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IDMA BULLETIN

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INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

REGISTER NOW FOR VRIDDHI S1 ~ Founder's Mentality ~ organized by IDMA and BAIN & COMPANY

on Friday, 16th September 2022

at Hotel The Trident, Nariman Point, Mumbai from 8.30 am to 5.00 pm

(Details on Page: 4)

HIGHLIGHTS

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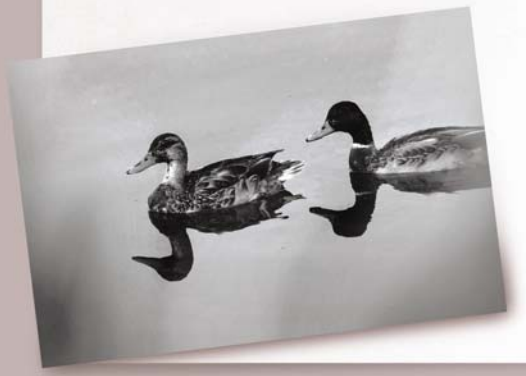

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IDMA BULLETIN

Vol. No. 53 Issue No. 33 01 to 07 September 2022

IDMA ACTIVITIES:

MoEFCC MATTERS:

PARLIAMENT NEWS:

NATIONAL NEWS:

REGISTER NOW FOR VRIDDHI S1 ~ Founder's Mentality ~ organized by IDMA and BAIN & COMPANY on Friday, 16th September 2022 at Hotel The Trident, Nariman Point, Mumbai from 8.30 am to 5.00 pm

The Indian Drug Manufacturers' Association (IDMA) is pleased to invite you to the **first session (S1) of "Vriddhi",** an insights-exchange series envisaged with the objective of supporting Indian pharmaceutical companies to expand their vision by embracing **founder's mentality** and making PE work to their advantage. **IDMA has partnered with Bain & Company**, one of the world's most respected management consulting firms, to design and deliver Vriddhi. The program schedule is attached for your reference.

Vriddhi S1 is being organised at **The Trident Hotel, Nariman Point, Mumbai on Fri, Sep 16, 2022, 08:30 to 17:00 IST.** The event is expected to draw in-person participation of 70-80 promoter and Vice-President and above professional leaders from the industry.

Registration Form: **https://forms.gle/G67ua71bxWyyHivj9**

The registration fees is 6,000 INR + taxes per person and includes cost of breakfast, lunch, and evening high-tea. ***For every 3 registrations from a company, the 4th registration will be complimentary***. If you have more than one (1) person attending, you are requested to fill the form for every individual. **The Platinum, Diamond, and Gold sponsors for the IDMA Diamond Jubilee (60th Year) Celebrations have one (1) registration complimentary** to reciprocate their long-standing and generous patronage to IDMA.

IDMA has obtained **special rate of 9,000 INR + taxes per night per room** including buffet breakfast at The Trident. Please convey through this form on your desire to make a reservation - IDMA team will facilitate it.

IDMA Bank Transfer Details for Registration Fees Payment of 7,080 INR (6,000 INR + 18% GST)

Account Holder's Name: **Indian Drug Manufacturers Association**

Current Account Number: **76080200000242**

Bank: **Bank of Baroda**

IFSC Code: **BARB0DBWORL**

Branch: **Worli, Mumbai 400 018**

We look forward to receiving your participation and hosting you. Best wishes.

Sincere Regards,

Dr. Viranchi Shah	**Shri Mehul Shah**	**Shri Daara Patel**
National President	*Honourary General Secretary*	*Secretary General*

RSVP: Mr. Melvin Rodrigues (Senior Manager, IDMA) - actadm@idmaindia.com and +91 9821868758.

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Speakers

Karan Singh
Managing Partner
Bain & Company

Vivek Gambhir
Chief Executive Officer
boAt

Rajesh Vedak
Managing Director & President
Körber India

Parijat Ghosh
Partner
Bain & Company

Kshitij Sheth
Director
ChrysCapital

Manish Gaur
Managing Director
Multiples PE

Speakers

Pankaj Patwari
Managing Director
Advent International

Sunil Thakur
Partner
Quadria Capital

Dharmesh Shah
Managing Director
BDR Pharmaceuticals

Mehul Shah
Managing Director
Encube Ethicals

Nirav Mehta
Executive Director
Corona Remedies

Sanjiv Navangul
Managing Director & CEO
Bharat Serums and Vaccines

Reasons to Attend Vriddhi S1

Receiving insights and approaches on growth strategies and raising or managing private equity investments

Networking with some of the respected pharmaceutical, private equity, and management consulting leaders in a closed-door setting

Shaping narrative and fostering collaboration on technology advancement and best practices.

Schedule

08:30	09:30	Arrival and Registration including Breakfast
09:30	10:00	**Inaugural Session**
10:00	11:00	**Founder's Mentality and Micro-battles** {Presentation and Q&A} Karan Singh, *Managing Partner - Bain & Company*
11:00	11:45	**Case Study: Transformation Journey** {Presentation and Fireside Chat} Vivek Gambhir, *CEO - boAt* and *ex.MD & CEO - Godrej Consumer Products*
11:45	12:00	Break
12:00	12:30	**The Digital Future of the Pharmaceutical Industry** Rajesh Vedak, *Managing Director & President - Körber India*
12:30	13:30	**Private Equity: A Source of Competitive Advantage** {Presentation and Q&A} Parijat Ghosh, *Partner - Bain & Company*
13:30	14:15	Lunch

Schedule

14:15	15:15	**Raising External Capital and Working with PE Investors** {Discussion} Kshitij Sheth, *Director - ChrysCapital* Manish Gaur, *Managing Director - Multiples PE* Pankaj Patwari, *Managing Director - Advent International* Sunil Thakur, *Partner - Quadria Capital* Parijat Ghosh, *Partner - Bain & Company* (Moderator)
15:15	16:15	**Importance of Founder's Mentality and Navigating the Future** {Discussion} Dharmesh Shah, *Managing Director - BDR Pharmaceuticals* Mehul Shah, *Managing Director - Encube Ethicals* Nirav Mehta, *Executive Director - Corona Remedies* Sanjiv Navangul, *Managing Director & CEO - Bharat Serums and Vaccines* Karan Singh, *Managing Partner - Bain & Company* (Moderator)
16:15	16:25	**Vote of Thanks**
16:25	17:00	High-Tea

Conveners

Dr. Viranchi Shah
National President - IDMA
Director - Saga Laboratories

Karan Singh
Managing Partner
Bain & Company

Mehul Shah
Hon. General Secretary - IDMA
Managing Director - Encube Ethicals

Parijat Ghosh
Partner
Bain & Company

Daara Patel
Secretary General - IDMA

I look forward to welcoming you at Vriddhi S1 on Fri, Sep 16, 2022 in Mumbai.

Thank you. Best wishes.

IDMA — BAIN & COMPANY

The Indian Drug Manufacturers' Association (IDMA) and Bain & Company
are pleased to invite you to the first session (S1) of

Vriddhi

An insights exchange series for pharmaceutical entrepreneurs to expand their vision by embracing founder's mentality and making private equity work to their advantage.

on **Fri, Sep 16, 2022, 08:30 to 17:00 IST** at **The Trident, Nariman Point, Mumbai.**

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IDMA National President Dr Viranchi Shah along with Officials & Dignitaries of NPPA and Ministry of Chemicals & Fertilizers at Silver Jubilee celebrations of NPPA held on 29th August 2022 at Dr Ambedkar International Centre, New Delhi

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IDMA Congratulates Dr. Mansukhbhai Mandaviya Ji, Hon'ble Minister of Health & Family Welfare and Chemicals & Fertilizers on the Approvals of Three Bulk Drug Parks to Himachal Pradesh, Gujarat, and Andhra Pradesh

IDMA have submitted following congratulatory letter to Dr. Mansukhbhai Mandaviya Ji, Hon'ble Minister of Health & Family Welfare and Chemicals & Fertilizers dated 3rd September 2022 on the above subject. Government Press release reproduced below for member information

Respected Dr. Mansukhbhai Mandaviya Ji,

Namaste!

We are glad to note that under your stewardship the Government has truly risen to the occasion to reduce the country's dependence on imports of APIs by taking a series of steps.

One such very significant step has come in form of the in-principle approvals for three Bulk Drugs Parks, one each to Himachal Pradesh, Gujarat, and Andhra Pradesh.

We believe that these parks, as well as other initiatives like PLI-1, PLI-2, and others, will significantly contribute to the strengthening of the domestic API industry. We are sure that this will enhance the competitiveness of the Pharma Formulation industry, besides also contributing to the growth in exports. This will also further contribute to the Atma Nirbhar Bharat initiatives in the API sector. We are sure that the Bulk Drug Parks will help in creating a robust self-reliant supply chain for the Indian Pharmaceutical industry, thus contributing to National Drug and Healthcare Security.

On behalf of IDMA, we congratulate you and the Honourable Prime Minister for taking visionary and impactful steps and supporting this very critical industry.

IDMA is always with you and the Government in all its endeavours, and shall continue to play a constructive role in all avenues of building a strong INDIA.

I would also like to take this opportunity to express my sincere gratitude to you and to the Government.

Jai Hind.

Thanking you.

Yours sincerely,

For Indian Drug Manufacturers' Association,

Dr Viranchi Shah
National President

GOVERNMENT PRESS RELEASE

Centre Grants 'in-Principle' Approval of three Bulk Drug Parks to Himachal Pradesh, Gujarat and Andhra Pradesh

Another move towards making the Country Atmanirbhar in Bulk Drugs

Three States to submit their detailed project reports in next 90 days

The Department of Pharmaceuticals has conveyed 'in-principle' approval to the proposals of the three States Viz, Himachal Pradesh, Gujarat and Andhra Pradesh under the Scheme for *"Promotion of Bulk Drug Parks"*, a key initiative to support the Bulk Drugs manufacturing in the country. The Scheme, with a financial outlay of

Rs. 3,000 crores notified in 2020, provides for financial assistance to three States for establishing Bulk Drug Parks and aims to bring down the cost of manufacturing of bulk drugs by creation of world class common infrastructure facilities supported by the Central Government and thereby increase the competitiveness of the domestic bulk drug industry.

The Indian Pharmaceutical industry is the 3rd largest in the world by volume. India exported pharmaceuticals worth Rs. 1,75,040 crore in the financial year 2021-22, including Bulk Drugs/ Drug Intermediates. Also, India is one of the major producers of Active Pharma Ingredients (API) or bulk drugs in the world. India exported Bulk Drugs/ Drug Intermediates worth Rs. 33,320 crore in financial year 2021-22.

However, the country also imports various Bulk Drugs/ APIs for producing medicines from various countries. Most of the imports of the Bulk Drug/APIs being done in the country are because of economic considerations.

The Government strives to minimize country's dependence on imports and to give fillip to indigenous manufacturing. In order to make the country self-reliant in APIs and drug intermediates, the Department of Pharmaceuticals is implementing various schemes and one of the key interventions is the Scheme for Bulk Drug Parks.

The Bulk Drug Parks to be developed under the scheme will provide common infrastructure facilities at one place thereby creating a robust ecosystem for the Bulk Drug manufacturing in the country and also reducing the manufacturing cost significantly.This scheme is expected to encourage domestic manufacturing of bulk drugs to reduce import dependence and to establish a dominant position in the global market by providing easy access to standard testing & infrastructure facilities. This scheme will also help industry meet the standards of environment at a reduced cost through innovative methods of common waste management system and also to exploit the benefits arising due to optimization of resources and economies of scale.

Under the scheme, proposals were received from 13 States. The Department was guided by an Advisory Committee under CEO, NITI Aayog in the appraisal of the proposals, based on the quantitative as well as qualitative methodology.

The financial assistance to the proposed Bulk Drug Park in Gujarat and Andhra Pradesh would be 70% of the project cost of common infrastructure facilities. In case of Himachal Pradesh, being Hilly States, financial assistance would be 90% of the project cost.Maximum assistance under the scheme for one Bulk Drug Park would be limited to Rs. 1000 crores.

As per the proposals submitted by these States, the Bulk Drugs will be established in 1402.44 acres of land at Tehsil Haroli, District Una, Himachal Pradesh, 2015.02 acres of land at Tehsil Jambusar, District Bharuch, Gujarat and 2000.45 acres of land at K.P. Puram & Kodhada of Thondagi Mandal of East Godavari District, Andhra Pradesh. These three States were instructed to submit their Detailed Project Reports in next 90 days, to appraise the same and to process for issuance of final approval under the scheme.

The scheme reflects the spirit of co-operative federalism where the Central Government and State Governments will partner to develop the Bulk Drug parks for better performance of the sector.

Other interventions of the Department, in ensuring domestic manufacturing of the Bulk Drugs, include,

Production Linked Incentive (PLI) Scheme for *domestic manufacturing of KSMs/ Drug Intermediates (DIs) and APIs.* Under this scheme, a total of 51 projects have been approved, out of which, 14 projects have already commissioned and started manufacturing of the drugs.

PLI for Pharmaceuticals, provides for financial incentive to 55 selected applicants for manufacturing of identified products under three categories and eligible drugs under this scheme include APIs.

Source: PIB Delhi, 01.09.2022

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Environment (Protection) Rules, 1986 amended (Second Amendment of 2022)

Environment Notification G.S.R.682(E), dated 05th September 2022

In exercise of the powers conferred by sections 3, 6 and 25 of the Environment (Protection) Act, 1986 (29 of 1986), the Central Government hereby makes the following rules further to amend the Environment (Protection) Rules, 1986, namely:-

1. (1) These rules may be called the **Environment (Protection) Second Amendment Rules, 2022.**

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

2. In the Environment (Protection) Rules, 1986, in Schedule-I, in serial number 25 for "* (i) Table 1" the following shall be substituted, namely:-

Table-I

Sr. No.	Category	Location/area	Timelines for compliance (Non-retiring units)		Last date for retirement of units for exemption from compliance	
			parameters other than SO_2 emissions	SO_2 emissions	parameters other than SO_2 emissions	SO_2 emissions
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	Category A	With 10 km radius of National Capital Region or cities having million plus population[1].	Up to 31st December 2022	Up to 31st December 2024	Up to 31st December 2022	Up to 31st December 2027
2	Category B	With 10 km radius of Critically Polluted Areas[2] or Non- attainment cities[2]	Up to 31st December 2023	Up to 31st December 2025	Up to 31st December 2025	
3	Category C	Other than those included in category A and B	Up to 31st December 2024	Up to 31st December 2026	Up to 31st December 2025	

[1]As per 2011 census of India.

[2]as defined by CPCB.

3. For "* (ii)" the following shall be substituted, namely:-

"(ii) (a) The thermal power plant declared to retire before the date as specified in column (6) of Table -I shall not be required to meet the specified norms for parameters other than SO_2 emissions in case such plants submit an undertaking to CPCB and CEA for exemption on ground of retirement of such plant:

Provided that such plants shall be levied environment compensation from the dates as specified in column (4) of table–I, at the rate of rupees 0.40 per unit electricity generated in case their operation is continued beyond the date as specified in the undertaking;

(ii) (b) The thermal power plant declared to retire before the date as specified in column (7) of Table-I shall not be required to meet the specified norms for SO_2 emissions in case such plants submit an undertaking to CPCB and CEA for exemption on ground of retirement of such plant:

Provided that such plants shall be levied environment compensation from the dates as specified in column (5) of table–I, at the rate of rupees 0.40 per unit electricity generated in case their operation is continued beyond the date as specified in the undertaking;"

4. For "* (iii)" the following shall be substituted, namely: -

"(iii) there shall be levied environment compensation on the non-retiring thermal power plants, after the date as specified in column (4) and (5) of Table-I, as per the rates specified in the Table-II, namely:-

Table-II

Non-Compliant operation beyond the Timeline	Environmental Compensation (Rs. per unit electricity generated)
0-180 days	0.20
181-365 days	0.30
366 days and beyond	0.40"

F.No.Q-15017/40/2007-CPW

Naresh Pal Gangwar, Addl. Secy, Ministry of Environment, Forest and Climate Change, New Delhi

Note: *The principle rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number S.O.844(E), dated the 19th November, 1986 and lastly amended vide notification G.S.R.143(E), dated the 22nd February, 2022.*

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In Lok Sabha & In Rajya Sabha

In Lok Sabha

Research and Development of Drugs

Lok Sabha Unstarred Question No. 2139

Shri Manoj Kotak:

Shrimati Raksha Nikhil Khadse:

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

(a) whether the Government has launched any programme or policy for Research and Development (R&D) of drugs through various schemes;

(b) if so, the details thereof along with the new drugs developed, R&D expenditure of Indian pharmaceutical companies/Public Sector Undertakings (PSUs) during the last three years, year- wise; and

(c) whether National Institutes of Pharmaceutical Education & Research (NIPERs) has conducted research in various pharma specializations and if so, the details thereof?

Answered on 29th July, 2022

A. (a) and (b): Research and Development (R&D) in pharma sector is done by number of institutions and organizations under various scientific Ministries/ Departments as well as by pharmaceutical companies.

Department of Pharmaceuticals (DoP) has set up seven National Institutes of Pharmaceutical Education & Research (NIPERs) as institutes of national importance to nurture and promote quality and excellence in pharmaceutical education and research in India, which besides imparting postgraduate and doctorate education, conduct high end research in various pharma specializations. DoP has also set up an Inter- Departmental Committee (IDC) to periodically review and coordinate research work undertaken by various organizations under different Ministries/ Departments so as to ensure optimum utilization of funds and avoid overlapping and duplication of efforts and resources.

Department of Biotechnology (DBT), along with its Public Sector Undertaking (PSU) Biotechnology Industry Research Assistance Council (BIRAC) has facilitated implementation of Research and Development (R&D) projects for drug discovery in the areas of Tuberculosis (TB), Anti-Microbial Resistance (AMR), Diabetes, Cancer, Wound management, Autoimmune disorders and Rare Diseases, through the regular schemes of DBT and BIRAC.

The year-wise details of the fund disbursements by BIRAC to grantees during the last 3 years to support R&D projects for drug development are as follows:

	2019-20	2020-21	2021-22	Total
Amount Released (Rs in Lakhs)	826.72	498.13	419.13	1743.98

Council of Scientific and Industrial Research (CSIR) through its various constituent laboratories is engaged in the research and development of the process technologies for Active Pharmaceutical Ingredients (API) and intermediates. CSIR has approved various significant projects, including projects on basic research, in the area of drug discovery and development worth about Rs. 284.88 cr. for the period 2020-21 to 2025-26.

The details of R&D expenditure incurred by pharmaceutical companies are not readily available with the department. As regard pharma PSUs under DoP, it is informed that all of them have been identified for closure or strategic sale. The details of R&D expenditure of three functional PSUs (KAPL, HAL & BCPL) under DoP are as under:

(Rs. in Lakh)

PSU	2019-20	2020-21	2021-22
Karnataka Antibiotics & Pharmaceuticals Ltd. (KAPL)	125.48	35.88	41.24
Hindustan Antibiotics Ltd. (HAL)	127.86	97.00	92.66
Bengal Chemicals & Pharmaceuticals Ltd. (BCPL)	11.00	15.00	16.00

(c): NIPERs are actively & dedicatedly engaged in cutting-edge advanced translational pharmaceutical research in various pharma specializations. The areas of research include cancer, diabetes, Neurodegenerative Disease, TB, Phytopharmaceuticals, New process development of Generic API molecules, Drug Delivery System, development of Nano-drug Formulations etc.

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

Fake/Spurious Drugs

Lok Sabha Unstarred Question No. 2141

Shri Dhairyasheel Sambhajirao Mane:

Shri Lavu Sri Krishna Devarayalu:

Shri Ravi Kishan:

Shri Ravindra Kushwaha:

Shri Prataprao Jadhav:

Shri Sudheer Gupta:

Shri Shrirang Appa Barne:

Shri Sanjay Sadashivrao Mandlik:

Shri Bidyut Baran Mahato:

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

(a) whether the Government is aware of the fact that the business of fake/spurious drugs is spreading throughout the market in the country without any intervention and if so, the details thereof;

(b) whether there is a network of manufacturing and sale of spurious drugs/medicines in various parts of the country;

(c) if so, the details thereof and the action taken by the Government to check the same;

(d) whether the non-existence of manufacturing plant(s) of pharma companies could be one of the reasons for spread of spurious drug and its manufacturing across the country;

(e) whether the Government has received any complaints regarding the sale of spurious medicines across the country; and

(f) if so, the details thereof and the action taken by the Government to check the same?

Answered on 29th July, 2022

A. (a) to (f) : The manufacture, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945. The regulatory control over the manufacture, sale and distribution of drug in the country is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs) appointed by respective State Governments. The SLAs are legally empowered to take action in case of violation of the condition of Licence.

The Government has taken measures including strengthening of legal provisions, workshops and training programmes for manufacturers and regulatory officials and measures such as risk based inspection. As per the information received from various State/UTs Drugs Controllers, the enforcement actions carried out in terms of samples tested, number of drugs samples declared sub-standard and spurious/ adulterated during the last three years are as below:

Year	No. of drugs samples tested	No. of drugs samples declared not of standard quality	No. of drugs samples declared spurious/ adulterated	No. of pros-ecu-tions	No. of persons arrested
2018-19	79,604	2,549	205	484	153
2019-20	81329	2497	199	421	220
2020-21	84874	2652	263	236	164

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

Drugs for Covid-19 Infection

Lok Sabha Unstarred Question No. 2167

Shri Dushyant Singh:

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

(a) whether drugs for treatment of COVID-19 infection are under various stages of approval;

(b) if so, the details thereof along with the organization undertaking the clinical trials;

(c) whether the Government has proposed to export the COVID-19 treatment drugs to other nations;

(d) if so, the details thereof; and

(e) whether the Government has entered into any partnerships or collaborations for R&D on COVID-19 treatment drug and if so, the details thereof?

Answered on 29th July, 2022

A. (a) to (e): Central Drugs Standard Control Organisation (CDSCO) has approved various drugs for restricted use in emergency situation for COVID-19 treatment namely Remdesivir, Favipiravir, 2-Deoxy-D-Glucose, Baricitinib, Molnupiravir, Nitric oxide nasal spray, Inosine pranobex, Co-pack of Nirmatrelvir & Ritonavir, Aviptadil Injection, Itolizumab Injection, Pegylated Interferon alfa-2b Injection, Casirivimab and Imdevimab (combination therapy) etc.

Further, permission has been granted to the various pharmaceutical companies for conduct of clinical trials of various drugs for COVID-19 including Umifenovir, Aqueous Chloride Solution, Adalimumab, Bevacizumab, Etanercept, SARC-CoV2-Equine Antiserum immunoglobulin.

Export of COVID-19 treatment drugs to other nations is free which means that there is no requirement of any export authorisation from Directorate General of Foreign Trade (DGFT). Further, Indian Council of Medical Research (ICMR) has informed that it has not entered into any partnership for R&D on COVID-19 treatment drug.

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

National Policy for Rare Diseases, 2021

Lok Sabha Unstarred Question No. 2194

Dr. Beesetti Venkata Satyavathi:

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

(a) the salient features of National Policy for Rare Diseases, 2021;

(b) whether the policy states the need for promotion of affordability and indigenous manufacturing of drugs for Rare Diseases;

(c) if so, the details thereof; and

(d) the steps being taken by the Government in this regard?

Answered on 29th July, 2022

A. (a) The Government has launched National Policy for Rare Diseases (NPRD), 2021 in March, 2021 for the treatment of rare disease patients. The salient features of NPRD, 2021 are as under:

- The rare diseases have been identified and categorized into 3 groups namely Group 1, Group 2 and Group 3.

  Group 1: Disorders amenable to one-time curative treatment.

  Group-2: Diseases requiring long term/lifelong treatment having relatively lower cost of treatment and benefit has been documented in literature and annual or more frequent surveillance is required.

  Group 3:- Diseases for which definitive treatment is available but challenges are to make optimal patient selection for benefit, very high cost and lifelong therapy.

- Provision for financial support upto Rs. 50 lakhs to the patients suffering from any category of the Rare Diseases and for treatment in any of the Centre of Excellence (CoE) mentioned in NPRD-2021, outside the Umbrella Scheme of Rashtriya Arogaya Nidhi.

- In order to receive financial assistance for treatment of rare disease, the patient of the nearby area may approach the nearest Centre of Excellence to get him assessed and avail the benefits.

- Eight (08) Centres of Excellence (CoEs) have been identified for diagnosis, prevention and treatment of rare diseases.

- Five Nidan Kendras have been set up for genetic testing and counselling services.

(b) & (c): The NPRD, 2021 has provisions for promotion of research and development for diagnosis and treatment of rare diseases; promotion of local development and manufacture of drugs and creation of conducive environment for indigenous manufacturing of drugs for rare diseases at affordable prices.

(d): Department of Pharmaceuticals has initiated the implementation of Production Linked Incentive Scheme for Pharmaceuticals. The Scheme provides for financial incentives to manufacturers selected under the Scheme for domestic manufacturing of various product categories, which also include Orphan drugs.

Department of Revenue, Ministry of Finance vide their Notification No. 46/2021-Customs dated 30.09.2021 gives full waiver of Basic Customs Duty (BCD) and Integrated Goods and Services Tax (IGST) to drugs imported (personal use only) for treatment of Spinal Muscular Atrophy (SMA) rare disease, thereby making the medicines for SMA rare disease more affordable.

In addition, Department of Revenue, Ministry of Finance vide their Notification No. 02/2022-Customs dated 01.02.2022 has given exemption from Basic Customs Duty to drugs or medicines, which are used in the treatment of Rare Diseases when imported by Centres of Excellence (CoEs) as specified in NPRD, 2021 or any person or institution on recommendation of any Centre of Excellence listed in NPRD, 2021, certifying that the person (by name) for whom the drugs or medicines are imported, is suffering from a rare disease (to be specified by name) and requires the drugs or medicines for the treatment of said rare disease.

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

Price Hike of Key Drugs

Lok Sabha Unstarred Question No. 2206

Shri Sanjay Kaka Patil:

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

(a) whether the Government has taken note that the National Pharmaceutical Pricing Authority has allowed a one-time price hike of 50 percent for three key drugs - ibuprofen, ranitidine, and carbamazepine and if so, the details thereof;

(b) whether the Government is also aware that such drugs are being used as the first line of treatment and therefor such revised prices of bulk quantities would exceed the concessional rates set for them under 'scheduled drugs'; and

(c) if so, the details thereof and the measures proposed to be taken up by the Government in this regard?

Answered on 29th July, 2022

A. (a) to (c): National Pharmaceutical Pricing Authority (NPPA) under Department of Pharmaceuticals (DoP) has been receiving applications for upward price revision under Para 19 of the Drugs (Prices Control) Order 2013 (DPCO, 2013) citing various reasons, including increase in cost of production, mainly on account of increase in prices of Active Pharmaceutical Ingredients (APIs), exchange rate variation, etc. making the sustainable production and marketing of the drugs unviable.

NPPA, after examining the applications for upward price revision for 3 drugs, viz., ibuprofen, ranitidine, and carbamazepine, noted that these scheduled formulations are low priced drugs and have been under repeated price control. It was further noted that these drugs are used as first line of treatment and are important to the public health program of the country. NPPA noted that while ensuring affordability, access cannot be jeopardized and the lifesaving essential drugs must remain available to the general public at all times. Accordingly, NPPA took the considered view that unviability of these formulations should not lead to a situation where these drugs become unavailable in the market and the public is forced to switch to costly alternatives.

In order to address the situation, NPPA has revised the ceiling price of 3 drugs, viz., ibuprofen, ranitidine and carbamazepine vide SO. 2654(E) dated 01.07.2021 by allowing one-time price hike of 50 percent on the extant ceiling price as an exceptional measure under provisions of Para 19 of the DPCO, 2013.

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

In Rajya Sabha

Foreign Investments in the Manufacturing Sector

Rajya Sabha Unstarred Question No. 1480.

Smt. Priyanka Chaturvedi:

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

(a) whether Government claimed that India is rapidly emerging as a preferred country for foreign investments in the manufacturing sector;

(b) whether Government is aware that Foreign Institution Investors (FIIs) have withdrawn ₹ 1.62 lakh crore in the five months till May 2022;

(c) whether Government has plans to adjust the monetary and fiscal implications of this withdrawal; and

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

Answered on 29th July, 2022

A. (a): The Government has put in place a liberal and transparent policy for attracting Foreign Direct Investment (FDI), wherein most sectors, except certain strategically important sectors, are open for 100% FDI under the automatic route. Subject to the provisions of the FDI Policy, foreign investment in 'manufacturing' sector is under automatic route. Manufacturing activities may be either self-manufacturing by the investee entity or contract manufacturing in India through a legally tenable contract, whether on Principal to Principal or Principal to Agent basis. Further, a manufacturer is permitted to sell its products manufactured in India through wholesale and/or retail, including through e-commerce, without Government approval. Measures taken by the Government on FDI policy reforms have resulted in increased FDI inflows in the country. India has received its highest ever FDI inflow of INR 6,31,050 crores in Financial Year 2021-22. Further, FDI Equity inflow in Manufacturing sectors has increased to INR 1,58,332 crore in Financial Year 2021-22 from INR 89,766 crore (FY 2020-21), which is an increase of 76%.

(b) to (d:) India's monetary and fiscal Policies have been positioned to lowering inflation and managing the Current Account Deficit (CAD). Under this overarching framework, monetary and fiscal adjustments are done to address emerging economic issues.

Further, Reserve Bank of India has undertaken several measures to enhance forex inflows. These measures include:

i. exemption of incremental Foreign Currency Non-Resident (Bank) [FCNR(B)] and Non-Resident (External) Rupee (NRE) deposits from Cash Reserve Ratio (CRR) and Statutory Liquidity Ratio (SLR),

ii. permission to banks to raise fresh FCNR(B) and NRE deposits without reference to the extant regulations on interest rates until end-October 2022,

iii. inclusion of all new issuances of G-Secs of 7-year and 14-year tenors under the Fully Accessible Route (FAR) for FPIs,

iv. exemption of investments by FPIs in G-Secs and corporate debt made till October 31, 2022 from short term limit,

v. allowing FPI in commercial paper and non-convertible debentures with an original maturity of up to one year,

vi. temporary increase in the limit for external commercial borrowings (ECBs) under the automatic route from US$ 750 million or its equivalent per financial year to US$ 1.5 billion,

vii. increase in the all-in cost ceiling under the ECB framework by 100 basis points, subject to the borrower being of investment grade rating, and

viii. permission to AD Cat-I banks to utilise overseas foreign currency borrowings for lending in foreign currency to entities for a wider set of end-use purposes, besides exports.

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

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IPC adds 5 new Indian Pharmacopoeial Reference Standards & 7 new impurities to IP 2022

In a bid to ensure quality, safety and efficacy of pharmaceutical products, the Indian Pharmacopoeia Commission (IPC) has added five new Indian Pharmacopoeial Reference Standards (IPRS) and seven new impurity reference substances to Indian Pharmacopoeia (IP) 2022.

Ghaziabad-based IPC provides IPRS which acts as a fingerprint for the identification of an article under test and its purity as prescribed in IP. They are the official standards to be used in cases of arbitration.

The newly launched IPRS are disopyramide phosphate, dolutegravir sodium, estradiol hemihydrate, propofol, tenofovir alafenamide fumarate.

On the other hand, impurity standards are used to perform the system suitability, qualitative and quantitative parameters for compliance to Indian Pharmacopoeia monograph.

The commission stated that certain monographs require the use of a chemical reference substance or a biological reference preparation or a reference spectrum.

These are authentic specimens chosen and verified on the basis of their suitability for intended use as prescribed in the pharmacopoeia and are not necessarily suitable in other circumstances.

The list of newly launched impurity reference substances contains clobazam impurity A, levocetirizine amide, lumefantrine related compound A, quetiapine impurity I, tamoxifen citrate impurity standard, tinidazole impurity B, trimethoprim impurity B.

Buying Indian Pharmacopoeial Reference Standard is a social and legal responsibility of the industry, stated the commission. Last month the Union ministry of health and family health launched the 9th edition of IP (IP 2022) containing 652 pharma reference substances covering 70 per cent requirement of reference materials used for quality control in the country. The newly launched IPRS has taken the number of pharma reference substances in IP to 657.

The IP 2022 also contained 300 impurity standards which are crucial for managing pharmaceutical quality. With the launch of 7 new impurities, the number of impurities in IP has increased to 307. The vision of IPC is to promote the highest standards of drugs for use in humans and animals within practical limits of the technologies available for manufacture and analysis.

IPC is created to set standards of drugs in the country. Its basic function is to regularly update the standards of drugs commonly required for treatment of diseases prevailing in this region. The mandate of the commission is to perform, inter-alia, functions such as revision and publication of the Indian Pharmacopoeia and National Formulary of India on a regular basis besides providing IP reference substances and training to the stakeholders on pharmacopoeial issues.

Source: Laxmi Yadav, Pharmabiz, 17.08.2022

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Govt launches first India-made cervical cancer vaccine Ceravac

New Delhi: In a major scientific breakthrough, India has developed its own vaccine for cervical cancer, which is becoming a major cause of concern among women. While announcing the scientific development, Union Minister of State of Science & Technology Jitendra Singh said that the country's first indigenously-developed Ceravac vaccine to treat cervical cancer would be available in a few months.

As per vaccine manufacturer Serum Institute of India, Ceravac vaccine will be priced between Rs 200-400 per dose and available in a few months. Cervical cancer is caused by the human-papillomavirus (HPV). It is expected that the vaccine will be launched by the year's end.

Speaking at the launch of the vaccine, Singh said that Covid-19 has raised awareness about preventive healthcare leading to the development of vaccines like the one against cervical cancer. "The schemes like Ayushman Bharat have made us think about preventive healthcare and we can now afford it. The Department of Biotechnology has taken a lead in the matter and is in collaborative mode. Scientific efforts at times do not get the scale of recognition they deserve. So this event is to celebrate that scientific completion," the union minister said.

Meanwhile, CEO of the Serum Institute of India (SII) Adar Poonawalla, who was also present at the event, told reporters that the cervical cancer vaccine will be affordable

and would be available in the range of Rs 200-400. However, he maintained that the final price is yet to be decided". Two HPV vaccines are available in the private market presently, both made by foreign companies -- Gardasil by Merck and Cervarix by GlaxoSmithkline. HPV vaccines sell for Rs 2,000-3,500 per dose now, and Serum India's entry is expected to bring down prices.

Announcing the scientific completion of the vaccine that took more than a decade to develop, the minister said that around 2,000 volunteers had participated in the country for clinical trials. Pune-based Serum India has developed Ceravac in collaboration with the government's biotechnology department. Work started in September 2011 and the vaccine was approved by India's drug regulator in July this year. On the occasion, DBT secretary Rajesh Gokhale said, "Partnerships between private-public are becoming very important in such research, this co-creation is what is going to make all the difference in the world."

Cervical cancer is the second most frequent cancer among women in India. About 5 per cent of women in the general population are estimated to have cervical HPV-16/18 infection, and 83.2 per cent of invasive cervical cancers are attributed to HPVs 16 or 18. India has 483.5 million women aged 15 and older who are at risk of cervical cancer. Current estimates say that every year 123,907 women are diagnosed with cervical cancer and 77,348 die from the disease. Cervical is the second-most frequent cancer among women in India.

Source: Millennium Post, 02.09.2022

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Domestic pharma firms should focus on quality: Mansukh Mandaviya

New Delhi: Domestic pharmaceutical companies should focus on quality and development of innovative products which offer more value in global markets, Union minister Mansukh Mandaviya said on Monday. Speaking at an event here to commemorate Silver Jubilee celebrations of National Pharmaceutical Pricing Authority (NPPA), the Union chemicals and fertilisers minister said that if the industry consolidates its research initiatives, it can further offer solutions in the global market. "We are there in terms of volumes with generic products. We are already exporting medications in containers. I wish the industry in the coming days will come with innovative products where one small envelope of formulations is equal to a container

in terms of value," Mandaviya, who is also Union health minister, said.

The minister assured the pharma industry of continuous support from the government. Elaborating on the role of NPPA, Mandaviya said the organisation is critical as it deals with the pricing of the pharmaceutical products in the country. The NPPA is mandated to fix/revise the prices of controlled bulk drugs and formulations and enforce prices and availability of the medicines in the country. It also monitors the prices of decontrolled drugs in order to keep them at reasonable levels. The regulator implements and enforces the provisions of the Drugs (Prices Control) Order.

It is also entrusted with the task of recovering amounts overcharged by manufacturers for the controlled drugs. Mandaviya launched the integrated Pharmaceutical Database Management System (PDMS) 2.0 version, which helps in facilitating online submission of mandatory cost data by pharmaceutical companies. "I have been told that 800-900 companies have started to feed data through this initiative. There are 3,000 companies and they should also start sharing the data, it is very important," he added.

PDMS 2.0 is an integrated cloud platform to provide a single window for submissions of various forms as mandated under Drug Price Control Order (DPCO), 2013. It would also enable paperless functioning of NPPA and facilitate the stakeholders to connect with the national pharma pricing regulator from across the country. The minister also launched the updated Pharma Sahi Dham App which now comes with updated features like speech recognition; availability in Hindi and English; share button and bookmarking medicines. Mandaviya said the pharma industry is just not a commercial activity but is responsible for taking care of the health of the citizens.

Source: Hans News Service, 31.08.2022

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Patented/Patent Pending Pharmaceutical technologies are available for licensing/assigning with technology transfer assistance and hand holding from JSS College of Pharmacy, Ooty, through the Co-ordination by M/s. Gopakumar Nair Associates. Confidentiality and exclusivity will be assured.

Patented Technologies

S. No	Patent/ Application No.	Title of Patent
1.	Pat No: 284768	Novel Glitazones Incorporated With Tyrosine: Synthesis And Antidiabetic Activity
2.	Pat No: 332264	Method of Processing Nanoemulsion gel comprising terbinafine or its salt form for Mycotic Infections
3.	Pat No. 352435	Isolation of Sulpha Quinovosyl Diacyl Glycerol (Sl) (A Human Topopoison I), Using Flash Chromatography
4.	Pat No: 353946	Naturally Derived water soluble fraction of Fenugreek mucilage and its uses thereof in the Preparation nanoparticles
5.	Pat No. 365340	5-heptadeca-5, 8, 11-trienyl 1, 3,4-oxadiazole-2thiol (gla-1) a human topo-poison and synthesis thereof
6.	Pat No. 382881	Novel Glitazones as Ppar-α And Ppar-γ Agonists And α-Glucosidase Inhibitors
7.	Pat. No: 388590	1. Surface Modified Benzyl quinolone carboxylic acid- Stearylamine Conjugates for management of Alzheimer's disease
8.	Pat. No : 393780	2-oxo-2H-chromen-4-yl 1H-benzo[d]imidazole- 2(3H)-ylidene sulfamate and its functionalized carbon nanotubes thereof for treatment of breast cancer
9.	Pat No: 245830	Thiazolidine-2, 4diones and process thereof
10.	Pat No: 286441	Process for isolation of bergenin from *Caesalpinia digyna Rottler*

Pending Patent Technologies

11.	201741025232	Encapsulated drug admixture composition for brain targeting via intranasal route.
12.	201941031322	Solid Lipid Nanocarriers of Surface Modified Niclosamide for targeting of Sialic Acid Receptors
13.	201941044342	A sustained release matrix tablets for treating herpes simplex and a process for formulating the same
14.	202041008119	Mono Esterification Process for the synthesis of carboxymethyl Ch9itosan hybrid with WZB117
15.	202041027368	Tissue engineered acellular scaffold for the treatment of diabetic wounds
16.	202041032882	Nanocarrier based Improved Blood Brain Barrier Penetrationand Combinatorial Delivery of Anti-Retro Viral Drugs
17.	202041052620	Bidirectional release of customizable fused multifractional oral release system
18.	202041053673	Kabasura Kudineer Effervescent Tablets
19.	202041055661	Donepezil Loaded Lipid Coated Nanoceria for Effective Management of Alzheimer Disease
20.	202141003113	INDOLE TRIAZOLE CONJUGATES AS ANTIBACTERIAL AGENTS
21.	202141024278	A composition of Papain enzyme for nutraceutical/ therapeutic purpose & a process for formulating the same
22.	202141029028	Process for bioassay guided fractionation of M Olefera L leaves to isolate Niazirin

23.	202141032777	1,3,4-Thiadiazolo (3,2-A) Pyrimidine-6-Carbonitrile compounds as PARP1 Inhibitors
24.	202141042924	2-(1-substituted-1H-benzo[d]imidazol-2-yl)-N acetamide compounds having dual inhibitory activity
25.	202141033940	A process for fabrication of transdermal microneedle patch for controlled release of insulin
26.	202141039298	Methodology for the synthesis and neuroprotective activity of two glitazones to treat neurodegeneration
27.	202141054086	Surface modified methotrexate loaded solid lipid nanoparticles to overcome abcb1 polymorphism
28.	202141060827	Method for quantification of degradation products formed during forced degradation studies for raltegravir
29.	202141040144	Ibrutinib loaded onto multiwalled carbon nanotubes and conjugated with T30 oligonucleotide
30.	202241003547	3-(5-benzyl-1, 3, 4-oxadiazol-2-yl)-2-substituted phenyl thiazolidin-4-one, as sirt-3 activators, and process for preparation thereof
31.	202241013079	Human Beta Defensin-2 Nanoparticles Impregnated Acellular Scaffold for Diabetic Wound Healing
32.	202241013361	(2-((E)-7-hydroxy-4-methyl-2H-chromen-2-ylidene)-N-((E)-2-nitro benzylidene) hydrazine-1-carbothioamide), BRCA-1 mimetic useful for breast cancer treatment.
33.	202241014943	Biodegradable phytoabosrbent article for sanitary and a method thereof
34.	202241018870	Synthesis and Ppargamma Competitive Binding Analysis of Four Novel Glitazones Incorporated with Imidazole and Phenyl Glycine
35.	202241026428	Benzothiazole and Benzotriazole Hybrids as Antibacterial Agents
36.	202241022997	Dual antibody conjugated lipidic nanoparticles of DAPT to target triple negative breast cancer cells
37.	202241023744	Lyophilized surface modified formoterol stearylamine solid lipid nanoparticles and compositions thereof
38.	202241017503	Pioglitazone nanoparticles functionalized with RGD and P3 peptides and compositions thereof for adipocytespecific drug delivery
39.	202241024942	A Composition for Nasal Inhalation
40.	202241039540	Fabrication and Design of Natural Insole Fiber Powder Containing Banana Pseudo Stem Fiber and Coconut Pith
41.	202241040738	Film-forming Transdermal spray containing Terbinafine Hydrochloride and its composition
42.	202241042228	Levodopa stearic acid hydrazide conjugate for the management of Parkinson's disease
43.	202241047171	Engineered Affibody Conjugated Oxaliplatin nanoparticles for the management of Colorectal Cancer
44.	202241047806	Multipurpose Herbal Skin Care Lotion Formulation

Please respond to : **Dr. Gopakumar G. Nair,** Email: gopanair@gnaipr.net
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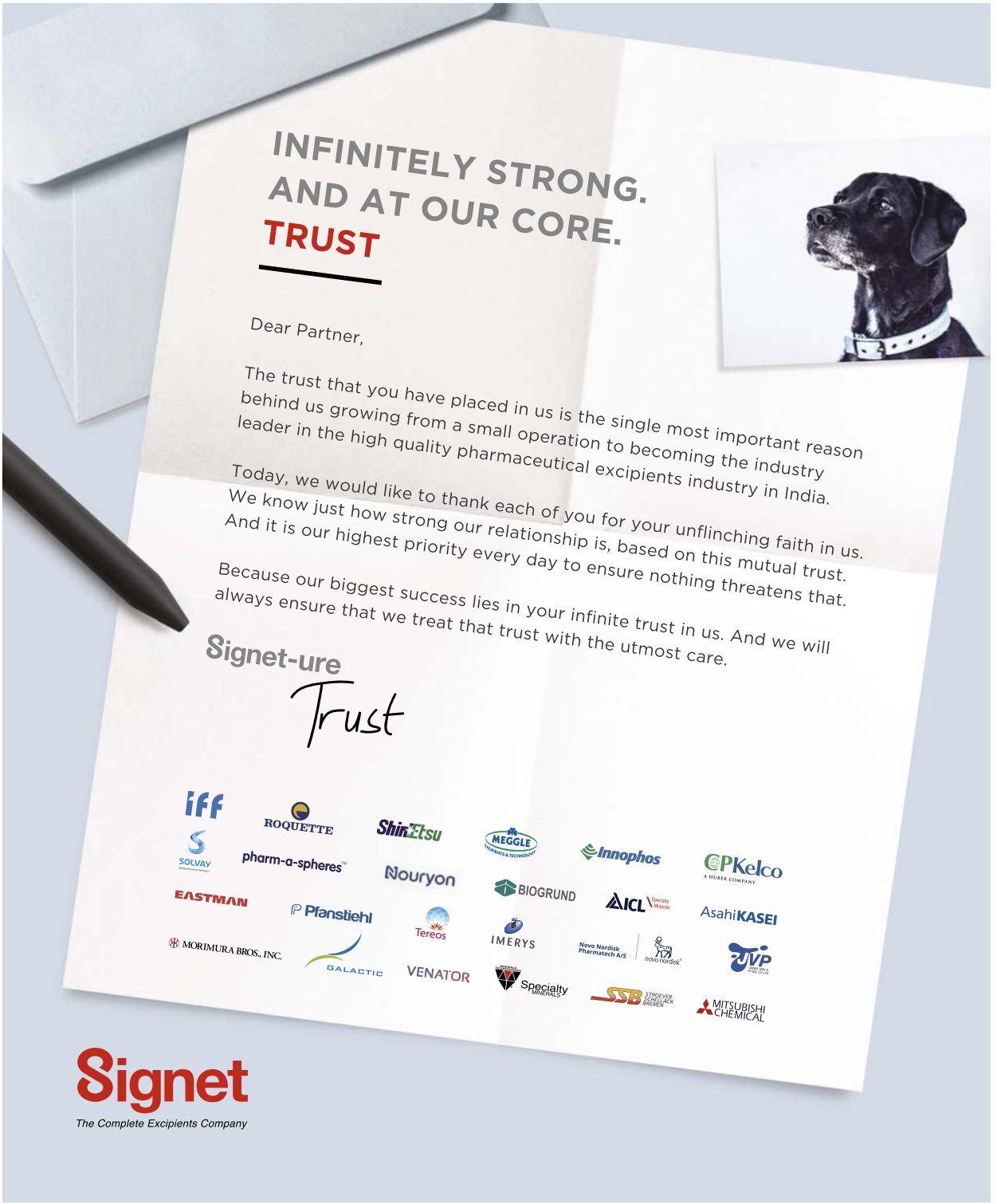
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