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IDMA BULLETIN

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INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

GOOD NEWS FOR OUR MEMBERS AND READERS

IDMA 60th Year Diamond Jubilee Celebrations held on 14th and 15th April 2022 was a huge hit and very successful

(DETAILED REPORT IN COMING WEEKS)

HIGHLIGHTS

UNWAVERING ATTENTION TO DETAIL. FOR ABSOLUTE **PRECISION.**

Dear Partner,

We are firm believers in partnering with those who make us stronger and add value to our customers. Partners such as Tereos and Biogrund who allow us to provide for even the most highly technical and specialised needs, with perfect precision.

Tereos is one of the world's leading sucrose producers, with expert products that allow for a wide variety of pharmaceutical applications. Over the last two decades, Biogrund has built itself as the specialists in top-quality solutions for oral dosage forms, such as film coating, tableting and colouration.

Together, we ensure that customers get exactly what they want, when they want it.

Signet-ure *Precision*

Tereos

COMPRESSUC (Directly Compressible Sucrose)
ICING SUGAR (Milled Sucrose)
CASTER SUGAR (Screened Sucrose)
ALVEOSUCRE (Agglomerated Sucrose)

BIOGRUND

AQUAPOLISH (Film Coating Systems)
HME CLEANER PLUS (Cleaning Agent for Hot Melt Extrusion)
BONUWAX (Ready-to-use Waxes)
ISUPOLISH (Sugar & Sugar-free Coating Systems)

Signet

The Complete Excipients Company

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Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 53 **Issue No. 14** **08 to 14 April 2022**

IDMA ACTIVITIES:

NPPA MATTERS:

GOVERNMENT NOTIFICATIONS:

CUSTOMS MATTERS:

PARLIAMENT NEWS:

INTERVIEW:

NATIONAL NEWS:

Report on Aptar Pharma and Indian Drug Manufacturers' Association (IDMA) Webinar on Stability challenges on "Enhance Oral Solid Doses Stability and Drug Delivery Devices through the use of Active Packaging"

Aptar Pharma and Indian Drug Manufacturers' Association (IDMA) organized a Webinar on stability challenges on "Enhance Oral Solid Doses Stability and Drug Delivery Devices through the use of Active Packaging" held on 01st April 2022. There were more than 50 numbers of participants in the webinar. Webinar was successful with the active participation of speakers and Members.

Following speech and presentation made at the webinar (as reproduced below)

Welcome address by Mr S R Vaidya, Chairman, MSME Committee, IDMA.

Presentation on Enhance Oral Solid Doses Stability and Drug Delivery Devices through the use of Active Packaging made by Mr. Francois Bidet, VP Business Development, EMEA Aptar CSP Technologies.

(Note: As presentation is too long only specific slide presentation is reproduced here, for more details members may contact IDMA secretariat at admin@idmaindia.com)

Welcome address by Mr S R Vaidya, Chairman, MSME Committee, IDMA

Good evening Ladies and Gentlemen!

Greetings from Indian Drug Manufacturers' Association (IDMA) and Aptar Pharma.

It gives me great pleasure to address this august gathering & on behalf of our National President, Dr. Viranchi Shah, Mr. Daara B Patel, Secretary General of IDMA & Mr. Kanwal Tikoo of Aptar Pharma, I welcome you all to this interesting & informative webinar titled **"Enhance Oral Solid Doses Stability and Drug Delivery Devices through the use of Active packaging"**

Aptar pharma's purpose statement is Transforming ideas into solutions that improve everyday life.

Aptar's greatest impact on society undoubtedly comes from the benefits of their products and solutions provided which transform and enhance everyday user experiences and in some cases, even save lives.

Aptar Pharma is a global leader in drug delivery, consumer product dispensing and active material science solutions, they use insights, design, engineering and science to create dosing, dispensing and protective packaging technologies for the world's leading brands.

Indian Drug Manufacturers' Association (IDMA) has successfully completed 60 glorious years of its existence, providing support to its members for supplying affordable quality medicines, not only to the people of India, but also to people all over the world. The IDMA Membership consists of over 1000 plus wholly-owned Indian large, medium and small companies manufacturing Formulations & APIs. At present, we have 8 State Boards located pan India.

We are pleased to announce that IDMA would be celebrating its 60th Year Celebrations on 14th& 15th April 2022 wherein we would be having our Honourable Ministers – Dr Mansukh Mandaviya Ji, Hon. Minister of Health & Family Welfare and Minister of Chemicals & Fertilizers as our Chief Guest at the Inaugural Ceremony and Shri Piyush Goyal, Hon'ble Minster of Commerce & Industry as our Chief Guest at the Valedictory Ceremony along with a host of dignitaries & speakers.

For today's webinar, we have got an excellent speaker from Aptar Pharma- Mr. Francois Bidet. Mr. Francois is the Vice-President of Business Development, EMEA at Aptar CSP Technologies. Mr. Francois main focus is on developing a robust pipeline of opportunities to drive long-term business growth in the EMEA region, across all of the company's application fields.

Stability challenges are likely to increase with the development of more potent APIs, larger molecules, and modified release tablets. Innovative and evolving dosage forms, such as chewable, micro-tablets and orally disintegrating tablets, also face heightened stability and shelf life challenges. These deficiencies are often linked to the presence of moisture and/or oxygen in the packaging headspace.

In this webinar, you will learn how active packaging solutions offer a practical way to increase efficiency and effectiveness of pharmaceutical packaging technology across a range of applications. Explore how 3-Phase Activ-Polymer™ technology can be integrated into blister packaging, stick packs, inhalers, medical devices, bottles, and more to control moisture and/or oxygen in the packaging headspace, ensuring drug product stability and enhancing shelf life.

Key Learning Objectives

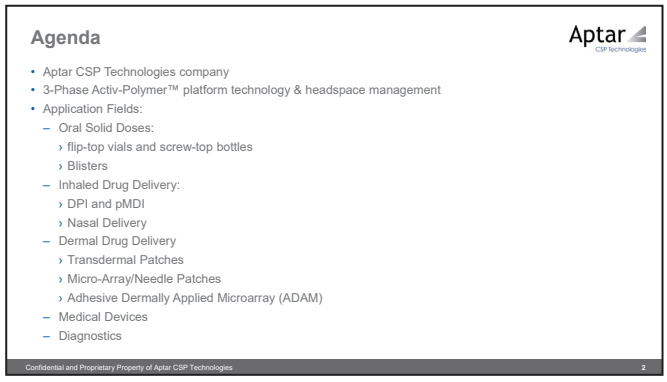
- Understand the impact of packaging choices on stability and shelf life of drugs
- Review best practices and new techniques for the management of microclimate in packaging
- Learn about the benefits of active packaging in challenging environments

I wish you all fruitful deliberations and I am sure at the conclusion of this webinar we will Learn about the benefits of active packaging in challenging environments.

Till Then, Stay Safe, Stay Well and Stay Connected.

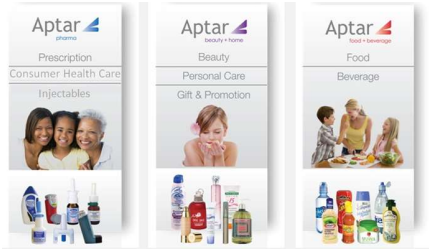
Thank you & Welcome

Presentation on Enhance Oral Solid Doses Stability and Drug Delivery Devices through the use of Active Packaging by Mr. Francois Bidet, VP Business Development, EMEA Aptar CSP Technologies



Aptar CSP Technologies

Aptar CSP Technologies is part of AptarGroup, Inc.



- **Leader in the global dispensing systems industry** with over **75 years** of experience operating in consumer packaging
- **Adding value** to the world's best known products
- **$2.9 billion company** with more than **13,000 employees** worldwide organized by 3 market segments
- Publicly traded on **NYSE** (ATR)
- **Strong** balance sheet

About Aptar CSP Technologies

- Joined **AptarGroup** in August 2018
- Premier active **material science solutions expert** delivering innovative, highly-engineered, **active packaging** solutions
- Headquarters Auburn, Alabama, USA, with **+500** dedicated employees in **4** countries
- **+1.2** billion components manufactured annually, **4** manufacturing locations worldwide (US, France & China)
- **+600** worldwide patents
- **ISO-9001**, **ISO-13485** and **ISO-14001** certified

Design and Production Capabilities

Many Partners in Food, Diagnostics and Pharma

Platform Technology Serving Broad Therapeutic Areas

Oral Solid Dose	Dermal Drug Delivery	Drug Delivery Systems	Diagnostics	Probiotics	Medical Device & Implants
Immunodeficiency Treatment	Hormone Patch/ MAP Device	Inhalation/ Nasal Drug Delivery	Blood Glucose Testing/COVID Testing	Dietary Supplement	Implant Neurostimulator

Determining the Need for Active Packaging

Product Attribute Questions

Do you have a package or device that is tight and has headspace?

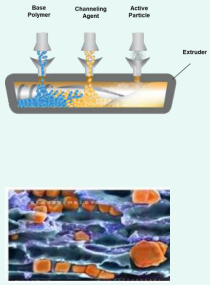
3-Phase Activ-Polymer™ technology is the solution to these situations

Active Material Science Platform Technology

Material Science: Adding Chemistry to Polymers

3-Phase Activ-Polymer™ Material

1	2	3
MAJORITY POLYMER Base Structure Component	**PARTICLE** Adsorbing/Absorbing – Active Component	**MINORITY POLYMER/ CHANNELING AGENT** Immiscible in majority polymer



Active Material Science Platform Technology

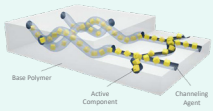
Material Science: Adding Chemistry to Polymers

3-Phase Activ-Polymer™ Material

1	2	3
MAJORITY POLYMER Base Structure Component	**PARTICLE** Adsorbing/Absorbing – Active Component	**MINORITY POLYMER/ CHANNELING AGENT** Immiscible in majority polymer

HOW IT WORKS:

- Channels created within a polymer allow movement of gases
- "Active" particles are added to polymer to:
  - **Adsorb** or **Absorb** (moisture)
  - **Scavenge** (gases, odors, reactive impurities, formaldehyde, other VOCs)
  - **Release/Emit** (aromas, biocides, antimicrobials, nutrients, CO_2)
- **Gas diffusion** is controlled through the channel composition
- Allow **high load of active compound** in limited headspace



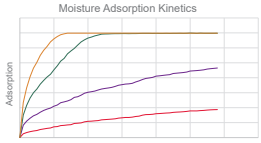
Active Packaging – Putting Chemistry into Polymers

3-Phase Activ-Polymer™ Material

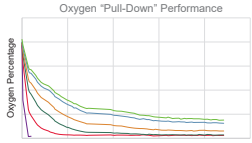
Allows **control of kinetics** based upon formulation:

- Uptake rate can be increased or decreased
- Absorption capacity can be increased or decreased
- Buffered RH solutions for products susceptible to over-drying

Moisture Adsorption Kinetics

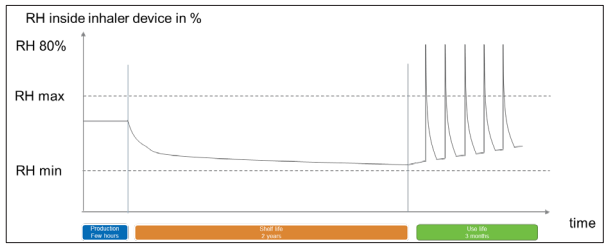


Oxygen "Pull-Down" Performance



Buffered RH Solutions for Products Susceptible to Over-Drying

RH inside inhaler using a custom Aptar CSP 3-Phase Activ-Polymer™ component throughout storage and use life of device

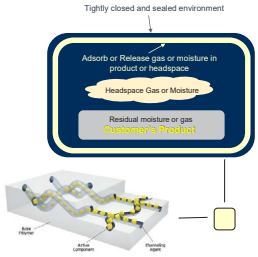


Active Packaging – Putting Chemistry into Polymers

Tightly Sealed Environment

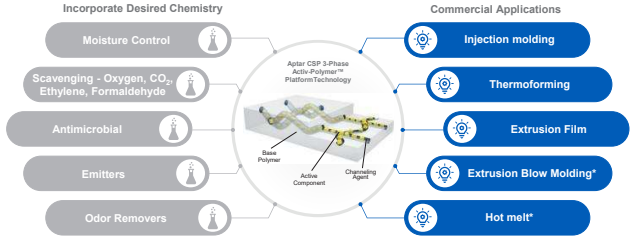
Utilizing 3-Phase Activ-Polymer™ technology requires a tightly sealed environment

- Chemistry required determined
- Gas or moisture transmission rates reviewed
- Focus on seals associated with package
- Amount of ***3-phase material*** required depends on how ***tight*** of an ***environment*** it will be placed in



Active Material Science Platform Technology

Ability to incorporate single or multiple chemistries into a polymer solution that retains the performance of the chemistries while maintaining the physical properties of the polymer



*Applications in development

3-Phase Activ-Polymer™ Injection Molded Containers and Components

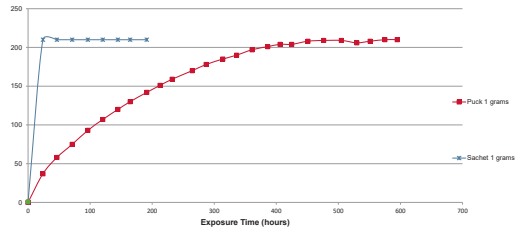
- Can be an integral component or the container for active packaging
- Molded components often replace a current plastic part in the customer's packaging or device
- Provides current plastic part's physical functioning while incorporating the chemistry's performance

Activ-Vial™Containers

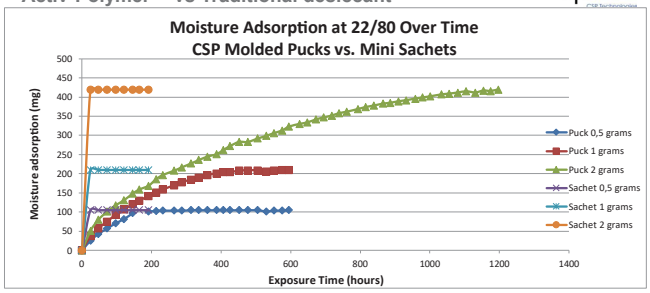
3-Phase Active Molded Components

Activ-Polymer™ vs Traditional desiccant

Moisture Adsorption at 22/80 Over Time
CSP Molded Pucks vs. Mini Sachets

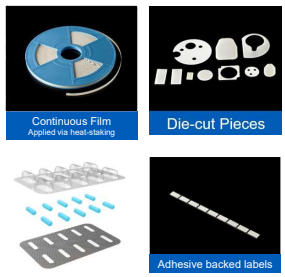


Activ-Polymer™ vs Traditional desiccant

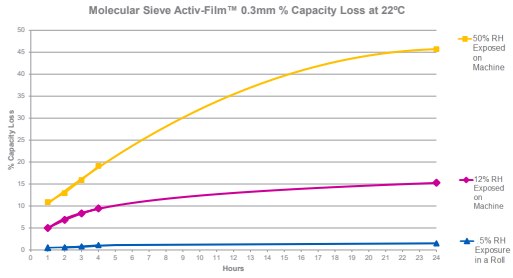


3-Phase Extrusion Film – Activ-Film™ Material

- Activ-Polymer™ is extruded in Activ-Film™
- Combined formulations available (e.g. moisture + oxygen)
- Optimized capacity and uptake rates (Scavenging or release rate of the film can be modified by selecting ratio and type of channeling agent)
- Manufactured at 0.3-1.2mm thickness
- Continuous film or die cut available
- Applied seamlessly via "heat-staking" or with adhesive to interior of package
- Heat staking & labeling solutions by industry known integrators



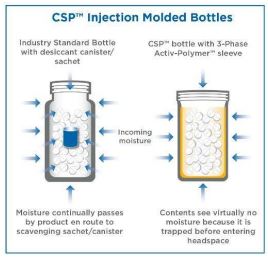
Controlled Moisture Kinetic Absorption in Activ-Film™



Application Field: Oral Solid Doses Activ-Vial™

Technology Applications

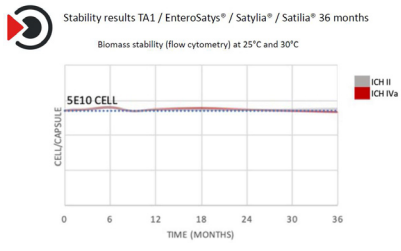
- **CSP™ Flip-Top Activ-Vial™** with integrated 3-Phase Activ-Polymer™ sleeve
- Patented "Close In The Mold" Technology Ensures **Moisture-Tight Seal**
- Maintains seal integrity throughout shelf life and consumer use life
- Child-Resistant/Senior-Friendly Closures
- Screw-Top versions also available



Probiotics are very sensitive to moisture
Aptar CSP Technologies' Active Vials are the reference

3 Years Stability Results

In collaboration with Targedys (France)



NPPA fixes the Retail Price of Specified 23 Formulation/ Brand Name under the Drugs (Price Control) Order, 2013

NPPA Order S.O.1782(E), dated 12th April 2022

-In exercise of the powers conferred by paragraphs 5, 11 and 15 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA), hereby fixes, the price as specified in column (6) of the table herein below as the retail price, exclusive of Goods and Services Tax, if any, in relation to the formulation specified in the corresponding entry in column (2) of the said Table with the strength, unit and name of manufacturer & marketing company, as specified in the corresponding entries in columns (3), (4) and (5) thereof;

TABLE

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Telmisartan + Cilnidipine + Chlorthalidone Tablet	**Each film coated tablet contains:** Telmisartan IP 40 mg Cilnidipine IP 10 mg Chlorthalidone IP 6.25 mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	11.61
2.	Paracetamol Bilayer Tablets 1000 mg	**Each uncoated bilayered tablet contains:** Paracetamol IP 300 mg (as immediate release) Paracetamol IP 700 mg (as sustained release)	1 Tablet	M/s Sterling Labs / M/s Micro Labs Limited	4.07
3.	Levetiracetam Tablet	**Each film coated tablet contains:** Levetiracetam IP 1000 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Zydus Healthcare Ltd.	30.38
4.	Torsemide and Spironolactone Tablets	**Each film coated tablet contains:** Torsemide IP 10mg Spironolactone IP 25mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s J. B. Chemicals & Pharmaceuticals Limited	2.71
5.	Paracetamol, Phenylephrine Hydrochloride, Caffeine and Diphenhydramine Hydrochloride tablet	**Each film coated tablet contains:** Paracetamol IP 500mg Phenylephrine Hydrochloride IP 5mg Caffeine (anhydrous) IP 30mg Diphenhydramine Hydrochloride IP 25mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / Dr. Reddy's Laboratories Limited	3.21
6.	Metformin Hydrochloride (as Prolonged-Release)+ Glimepiride Tablet IP	**Each Uncoated bilayered tablet contains:** Metformin Hydrochloride IP 500mg (as Prolonged-Release)	1 Tablet	M/s East African (India) Overseas / M/s La-Medica Life Sciences Pvt. Ltd.	8.24

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Glimepiride IP 2mg			
7.	Metformin Hydrochloride (as Prolonged-Release)+ Glimepiride Tablet IP	**Each uncoated bilayered tablet contains:** Metformin Hydrochloride IP 500mg (as Prolonged-Release) Glimepiride IP 1mg	1 Tablet	M/s East African (India) Overseas / M/s La-Medica Life Sciences Pvt. Ltd.	5.63
8.	Cefixime, Cloxacillin & Lactic Acid Bacillus Tablets	**Each film coated tablet contains:** Cefixime IP as Trihydrate eq. to Anhydrous Cefixime 200mg, Cloxacillin Sodium IP eq. to Cloxacillin 500mg (in extended release form), Lactic Acid Bacillus 90 Million Spores.	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	14.65
9.	Diclofenac Transdermal Patch	**Each 75Sq cm Transdermal Patch contains:** Diclofenac Diethylamine IP 200mg	1 Patch	M/s Azista Industries Pvt. Ltd. / M/s Hetero Healthcare Ltd.	40.18
10.	Efonidipine Hydrochloride Ethanolate + Telmisartan Tablet	**Each uncoated bilayered tablet contains:** Efonidipine Hydrochloride Ethanolate 20mg, Telmisartan IP 40mg	1 Tablet	M/s Zuventus Healthcare Limited	9.94
11.	Gliclazide ER + Metformin ER Tablet	**Each uncoated bilayered tablet contains:** Gliclazide IP (as extended release form) 60mg Metformin Hydrochloride IP (as extended release form) 1000mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Lupin Limited	8.53
12.	Bisoprolol Fumarate & Amlodipine tablet	**Each film coated tablet contains:** Bisoprolol Fumarate IP 5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	1 Tablet	M/s Swiss Garnier Biotech Ltd. / Dr. Reddy's Laboratories Limited	6.69
13.	Bisoprolol Fumarate & Amlodipine tablet	**Each film coated tablet contains:** Bisoprolol Fumarate IP 2.5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	1 Tablet	M/s Swiss Garnier Biotech Ltd. / Dr. Reddy's Laboratories Limited	4.46
14.	Paracetamol & Mefenamic Acid tablet	**Each Uncoated Tablet contains:** Paracetamol IP 325mg Mefenamic Acid IP 500mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Alkem Laboratories Limited	3.27
15.	Levofloxacin Infusion IP (0.5% w/v)	**Each 100 ml contains:** Levofloxacin Hemihydrate IP eq. to Levofloxacin 500 mg Sodium Chloride IP 900 mg , Water for Injection IP q. s.	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd./M/s Emcure Pharmaceuticals Ltd.	1.32

16.	Paracetamol & Tramadol HCl tablet USP	**Each uncoated Tablet contains:** Paracetamol IP 325mg Tramadol HCL IP 37.5mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Hetero Healthcare Ltd.	8.35
17.	Ceftriaxone & Tazobactam for Injection 1125mg	**Each vial contains:** Sterile Ceftriaxone Sodium IP eq. to Ceftriaxone 1000mg Sterile Tazobactam Sodium IP eq. to Tazobactam 125mg Each ampoule contains: 10ml Sterile water for Injection IP	1 Vial	M/s Prosperity Six Pharmaceuticals / M/s Torrent Pharmaceuticals Limited	167.87
18.	Telmisartan + Cilnidipine + Chlorthalidone Tablet	**Each film coated tablet contains:** Telmisartan IP 40 mg + Cilnidipine IP 10 mg + Chlorthalidone IP 12.50 mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	12.94
19.	Amoxycillin + Potassium Clavulanate Oral Suspension	**Each ml of constituted suspension contains:** Amoxycillin Trihydrate IP eq. to Amoxycillin 80mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 11.4mg	1 ml	M/s Copmed Pharmaceuticals Pvt. Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	7.42
20.	Tramadol HCl + Acetaminophen (Paracetamol)Tablet	**Each uncoated tablet contains:** Tramadol HCl 37.5mg Acetaminophen (Paracetamol) 325mg	1 Tablet	M/s Penta Kraft / M/s Mankind Prime Labs Pvt. Ltd.	8.35
21.	Clonazepam mouth dissolving Tablet	**Each uncoated mouth dissolving tablet contains:** Clonazepam IP 2mg	1 Tablet	M/s Lifecare Neuro Products Ltd./ M/s Mankind Pharma Ltd.	8.60
22.	Cefixime, Dicloxacillin MR & Lactic Acid Bacillus Tablets	**Each modified release tablet contains:** Cefixime IP as Trihydrate eq. to Anhydrous Cefixime 200mg (in immediate release form), Dicloxacillin Sodium IP eq. to Dicloxacillin 500mg (in modified release form), Lactic Acid Bacillus 2.5 Billion Spores.	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	18.24
23.	Efonidipine Hydrochloride Ethanolate + Telmisartan Tablet	**Each uncoated bilayered tablet contains:** Efonidipine Hydrochloride Ethanolate 40mg, Telmisartan IP 40mg	1 Tablet	M/s Zuventus Healthcare Limited	15.67

Note:

(a) The manufacturer of above mentioned formulations i.e. "new drug" under paragraph 2(u) of the DPCO, 2013 shall fix the retail price as specified in column (6) of the table hereinabove.

(b) The manufacturer may add Goods and Services Tax only if they have paid actually or it is payable to the Government on the retail price mentioned in column (6) of the above said table.

(c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (6) of the above table as per provisions contained in paragraph 11 of the DPCO, 2013. The manufacturer shall issue a price list in Form–V from date of

paragraph 11 of the DPCO, 2013. The manufacturer shall issue a price list in Form–V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.

(d) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

(e) The above mentioned retail price is applicable only to the individual manufacturer / marketer as mentioned above i.e. who have applied for the same by submitting Form-I for price fixation / revision as stipulated under DPCO, 2013 and subject to fulfilment of all the applicable statutory requirements as laid down by the Govt. under relevant statutes/ rules, including manufacturing license permission from the Competent Authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturer/marketing companies.

(f) In case the retail price of any of the aforesaid formulations is not complied with, as per instant price notification and notes specified hereinabove, then the concerned manufacturer/marketing company shall be liable to deposit the overcharged amount along with the interest thereon under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.

(g) Consequent to the issue of ceiling price of such formulation as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

PN/228/96/2022/F /
F. No. 8(96)/2022/D.P./NPPA-Div.-II

Prasenjit Das, Deputy Director, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, National Pharmaceutical Pricing Authority, New Delhi .

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GOVERNMENT NOTIFICATIONS

Drugs Rules, 1945 amended (4th Amendment of 2022)

Drugs & Cosmetics Notification G.S.R.276(E), dated 04th April 2022

(Published in the Gazette of India on 6th April, 2022)

In exercise of the powers conferred by proviso of sub-section (1) of section 33N of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, hereby makes the following rules further to amend the Drugs Rules, 1945, namely,-

1. Short title, and commencement

(1) These rules may be called the **Drugs (4th Amendment) Rules, 2022.**

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

2. In the Drugs Rules, 1945, (a) in rule 153, in the second proviso, for the words "within six months" the words "within eighteen months" shall be substituted;

(b) in Rule 153A, in the second proviso, for the words "within six months", the words "within eighteen months" shall be substituted;

(c) FORM 26 D and FORM 26 E shall be omitted.

F.No.T-11011/7/2021-DCC(AYUSH)

Kavita Garg, Joint Secretary, Ministry of Ayush, New Delhi.

Note: The Principal Rules were published in the Gazette of India, vide, Notification No.F.28-10/45-H(1), dated the 21st December, 1945 and last amended, vide, Notification Number G.S.R.158 (E), dated the 24th February, 2022.

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Dr. Raghuram Reddy Adidala appointed at Central Drugs Testing Laboratory, Hyderabad to be the Government Analyst - reg.

Drugs & Cosmetics Notification S.O.1520(E), dated 07th April 2022

(Published in the Gazette of India on 9th April, 2022)

In exercise of the powers conferred by sub-section (2) of section 20 of the Drugs and Cosmetics Act, 1940 (23 of 1940) read with rule 44 of the Drugs Rules, 1945, the Central Government hereby appoints Dr. Raghuram Reddy Adidala at Central Drugs Testing Laboratory, Hyderabad to be the Government Analyst for the whole of India in respect of all classes of drugs, except the classes of drugs mentioned below, namely:-

(1) Sera;

(2) Solution of Serum Proteins intended for injection;

(3) Vaccines (parenteral and Oral);

(4) Toxins;

(5) Antigens;

(6) Anti-toxins;

(7) Sterilized Surgical Ligature and Sterilized Surgical Sutures;

(8) Bacteriophages;

(9) Anti-sera for veterinary use;

(10) Vaccine for veterinary use;

(11) Toxoid for veterinary use;

(12) Diagnostic Antigens for veterinary use;

(13) VDRL Antigen;

(14) Human Blood and Human Blood Products including components, to test for freedom for HIV antibodies;

(15) Blood Grouping reagents and diagnostic kits for Human Immunodeficiency Virus, Hepatitis B surface Antigen and Hepatitis C Virus;

(16) Condoms.

F.No.X.11014/11/2020-DR

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

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CUSTOMS MATTERS

Corrigendum to Notification No. 21/2022-Customs (N.T.) dated 31st March, 2022

Customs Corrigendum N.T. S.O.1598(E), dated 04th April 2022

In the notification of the Government of India, Ministry of Finance (Department of Revenue) No.21/2022-Customs (N.T.) dated the 31st March, 2022, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O.1537(E), dated the 31st March, 2022 :-

i. at page number 9, in line 24, after the words 'Deputy Commissioner of Customs or', the word 'Joint' may be read as 'Assistant';

ii. at page number 9, in line 25, 'Commissioner of Customs' may be read as 'Commissioner of Customs, as the case may be,' ;

iii. at page number 9, in line 29, '(iv)' may be read as '(i)';

iv. at page number 9, in line 31, '(v)' may be read as '(ii)';

v. at page number 9, in line 47, '(vi)'may be read as '(iii)';

vi. at page number 9, in line 50, '(vii)' may be read as '(iv)';

vii. at page number 10, in line 27, '(iii)' may be read as '(i)';

viii. at page number 10, in line 28, '(iv)' may be read as '(ii)';

ix. at page number 10, in line 31, '(iv)' may be read as '(i)';

x. at page number 12, in line 20, '(VI)' may be read as'(I)';

xi. at page number 12, in line 23, '(VII)' may be read as '(II)';

xii. at page number 12, in line 26, '(VIII)' may be read as'(III)';

xiii. at page number 12, in line 29, '(IX)' may be read as '(IV)';

xiv. at page number 12, in line 32, '(X)' may be read as '(V)';

xv. at page number 12, in line 36, '(VI)' may be read as '(I)';

xvi. at page number 12, in line 39, '(VII)' may be read as '(II)';

xvii. at page number 12, in line 42, '(VIII)' may be read as '(III)';

xviii. at page number 12, in line 46, '(IX)' may be read as '(IV)';

xix. at page number 12, in line 49, '(X)' may be read as '(V)';

xx. at page number 13, in line 44, '(i) (i)' may be read as '(i)';

xxi. at page number 14, in line 38, 'VII' may be read as '(i)';

xxii. at page number 14, in line 40, 'VIII' may be read as '(ii)';

xxiii. at page number 14, in line 42, 'IX' may be read as '(iii)';

xxiv. at page number 14, in line 44, 'X' may be read as '(iv)';

xxv. at page number 14, in line 46, 'XI' may be read as '(v)';

xxvi. at page number 14, in line 49, 'XII' may be read as '(vi)'.

F.No.450/72/2021-Cus IV

Manish Kumar Choudhary,
Under Secretary,
Ministry of Finance,
Department of Revenue,
Central Board of Indirect Taxes and Customs,
New Delhi .

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Corrigendum to Notification No. 24/2022-Customs (N.T.) dated 31st March, 2022

Customs Corrigendum N.T. S.O.1599(E), dated dated 04th April 2022

In the notification of the Government of India, Ministry of Finance (Department of Revenue) No.24/2022-Customs (N.T.) dated the 31st March, 2022, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O.1540(E), dated the 31st March, 2022:-

i. at page number 22, after line 24, a new line is inserted, namely ,-

'(vii) Commissioner of Customs (Audit), Mumbai.';

ii. at page number 22, in line 36, 'Mumbai II' may be read as 'Nhava Sheva';

iii. at page number 24, in line 23, '(4)' may be read as '(3)';

iv. at page number 24, in line 26, '(i)' may be read as '(ii)';

v. at page number 24, in line 27, '(ii)'may be read as '(iii)';

vi. at page number 24, in line 28, '(iii)'may be read as '(iv)'.

F.No.450/72/2021-Cus IV

Manish Kumar Choudhary,
Under Secretary,
Ministry of Finance,
Department of Revenue,
Central Board of Indirect Taxes and Customs,
New Delhi .

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Corrigendum to Notification No. 25/2022-Customs (N.T.) dated 31st March, 2022

Customs Corrigendum N.T. S.O.1600(E) dated 04th April 2022

In the notification of the Government of India, Ministry of Finance (Department of Revenue) No.25/2022-Customs (N.T.) dated the 31st March, 2022, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O.1541(E), dated the 31st March, 2022, at page number 26, in line 31, 'to' may be read as 'over'.

F.No.450/72/2021-Cus IV

Manish Kumar Choudhary, Under Secretary, Ministry of Finance, Department of Revenue, Central Board of Indirect Taxes and Customs, New Delhi .

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Corrigendum to Notification No. 26/2022-Customs (N.T.) dated 31st March, 2022

Customs Corrigendum N.T. S.O.1601(E) dated 04th April 2022

In the notification of the Government of India, Ministry of Finance (Department of Revenue) No.26/2022-Customs (N.T.) dated the 31st March, 2022, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O.1542(E), dated the 31st March, 2022:-

i. at page number 32, in line 38, '(xxv)' may be read as '(i)';

ii. at page number 32, in line 39, '(xxvi)' may be read as '(ii)';

iii. at page number 32, in line 41, '(xxvii)' may be read as '(iii)';

iv. at page number 32, in line 42, '(xxviii)' may be read as '(iv)';

v. at page number 32, in line 43, '(xxix)' may be read as '(v)';

vi. at page number 32, in line 44, '(xxx)' may be read as '(vi)';

vii. at page number 32, in line 45, '(xxxi)' may be read as '(vii)';

viii. at page number 33, in line 3, '(xxxii)' may be read as '(viii)';

ix. at page number 33, in line 4, '(xxxiii)' may be read as '(ix)';

x. at page number 33, in line 6, '(xxxiv)' may be read as '(x)';

xi. at page number 33, in line 8, '(xxxv)' may be read as '(xi)';

xii. at page number 33, in line 9, '(xxxvi)' may be read as '(xii)';

xiii. at page number 33, in line 10, '(xxxvii)' may be read as '(xiii)';

xiv. at page number 33, in line 11, '(xxxviii)' may be read as '(xiv)';

xv. at page number 33, in line 12, '(xxxix)' may be read as '(xv)';

xvi. at page number 33, in line 13, '(xl)' may be read as '(xvi)';

xvii. at page number 33, in line 14, '(xli)' may be read as '(xvii)';

xviii. at page number 33, in line 15, '(xlii)' may be read as '(xviii)';

xix. at page number 33, in line 16, '(xliii)' may be read as '(xix)';

xx. at page number 33, in line 17, '(xliv)' may be read as '(xx)';

xxi. at page number 33, in line 18, '(xlv)' may be read as '(xxi)';

xxii. at page number 33, in line 19, '(xlvi)' may be read as '(xxii)';

xxiii. at page number 33, in line 20, '(xlvii)' may be read as '(xxiii)';

xxiv. at page number 33, in line 21, '(xlviii)' may be read as '(xxiv)';

xxv. at page number 33, in line 25, '(ix)' may be read as '(i)';

xxvi. at page number 33, in line 26, '(x)' may be read as '(ii)';

xxvii. at page number 33, in line 27, '(xi)' may be read as '(iii)';

xxviii. at page number 33, in line 28, '(xii)' may be read as '(iv)';

xxix. at page number 33, in line 29, '(xiii)' may be read as '(v)';

xxx. at page number 33, in line 30, '(xiv)' may be read as '(vi)';

xxxi. at page number 33, in line 32, '(xv)' may be read as '(vii)';

xxxii. at page number 33, in line 33, '(xvi)' may be read as '(viii)';

xxxiii. at page number 33, in line 34, '(xvii)' may be read as '(i)';

xxxiv. at page number 33, in line 35, '(xviii)' may be read as '(ii)';

xxxv. at page number 33, in line 37, '(xix)' may be read as '(iii)';

xxxvi. at page number 33, in line 38, '(xx)' may be read as '(iv)';

xxxvii. at page number 33, in line 39, '(xxi)' may be read as '(v)';

xxxviii. at page number 33, in line 40, '(xxii)' may be read as '(vi)';

xxxix. at page number 33, in line 42, '(xxiii)' may be read as '(vii)';

xl. at page number 33, in line 43, '(xxiv)' may be read as '(viii)';

xli. at page number 33, in line 44, '(xxv)' may be read as '(ix)';

xlii. at page number 33, in line 45, '(xxvi)' may be read as '(x)';

xliii. at page number 33, in line 46, '(xxvii)' may be read as '(xi)';

xliv. at page number 33, in line 47, '(xxviii)' may be read as '(xii)';

xlv. at page number 34, in line 3, '(xxix)' may be read as '(xiii)';

xlvi. at page number 34, in line 4, '(xxx)' may be read as '(xiv)';

xlvii. at page number 34, in line 6, '(xxxi)' may be read as '(xv)';

xlviii. at page number 34, in line 7, '(xxxii)' may be read as '(xvi)';

xlix. at page number 34, in line 8, '(iii)' may be read as '(i)';

l. at page number 34, in line 9, '(iv)' may be read as '(ii)'.

F.No.450/72/2021-Cus IV

Manish Kumar Choudhary, Under Secretary, Ministry of Finance, Department of Revenue, Central Board of Indirect Taxes and Customs, New Delhi .

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Corrigendum to Notification No. 27/2022-Customs (N.T.) dated 31st March, 2022

Customs Corrigendum N.T. S.O.1602(E), dated 04th April 2022

In the notification of the Government of India, Ministry of Finance (Department of Revenue) No.27/2022-Customs (N.T.) dated the 31st March, 2022, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O.1543(E), dated the 31st March, 2022:-

i. at page number 35, in line 27, 'under sub-sections' may be read as 'sub-sections';

ii. at page number 35, in line 33, 'under sub-section' may be read as 'sub-section';

F.No.450/72/2021-Cus IV

Manish Kumar Choudhary, Under Secretary, Ministry of Finance, Department of Revenue, Central Board of Indirect Taxes and Customs, New Delhi .

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Corrigendum to Notification No. 28/2022-Customs (N.T.) dated 31st March, 2022

Customs Corrigendum N.T. S.O.1603(E), dated 04th April 2022

In the notification of the Government of India, Ministry of Finance (Department of Revenue) No.28/2022-Customs (N.T.) dated the 31st March, 2022, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O.1544(E), dated the 31st March, 2022:-

i. at page number 37, in line 43, '(viii)' may be read as '(v)';

ii. at page number 38, in line 5, '(ix)' may be read as '(vi)';

iii. at page number 38, in line 5, 'Deputy' may be read as '(vi) Deputy'.

F.No.450/72/2021-Cus IV

Manish Kumar Choudhary,
Under Secretary,
Ministry of Finance, Department of Revenue,
Central Board of Indirect Taxes and Customs,
New Delhi .

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Corrigendum to Notification No. 29/2022-Customs (N.T.) dated 31st March, 2022

Customs Corrigendum N.T. S.O.1604(E), dated 04th April 2022

In the notifications of the Government of India, Ministry of Finance (Department of Revenue) No.29/2022-Customs (N.T.) dated the 31st March, 2022, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii), vide number S.O.1545(E), dated the 31st March, 2022:-

i. at page number 39, in line 28, 'Revenue Intelligence' may be read as 'Revenue Intelligence, Mumbai';

ii. at page number 39, in line 28, 'or by' may be read as 'and';

iii. at page number 39, in line 31, 'by' may be read as 'to';

iv. at page number 39, in line 32, 'by' may be read as 'to';

v. at page number 39, in line 36, 'by' may be read as 'to';

vi. at page number 40, in line 1, 'by' may be read as 'to';

vii. at page number 40, in line 4, 'by' may be read as 'to';

viii. at page number 40, in line 8, 'by' may be read as 'to';

ix. at page number 40, in line 11, 'by' may be read as 'to'.

F.No.450/72/2021-Cus IV

Manish Kumar Choudhary, Under Secretary, Ministry of Finance, Department of Revenue, Central Board of Indirect Taxes and Customs, New Delhi.

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In Raiya Sabha & In Lok Sabha

In Rajya Sabha

Revival of Ayurvedic Medicines

Rajya Sabha Unstarred Question no.2089

Shri Rakesh Sinha:

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

(a) whether it is a fact that the revival of Ayurvedic medicines and their role has become significant;

(b) how much India earned by selling Ayurvedic medicines in 2020-21 and onwards;

(c) the steps being taken to stop Ayurveda companies which are producing unauthorized medicines which may be detrimental to health; and

(d) how many laboratories are in the country to examine and certify the authenticity and claims of such medicines?

Answered on 22nd March 2022

A. (a) Yes Sir, Ayurvedic system of medicine is an existing ancient traditional system of medicine of India. Its role has significantly been boosted with the establishment of Ministry of Ayush, which has resulted into focused growth of the sector in terms of medical education, practice, manufacturing, research and International cooperation. The significance and usage of Ayurvedic medicines has been further noticed during the wake of Covid -19.

(b) Separate data of earning from selling Ayurvedic medicines is not available. However, as per records the total Ayush and herbal medicines export of India has been of US$ 1.54 billion in the year 2020. (Source: Ayush Sector in India prospects and challenges published by Forum on India Traditional Medicines FITM-Research and Information Systems RIS-Ministry of AYUSH).

In domestic market Indian Medicines Pharmaceutical Corporation Limited (IMPCL), a Government of India Enterprises under Ministry of Ayush has reported sale of Ayurvedic & Unani Medicines of about Rs. 164.02 Crore during the year 2020-21.

(c) Under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder, it is mandatory for the manufacturer of Ayurvedic drugs to comply with the prescribed Good Manufacturing Practices (GMP) and quality standards of drugs given in the Ayurvedic Pharmacopoeia for obtaining licence from the concerned State Licensing Authority (SLA). The SLA grants the licence after verification of the required infrastructural facilities, equipment / machinery, manpower of the manufacturing unit through inspection(s) conducted by the inspector.

Further, the following steps are being taken to ensure safety and quality of Ayurvedic medicines by the State Government Officers empowered under Drugs and Cosmetics Act, 1940 and Rules thereunder:

(i) Survey samples, legal samples and market samples are drawn regularly and sent to Government Drug Testing Laboratory to ascertain the quality of medicine.

(ii) Investigation of the complaints related to quality of Drugs.

(iii) Launch of prosecution in case of violation of Drugs and Cosmetics Act, 1940 and Rules thereunder.

(d) There is one central appellate laboratory of Pharmacopoiea Commission of Indian Medicine & Homoeopathy (PCIM&H), Ghaziabad for testing of Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs. Apart from this 35 State Drug Testing Laboratories for testing of Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs are funded by the Ministry of Ayush through its schemes. Also, 67 Private Drug Testing Laboratories have been approved for testing of Ayush drugs under Drugs & Cosmetics Rules 1945 as on 1.4.2021.

The Minister of Ayush
(Shri Sarbananda Sonowal)

Export of Ayurvedic Medicines

Rajya Sabha Unstarred Question No-2090

Shri Prakash Javadekar:

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

(a) the growth in export of Ayurvedic medicines during the last seven years, the details thereof ;

(b) the steps Government has taken to remove impediments in the export of Ayurvedic medicines; and

(c) the plans for increasing the availability of medicinal plants for Ayurvedic medicines ?

Answered on 22nd March 2022

A. (a) The details of the growth in export of Ayurvedic medicines during the last seven years are attached at Annexure-A.

(b) The Ministry has developed a Central Sector Scheme for Promotion of International Co- operation in AYUSH (IC Scheme) under which Ministry of Ayush provides support to Indian Ayush Manufacturers/ Ayush Service providers to give boost to export of AYUSH products & services; facilitate International promotion, development and recognition of AYUSH system of medicine; foster interaction of stakeholders and market development of AYUSH at international level; promote academics and research through establishment of AYUSH Academic Chairs in foreign countries and holding training workshop/symposiums for promoting and strengthening awareness and interest about AYUSH Systems of Medicine at international level.

Ministry of Ayush has taken following steps towards promoting export of Ayurvedic medicines:

- Ministry has signed 25 Country to Country MoUs for Cooperation in field of Traditional Medicine and Homoeopathy with foreign nations.
- 32 MoUs have been signed with international institutes for undertaking Collaborative Research / Academic collaboration.
- 14 MoUs have been signed with international institutes for setting up of Ayush Academic Chairs in foreign nations.
- Ministry of Ayush has provided support for establishment of 38 Ayush Information Cells in 34 foreign nations.
- The “Ayush Export Promotion Council” has been registered under section 8(4) of the Companies Act 2013 on 04.01.2022 under the Ministry of Ayush in support of the Ministry of Corporate Affairs to tackle the obstacles for registration of AYUSH products abroad, undertaking of market studies and research activities abroad
- Ministry of Ayush provides scholarship to foreign nationals under AYUSH Fellowship scheme.
- MoUs have been signed with London School of Hygiene & Tropical Medicine (LSH&TM), UK and Frankfurter Innovationszentrum Biotechnologie GmbH (FIZ), Frankfurt Germany for clinical research studies on mitigation of Covid-19 through Ayurveda.
- Ministry of Ayush issued advisories on protecting people from COVID and staying healthy in English as well as in 08 other foreign languages.
- Ministry of Ayush provides AYUSH Educational Training to regulators of foreign nations.

(c) Medicinal Plants are the major resources base for Ayurvedic medicines and to increase the availability of medicinal plants for Ayurvedic medicines, the National Medicinal Plants Board (NMPB), Ministry of Ayush under its “Central Sector Scheme for Conservation, Development and Sustainable Management of Medicinal Plants” has the provision to support State Forest Departments for resource augmentation of medicinal plants in the country. The project-based financial assistance is also provided to Government and Non-government organizations for developing Quality Planting Material (QPM) of medicinal plants and thereby ensure the sustainable availability of medicinal plants raw material for Ayurvedic medicines.

NMPB has developed “e-CHARAK” portal which is a virtual market place for collectors, farmers, traders of medicinal plants and ASU&H drug manufacturers. It facilitates trade of medicinal plants by providing a platform for sale, purchase of Medicinal plants raw material and also facilitate information exchange between various stakeholders involved in the medicinal plants sector. It is a multilingual platform available as Web and Mobile (IOS and Android) in 7 languages hosting agro-techniques of Medicinal and Aromatic plants, GAP, GFC, post-harvest management techniques, schemes, etc.

The Minister of Ayush
(Shri Sarbananda Sonowal)

Annexure-A

India's export of AYUSH and Herbal Products during the last seven financial years and current financial year (Apr-Jan)

Year	Group	Unit	Qty
2014-15	AYUSH AND HERBAL PRODUCTS	KGS	92059212
2015-16			95883497
2016-17			83357976
2017-18			89098226
2018-19			108051055
2019-20			92241987
2020-21			120558428
2021-22 (Apr-Jan)			104511320

(Note: Figures for 2021-22 are provisional and subject to c hange) *(Source: DGCIS)*

Request to set up Medical Device Parks in States

Rajya Sabha Unstarred Question No. 2107

Shri Narhari Amin:

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

(a) whether Government has received any proposal from the State Governments for setting up Medical Device Parks;

(b) if so, the State-wise number of proposals received and status thereof;

(c) whether any policy/plan has been formulated for providing an assistance to promote/set up such Medical Device Park in States, and if so, the details thereof;

(d) whether an approval has been granted to set up a Medical Device Park in Gujarat, and if so, the details thereof; and

(e) the details of current progress made for the said project and the aims and objective to set up such Medical Device Parks?

Answered on 22nd March 2022

A. (a) to (e): The Department is implementing the scheme "Promotion of Medical Devices Parks" with the objectives:

- To create world class infrastructure facilities in order to make Indian medical device industry a global leader,
- To provide easy access to standard testing and infrastructure facilities through creation of world class Common Infrastructure Facilities for increased competitiveness, that will result into significant reduction of the cost of production of medical devices leading to better availability and affordability of medical devices in the domestic market and
- To exploit the benefits arising due to optimization of resources and economies of scale.

The Total financial outlay of the scheme in Rs. 400 crore and the maximum assistance under the scheme for one Medical Device Park would be limited to Rs. 100 crore. The tenure of the scheme is from FY 2020-2021 to FY 2024-2025 and the selected Medical Device Park project will be implemented by a State Implementing Agency (SIA).

Under the scheme, Department of Pharmaceuticals has received proposals from 16 States/Union Territories viz. Uttar Pradesh, Tamil Nadu, Telangana, Karnataka, Maharashtra, Gujarat, Madhya Pradesh, Rajasthan, Punjab, Haryana, Himachal Pradesh, Uttarakhand, Chhattisgarh, Kerala, Goa and Jammu & Kashmir.

The proposals were evaluated as per the criteria given in the scheme guidelines and 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.

Minister of State in the Ministry of Chemicals & Fertilizers (Shri Bhagwanth Khuba)

Import of chemicals and fertilizers from China

Rajya Sabha Unstarred Question No. 2110

Shri M. Mohamed Abdulla:

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

(a) whether Government has stopped import of chemicals and fertilizers from China and the details thereof;

(b) the total pharmaceutical imports from China, year-wise from 2015;

(c) whether Government has taken any concrete steps to reduce the dependency on Chinese imports particularly the Active Pharmaceutical Ingredients (API) and the details thereof and the decision taken by Government in this regard; and

(d) the measures taken by Government to provide adequate support to Indian pharma companies in this regard?

Answered on 22nd March 2022

A. (a) and (b): Import of Chemicals, Fertilizers and Pharmaceuticals has not been stopped.

The Indian Pharmaceutical industry is the 3rd largest in the world by volume. India exported pharmaceuticals worth Rs. 1,80,551 crore in the financial year 2020-21. India exported Bulk Drugs/ Drug Intermediates worth Rs.32,857 crore in financial year 2020-21. However, the country also imports various Bulk Drugs/ Active Pharmaceutical Ingredients (APIs) for producing medicines from various countries including China.

The details of pharmaceuticals imports from China from 2015 to December 2021 are given below:

Value in Crore Rupees							
Category of pharmaceuticals	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21	2021-22 (upto December 2021)
Bulk Drugs, Drug Intermediates	13,854	12,255	13,247	16,777	16,443	19,403	19,810
Drug Formulations, Biologicals	946	907	830	1,046	1,164	1,476	1,364

Source: DGCIS

(c) and (d): Most of the imports of the Bulk Drug/APIs being done in the country are because of economic considerations and also, China is one of the largest producers of KSMs and API in the world.

The Government strives to minimize country's dependence on imports and to give fillip to indigenous manufacturing.

- In order to make the country Atmanirbhar in pharmaceuticals, the Department of Pharmaceuticals has launched the *Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) In India*. The total financial outlay of the scheme is Rs. 6,940 crore and the tenure from FY 2020-2021 to FY 2029-30.
- Another *Production Linked Incentive Scheme for Pharmaceuticals* has been launched with total financial outlay of Rs. 15,000 crore and tenure from FY 2020- 2021 to FY 2028-29. The scheme intends to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. The eligible drugs under this scheme include APIs among other categories of pharmaceutical products.
- The Department has launched a scheme to provide further support to API pharma companies through providing financial assistance to the States for establishing three *Bulk Drug Parks*.
- Further, Department provides support to the pharma clusters for creating common infrastructure facilities under *Assistance to Pharmaceutical Industry for Common Facilities* (API-CF).
- The SME Pharma Industries are planned to be supported for quality and technical upgradation under *Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)*.

Minister of State in the Ministry of Chemicals & Fertilizers (Shri Bhagwanth Khuba)

Social Spending by Companies

Rajya Sabha Unstarred Question No. 2112

Shri Sushil Kumar Gupta:

Q. Will the Minister of Corporate Affairs be pleased to state:

(a) whether it is a fact that social spending by companies mandated by law has gone down;

(b) if so, the details in this regard; and

(c) the total contribution towards Corporate Social Responsibility (CSR) for the last five years, year-wise?

Answered on 22nd March 2022

A. (a) to (c): The broad framework for Corporate Social Responsibility (CSR) has been provided under

Section 135 of the Companies Act, 2013 ('Act'), Schedule VII of the Act and Companies (CSR Policy) Rules, 2014. Section 135 of the Act, mandates every company having net worth of Rs. 500 crore or more, or turnover of Rs. 1000 crore or more, or net profit of Rs. 5 crore or more during the immediately preceding financial year, to spend at least two per cent of the average net profits of the company made over immediately preceding three financial years towards CSR as per the CSR Policy of the Company.

The CSR framework is disclosure based and CSR mandated companies are required to file details of CSR activities annually in MCA21 registry. All data related to CSR filed by companies in MCA21 registry is available in public domain at www.csr.gov.in. On the basis of filings made by the companies in the MCA21 registry, the CSR spent by all the companies during the last five financial years are given below:

Financial Years	FY 2016-17	FY 2017-18	FY 2018-19	FY 2019-20	FY 2020-21
Amount Spent (INR Cr.)	14,344.40	17,097.66	20,163.18	24,863.84	20,360.25*

(Data upto 31.12.2021) [Source: National CSR Data Portal]

*The data for FY 2020-21 is subject to change as the levy of additional fees for the late filing had been relaxed till 15.03.2022.

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

In Lok Sabha

E-Commerce Companies

Lok Sabha Unstarred Question No. 2771

Shri Parthiban S. R.:

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

(a) whether a large number of e-Commerce companies have been found to be indulging in predatory prices;

(b) if so, the details thereof; and

(c) the remedial steps taken by the Government to protect millions of small retailers from this illegal practice?

Answered on 21st March 2022

A. (a)&(b): The Competition Commission of India ('Commission') has received information against certain e-commerce companies alleging, *inter alia*, deep discounting/predatory pricing etc., which are in contravention of the provisions of Section 4 of the Competition Act, 2002 ('Act'). In some of these cases, the Commission found prima facie contravention of the Act and accordingly passed orders directing investigation in the matter.

(c): Section 4 of the Act prohibits abuse of dominant position by enterprises or their groups, including any deep discounting/predatory pricing. The e-Commerce companies are covered within the ambit of this provision of the Act.

The Commission has been undertaking various initiatives from time to time to ensure effective competition and fair play in the market. These, inter-alia, include conducting market studies on relevant sectors, advocacy outreach initiatives, conducting roadshows on competition laws & practices, upgradation of IT infrastructure and increased use of technology in functioning, opening of regional offices etc. The Commission in the recent past had undertaken a "Market Study on E-Commerce in India" to better understand the functioning of e-commerce and its implications for markets and competition. The Report enumerates certain areas for self-regulation by the e-commerce platforms. These include transparency in search ranking parameters, clear and transparent policy on the actual and potential use of data collected by platforms, adequate transparency over user review and rating mechanisms, notification to business users regarding proposed revision in contract terms, and clear and transparent policies on discounts including discount rate and participation in discount schemes. The report is publicly available on the website of the Commission at www.cci.gov.in.

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

Proposal for Effluent Treatment Plants

Lok Sabha Unstarred Question No.2784

Shri Hemant Tukaram Godse:

Q. Will the Minister of **ENVIRONMENT, FOREST AND CLIMATE CHANGE** be pleased to state:

(a) the number and the details of proposals for effluent treatment plants sent by the State Government of Maharashtra to the Central Government;

(b) whether all the proposals sent by the State Government have been approved and if so, the date of their approvals and if not, the time by which the said proposals are likely to be approved; and

(c) whether the funds for approved proposals has been disbursed to the State Government and if not, the time by which the funds would be provided?

Answered on 21st March 2022

A. (a) & (c): Ministry of Environment, Forest and Climate Change (MoEF&CC) was implementing a scheme to fund setting up of Common Effluent Treatment plants (CETPs) for treatment of effluents generated from Small Scale Industries located in clusters since 1991 and the said scheme has been discontinued in FY 2017-18. Moreover, no proposal for setting up of CETP from the State of Maharashtra is pending with MoEF&CC.

Setting up of CETP for Micro, Small and Medium Enterprises through a cluster development approach is undertaken by Ministry of Textiles under Integrated Processing Development Scheme (IPDS) for textile processing sector. As per information provided by the Ministry of Textile, no project proposal under IPDS for the State of Maharashtra has been received.

Minister of State in the Ministry of Environment, Forest and Climate Change (Shri Ashwini Kumar Choubey)

Pollution caused by Industries

Lok Sabha Unstarred Question No. 2887

Shri Saumitra Khan:

Q. Will the Minister of **ENVIRONMENT, FOREST AND CLIMATE CHANGE** be pleased to state:

a) whether the Government is taking any steps to control the air pollution coming from industries and if so, the details thereof;

b) whether the Government is planning to manufacture any machine or tower to control the air pollution in the cities and if so, the details thereof;

c) whether the Government has received complaints regarding environmental pollution caused by pharmaceutical industries in West Bengal during the last three years and current year till date and if so, the details thereof;

d) the action taken thereon along with the penalties imposed/collected and number of such industries closed till date; and

e) if not, the reasons therefor and the role of State Pollution Control Board in this regard?

Answered on 21st March 2022

A. (a) & (b) The Ministry of Environment Forest and Climate Change (MoEF&CC), Government of India notifies industry specific emission or discharge standards under Schedule-I: 'Standards for Emission or Discharge of Environmental Pollutants from various Industries' of Environment Protection Act, 1986. State Pollution Control Boards (SPCBs) and Pollution Control Committees (PCCs) in States and Union Territories respectively ensure the compliance of these standards. So far, industry specific environmental standards for 80 industrial sectors have been notified.

The SPCBs/PCCs issue consent to establish/ consent to operate and authorization to the industries in their respective States/UTs as per the provisions of the Water (Prevention and Control of Pollution) Act, 1974, Air (Prevention and Control of Pollution), 1981 and Environment (Protection) Act, 1986 and rules made their in. SPCBs/PCCs monitors the compliance of consent conditions and other operational activities.

For strengthening of monitoring mechanism and effective compliance through self- regulatory mechanism, directions have been issued to all 17 categories of Highly Polluting Industries, Grossly Polluting Industries (GPIs) of Ganga basin, Common Effluent Treatment Plants (CETPs), biomedical waste management facilities and common hazardous waste management facilities to install Continuous Effluent/ Emission Monitoring Systems and also to have constant vigil on pollutant release. Further, Industries are categories based on its pollution potential, 254 industrial sectors are categorised into red (61), orange (90), green (65) and white (38) categories.

There is no plan to manufacture any machine or tower to control the air pollution in the cities. Central Government has already launched National Clean Air Programme (NCAP), which is being implemented in 132 non-attainment cities of the country.

(c) to (e) No complaint(s) has been received in Central Pollution Control Board and West Bengal Pollution Control Board (WBPCB) against pharmaceuticals industries in West Bengal during the last three years.

For prevention and control of pollution CPCB, SPCBs/ PCCs issue various directions under Water (Prevention and Control of Pollution) Act, 1974, Air (Prevention and Control of Pollution) Act, 1981 and Environment (Protection) Act, 1986, etc. The CPCB has identified 17 categories of highly polluting industries, and is carrying out inspection of these industries based on computer generated alerts from Online Continuous Effluent/ Emission Monitoring System (OCEMS) since 2016-17. Industries are selected for inspection on the basis of Short Message Service (SMS) alerts generated from the online monitoring systems and necessary action is taken against the defaulting industries.

Minister of State in the Ministry of Environment, Forest and Climate Change (Shri Ashwini Kumar Choubey)

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Manufacturing Equipment Evolves to Address Today's Production Needs

Dr. Andreas Mattern, VP Strategy & Global Product Management Pharma at Syntegon discusses some of the latest advances in manufacturing equipment.

With the increasing number of biologics, complex oncology therapies, and rare and orphan drugs comprising pharma and biopharma pipelines, manufacturing equipment must provide substantial flexibility. Additionally, the COVID-19 pandemic and vaccine production is significantly impacting equipment needs.

As batches and regimens trend shorter and more customized, the need for flexible equipment to accomplish more than one task is essential. The latest trends impacting pharmaceutical manufacturing equipment include flexibility in product and container types, digitalization in pharma production, and processing of Advanced Therapy Medicinal Products (ATMPs). Additionally, the level of automation is increasing.

Dr. Andreas Mattern, VP Strategy & Global Product Management Pharma at Syntegon discusses some of the latest advances in manufacturing equipment.

Contract Pharma: *What are the pharma/biopharma trends impacting manufacturing equipment?*

Andreas Mattern: Covid-19 (vaccine production): According to the World Health Organization, 4.9 billion people, or 61.6 percent of the world population have received at least one dose of a Covid-19 vaccine, gradually decreasing the pathogen's virulence. Despite these first successes, the virus' threat remains persistent, as new variants like Omicron are changing the game time and again. This urges leading vaccine manufacturers to continuously adapt existing vaccines and keep up global supply. Besides the vaccines themselves, their packaging and administration is also changing – from vials to pre-filled syringes. They contain a single dose and can be administered even more quickly. We are already experiencing this changing demand. While we supported drug producers with new vial lines and modernizations of existing equipment during the first years of the pandemic, we now see a rising demand for high-performance and highly accurate syringe filling machines. According to our analysis, about half of the global Covid production sites listed on the UNICEF Covid dashboard have processing or packaging equipment from Syntegon installed.

Specialized treatments (small batch sizes): The specialized treatments of a wide range of conditions, including many types of cancer and rare diseases like genetic disorders all share a common trait. In addition to their high potency, which requires effective containment solutions, they are produced in increasingly small batch sizes. The latter call for dedicated production platforms that cater to the production requirements of only several hundred containers per batch in the most extreme cases, asking for pioneering small batch manufacturing solutions that allow for fast changeovers between batches with the lowest possible time and product loss. Leading equipment manufacturers like Syntegon have taken on the challenge and are developing matching platforms.

Re-localizing antibiotics production: Besides all specialized treatments, the production of more common drugs like antibiotics cannot be neglected. They are essential for curing a wide range of conditions, including pneumonia or tonsillitis. Over the past few decades, however, the production of these drugs has been outsourced to lower-cost markets, mainly in Asia. Especially the Covid-19 pandemic has shown how fragile supply chains are and how important it is to re-localize production of life-saving antibiotics such as penicillin and cephalosporins. Apart from local investments by heath authorities and governments, pharmaceutical manufacturers need efficient equipment and comprehensive knowledge of the highly regulated powder filling processes.

Digitalization has been changing processes for some years. The ability to monitor machine conditions in real time helps drug producers to take data-based decisions and optimize operations. Digital service offerings such as remote maintenance, virtual training and even FATs have proven their worth during the pandemic with its travel restrictions – and have come to stay. Another important software-based trend is Artificial Intelligence (AI).

CP: *What are some of the latest advances in manufacturing equipment?*

AM: Small and micro batch production: In the wake of the biopharmaceutical and specialized treatments surge, equipment manufacturers like Syntegon have started developing solutions for small and micro batch filling that meet several requirements at once. For high-priced biotech drugs, it's all about low output and high product yield. Syntegon's small batch solution Versynta Flexible Filling Platform (FFP) with an integratable isolator, which was launched last year, ensures maximum flexibility and product safety. Versynta FFP consists of pre-tested modules that can be selected individually, including different filling systems and Syntegon's four axis handling robot specifically developed for aseptic operation. For even smaller batch sizes of only several hundred containers per hour, the fully automated, gloveless production cell Versynta microBatch is currently being developed. Typical use cases are fill/finish of drugs for clinical trials or production of gene and cell therapies. Both solutions will be presented to the public at this year's Achema in Frankfurt, Germany.

Parenteral drug production: as the Covid-19 pandemic has shown, shorter delivery times are becoming increasingly important to drug manufacturers. With the new SVP Essential, the Syntegon subsidiary Pharmatec has launched a modular, cost-efficient system for the production of small-volume liquid pharmaceuticals, which can be supplied within just six months. Just like Versynta FFP, the SVP Essential is based on a large portfolio of pre-tested modules, which can be assembled to produce simple parenterals such as analgesics or insulin, as well as generic drugs. Especially start-ups and pharmaceutical manufacturers in price-sensitive markets benefit from the fully automated, completely closed system for volumes of 50 to 1,000 liters.

OSD drug development: Speed is also important when bringing new drugs to regulatory approval. The new GKF 60 lab-scale capsule filling machine enables the development of new drugs and formulations with a wide variety of dosing systems that can also dose pure APIs. It is mobile, highly flexible, scalable, and can be adapted for both simple and highly potent formulations up to OEB5 high containment in just a few steps. The level of automation is also increasing in lab-scale equipment: with the Automated Process Development (APD) tool developed by Syntegon, pharmaceutical manufacturers can determine the optimum parameters for capsule filling and automatically adjust them during the process.

Artificial intelligence: Albeit slowly, AI is starting to make its way into pharmaceutical production steps, such as inspection technology, promising greater precision and efficiency than ever before. In fact, AI is already a reality in some pharmaceutical manufacturing operations. Here, Syntegon set new standards in 2021 with the first fully validated visual inspection system utilizing AI for Amgen. With the new AI capabilities, the inspection machine can increase its particle detection rate by 70 percent, while reducing the false detection rate by 60 percent. Syntegon is set to implement AI in further inspection and other pharmaceutical equipment in the future. In July 2021, Syntegon already added a new member to its highly successful AIM 5 inspection range: the fully integrated syringe inspection line not only features a de-nester and a re-nester, but also comes with an AI function by default.

CP: *What capabilities do clients look for in manufacturing equipment? What specific manufacturing challenges do clients look to overcome?*

AM: As mentioned above, fast time-to-market, short delivery times, digitalization options with reduced validation efforts, and the highest flexibility in batch sizes with minimal product loss are among the major prerequisites of pharmaceutical manufacturers.

Another important challenge is **product and operator protection**. High-containment systems up to OEB5 are required in both parenteral and OSD production to make sure the sometimes highly potent products have no effect on the operators' health. Take the example of antibiotic powders: their consistency requires special air handling concepts. In the filling areas, dust-tight barriers and a sealed air supply with efficient and powerful filter systems are a must. A UDAF ventilation system cleans and tempers the circulating air of the filling area and regulates humidity. Machine cleaning is also particularly complex with powders, as the fine dust particles can settle anywhere within the machine. An open design, easy accessibility, and CIP-SIP for cleaning the product in-feed system provide an effective remedy. In liquid filling operations, robotic systems are increasingly used to reduce operator intervention to a minimum. The Pharma Handling unit of the Versynta FFP is a good example. It offers a high degree of flexibility in manufacturing processes, while making them safer, more precise, reproducible and validatable.

Flexibility is just as important in the choice of **pack styles and filling systems**. Advances in specialized treatment increase the need for systems that make it possible to process more than one container type on a single platform, without compromising on yields or changeover times. Innovations like Syntegon's Versynta portfolio but also proven fill-finish machines like the FXS Combi platform for syringes, vials and cartridges specifically address this trend. The choice between different filling systems such as piston pump or peristaltic pump (which has become the standard for filling proteins in combination with disposable filling systems) further speeds up production.

CP: *Where does the industry stand with adopting production innovations or new technologies?*

AM: The pharmaceutical industry is not known for its fast adoption of new technologies or processes. This is mainly due to the strict regulatory guidelines, which are in place to ensure maximum product and patient safety. In many cases, **working on pilot projects or in strategical partnerships** has shown to speed up innovation significantly.

Artificial intelligence is the most prominent example. Deep Learning vision tools, which only require moderate software modifications, have been available for a while. It took a machine manufacturer (Syntegon) with sound software, process, and validation expertise, and a pharmaceutical producer (Amgen) with the wish to make processes even safer and more reliable to implement the first fully validated visual inspection system utilizing AI.

Partnerships have also been driving innovations in **small batch liquid fill-finish operations**. Versynta microBatch, the highly flexible and fully automated production cell with a gloveless isolator, is a joint development of Vetter and Syntegon. Together, both companies are addressing the need for ever more flexible platforms that process smallest batches of highly effective drugs. In fact, Syntegon and Vetter were awarded the PDA Drug Delivery Innovation Award in the "Partnership Innovation" category for Versynta microBatch.

Continuous manufacturing for OSD forms has also been trending for a few years. Developments like the Xelum platform form the Syntegon subsidiary Hüttlin have already set new standards: the platform doses, mixes and granulates individual packages, so-called X-keys, which continuously run through the process chain and are removed from the system successively. This way, even smallest amounts of APIs of less than one percent can be dosed precisely. Syntegon has now entered a strategic partnership with Bayer to further advance this process and establish it as a standard in the pharmaceutical industry. In the same vein, Syntegon and Shanghai Pharmaceuticals signed an agreement to build a joint laboratory for continuous manufacturing technology in China.

Source: Kristin Brooks, Managing Editor, Contract Pharma, 07.04.2022

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Govt plans to hire specialists to drive its trade negotiations

The department of commerce is also exploring setting up separate specialized teams for bilateral negotiations and WTO negotiations. Reuters

- It may onboard experts from services, agriculture, pharma, and trade remedies, among others

The government is exploring ways to involve sector specialists from the public and private sectors during the negotiations on key bilateral free trade agreements (FTAs) to ensure best possible outcomes for India, said two senior government officials.

The Centre has set an exports target of over $2 trillion by 2027, and will try to negotiate terms that would serve India's interests by onboarding experts from services, agriculture, pharmaceuticals, trade remedies, and digital trade, among others, one of the two officials said, seeking anonymity. "The idea is to create a team of specialists when we go for trade agreement talks. Whichever country, especially if we negotiate with developed nations, they have specialists on the negotiation table. Experts in services, goods, or agriculture attend the talks. There is a realization that it shouldn't be the case that officers negotiating a deal for India have no subject knowledge. It could be a government official or a private sector expert."

Experts from the private sector may also be roped in to drive export promotion activities by the department of commerce in key markets, he said.

India has signed an FTA with the United Trade Emirates (UAE) and concluded an interim trade deal with Australia. It is also in talks with the UK, European Union, Canada, and Israel for bilateral trade deals.

The discussions are on internally, and will need to get approval from the department of personnel and training (DoPT) before the Prime Ministers' Office (PMO) sanctions it, said a second official, also requesting anonymity.

India will start talks with Australia to transform the mini-trade deal into a full-fledged comprehensive economic cooperation agreement (CECA) within two months, and hopes to conclude early harvest deals with Canada and the UK this year.

The proposal is to strengthen the negotiation ecosystem with the right expertise and robust end-to-end processes, with clearly defined focus areas. "The goal is to achieve an optimal mix of talent with specialists and generalists sourced from the private and government sectors," he added.

Queries sent to the spokesperson of the ministry of commerce and industry on Thursday remained unanswered till press time.

The proposal is part of the government's broader strategy to revamp the department of commerce and create a stronger active role for missions in trade promotion for market intelligence, leads generation, and localized research.

The department is also exploring setting up separate specialized teams for bilateral negotiations and World Trade Organization (WTO) negotiations. "Most developed countries involve private players in FTA negotiations, mostly lawyers and economists. India has always been inclined towards using economists from educational institutions but including private participants will be a sensible decision," Pradeep S. Mehta, secretary-general, CUTS International, said.

It will be interesting to see whether they will be part of the frontal negotiating team or work at the back-end, he added. "There is no institutional memory when officers are transferred. That is a problem. Bringing in private players could solve this. The government has already allowed lateral entry of experienced people."

Arpita Mukherjee, professor, Indian Council for Research on International Economic Relations, concurred saying its an "extremely good move". "Most developed countries like the US and developing ones like Vietnam follow this process where their core industry bodies both in domestic market and for exports representing 70-80% of stakeholders provide detailed feedback on sectors during the negotiation process." She said in India, there is no

process of holistic consultation. "Hence, the proposal by the commerce department will prove to be effective for India in signing good deals."

The department of commerce is also looking at setting up a dedicated 'trade promotion body' to drive promotion strategy, export targets, and execution.

India's exports had touched a record $418 trillion in 2021-22.

The pacts signed under the United Progressive Alliance (UPA) government came under intense criticism for driving up imports from partner countries rather than benefiting India's exports.

Share of imports from the 10-nation bloc ASEAN in the Indian basket has grown from 8.2% in FY11 to 12% in FY21, while exports have remained stagnant at 10%. Similarly, while South Korea's imports increased from 2.83% in FY11 to 3.23% in FY21, the exports share is up from 1.5% to 1.6%.

Centralization and digitization of the trade facilitation processes are other key areas that the department is working on to drive compliance and administration.

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Source: HT Mint, 11.04.2022

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Conducting Clinical Trials During the Pandemic: What Did We Learn?

Key takeaways from MHRA's Good Clinical Practice Symposium.

The MHRA Good Clinical Practice Symposium was a virtual event this year due to COVID 19. More than 800 individuals from over forty countries across the globe attended. Throughout the three-day event, speakers provided their perspectives on clinical trials from their roles as inspectors, assessors and reviewers representing the MHRA, FDA and Health Canada. The agenda provided an opportunity for the audience to understand the challenges faced by these regulatory bodies during the pandemic, how they had to quickly pivot to alternative means to continue to carry out their responsibilities, what the agencies learned, how they may consider adapting their inspections post-pandemic and potential efficiencies gleaned from these last two years. Attendees took advantage of the opportunities to ask questions of the speakers and the Q&A sessions were quite informative.

The first two days of this remote symposium covered various clinical trial topics such as clinical trial design, sponsor oversight, real-world data and real-world evidence, decentralized trials, use of artificial intelligence (AI) and machine learning (ML) in clinical trials, and updates for legislation/guidance from each of the three regulatory bodies.

Day 3 was dedicated to BE/BA studies and the issues and challenges experienced both within the clinics and bioanalytical laboratories. Regulatory updates were also provided, along with a presentation for the draft of ICH M10 "Bioanalytical Method Validation Guideline." As expected (and eagerly anticipated by the attendees, I'm sure) the regulators shared recent case studies including intentionally compromising data integrity from the clinical and bioanalytical aspects of BE/BA studies.

The main takeaways from my perspective were:

1. Do not be surprised if future inspections from MHRA and Health Canada utilize a hybrid approach (an inspection having both remote and on-site elements).
2. Regulators were encouraging sponsors of clinical trials to have communication with them up front for novel trial designs or anticipated challenges to conducting a clinical trial.
3. Sponsors and other stakeholders should constantly evaluate the risks associated with trials and mitigate these risks as much as possible.
4. All stakeholders need to be involved in a study's design.
5. Sponsors, although you may delegate trial-related duties to CROs, you are ultimately responsible for your clinical trials—you have everything to gain in their success, or everything to lose if there is a critical failure.
6. Despite the pandemic, the fundamentals of running clinical trials have not changed as you must: continue to follow the regulations and your protocols; ensure adequate documentation with justification and impact when you do not; ensure that the rights, health and safety of the trial participants are front and foremost; and ensure that the data generated is accurate, complete, and consistent and meets the requirements of ALCOA (Attributable, Legible, Contemporaneous,

Original, Accurate); however, the precise ways that clinical trials are conducted are always evolving, as this pandemic demonstrated.

If you have a need for assistance in supporting your clinical trials, whether it is initial discussions with the Agency through to submission of the application (or any point in between), our team at Lachman Consultants are here to work with you.

For more information email D.OConnor@LachmanConsultants.com

Source: Contract Pharma, 08.04.2022

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Govt wants to reduce compliance burden on pharma sector: Dr. Mandaviya

Union Minister for Chemicals and Fertilizers Mansukh Mandaviya on Thursday said that the government wants to reduce the compliance-burden on the pharma industry for ease of doing business. Speaking as the chief guest at an Indian Drug Manufacturers' Association (IDMA) event here, Mandivya, who is also the Minister for Health and Family Welfare, said that the Narendra Modi-led government at the Centre is not only "pro-poor" and "pro-farmer" but "industry-friendly" as well.

"We want the ease of doing business for the industry and lessen the compliance burden on it.

This is why we always carry out consultations with all stakeholders prior to the formulation of any policy or regulation (governing the pharma industry)," Mandaviya said.

The government is helping the industry by amending the Drugs and Cosmetics Act, 1940 and promoting Ease of Doing Business, he said, adding, "We are involving the industry in decision-making processes". Also, through a series of webinars, the government has tried to reach out and consult industry and other stakeholders on the implementation of Union Budget provisions, the minister stated. "Our government is pro-poor, pro-farmer and industry-friendly government. It is dedicated to the poor and farmers but at the same time it is an industry-friendly government as well," he emphasized. Stating that the industry plays an important role in nation-building and also in achieving self-reliance, the Minister said that today the Indian pharma industry is known in the world which is due to the efforts of both the Government and the industry.

He said that the government is working to make the pharma industry self-reliant and also enhancing and the introduction of the Rs 15,000 crore Productivity Linked Incentive (PLI) scheme is a step in this direction.

Through the Production Linked Incentive Scheme, the government has tried to reduce imports by encouraging domestic manufacturing of pharmaceuticals, he said. Manufacturing of 35 Active Pharma Ingredients (API), which used to be imported earlier, has started in the country now under the PLI Scheme for the pharma sector, Mandaviya said.

The Minister urged the pharmaceutical sector to prepare a plan for the next 25 years "Government does not view the health sector as a profit-making industry. When we export medicines, we do it with an attitude of 'Vasudhaiva Kutumbakam'. During the first wave of COVID-19 pandemic, India supplied medicines to 125 countries," he added.

Source: PTI, 14.04.2022

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