated tablet contains:** Paracetamol IP 500mg Phenylephrine HCl IP 5mg Caffeine IP 30mg Diphenhydramine HCl IP 25mg	1 Tablet	M/s Dallas Drugs Pvt. Ltd. / M/s Micro Labs Pvt. Ltd.	2.76
9.	Rabeprazole and Ondansetron tablets	**Each Enteric coated tablet contains:** Rabeprazole Sodium IP 20mg Ondansetron Hydrochloride eq. to Ondansetron IP 4mg	1 Tablet	M/s Dallas Drugs Pvt. Ltd. / M/s Micro Labs Pvt. Ltd.	5.90
10.	Amoxycillin and Potassium Clavulanate Oral Suspension IP	**Each 5ml of Reconstituted suspension contains:** Amoxycillin Trihydrate IP eq. to Amoxycillin 600mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9mg	Per Vial (50ml)	M/s Malik Lifesciences Pvt. Ltd. / M/s Zuventus Healthcare Limited	168.43

5. Agenda item no. 5 - Status of implementation of Review cases

5. 1 Noted.

6. Agenda item no. 6-Proposed Framework for undertaking Suo Moto corrections in the notified prices by NPPA.

6.1 Fixation of ceiling prices of scheduled formulations and retail prices of new drugs is done based on the market based data as per the methodology laid down in DPCO, 2013. The source of market base data at present is the Pharmatrac database provided by AIOCD-AWACS on a monthly basis, which is an independent third party that provides the market-based data to NPPA as per the terms of contract entered into with it.

6.2 The draft working sheets for fixation of prices are uploaded on NPPA website to invite comments from the affected companies/ any person in compliance to DoP's O.M. dated 11.07.2016. If no comments are received within 10 working days, the prices as proposed in draft working sheets are placed for approval by the Authority. Once approved, the prices are notified by a Gazette notification.

6.3 NPPA has come across, few cases of data inconsistency/errors in the Pharmatrac data base, which normally fall under the following categories:

i. Error in pack size of formulations, for example, pack of 4 medicines shown as 1 in database.

ii. Formulations apparently not available in a relevant subgroup but recorded under a separate subgroup by Pharmatrac and price fixed by NPPA ignoring item(s) in that other subgroup.

iii. Wrong PTR reported in Pharmatrac (for example, PTR higher than MRP appearing on web sources) and later on the same is rectified by Pharmatrac

iv. Typographical error etc.

6.4 The above inconsistency/ errors may not be always ascertainable at the time of calculation of the prices despite exercising appropriate rigorous verification process. Therefore, prices are fixed based on available data and in case, no representation is received, the prices after approval by the Authority are notified.

6.5 Where any data inconsistency/errors are identified while fixing the prices of any formulation, NPPA also looks at the working sheets for the prices fixed for the same formulation in the recent past. While undertaking such exercise, NPPA may come across data inconsistency/errors that might have occurred in the past.

6.6 These have to be rectified as the primary function of NPPA is to ensure that pricing of the formulations is done correctly as per the provisions of DPCO. It is also in the public interest to ensure that the drugs are priced correctly so as to avoid their overpricing/ underpricing. DPCO, 2013 also does not prohibit NPPA from taking any corrective action once an error is noticed. The opinion of Legal Division, NPPA was also sought in this matter.

6.7 After detailed deliberations, the authority decided that Suo Moto action may be taken by NPPA for carrying out corrections even after the notification of prices only in the following cases:

a. Where such errors are duly acknowledged by Pharmatrac and/or correct data is confirmed from the companies.

b. There is no deviation from the pricing methodologies being followed by NPPA.

c. No review proceeding is pending for the subject formulation.

6.8 The corrected working sheet shall be uploaded on NPPA website for 10 working days for comments, if any. In case of non-receipt of any comments or after addressing any issues received on the revised working sheets, the same shall be placed before the Authority for decision. In those cases where the data has been verified and confirmed by Pharmatrac, prices will be re-computed based on revised data. Accordingly, corrigendum/ addendum/new price notifications will be issued.

6.9 The Authority agreed to the above framework and based on the detailed discussions also noted that such instances/cases would be few. However, utmost care must be exercised while processing such cases including

verification of data. It was also noted that such rectifications may either lead to upward or downward revision of prices.

7. Agenda item no. 7 -Form-IV intimation received from M/s Serum Institute of India Pvt. Ltd in respect of 2 scheduled formulations (1) Tetanus Toxoid Injection 0.5ml and (ii) Tetanus Toxoid Injection 5 ml of M/s Serum Institute of India Pvt. Ltd-reg.

7.1 The Authority noted that directions under Para 3 of DPCO, 2013 were issued to M/s Serum Institute of India Pvt. Ltd. from time to time by the Authority for continued production/ sale in respect of 2 scheduled formulations (i) Tetanus Toxoid Injection in 0.5 ml pack and (ii) Tetanus Toxoid Injection in 5 ml pack manufactured by M/s Serum Institute of India Pvt. Ltd. The period of continuation of production/ sale was extended up to 22.12.2022 in the 99th Authority meeting held on 28.06.2022.

7.2 The Authority deliberated upon the matter in detail and decided to re-invoke Para 3 of DPCO, 2013 to direct M/s Serum Institute of India Pvt. Ltd to continue the production and sales of 2 scheduled formulations (1) Tetanus Toxoid Injection in 0.5 ml pack and (ii) Tetanus Toxoid Injection in 5 ml pack up to 31.12.2023.

8. Agenda item no. 8-Fixation of Ceiling Price of scheduled formulations under Revised Schedule-I (NLEM, 2022)

8.1 The methodology for fixation of ceiling price of scheduled formulations under revised Schedule-I (NLEM, 2022) was deliberated in the 104th meeting of Authority held on 23.11.2022. Based on methodology approved, ceiling prices for 121 formulations were uploaded on NPPA website on 25.11.2022 for 10 working days to invite comments in compliance to O.M. No. F. NO. 31015/44/2016-PI.1 dated 11.07.2016 issued by Department of Pharmaceuticals. The last date for receiving the representations for these 121 formulations was 09.12.2022.

8.2 The Authority was apprised that till 9.12.2022, 267 representations from companies were received for 91 formulations out of 121 formulations uploaded on 25.11.2022. Companies have submitted copy of invoice showing the revised PTR and snapshots of sample pack showing revised MRP. It was informed that these representations can be broadly categorized as under:

(a) Related to data in worksheets:

i. Price to Retailer considered as per July, 2022 Pharmatrac database is not reflecting the WPI increase availed by the companies in April, 2022;

ii. Incorrect pack sizes; and

iii. Considering MR variant along with conventional variant in cases where MR variant is separately included in schedule.

(b) Related to methodology:

i. Representations on methodology mainly relating to using July, 2022 database;

ii. Consideration of all variant for pricing of drugs i.e. SR, ER, PR etc.;

iii. 16% retailer margin is considered for fixation of ceiling prices whereas the industry practice is to allow 20% margin on MRP etc.; and

iv. Prices of formulation which were increased under Para 19 like Heparin, Metronidazole, etc. and period of 5 years has not lapsed since such revision should not be considered for ceiling price fixation.

8.3 The Authority noted that the issues related to methodology as per the representations have been already deliberated and decided in 104th meeting of the authority. However, with regard to representations related to data, the Authority was informed that the claims made by the companies in their representations have been cross verified with the Form-II/Form-V submitted by the companies till 15.05.2022 in IPDMS as per provisions of DPCO, 2013. As result there was price revision in 69 formulations as compared to the ceiling prices reflected in the draft uploaded working sheets.

8.4 The Authority also noted the representation of M/s Glenmark Pharmaceuticals Limited dated 07.12.2022 stating that their product is capsule and not tablet in respect of two formulations i.e. Dabigatran 110 mg (Tablets) and Dabigatran 150 mg (Tablets). It was also informed that the same has been confirmed with Pharmatrac and web sources. Only one company is qualifying with MAT of more than 1% in respect of two formulations i.e. Dabigatran 110 mg (Tablets) and Dabigatran 150 mg (Tablets). Hence, the case falls under Para 6 of DPCO, 2013 for calculation of ceiling price by applying monopoly clause. Therefore, the matter of fixation of ceiling prices of two formulations i.e. Dabigatran 110 mg (Tablets) and Dabigatran 150 mg (Tablets) is deferred.

8.5 The Authority deliberated and approved the ceiling prices of 119 formulations as appearing in column (7) of the Table below:

S.No.	Section of revised Schedule-I	Formulation	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Price With immediate effect	Unit
(1)	(2)	(3)	(4)	Rs./Unit (5)	SO No. & dated (6)	(7)	(8)
1	2.1.5	Paracetamol	Tablet650mg	2.04	(S.O. 1499(E) dated 30.03.2022)	1.78	Per Tablet
2	2.3.1	Allopurinol	Tablet300mg	8.31	(S.O. 1499(E) dated 30.03.2022)	5.02	Per Tablet
3	2.4.2	Hydroxychloroquine	Tablet400mg	13.26	(S.O. 1499(E) dated 30.03.2022)	12.31	Per Tablet
4	5.1.1	Carbamazepine	Modified Release – Tablet200mg	2.59	(S.O. 1499(E) dated 30.03.2022)	2.14	Per Tablet
5	5.1.1	Carbamazepine	Modified Release – Tablet400mg	5.11	(S.O. 1499(E) dated 30.03.2022)	4.16	Per Tablet
6	5.1.1	Carbamazepine	Tablet400mg	3.67	(S.O. 1499(E) dated 30.03.2022)	3.17	Per Tablet
7	5.1.2	Clobazam	Tablet5mg	5.7	(S.O. 1499(E) dated 30.03.2022)	4.94	Per Tablet
8	5.1.2	Clobazam	Tablet10mg	10.04	(S.O. 1499(E) dated 30.03.2022)	8.55	Per Tablet
9	5.1.4	Levetiracetam	Tablet250mg	6.49	(S.O. 1499(E) dated 30.03.2022)	5.57	Per Tablet
10	5.1.4	Levetiracetam	Tablet500mg	13.13	(S.O. 1499(E) dated 30.03.2022)	11.4	Per Tablet
11	5.1.4	Levetiracetam	ModifiedReleaseTablet750mg	19.31	(S.O. 1499(E) dated 30.03.2022)	16.32	Per Tablet
12	5.1.4	Levetiracetam	Tablet750mg	20.19	(S.O. 1499(E) dated 30.03.2022)	16.98	Per Tablet
13	5.1.5	Lorazepam	Tablet1 mg	2.29	(S.O. 1499(E) dated 30.03.2022)	2.06	Per Tablet
14	5.1.5	Lorazepam	Tablet2 mg	2.79	(S.O. 1499(E) dated 30.03.2022)	2.51	Per Tablet
15	5.1.10	SodiumValproate	Tablet300mg	4.41	(S.O. 1499(E) dated 30.03.2022)	3.98	Per Tablet
16	6.1.1.2	Mebendazole	Tablet100 mg	3.26	(S.O. 1499(E) dated 30.03.2022)	2.59	Per Tablet
17	6.1.2.2	Diethylcarbamazine(DEC)	Tablet100mg	1.57	(S.O. 1499(E) dated 30.03.2022)	1.49	Per Tablet
18	6.2.1.6	Cefadroxil	Tablet500mg	4.47	(S.O. 1499(E) dated 30.03.2022)	3.99	Per Tablet
19	6.10.1.1	Artemether (A)	Tablet80mg(A)+480mg(B)	25.72	(S.O. 1499(E) dated	22.75	Per

		+Lumefantrine(B)			30.03.2022)		Tablet
20	6.10.1.1	Artemether (A) +Lumefantrine(B)	Tablet 20 mg (A) + 120 mg (B)	13.9	(S.O. 1499(E) dated 30.03.2022)	11.28	Per Tablet
21	6.2.1.8	Cefixime	Tablet400mg	24.5	(S.O. 1499(E) dated 30.03.2022)	19.71	Per Tablet
22	6.2.2.4	Clarithromycin	Tablet250mg	31.09	(S.O. 1499(E) dated 30.03.2022)	21.04	Per Tablet
23	6.2.2.4	Clarithromycin	Tablet500mg	54.8	(S.O. 1499(E) dated 30.03.2022)	34.61	Per Tablet
24	6.4.5	Cycloserine	Capsule250mg	60.28	(S.O. 1499(E) dated 30.03.2022)	52.79	Per Capsule
25	6.4.8	Ethionamide	Tablet250mg	17.52	(S.O. 1499(E) dated 30.03.2022)	13.21	Per Tablet
26	6.4.10	Levofloxacin	Tablet250mg	4.9	(S.O. 1499(E) dated 30.03.2022)	4.25	Per Tablet
27	6.4.10	Levofloxacin	Tablet500mg	8.95	(S.O. 1499(E) dated 30.03.2022)	7.85	Per Tablet
28	6.4.10	Levofloxacin	Tablet750mg	12.14	(S.O. 1499(E) dated 30.03.2022)	10.69	Per Tablet
29	6.4.11	Linezolid	Tablet600mg	36.69	(S.O. 1499(E) dated 30.03.2022)	31.81	Per Tablet
30	6.4.12	Moxifloxacin	Tablet400mg	28.13	(S.O. 1499(E) dated 30.03.2022)	22.79	Per Tablet
31	6.4.15	Rifampicin	Capsule600mg	12.87	(S.O. 1499(E) dated 30.03.2022)	10.13	Per Capsule
32	6.5.3	Fluconazole	Tablet400mg	34.69	(S.O. 1499(E) dated 30.03.2022)	26.53	Per Tablet
33	6.7.1.1	Abacavir	Tablet300 mg	52.36	(S.O. 1499(E) dated 30.03.2022)	43.34	Per Tablet
34	6.7.1.2	Abacavir (A) +Lamivudine(B)	Tablet600mg(A)+300mg(B)	101.18	(S.O. 1499(E) dated 30.03.2022)	64.5	Per Tablet
35	6.7.2.2	Nevirapine	Tablet200 mg	15.89	(S.O. 1499(E) dated 30.03.2022)	14.09	Per Tablet
36	6.7.3.2	Raltegravir	Tablet400mg	173.77	(S.O. 1499(E) dated 30.03.2022)	131.81	Per Tablet
37	6.7.4.2	Darunavir	Tablet600mg	185.33	(S.O. 1499(E) dated 30.03.2022)	137.73	Per Tablet
38	6.8.2	Entecavir	Tablet1mg	140.76	(S.O. 1499(E) dated 30.03.2022)	116.15	Per Tablet
39	6.8.4	Sofosbuvir	Tablet400mg	741.12	(S.O. 1499(E) dated 30.03.2022)	468.32	Per Tablet
40	6.10.1.5	Clindamycin	Capsule150mg	16.07	(S.O. 1499(E) dated 30.03.2022)	14.59	Per Capsule
41	6.10.1.5	Clindamycin	Capsule300mg	26.24	(S.O. 1499(E) dated 30.03.2022)	25.3	Per Capsule
42	5.2.1.2	Flunarizine	Tablet5mg	3.06	(S.O. 1499(E) dated 30.03.2022)	2.21	Per Tablet
43	5.2.1.2	Flunarizine	Tablet10mg	5.26	(S.O. 1499(E) dated 30.03.2022)	4.3	Per Tablet
44	5.3.1	Levodopa (A) +Carbidopa(B)	Tablet 100 mg (A) + 25 mg (B)	2.5	(S.O. 1499(E) dated 30.03.2022)	2.3	Per Tablet
45	5.3.1	Levodopa (A) +Carbidopa(B)	Tablet 100 mg (A) + 10 mg (B)	1.73	(S.O. 1499(E) dated 30.03.2022)	1.57	Per Tablet
46	5.3.1	Levodopa (A) +Carbidopa(B)	Tablet250mg(A) +25mg(B)	4.15	(S.O. 1499(E) dated 30.03.2022)	3.94	Per Tablet

47	10.1.3	Isosorbidedinitrate	Tablet5mg	0.83	(S.O. 1499(E) dated 30.03.2022)	0.73	Per Tablet
48	10.3.1	Amlodipine	Tablet2.5mg	1.84	(S.O. 1499(E) dated 30.03.2022)	1.59	Per Tablet
49	10.3.1	Amlodipine	Tablet5mg	2.89	(S.O. 1499(E) dated 30.03.2022)	2.23	Per Tablet
50	10.3.1	Amlodipine	Tablet10mg	5.63	(S.O. 1499(E) dated 30.03.2022)	4.81	Per Tablet
51	10.3.5	Ramipril	Tablet2.5 mg	5.53	(S.O. 1499(E) dated 30.03.2022)	4.65	Per Tablet
52	10.3.5	Ramipril	Tablet 5mg	8.7	(S.O. 1499(E) dated 30.03.2022)	7.3	Per Tablet
53	10.3.7	Telmisartan	Tablet20mg	4.05	(S.O. 1499(E) dated 30.03.2022)	3.44	Per Tablet
54	10.3.7	Telmisartan	Tablet40mg	7.32	(S.O. 1499(E) dated 30.03.2022)	6.03	Per Tablet
55	10.3.7	Telmisartan	Tablet80mg	11.15	(S.O. 1499(E) dated 30.03.2022)	9.24	Per Tablet
56	18.3.1.6	Metformin	Tablet1000mg	4	(S.O. 1499(E) dated 30.03.2022)	3.11	Per Tablet
57	18.3.1.6	Metformin	Tablet500mg	2.13	(S.O. 1499(E) dated 30.03.2022)	1.77	Per Tablet
58	18.3.1.1	Glimepiride	Tablet2mg	6.34	(S.O. 1499(E) dated 30.03.2022)	5.11	Per Tablet
59	18.3.1.1	Glimepiride	Tablet1mg	3.99	(S.O. 1499(E) dated 30.03.2022)	3.27	Per Tablet
60	5.4.1	Donepezil	Tablet10mg	17.82	(S.O. 1499(E) dated 30.03.2022)	15.24	Per Tablet
61	5.4.1	Donepezil	Tablet5mg	12.48	(S.O. 1499(E) dated 30.03.2022)	10.57	Per Tablet
62	10.6.1	Atorvastatin	Tablet80mg	New	New	36.19	Per Tablet
63	10.6.1	Atorvastatin	Tablet40mg	21.42	(S.O. 1499(E) dated 30.03.2022)	16.92	Per Tablet
64	10.6.1	Atorvastatin	Tablet20mg	14.75	(S.O. 1499(E) dated 30.03.2022)	11.01	Per Tablet
65	10.6.1	Atorvastatin	Tablet10mg	6.09	(S.O. 1499(E) dated 30.03.2022)	4.38	Per Tablet
66	1.4.2	Baclofen	Tablet20mg	16.43	(S.O. 1499(E) dated 30.03.2022)	14.52	Per Tablet
67	1.4.2	Baclofen	Tablet10mg	11.94	(S.O. 1499(E) dated 30.03.2022)	10.39	Per Tablet
68	1.4.2	Baclofen	Tablet5mg	6.15	(S.O. 1499(E) dated 30.03.2022)	5.68	Per Tablet
69	18.6.2	Levothyroxine	Tablet 50mcg	1.1	(S.O. 1499(E) dated 30.03.2022)	0.92	Per Tablet
70	18.6.2	Levothyroxine	Tablet75mcg	1.44	(S.O. 1499(E) dated 30.03.2022)	1.28	Per Tablet
71	18.6.2	Levothyroxine	Tablet88mcg	1.71	(S.O. 1499(E) dated 30.03.2022)	1.47	Per Tablet
72	18.6.2	Levothyroxine	Tablet150mcg	1.72	(S.O. 1499(E) dated 30.03.2022)	1.59	Per Tablet
73	18.6.2	Levothyroxine	Tablet112mcg	1.6	(S.O. 1499(E) dated 30.03.2022)	1.48	Per Tablet
74	18.6.2	Levothyroxine	Tablet25mcg	1.45	(S.O. 1499(E) dated 30.03.2022)	1.29	Per Tablet
75	18.3.1.6	Metformin	ModifiedreleaseTablet1000mg	4.05	(S.O. 1499(E) dated 30.03.2022)	3.52	Per Tablet
76	1.4.5	Vecuronium	Powderforinjection10mg	209.93	(S.O. 1499(E) dated	104.67	Each

					30.03.2022)		vial
77	1.4.5	Vecuronium	Powderforinjection 4 mg	101.32	(S.O. 1499(E) dated 30.03.2022)	66.36	Each vial
78	7.1.10	Capecitabine	Tablet500mg	140.33	(S.O. 1499(E) dated 30.03.2022)	100.53	Per Tablet
79	22.1.4	Misoprostol	Tablet200mcg	18.54	(S.O. 1499(E) dated 30.03.2022)	16.92	Per Tablet
80	26.4	Cholecalciferol	Solid oral dosage form 1000 IU Tablet	4.16	(S.O. 1499(E) dated 30.03.2022)	3.84	Per Tablet
81	6.2.2.2	Cefuroxime	Oralliquid125mg/5mL(p)	New	New	4.71	Per ML
82	7.4.11	Mesna	Injection100mg/mL	18.62	(S.O. 1499(E) dated 30.03.2022)	13.83	Per ML
83	2.1.4	Mefenamicacid	Oralliquid100mg/5mL(p)	0.58	(S.O. 1499(E) dated 30.03.2022)	0.5	Per ML
84	6.7.1.3	Lamivudine	Tablet100mg	New added	New added	9.28	Per Tablet
85	6.7.1.3	Lamivudine	Tablet150mg	New added	New added	9.69	Per Tablet
86	6.5.5	Itraconazole	Oralliquid10mg/mL	New added	New added	4.41	Per ML
87	7.4.7	Haloperidol	Tablet1.5mg	1.84	(S.O. 1499(E) dated 30.03.2022)	1.37	Per Tablet
88	7.4.7	Haloperidol	Tablet5mg	3.82	(S.O. 1499(E) dated 30.03.2022)	3.18	Per Tablet
89	23.1.3	Haloperidol	Tablet10mg	4.9	(S.O. 1499(E) dated 30.03.2022)	4.26	Per Tablet
90	7.2.1	Bicalutamide	Tablet50mg	76.18	(S.O. 1499(E) dated 30.03.2022)	38.62	Per Tablet
91	7.2.2	Letrozole	Tablet2.5mg	39.03	(S.O. 1499(E) dated 30.03.2022)	26.15	Per Tablet
92	7.3.3	Mycophenolatemofetil	Tablet500mg	91.19	(S.O. 1499(E) dated 30.03.2022)	65.89	Per Tablet
93	23.2.1.1	Amitriptyline	Tablet50mg	6.45	(S.O. 1499(E) dated 30.03.2022)	5.34	Per Tablet
94	5.2.1.1	Amitriptyline	Tablet75mg	6.23	(S.O. 1499(E) dated 30.03.2022)	4.77	Per Tablet
95	8.2.2	Heparin	Injection1000IU/mL	24.39	(S.O. 2151(E) dated 30.06.2020)	18.92	Per ML
96	8.2.2	Heparin	Injection5000IU/mL	60.54	(S.O. 2151(E) dated 30.06.2020)	53.48	Per ML
97	5.2.1.1	Amitriptyline	Tablet25mg	2.5	(S.O. 1499(E) dated 30.03.2022)	2.16	Per Tablet
98	7.4.6	Fluoxetine	Capsule20 mg	4.05	(S.O. 1499(E) dated 30.03.2022)	3.56	Per Capsule
99	23.2.1.3	Fluoxetine	Capsule60 mg	10.87	(S.O. 1499(E) dated 30.03.2022)	9.9	Per Capsule
100	23.2.1.3	Fluoxetine	Capsule40 mg	6.15	(S.O. 1499(E) dated 30.03.2022)	5.79	Per Capsule
101	23.2.1.3	Fluoxetine	Capsule10 mg	3.3	(S.O. 1499(E) dated 30.03.2022)	2.96	Per Capsule
102	7.3.4	Tacrolimus	Capsule0.5mg	24.56	(S.O. 1499(E) dated 30.03.2022)	18.43	Per Capsule
103	7.3.4	Tacrolimus	Capsule1mg	43.38	(S.O. 1499(E) dated	36.23	Per

					30.03.2022)		Capsule
104	7.3.4	Tacrolimus	Capsule2mg	84.97	(S.O. 1499(E) dated 30.03.2022)	75.22	Per Capsule
105	7.1.34	Temozolomide	Capsule20 mg	662.24	(S.O. 1499(E) dated 30.03.2022)	393.6	Per Capsule
106	7.1.34	Temozolomide	Capsule250mg	5203.58	(S.O. 1499(E) dated 30.03.2022)	3838.48	Per Capsule
107	23.3.2	Zolpidem	Tablet5mg	5.98	(S.O. 1499(E) dated 30.03.2022)	5.44	Per Tablet
108	23.3.2	Zolpidem	Tablet10mg	9.38	(S.O. 1499(E) dated 30.03.2022)	7.59	Per Tablet
109	6.6.2.1	Valganciclovir	Tablet450 mg	New added	New added	357.39	Per Tablet
110	7.1.28	Lenalidomide	Capsule5mg	New added	New added	59.98	Per Capsule
111	24.1.5	Montelukast	Tablet4 mg	New added	New added	8.95	Per Tablet
112	24.1.5	Montelukast	Tablet5 mg (including chewable tablets)	New added	New added	10.45	Per Tablet
113	24.1.5	Montelukast	Tablet10 mg	New added	New added	14.66	Per Tablet
114	6.8.1	Daclatasvir	Tablet60mg	New added	New added	178.34	Per Tablet
115	7.4.9	Loperamide	Tablet2mg	2.19	(S.O. 1499(E) dated 30.03.2022)	2.03	Per Tablet
116	23.1.4	Risperidone	Tablet1 mg	3.42	(S.O. 1499(E) dated 30.03.2022)	2.66	Per Tablet
117	23.1.4	Risperidone	Tablet2 mg	5.47	(S.O. 1499(E) dated 30.03.2022)	4	Per Tablet
118	23.1.4	Risperidone	Tablet4 mg	11.1	(S.O. 1499(E) dated 30.03.2022)	6.56	Per Tablet
119	6.7.3.1	Dolutegravir	Tablet50mg	New added	New added	100.59	Per Tablet

The meeting ended with a vote of thanks to the Chair and all the participants in the meeting.

F. No. 8(105)/2022/DP/NPPA-Div. II

Dr. Vinod Kotwal, Member Secretary, NPPA

In Lok Sabha & In Rajya Sabha

In Lok Sabha

Attracting Foreign Invesment

Lok Sabha Unstarred Question No. 33

Shri G.M. Siddeshwar:

Shrimati Poonam Mahajan:

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

(a) whether any reformative efforts have been taken by the Government to attract investment by foreign companies and setting up trading units in India;

(b) if so, the efforts made in this direction and the sectors in which said efforts have been made;

(c) whether the Government is currently taking steps or proposes to take steps in this direction; and

(d) if so, the details of possible measures for attracting foreign investment in the country?

Answered on 07th December, 2022

A. (a) & (b): To promote Foreign Direct Investment (FDI), the Government has put in place an investor-friendly policy, wherein most sectors, except certain strategically important sectors, are open for 100% FDI under the automatic route. FDI Policy in India has been liberalized and simplified in the past few years. In order to make India a more attractive destination, in the recent past, reforms in the FDI Policy have been undertaken in sectors such as Defence, Insurance, Petroleum & Natural Gas and Telecom. Further in the trading sector, 100% FDI is permitted in Single Brand Product Retail Trading (SBRT) and 51% FDI is permitted in Multi Brand Retail Trading (MBRT).

(c) & (d): The Government reviews the FDI policy on an ongoing basis and makes changes from time to time, to ensure that India remains an attractive and investor friendly destination. The intent is to remove policy bottlenecks that may be hindering investment inflows into the country. Changes are made in the policy after having intensive consultations with stakeholders including apex industry chambers, Associations, representatives of industries/groups and other organizations taking into consideration their views/comments.

The Minister of State in the Ministry of Commerce & Industry (Shri Som Parkash)

Import-Export and Trade Surplus

Lok Sabha Unstarred Question No. 36

Shri C.R. Patil:

Shri Pratap Chandra Sarangi:

Shri Brijbhushan Sharan Singh:

Shri P.P. Chaudhary:

Dr. Ramapati Ram Tripathi:

Shri Sangam Lal Gupta:

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

(a) the details of India's total import-export and trade surplus during the last five years;

(b) whether the Government has formulated an Action Plan to enhance India's trade surplus; and

(c) if so, the details thereof?

Answered on 07th December, 2022

A. (a) The details of India's overall export (merchandise plus services), import and trade balance in the last five years and current year are as follows:

Year	Export (Value in US$ Billions)	Import (Value in US$ Billions)
2016-17	440.05	480.21
2017-18	498.62	583.11
2018-19	538.08	640.09
2019-20	526.55	602.98
2020-21	497.90	511.12
2021-22	676.53	760.06

Source: RBI and DGCI&S, Kolkata.

(b) & (c) : The Government has taken the following

measures to enhance India's export and trade balance:

(i) Foreign Trade Policy (2015-20) extended by 31-03-2023.

(ii) Interest Equalization Scheme on pre and post shipment rupee export credit has also been extended upto 31-03-2024.

(iii) Assistance provided through several schemes to promote exports, namely, Trade Infrastructure for Export Scheme (TIES) and Market Access Initiatives (MAI) Scheme.

(iv) Rebate of State and Central Levies and Taxes (RoSCTL) Scheme to promote labour oriented textile export has been implemented since 07.03.2019.

(v) Remission of Duties and Taxes on Exported Products (RoDTEP) scheme has been implemented since 01.01.2021.

(vi) Common Digital Platform for Certificate of Origin has been launched to facilitate trade and increase Free Trade Agreement (FTA) utilization by exporters.

(vii) 12 Champion Services Sectors have been identified for promoting and diversifying services exports by pursuing specific action plans.

(viii) Districts as Export Hubs has been launched by identifying products with export potential in each district, addressing bottlenecks for exporting these products and supporting local exporters/ manufacturers to generate employment in the district.

(ix) Active role of Indian missions abroad towards promoting India's trade, tourism, technology and investment goals has been enhanced.

(x) Package announced in light of the COVID pandemic to support domestic industry through various banking and financial sector relief measures, especially for MSMEs, which constitute a major share in exports.

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

Trade with Vietnam

Lok Sabha Unstarred Question No. 141

Shri Abdul Khaleque:

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

(a) the total volume and value of trade with Vietnam in the last five years; and

(b) the major sectors for trade, import as well as export with Vietnam including expected value of trade between the two countries by 2025?

Answered on 07th December, 2022

A. (a) India's trade with Vietnam in the last five years is as below:

(Values in USD Million)

Particulars	2017-18	2018-19	2019-20	2020-21	2021-22
Total trade between India and Vietnam	12831.64	13699.61	12343.32	11120.30	14141.19

(Source: DGCI&S)

(b) The major sectors for import from Vietnam are Telecom instruments, Consumer electronics, Copper and its products, Computer hardware/peripherals and Inorganic chemicals. The major sectors for export to Vietnam are Iron and steel, Bovine meat, Raw cotton, Marine products, and Aluminum and its products. If the present Compound Annual Growth Rate (CAGR) of 6.95% in bilateral trade with Vietnam from 2016-17 to 2021-22 is maintained, the expected value of trade between the two countries will be USD 18.50 Billion by 2025-26.

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

Export and Import

Lok Sabha Unstarred Question No. 76

Shri Adhikari Deepak (Dev):

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

(a) the details of the Export and Import of the country in the last five years, year and amount wise; and

(b) the names of top five exporting and importing countries in the last three years along with trade amount?

Answered on 07th December, 2022

A. (a): The value of overall (merchandise plus services) export and import in the last five years are as follows:

(Value in US$ billions)

Years	Export	Import
2017-18	498.61	583.11
2018-19	538.08	640.09
2019-20	526.55	602.98
2020-21	497.90	511.12
2021-22	676.53	760.06

Source: DGCI&S, Kolkata

(b): India's merchandise export to top 5 countries in the last three years are as follows:

(Value in US$ billions)

S. No.	Country	2019-20	2020-21	2021-22
1	U S A	53.1	51.6	76.2
2	United Arab Emirates	28.9	16.7	28.0
3	China P Rp	16.6	21.2	21.3
4	Bangladesh PR	8.2	9.7	16.2
5	Netherland	8.4	6.5	12.5

Source: DGCI&S, Kolkata.

India's merchandise import from top 5 countries in the last three years are as follows:

(Value in US$ billions)

S. No.	Country	2019-20	2020-21	2021-22
1	China P Rp	65.3	65.2	94.6
2	United Arab Emirates	30.3	26.6	44.8
3	U S A	35.8	28.9	43.3
4	Saudi Arab	26.9	16.2	34.1
5	Iraq	23.7	14.3	31.9

Source: DGCI&S, Kolkata.

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

FDIs

Lok Sabha Unstarred Question No. 1.

Shrimati Sarmistha Sethi:

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

(a) whether the Foreign Direct Investments (FDIs) into India has declined recently and if so, the details thereof;

(b) whether the Government has assessed the reasons for the same;

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

(d) whether the Government has the data of FDI invested and/or proposed in various States, State-wise, during the last three years and if so, the details thereof?

Answered on 07th December, 2022

A. **(a):** The Foreign Direct Investments (FDIs) into India is increasing year to year basis since 2014-15. The details can be seen in the following table:

S. No.	Financial Year	Total FDI Inflow (in USD billion)
1.	2014-15	45.15
2.	2015-16	55.56
3.	2016-17	60.22
4.	2017-18	60.97
5.	2018-19	62.00
6.	2019-20	74.39
7.	2020-21	81.97
8.	2021-22 (P)	84.84

Source: Reserve Bank of India. (P) – Figures are provisional.

(b) & (c): Do not arise.

(d): State wise data on FDI invested and/or proposed during the last three years is not centrally maintained.

The Minister of State in the Ministry of Commerce & Industry (Shri Som Parkash)

In Rajya Sabha

Increase in Chinese Imports

Rajya Sabha Unstarred Question No. 375

Shri Mallikarjun Kharge:

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

(a) whether it is a fact that the Chinese imports in India have increased exponentially in the last few years;

(b) if so, the steps Government has taken to reverse such a situation; and

(c) the details of Indian exports and imports with China in the last five years, year-wise?

Answered on 09th December, 2022

A. (a) to (c): The details of the merchandise imports and exports from China in the last five years, year-wise, are as follows:

Values in USD Billion

Year	Import	Export
2017-18	76.38	13.33
2018-19	70.32	16.75
2019-20	65.26	16.61
2020-21	65.21	21.19
2021-22	94.57	21.26

Source: DGCI&S, Kolkata

Imports take place to meet the gap between domestic production and supply, consumer demand and preferences for various products. Many imports are inputs for further manufacturing in India and exports from India. Several steps have been taken by the Government to reduce import, which include creating/ enhancing of domestic capacity, incentivizing domestic manufacturing through Production Linked Incentive (PLI) schemes, phased manufacturing plans, adoption of mandatory technical standards and enforcement of FTA Rules of Origin (RoO). Besides, an 'Import Monitoring Cell' of the Department of Commerce regularly monitors the import surges on monthly basis and sensitizes the concerned Ministries for remedial action. Compulsory registration under "Electronics and IT Goods (Requirement of Compulsory Registration) Order 2021" addresses safety standards for 63 notified electronic products including mobile phones. The stock, sale, import, manufacture, etc. without having valid Registration and Standard Mark of these items is prohibited. The Directorate General of Trade Remedies (DGTR) of Department of Commerce recommends restrictions on import of a product by imposition of additional duty or quantitative restrictions (QRs) if Indian industry is 'seriously injured' or 'threatened with injury' on account of surge in imports or unfair trade practices. Currently, 53 Anti-dumping measures and 4 Countervailing Duty measures are in force on Chinese products on account of unfair trade practices.

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

Increase in Trade Deficit

Rajya Sabha Unstarred Question No. 380

Shri Ayodhya Rami Reddy Alla:

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

(a) the details of exports, imports and trade deficit in the last three years;

(b) whether it is a fact that India's trade deficit has increased significantly, if so, the details thereof and the reasons therefor; and

(c) whether Government has taken any steps to reduce import reliance so as to counter the widening trade deficit, if so, the details thereof and if not, the reasons therefor?

Answered on 09th December, 2022

A. (a) & (b): The details of overall (merchandise plus services) exports, imports and trade deficit in the last three years are as given below:

Values in US$ Billion

Year	Export	Import
2019-20	526.55	602.98
2020-21	497.90	511.12
2021-22	676.53	760.06

Source: RBI and DGCI&S, Kolkata

Trade deficit depends upon relative fluctuations in the import and export of different commodities and services due to global and domestic factors such as demand and supply in domestic and international

markets, currency fluctuations, international prices, etc.

(c) : Government has taken several steps to reduce import reliance so as to curb the trade deficit. These include creating/enhancing of domestic capacity, incentivizing domestic manufacturing through Production Linked Incentive (PLI) schemes, phased manufacturing plans, timely use of trade remedy options, adoption of mandatory technical standards, enforcement of FTA Rules of Origin (RoO) and development of import monitoring system. At the same time, following steps have been taken to boost exports so as to narrow down the trade deficit :

(i) Foreign Trade Policy (2015-20) extended upto 31-03-2023.

(ii) Interest Equalization Scheme on pre and post shipment rupee export credit has also been extended upto 31-03-2024.

(iii) Assistance provided through several schemes to promote exports, namely, Trade Infrastructure for Export Scheme (TIES) and Market Access Initiatives (MAI) Scheme.

(iv) Rebate of State and Central Levies and Taxes (RoSCTL) Scheme to promote labour oriented textile export has been implemented since 07.03.2019.

(v) Remission of Duties and Taxes on Exported Products (RoDTEP) scheme has been implemented since 01.01.2021.

(vi) Common Digital Platform for Certificate of Origin has been launched to facilitate trade and increase Free Trade Agreement (FTA) utilization by exporters.

(vii) 12 Champion Services Sectors have been identified for promoting and diversifying services exports by pursuing specific action plans.

(viii) Districts as Export Hubs has been launched by identifying products with export potential in each district, addressing bottlenecks for exporting these products and supporting local exporters/ manufacturers to generate employment in the district.

(ix) Active role of Indian missions abroad towards promoting India's trade, tourism, technology and investment goals has been enhanced.

(x) Package announced in light of the COVID pandemic to support domestic industry through various banking and financial sector relief measures, especially for MSMEs, which constitute a major share in exports.

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

Schemes to Incentivize Manufacturing Sector

Rajya Sabha Unstarred Question No. 425.

Shri B. Parthasaradhi Reddy:

Q. Will the Minister of **Commerce and Industry** be pleased to state:

(a) whether Government is aware that the manufacturing sector has tremendous potential to generate enormous employment;

(b) if so, the details of the schemes approved by Government to incentivize the manufacturing sector;

(c) the funds allocated under the said schemes during the last three years, State-wise and year-wise; and

(d) the growth of the manufacturing sector in the country during the last three years, year- wise, category wise and State-wise?

Answered on 09th December, 2022

A. (a) to (c): Yes, Sir. Government of India has undertaken several schemes/initiatives to promote manufacturing sector. Some of them are indicated at **Annexure-I**.

(d) : The annual growth rate of Manufacturing Sector as per Index of Industrial production (IIP), with base year 2011-12, for last three years, is as under:

Annual Sectoral Growth rate (in %) from 2019-20 to 2021-22

Sector	2019-20	2020-21	2021-22
Manufacturing	-1.4	-9.6	11.8

Source: National Statistical Office.

The growth of manufacturing sector was adversely affected due to COVID-19 pandemic, which has shown positive growth in double digits in the Financial Year 2021-2022.

Within manufacturing sector, annual growth rate for NIC 2-digit categories as per IIP for last three years is indicated at **Annexure II**.

ANNEXURE-I

ANNEXURE RFERRED TO IN REPLY TO PARTS (a) TO (c) OF THE RAJYA SABHA UNSTARRED QUESTION NO. 425 FOR ANSWER ON 9TH DECEMBER, 2022.

Schemes undertaken by DPIIT to promote manufacturing sector

Government of India has undertaken various steps to promote manufacturing sector and to boost domestic and foreign investments in India. These include introduction of Goods and Services Tax, reduction in Corporate tax, interventions to improve ease of doing business, FDI policy reforms, measures for reduction in compliance burden, policy measures to boost domestic manufacturing through public procurement orders, Phased Manufacturing Programme (PMP), to name a few.

The series of measures taken by the Government to improve the economic situation and convert the disruption caused by COVID 19 into an opportunity for growth includes Atmanirbhar packages, introduction of Production Linked Incentive (PLI) Scheme in various Ministries, investment opportunities under National Infrastructure Pipeline (NIP) and National Monetisation Pipeline (NMP), India Industrial Land Bank (IILB), Industrial Park Rating System (IPRS), soft launch of the National Single Window System (NSWS), etc. An institutional mechanism to fast-track investments has been put in place, in the form of Project Development Cells (PDCs) in all concerned Ministries/ Departments of Government of India.

Keeping in view India's vision of becoming 'Atmanirbhar' and to enhance India's Manufacturing capabilities and Exports, an outlay of INR 1.97 lakh crore (over US$ 26 billion) has been announced in Union Budget 2021-22 for PLI schemes for 14 key sectors of manufacturing, starting from fiscal year (FY) 2021-22. With the announcement of PLI Schemes, significant creation of production, skills, employment, economic growth and exports is expected over the next five years and more.

The reforms taken by Government have resulted in increased Foreign Direct Investment (FDI) inflows in the country. FDI inflows in India stood at US $ 45.15 billion in 2014-2015 and have continuously increased since then, and India registered its highest ever annual FDI inflow of US$ 84.84 billion (provisional figures) in the financial year 2021-22.

As per Economic Survey 2021-22, inspite of Covid related disruptions there is trend of positive overall growth of Gross Value Addition (GVA) in manufacturing sector. The total employment in this sector has increased from 57 million in the year 2017-18 to 62.4 million in the year 2019-20.

Details of some of the major initiatives /schemes are as follows:

1. **Make in India initiative:** 'Make in India' is an initiative which was launched on 25th September 2014 to facilitate investment, foster innovation, build best in class infrastructure and make India a hub for manufacturing, design and innovation. It was one of the unique single, vocal for local initiative that promoted India's manufacturing domain to the world. 'Make in India' initiative is not the state/district/city/ area specific initiative, rather it is being implemented all over the country.
2. **Industrial Corridor Development Programme:** In order to accelerate growth in manufacturing, Government of India (GoI) has adopted the strategy of developing Industrial Corridors in partnership with State Governments. The objective of this programme is to develop Greenfield Industrial regions/areas/ nodes with sustainable infrastructure & make available Plug and Play Infrastructure at the plot level. As part of National Industrial Corridor Program, 11 Industrial Corridors are being developed in 4 phases.
3. **Ease of Doing Business:** The objective is to improve Ease of Doing Business and Ease of Living by Simplifying, Rationalizing, Digitizing and Decriminalizing Government to Business and Citizen Interfaces across Ministries/States/ UTs. The key focus areas of the initiative are simplification of procedures, rationalization of legal provisions, digitization of government processes, and decriminalization of minor, technical or procedural defaults.
4. **National Single Window System:** The setting up of National Single Window System (NSWS) was announced in the Budget 2020-21 with the objective to provide "end to end" facilitation and support to investors, including pre-investment

advisory, provide information related to land banks and facilitate clearances at Centre and State level. Envisioned as a one-stop shop for investor related approvals and services in the country, the National Single Window System (NSWS) was soft-launched on 22nd September, 2021 by Hon'ble Commerce & Industry Minister. Large number of States/UTs Single Window Systems have been linked with the NSWS Portal thereby providing access to approvals of these States/UTs to be applied through NSWS.

5. **PM Gati Shakti National Master Plan (NMP):** PM Gati Shakti National Master Plan (NMP), a GIS based platform with portals of various Ministries/Departments of Government, was launched in October, 2021. It is a transformative approach to facilitate data-based decisions related to integrated planning of multimodal infrastructure, thereby reducing logistics cost. Empowered Group of Secretaries (EGoS) and Network Planning Group (NPG) have been created as institutional arrangement. About 2000 data layers of various Central Ministries/Departments/State Governments have so far been uploaded on the NMP.

   For enhanced capital expenditure by states for infrastructure development, the Ministry of Finance, Department of Expenditure through the "Scheme for Special Assistance to States for Capital Investment for 2022-23" on 6th April 2022 has made a additional provision of Rs. 1,00,000 crore for disbursement among the states as long term loans at a zero interest rate. Out of this, under Part II of the scheme Rs 5,000 crore are specifically provided for PM GatiShakti related expenditure.

6. **National Logistics Policy:** National Logistics Policy (NLP) was launched on 17th September 2022, that aims to lower the cost of logistics and lead it to par with other developed countries. It is a comprehensive effort to address cost inefficiency by laying down an overarching interdisciplinary, cross-sectoral, and multi-jurisdictional framework for developing entire logistics ecosystem. This would boost economic growth, provide employment opportunities, and make Indian products more competitive in the global market.

7. **Production Linked Incentive scheme**: Keeping in view India's vision of becoming 'Atmanirbhar', Production Linked Incentive (PLI) Schemes for 14 key sectors have been announced with an outlay of Rs. 1.97 lakh crore to enhance India's Manufacturing capabilities and Exports. These schemes have potential for creation of high production, economic growth, exports and significant employment over the next five years and more.

8. **Indian Footwear and Leather Development Programme (IFLDP):** The Central Government has approved the Central Sector Scheme 'Indian Footwear and Leather Development Programme (IFLDP)' in January, 2022 with an allocation of Rs.1700 crore till 31.03.2026 or till further review, whichever is earlier. The expenditure of last three years made under previous scheme of Indian Footwear, Leather and Accessories Development Programme (IFLADP) is as under:

(Rs. in crore)

Year	2019-20	2020-21	2021-22
Expenditure under IFLADP	382.79	153.38	228.48

9. **North East Industrial and Investment Promotion Policy (NEIIPP), 2007:** North East Industrial and Investment Promotion Policy (NEIIPP), 2007 was notified for a period of 10 years from 1.4.2007 to 31.03.2017 with the purpose to boost industrialization of the region. The registered eligible units continue to receive benefits under grand-parenting of scheme. Funds allocated under the NER Schemes during the last three years are as below:

Subsidy released under NEIIPP, 2007

(Rs. in Crore)

Name of the State/ UT	2019-20	2020-21	2021-22	TOTAL
Arunachal Pradesh	4.60	0.99	16.75	22.34
Assam	396.75	168.98	139.40	705.13
Manipur	26.93	0	0	26.93
Meghalaya	61.16	20.91	9.33	91.40
Mizoram	0.17	2.11	1.17	3.45
Nagaland	1.82	0	0	1.82
Sikkim	86.81	2.23	10.39	99.43
Tripura	5.29	4.78	2.96	13.03
TOTAL	583.53	200.00	180.00	963.53

10. **North East Industrial Development Scheme (NEIDS), 2017:** To promote industrialization in NE States and to boost employment and income generation, a new Scheme namely North East Industrial Development Scheme (NEIDS), 2017, came into force w.e.f. 01.04.2017 for a period of five years. The scheme covered manufacturing and service sector.

Subsidy released under NEIDS, 2017

(Rs. in crore)

Name of the State/UT	2019-20	2020-21	2021-22	TOTAL
Assam	1.00	15.00	30.00	46.00
TOTAL	1.00	15.00	30.00	46.00

11. Industrial schemes covering manufacturing & service sector in the UTs of J&K and Ladakh and State of Himachal Pradesh and Uttarakhand were launched. Scheme-wise details of expenditure during the last three years are as under:

(Rs. in crore)

	Name of Scheme	2019-20	2020-21	2021-22	Total
a.	Special Package Scheme				
	J&K and Ladakh	79.91	42.16	28.17	150.24
	Himachal Pradesh	31.01	0.01	0	31.02
	Uttarakhand	21.04	2.79	0.16	23.99
b.	Industrial Development Scheme forJ&K and Ladakh	-	-	43.41	43.41
c.	Industrial Development Scheme for Himachal Pradesh and Uttarakhand	-	-	131.90	131.90
		-	-		

Schemes undertaken by other Ministries/ Departments to promote manufacturing sector

12. Schemes to encourage domestic manufacturing of Pharmaceutical drugs including bulk drugs and medical devices are as follows;

i. The Scheme for *Promotion of Bulk Drug Parks*, with a financial outlay of Rs. 3,000 crores and the tenure from FY 2020-2021 to FY 2024-25, provides for financial assistance to three States for establishing Bulk Drug Parks.

ii. The scheme of *Strengthening of Pharmaceutical Industry (SPI),* was launched with a financial outlay of Rs. 500 crores and the tenure from FY 2021-2022 to FY 2025-26, to provide infrastructure support for pharma MSMEs in clusters and to address the issues of technology upgradation of individual pharma MSMEs.

iii. Under the scheme *"Promotion of Medical Devices Parks"*, final approval for financial assistance of Rs. 100 crore each, has been given to the States of Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh for establishment of common facilities in their Medical Device Parks.

13. **Modified Programme for Semiconductors and Display Manufacturing Ecosystem**: In furtherance of the vision of Aatmanirbhar Bharat and positioning India as the global hub for Electronics System Design and Manufacturing, a comprehensive program for the development of semiconductors and display manufacturing ecosystem in India was approved by Government of India with an outlay of 76,000 crore (>10 billion USD). The Programme contained various schemes to attract investments in the field of semiconductors and display manufacturing.

14. **FAME-India Scheme (Faster Adoption and Manufacturing of (Hybrid &) Electric Vehicles):** In order to promote manufacturing of electric and hybrid vehicle technology and to ensure sustainable growth of the same, FAME-India Scheme- Phase-I [Faster Adoption and Manufacturing of (Hybrid &) Electric Vehicles in India] was implemented from 1st April 2015 for a period of two years which was subsequently extended upto 31st March, 2019. Total outlay of Phase-I of the FAME-India Scheme has been enhanced from Rs. 795 Crore to Rs. 895 Crore.

The Phase-II of FAME-India scheme proposes to give a push to electric vehicles (EVs) in public transport and seeks to encourage adoption of EVs by way of market creation and demand aggregation.

15. **Udyami Bharat Scheme:** 'Udyami Bharat' is reflective of the continuous commitment of the

government, right from day one, to work towards the empowerment of Micro Small and Medium Enterprises (MSMEs). The government has launched several initiatives from time to time like MUDRA Yojana, Emergency Credit Line Guarantee Scheme, Scheme of Fund for Regeneration of Traditional Industries (SFURTI) etc. to provide necessary and timely support to the MSME sector, which has helped benefit crores of people across the country. 'Raising and Accelerating MSME Performance' (RAMP) scheme with an outlay of around Rs 6000 crore, aims to scale up the implementation capacity and coverage of MSMEs in the States, with impact enhancement of existing MSME schemes.

16. **PM Mega Integrated Textile Region and Apparel (PM MITRA):** In order to have world-class industrial infrastructure which would attract cutting age technology and boost FDI and local investment in the textiles sector, Ministry of Textiles issued notification to set up 7 Mega Integrated Textile Region and Apparel (PM MITRA) Parks with a total outlay of Rs. 4,445 crore. These parks will offer an opportunity to create an integrated textiles value chain right from spinning, weaving, processing/dyeing and printing to garment manufacturing at one location.PM MITRA scheme aspires to position India strongly on the Global textiles map.

ANNEXURE-II

ANNEXURE RFERRED TO IN REPLY TO PART (d) OF THE RAJYA SABHA UNSTARRED QUESTION NO. 425 FOR ANSWER ON 9TH DECEMBER, 2022.

Annual Growth rate (in %) for NIC 2-digit category from 2019-20 to 2021-22

NIC 2008	Description	2019-20	2020-21	2021-22
10	Manufacture of food products	2.0	-2.7	5.9
11	Manufacture of beverages	-2.6	-25.8	11.5
12	Manufacture of tobacco products	1.3	-14.3	8.7
13	Manufacture of textiles	-2.5	-21.3	29.3
14	Manufacture of wearing apparel	0.3	-29.9	27.4
15	Manufacture of leather and related products	-1.8	-18.0	1.3
16	Manufacture of wood and products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials	8.3	-19.6	15.1
17	Manufacture of paper and paper products	-12.8	-23.3	17.7
18	Printing and reproduction of recorded media	-7.1	-28.0	12.4
19	Manufacture of coke and refined petroleum products	0.0	-12.2	8.9
20	Manufacture of chemicals and chemical products	-0.4	-2.1	4.3
21	Manufacture of pharmaceuticals, medicinal chemical and botanical products	-0.1	1.6	1.3
22	Manufacture of rubber and plastics products	-7.4	-3.7	8.0
23	Manufacture of other non-metallic mineral products	-1.9	-12.9	20.1
24	Manufacture of basic metals	11.0	-5.8	18.6
25	Manufacture of fabricated metal products, except machinery and equipment	-14.7	-13.7	10.9
26	Manufacture of computer, electronic and optical products	-10.5	-12.6	11.1
27	Manufacture of electrical equipment	-4.5	-12.3	12.2
28	Manufacture of machinery and equipment n.e.c.	-12.7	-14.1	11.0
29	Manufacture of motor vehicles, trailers and semi-trailers	-18.3	-19.1	18.4
30	Manufacture of other transport equipment	-6.2	-18.0	1.6
31	Manufacture of furniture	-7.2	-27.9	23.3
32	Other manufacturing	-12.5	-22.5	49.0

Source: National Statistical Office.

The Minister of State In the Ministry of Commerce & Industry (Shri Som Parkash)

Mandaviya inaugurates new ICMR facility for research to tackle zoonotic threat

Union minister Mansukh Mandaviya. (Photo: Reuters)

ICMR-NARFBR has potential to make India a key global player in biomedical research in 21st-century. Through provision of quality services in support of biomedical research & training with adherence to highest international standards for human & ethical animal care and use, this resource facility can play a crucial role in improving health and welfare of the nation

NEW DELHI: Union heath minister Mansukh Mandaviya on Saturday inaugurated ICMR's National Animal Resource Facility for Biomedical Research (NARFBR) at Genome Valley in Hyderabad to address zoonotic threats. The new ICMR centre will have great significance in animal studies for biomedical research as it is crucial in discovering causes, diagnosis and treatment of zoonotic agents and diseases.

NARFBR is an apex facility which will provide ethical care and use and welfare of laboratory animals during research. The newly build centre will work as the state-of-the-art facility for not just ethical animal studies but spans from basic, applied to regulatory animal research. It will help in capacity building of new researchers and will create processes for pre-clinical testing of new drugs, vaccines and diagnostics within the country along with quality assurance checks.

"ICMR-NARFBR has potential to make India a key global player in biomedical research in 21st-century. Through provision of quality services in support of biomedical research & training with adherence to highest international standards for human & ethical animal care and use, this resource facility can play a crucial role in improving health and welfare of the nation," Mandaviya said. For any society to move forward, research and innovation remain a crucial aspect. India has given push to indigenous research and this is reaping benefits for us now, he added.

Dr. Rajiv Bahl, director general of ICMR and secretary at the Department of Health Research, termed the facility to be not just best in the country but biggest in the world.

"From availability of various animals for ethical research to strengthening various processes under one umbrella, NARFBR would be an asset for the country to deal with zoonotic diseases" Bahl added.

Source: Priyanka Sharma, HT Mint, 17.12.2022

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Indian medical experts welcome US FDA guidance on developing drugs for treatment for pulmonary TB

Indian medical experts have noted that the US FDA draft guidance on 'Developing drugs for treatment for pulmonary TB' is a much desired policy. This is because tuberculosis has resurfaced in many countries and is a public health crisis.

There is a demand for new drugs and the purpose of this guidance is to assist sponsors in the clinical development of investigational drugs for the treatment of pulmonary tuberculosis under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, this guidance provides the FDA's current recommendations regarding the overall development program for a new investigational drug or drugs to be used in combination with approved drugs or as a new treatment regimen that includes one or more investigational drugs to support an indication for the treatment of pulmonary TB. This guidance does not address the development of drugs for latent TB infection or for extra pulmonary TB.

Infections caused by mycobacterium tuberculosis (M. tuberculosis) are diagnosed in the United States and are endemic in many parts of the world. Resistance to multiple drugs and coinfection with human immunodeficiency virus

(HIV) pose challenges in the management of TB. Drugs with new mechanisms of action, improved safety profiles, fewer drug-drug interactions, and treatment-shortening combination regimens are needed to manage TB, they said.

According to US FDA nonclinical evaluations provide valuable information for the development of investigational drugs. Activity of anti-mycobacterial drugs can be evaluated in trials of early bactericidal activity (EBA) and in phase 2 trials that evaluate microbiological outcomes at early time points. For a combination regimen, the sponsor should evaluate the contribution of each drug to the treatment effect. This can be evaluated in phase 2 clinical development and in nonclinical studies.

Treatment of pulmonary TB includes more than one drug in a treatment regimen, and sponsors may be developing more than one investigational drug as part of a new combination regimen. Sponsors should consult with the global regulatory authority early in development regarding plans to demonstrate the contribution of the investigational drugs as part of a combination regime.

Sponsors should conduct phase 2 trials to assess the antimycobacterial activity of an investigational drug regimen. In addition, if feasible, a phase 2 development program should include a dose ranging study. These studies need to help in determining the most appropriate dose regimen to be taken into phase 3.

The phase-2 exploratory endpoints can include, but are not limited to 8-week evaluation for absence of acid-fast bacilli (AFB) in sputum. It needs to look at time to sputum culture negativity for M. tuberculosis. There is also a need to look at symptom improvement; and a biomarker intended to predict clinical benefit. Therefore, US FDA recommends that as part of phase 2 trial designs, sponsors include long-term follow-up with collection of clinical endpoints in addition to earlier time points.

Current drugs available for treatment of TB are two antibiotics: isoniazid and rifampicin for 6 months. Then there are 2 additional antibiotics: pyrazinamide and ethambutol for the first 2 months of the 6-month treatment period. While the disease is preventable and curable, TB is present in all countries and age groups. The incidence of TB globally is 6 million men, 3.4 million women and 1.2 million children. In India it is affecting 2.5 million people which is 188 per 100,000 population.

Source: Nandita Vijay, Pharmabiz, 20.12.2022

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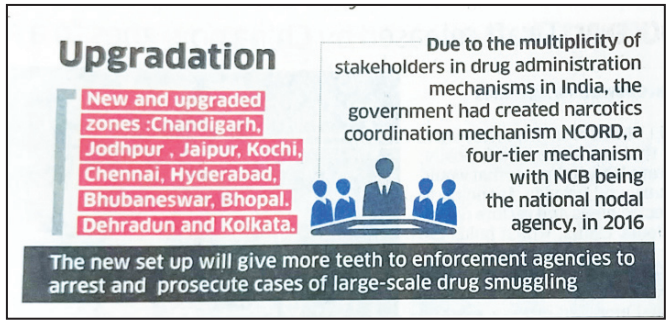
Centre boosts drug fight, creates new NCB zones

Faced with a serious challenge to contain rising drug proliferation, the Centre has given approval for creation and upgradation of seven regions and 30 zones of the Narcotics Control Bureau (NCB) across India.

NCB, the lead nodal agency on drug enforcement, earlier had 13 zones and 13 sub zones spread in different parts of the country. According to home ministry officials, new zones will be set up and sub zones will be upgraded while a larger regional bureau at key locations in Delhi, Mumbai, Chennai, Kolkata, Amritsar, Ahmedabad and Guwahati with additional manpower will be deployed.



"The increasing use of technology has given drug traffickers an edge where they can receive orders on darknet and order payments through cryptocurrencies. The prevailing narcotics use is emerging as a national threat," said an official.

In the border states of Jammu and Kashmir, the NCB will set up a zonal centre in Kashmir while upgrading the existing Jammu sub zone. Similarly, in coastal states of Kerala, Tamil Nadu, Gujarat and Maharashtra, the enforcement will be stringent with trained manpower deployed in the states, they added. As per the union home ministry data, narcotics worth ₹1,881 crore have been seized from 2018 to 2021, which is three times the value of drugs seized from 2011 to 2014 (₹604 crore).

The seizure of drugs along the Kerala, Gujarat and Mumbai coast have also increased manifold. In October this year, NCB seized 200 kg of heroin off the Kerala coast, allegedly linked to a Pakistan-based drug cartel, owned by Haji Salim.

Source: Rahul Tripathi, The Economic Times, 19.12.2022

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IDMA BULLETIN

PUBLISHED ON 7th, 14th, 21st and 30th of Every Month

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(Effective from 01.11.2017)

Magazine Size: 21.5 cm x 27.5 cm / Print Area: 18.5 cm x 23.5 cm

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For further details such as series discounts etc, please contact:
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PUBLICATIONS DIVISION

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Website: **www.idma-assn.org/www.indiandrugsonline.org**


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TRUST
Dear Partner,
The trust that you have placed in us is the single most important reason behind us growing from a small operation to becoming the industry leader in the high quality pharmaceutical excipients industry in India.
Today, we would like to thank each of you for your unflinching faith in us. We know just how strong our relationship is, based on this mutual trust. And it is our highest priority every day to ensure nothing threatens that.
Because our biggest success lies in your infinite trust in us. And we will always ensure that we treat that trust with the utmost care.
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LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2021-23
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 21.12.2022

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