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IDMA BULLETIN

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INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

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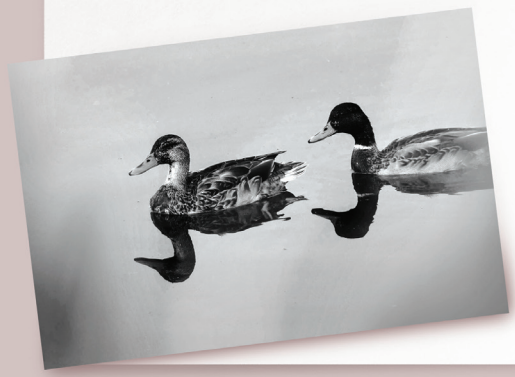

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IDMA BULLETIN

Vol. No. 53 **Issue No. 20** **22 to 30 May 2022**

IDMA ACTIVITIES:

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FDA MATTERS:

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Indian Drug Manufacturers' Association
102, A Wing, Poonam Chamber, Dr.A.B.Road, Worli, Mumbai - 400018. Maharashtra. India.
Tel No. 022 24974308 / 24944624, Mob No. 9619802299, E-mail : admin@idmaindia.com

Invitation to participate in ChemTECH + Biopharma World Expo from June 8-11, 2022 at Jio World Centre, Bandra BKC, Mumbai

Dear Members,

We are pleased to inform you that IDMA is the supporting partner for the **30th onground Edition of ChemTECH + BioPharma World Expo which is taking place from June 8-11, 2022 at Jio World Centre, Bandra BKC, Mumbai.**

ChemTECH + BioPharma World Expo 2022 is witnessing Exhibit display by over 275 Exhibitors along with 15,000+ Business Visitors and 5 concurrent conferences on EPC, Specialty Chemicals, Refining & Petrochemicals, Industry Automation & Process Control, Surface Engineering & Corrosion Control.

This Exhibition is providing an excellent opportunity to all the companies to upgrade their plant post Covid-19 pandemic as the event is providing the biggest congregation of technological and product display along with the industry leaders across the entire value chain of process industry.

Please find the concurrent conferences and industry leaders who are part of the event

EPC 8th & 9th June , 2022	Chairman CAB : **Mr. B Narayan,** Group President Projects & Procurement, Reliance Industries Ltd Co- Chairman CAB : **Mr. Subramanian Sarma,** Whole time Director, Sr. EVP (Energy), Larsen & Toubro	**Learnings from the Pandemic: Adopting to the New Normal**
Specialty Chemicals 8th June, 2022	Convener: **Dr Raman Ramachandran,** MDP Chairperson & Professor of Practice, K J Somaiya Institute of Management	**Green Growth of Specialty Chemicals Industry** **Roadmap to Net Zero**
Refining & Petrochemicals 9th June, 2022	Chairman CAB : **Dr SSV Ramakumar,** Director (R&D) & Member of Board, Indian Oil	**Future Refining Towards Net Zero**
Industry Automation & Control 10th June, 2022	Chairman CAB : **Mr U K Bhattacharya,** Director Projects, NTPC Ltd - Chairman, IAC + PVF World Expo 2022	**Industry 5.0: Envisioning New Paradigms in Automation**
Surface Engineering & Corrosion Control 10th June, 2022	Chairman CAB : **Mr R K Srivastava,** Director Exploration, ONGC Ltd Convener : **Mr K L Batra,** Advisor Chugoku Paints	**Corrosion Prevention Technology & Innovation**

Kindly note that there are no visitor registration Fees. Please find the **Link for FREE Business Visitor Registration- https://chemtech-online.com/pre-register-as-visitor/**

Looking forward to your usual excellent support and requesting you all to kindly attend the Exhibition and take benefits from the same.

Thanks & regards,

Daara B Patel, *Secretary – General*

IDMA Telangana State Board welcomes Dr. A Ramkishan, Dy. Drugs Controller, Hyderabad

IDMA Telangana State Board under the Chairmanship of Mr Shaik Janimiya met and welcomed Dr. A Ramkishan, Dy. Drugs Controller on 25th May, 2022 at CDSCO Zonal Office, Hyderabad.

The team had fruitful deliberations with Dr. Ramkishan.

Dr. Ramkishan has formed a New Committee as per the communication reproduced below.

CDSCO

सत्यमेव जयते

टेलीफोन/Telephone: 040-2381
फैक्स/Fax: 040-2381
ईमेल/email: hyderabad@cdsco.

भारत सरकार / Government of India
केंद्रीय औषध मानक नियंत्रण संगठन / Central Drugs Standard Control Organization
आंचलिक कार्यालय, सी. डी. एस. सी. ओ. भवन, हैदराबाद / Zonal Office, CDSCO BHAVAN, Hyderabad,
स्वास्थ्य एवं परिवार कल्याण मंत्रालय / Ministry of Health & Family Welfare,
स्वास्थ्य सेवा महानिदेशालय / Directorate General of Health Services,
एस.आर. नगर, हैदराबाद - ५ ० ० ० ३ ८ / S.R. Nagar, Hyderabad – 500038
An ISO 9001:2015 Certified

संदर्भ सं. /Ref: 26(DDCI)/HZ/2022-2023/596-597 **दिनांक/Date: 23.05.2022**

To
1) Director General/ Licensing Authority
Drugs Control Bhavan,
Drugs Control Administration,
Vengalrao Nagar, Hyderabad - 500 038

2) Director General/Licensing Authority,
Drugs and Copyrights,
Drugs Control Administration,
Chuttugunta, Guntur -522004, AP

Sub: Constitution of Plan Layout approval Committee for various Manufacturing units- under jurisdiction of CDSCO Zonal Office, Hyderabad– Regarding

Sir,

This is to bring to your kind notice that, the undersigned took the charge on 12.05.2022 at Zonal Office CDSCO Hyderabad in order to cater the needs of Stakeholders for the production of Quality Medicines including all CLAA (Central Licensing Approval Authority) products and Medical Devices, IVDs (in vitro diagnostic devices).

It has been decided to work this zonal office officials with your esteemed Drugs Control Administration to maintain close coordination, harmony, discipline, transparency and Accountability to the Public in respect of effective implementation of various provisions of Drugs and Cosmetics Act 1940. This office has committed to work more closely with your officials as a team for arrangement of joint Inspection of various manufacturing facilities for grant/renewal of licenses to meet Good Regulatory Practices and Good Reliance Practices as per WHO-TRS (WHO-Technical Report Series) 54th report TRS No. 1033 published in 2021.

Accordingly this office has taken a significant initiative first time in this zonal office in order to facilitate industry and devices manufacturers including IVD's by constituting a

committee comprising of your officials along with this office (Telangana and Andhra Pradesh) DCA Officials to meet tenets of GMP principles as per Schedule M 2001, draft Schedule M 2018, MDR 2017, Cosmetic Rules 2020, Blood Centres GSR 166 (E) dated 11.03.2020, GSR 1337 (E) dated 27.10.2017 perpetual licensing system, CDSCO guidance documents, ICMR documents, Biosimilars guidelines 2016 and WHO TRS guidelines for Human Vaccines including veterinary vaccines to meet quality assured drugs.

We will keep the credibility of Andhra Pradesh and Telangana states in order to boost the exports of various pharmaceutical preparations and medical devices/IVD's in domestic as well as international market to ensure quality assured & effective products for the growth of pharmaceutical sector as a part of Make in India initiative.

In view of above, you are kindly requested to nominate two officers from your esteemed organisation so that this office can coordinate every fortnight for conducting plan committee meeting at Conference Hall, Zonal Office, Hyderabad without delaying respective applications to act of priority for fast track disposal.

This office has nominated the following officers to convene the meeting of plan approval committee under the chairmanship of DDC (I), CDSCO Zonal Office Hyderabad as follows -

1. Smt B.Sarala Devi, ADC (I)
2. Shri K. Shiva Dev, DI
3. Shri. Veeraiah Banothu, ADI

Yours Sincerely

(Dr. A Ramkishan)
Deputy Drugs Controller (I)

Copy information to:

597 1. Drugs Controller General (India) (CDSCO-HQ), ITO, Kotla Road, New Delhi 110002.
2. Concerned Officers
3. Guard File

Page 2 of 2

IDMA Congratulates Ms. Radha Veeramani, Joint Managing Director, Fourrts (India) Laboratories Pvt. Ltd. on being Honoured with The Woman of Excellence Award

Ms. Radha Veeramani, Joint Managing Director of Fourrts (India) Laboratories Pvt. Ltd., which is one of the fastest growing pharmaceutical companies in India.

Fourrts has an impressive standing in the Pharma Industry for over 40 yrs & backed by a dedicated and well trained professional team of over 3000 professionals.

Ms. Radha Veeramani has played a pivotal role along with her husband Mr.Veeramani in nurturing this organisation from a simple business unit in 1977 to the Impressive brand that's marching ahead to scale global heights.

In 1990 when Fourrts faced turbulent times and company was in bad shape , most partners had deserted leaving Fourrts to a downward spiral but as they say 'When going gets tough, the tough get going' Ms. Radha Veeramani transformed herself overnight from being a homemaker to a business leader joining her husband Mr. Veeramani to bring the business back to shape and give it the much needed process foundation.

With her background of Post Graduation in Commerce, she took total charge of the company Finance as Director of Finance when it was in bad shape giving Fourrts its turning point.

In the following years Fourrts surpassed tough terrains to scale new heights, from a 1Cr turnover company in 1991, today Fourrts stands tall as 600+Cr Company and fast marching ahead to next milestone of crossing 1000Cr in next few years.

With her mantra of - "Work is not pressure , Work is pleasure" she has been instrumental in crafting the organisational culture into a divine space where everyone does their best and brings the family aura to their teams making Fourrts one big family. Most people who started their journey in 1991 with her are still serving the organisation.

She believes Trust, Honesty, Accountability is her strength and it serves as Pillars of Fourrts growth as well. She has an unflinching faith in Divine plans and it has worked magic in not just her life but in lives of everyone around her, especially her daughters & employees who believe good things happened to them when they are with Fourrts, such is her presence in the business world and home.

With her eye for excellence she has imbibed the Fourrts team with same values making the products stand out in market to be most trusted for its quality and health care value.

She is married to Rtn.Veeramani, Managing Director Fourrts who is also the Prestigious Arch Klump Society.

She is a caring mother to her two daughters, Dr. Gayatri Jayaraman, an American board Certified Nephrologist, trained in Harvard Medical School, who heads marketing and international business in the company and Dr. Nitia Mohan MBBS, FCLR who is a physician by training handling Medical & Administration at Fourrts.

Ms. Radha Veeramani has balanced home, family and business with grace, weaving an inspiring journey of excellence in all spheres.

We Rotary International District 3232 take great pleasure in conferring The Woman of Excellence Award on Ms. Radha Veeramani.

We wish her the very best for her future endeavours.

USFDA Team Visited Gujarat Food & Drugs Control Administration for 3 Days

In 2010, Mr. Brus Ross had visited Gujarat FDCA first time."FDCA Gujarat-USFDA Regulatory Forum" was constituted with a view to knowledge sharing, training, Capacity building and information sharing between FDCA Gujarat & USFDA. A first meeting was held on 12th March, 2019, at office of the Commissioner, FDCA, Gandhinagar with Dr. Letitia Robinson, Country Director & other officials from USFDA along with Dr.H.G.Koshia, Commissioner, FDCA, Gujarat & other officers from Gujarat FDCA.

As a part of that it was decided to organise quarterly subsequently meeting between both the regulatory bodies for the exchange / discussion of technical advancement and other regulatory related information.

This regulatory forum between the U.S. Food and Drug Administration (USFDA) and the Gujarat Food and Drug Control Administration (Gujarat FDCA) is designed as a collaborative effort to identify initiatives to further strategic collaboration in regulatory systems. The forum will also provide an opportunity to share information about the existing practices of the organizations and to explore synergies to advance the public health needs of the regulatory bodies.

As a part of that, USFDA-Gujarat FDCA Regulatory Forum was held on 17th, 18th & 19th May 2022. In this meeting first time 12 officials from USFDA, Senior Officers from Gujarat FDCA and 4 nominated officers from the CDSCO had participated.

In this meeting, USFDA had provided an overview of recent initiatives including OGPS reorganization, and GMP inspectional trends in India. USFDA officials and Gujarat FDCA officials had discussed on Drug Inspection Lifecycle: Site Selection, Planning, Execution, Reporting, Evaluation and Regulatory Action, Case study and Discuss elements of Observed Inspection SOP for future participation as an observer in the USFDA led inspection followed by panel discussion.

In the last meeting, USFDA officers met the Gujarat Cabinet Health Minister Shri. Rushikeshbhai Patel and Additional Chief Secretary(Health)Shri. Manoj Aggarwal. During their discussion minister suggested them to visit the Gujarat as well India's best Pharmacy College L. M. Pharmacy College, Ahmedabad and Government Ayurvedic Hospital, Kolavada. On 19th May 2022 USFDA officials visited both the places.

Indian Boiler (Amendment) Regulations, 2022 published

Industrial Policy Notification G.S.R.375(E), dated 20th May 2022

WHEREAS certain draft regulations further to amend the Indian Boiler Regulations, 1950 were published as required under sub-section (1) of section 31 of the Boilers Act, 1923 (5 of 1923) vide notification of the Government of India in the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade), (Central Boilers Board) number G.S.R.156(E), dated the 24th February, 2022 in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of the period of forty-five days from the date on which the copies of the said Gazette notification were made available to the public;

AND WHEREAS, the copies of the said notification were made available to the public on the 24th February, 2022;

AND WHEREAS, no objections and suggestions were received from the public on the said draft regulations;

NOW, THEREFORE, in exercise of the powers conferred by section 28 of the Boilers Act, 1923 (5 of 1923), the Central Boilers Board hereby makes the following regulations further to amend the Indian Boiler Regulations, 1950, namely:-

1. (1) These regulations may be called the **Indian Boiler (Amendment) Regulations, 2022.**

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

2. In the Indian Boiler Regulations, 1950, in regulation 4J, in sub-regulation (3), for clause (i), the following clause shall be substituted, namely:-

"(i) an examination shall be conducted by the Central Boilers Board Examination Standing Committee or an agency or Regional Examination Standing Committees authorised by it, as per the following examination methods, namely:-

(a) written Examination consisting of such number of papers as the Central Boilers Board Examination Standing Committee may decide, on design, manufacture, operation and maintenance of the boiler, Non Destructive Testing Techniques, inspection and certification of boilers during manufacture and use as per Indian Boiler Regulations(70% weightage);

(b) candidate shall secure at least 45% marks in individual written examination papers and at least 60% marks in aggregate to qualify for viva-voce;

(c) viva-voce on the above (30% weightage);

(d) candidate shall secure at least 60% marks in aggregate (written exam with 70% weightage and viva-voce with 30% weightage) in order to pass the examination;

(e) the Central Boilers Board shall issue a passing grade certificate to the candidate after passing the examination.".

F.No.P-30026/4/2020-Boiler

T S G Narayannen, Secretary, Ministry of Commerce and Industry, Department for Promotion of Industry and Internal Trade, Central Boilers Board, New Delhi.

Note : The principal regulations were published in the Gazette of India, vide, number S.R.O.600, dated the 15th day of September, 1950 and lastly amended vide G.S.R.551(E), dated the 11th September, 2020.

Customs Tariff (Determination of Origin of Goods under the Comprehensive Economic Partnership Agreement between the Republic of India and Japan) Rules, 2011 amended (1st Amendment of 2022)

Notification No.44/2022-Customs (N.T.), dated 20th May 2022

In exercise of the powers conferred by sub-section (1) of section 5 of the Customs Tariff Act, 1975 (51 of 1975), the Central Government hereby makes the following rules to further amend the Customs Tariff (Determination of Origin of Goods under the Comprehensive Economic Partnership Agreement between the Republic of India and Japan) Rules, 2011, namely:-

1. Short title and commencement

(1) These rules may be called the **Customs Tariff (Determination of Origin of Goods under the Comprehensive Economic Partnership Agreement between the Republic of India and Japan) Amendment Rules, 2022.**

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

2. In the Customs Tariff (Determination of Origin of Goods under the Comprehensive Economic Partnership Agreement between the Republic of India and Japan) Rules, 2011, in Annexure-1, in Part 2, in Section I, in Chapter 3, for the figures and words "03.01-03.07 Manufacture in which all the materials used are wholly obtained.", the following shall be substituted, namely:-

"0301.10-0304.92

Manufacture in which all the materials used are wholly obtained.

0304.99

A change to sub-heading 0304.99 from any other chapter.

0305.10-0307.99

Manufacture in which all the materials used are wholly obtained."

F.No.20000/3/2012-OSD(ICD)

Komila Punia, Deputy Secretary, Ministry of Finance, Department of Revenue, New Delhi.

Note: *The principal rules were published, vide notification No.55/2011-Customs(N.T.), dated the 1st August, 2011, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (i) vide number G.S.R.594(E), dated the 1st August, 2011 and was amended vide notification No.14/2018–Customs (N.T.), dated the 19th February, 2018, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide number G.S.R.177(E), dated the 19th February, 2018.*

● ● ●

Amendment in import policy condition under Chapter 29 and 30 of ITC (HS) 2022, Schedule - I (Import Policy)

DGFT Notification No.09/2015-2020, dated 23rd May 2022

1. In exercise of powers conferred by Section 3 and Section 5 of FT (D&R) Act, 1992, read with paragraph 1.02 and 2.01 of the Foreign. Trade Policy, 2015-2020, as amended from time to time, the Central Government hereby makes amendment in the item description in accordance with the Customs Tariff of India 2022 and policy condition of the following HS codes of Chapter 29 and 30 of ITC (HS), 2022, Schedule - I (Import Policy):

HS Code	Item Description	Import Policy	Existing Policy Condition	Revised Policy Condition
2937	Hormones, prostaglandins, thromboxanes and leukotrienes, natural or reproduced by synthesis; derivatives and structural analogues thereof, including chain modified polypeptides, used primarily as hormones.	-	-	-
29371900	Polypeptide hormones, protein hormones and glycoprotein hormones, their derivatives and structural analogues:-- Other	Free	Import of Oxytocin Import is Prohibited	Import of Oxytocin is Prohibited. However, import of Oxytocin reference standards is allowed exclusively for test and analysis subject to submission of Test License issued by the DGCI/ CDCSO.
29372900	Steroidal hormones, their derivatives and structural analogues : -- Other	Free	Import of Oxytocin is Prohibited.	Import of Oxytocin is Prohibited. However, import of Oxytocin reference standards is allowed exclusively for test and analysis subject to submission of Test License issued by the DGCI/ CDCSO.
29379019	--- Catecholamine hormones, their derivatives and structural analogues: -- -- Other	Free	Import of Oxytocin is Prohibited	Import of Oxytocin is Prohibited. However, import of Oxytocin reference standards is allowed exclusively for test and analysis subject to submission of Test License issued by the DGCI/ CDCSO.
29379090	Other	Free	Import of Oxytocin is Prohibited	Import of Oxytocin is Prohibited. However, import of Oxytocin reference standards is allowed exclusively for test and analysis subject to submission of Test License issued by the DGCI /CDCSO.

All HS codes at 8 digit under 3004	Medicaments (excluding goods of heading 30.02, 30.05 or 30.06) consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (including those in the form of transdermal administration systems) or in forms or packings for retail sale	Free	Import of Oxytocin is Prohibited	Import of Oxytocin is Prohibited. However, import of Oxytocin reference standards is allowed exclusively for test and analysis subject to submission of Test License issued by the DGCI / CDCSO.

2. Effect of this Notification:

Import of Oxytocin shall remain "Prohibited". However, import of Oxytocin reference standards falling under HS Codes 29371900, 29372900, 29379019, 29379090 and all HS Codes at 8 digit level under 3004 is permitted exclusively for the purpose of test and analysis subject to submission of Test License issued by the DGCI/ CDCSO.

This issues with the approval of Minister of Commerce & Industry.

F. No.01/89/180/Misc-3/AM-5/PC-2[A]/E-1477

Santosh Kumar Sarangi, Director General of Foreign Trade & Ex- officio Addl. Secretary, GoI, Ministry of Commerce & Industry, Department of Commerce, Directorate General of Foreign Trade, New Delhi.

● ● ●

GOVERNMENT NOTIFICATIONS

Micro, Small and Medium Enterprises Fund Rules, 2016 amended (2nd Amendment of 2022)

Micro, Small and Medium Enterprises Notification G.S.R.389(E), dated 24th May 2022

In exercise of the powers conferred by clause (c) of sub-section (2) of section 29 of the Micro, Small and Medium Enterprises Development Act, 2006 (27 of 2006), the Central Government hereby makes the following rules further to amend the Micro, Small and Medium Enterprises Fund Rules, 2016, namely:-

1. (1) These rules may be called the **Micro, Small and Medium Enterprises Fund (Amendment) Rules, 2022.**

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

2. In the Micro, Small and Medium Enterprises Fund Rules, 2016, after clause (a) of sub-rule (1) of rule 5, the following clause shall be inserted, namely:-

"(a i) Minister of State in the Ministry of the Micro, Small and Medium Enterprises-Vice Chairperson ex officio".

F.No.2/3(1)/2021-P&G/Policy/E

Shailesh Kumar Singh, Addl. Secy. and Development Commissioner (MSME), Ministry of Micro, Small and Medium Enterprises, New Delhi.

Note : The principal notification was published in the Gazette of India, Extraordinary, Part-II, Section 3, Sub-section (i) vide number G.S.R.1032 (E), dated the 28th October, 2016 and subsequently amended vide number G.S.R.29(E), dated the 19th January, 2022.

● ● ●

Draft rules to further amend the Drugs Rules, 1945 published (Notification G.S.R.382(E))

Drugs & Cosmetics Notification G.S.R.382(E), dated 23rd May 2022

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

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

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 437, C Wing, Nirman Bhavan, New Delhi -110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

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

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

2. In the Drugs Rules 1945, in rule 75,-

"(i) after sub-rule (3), the following sub-rule shall be inserted, namely:-

"(3A) The application,-

(a) referred in sub-rule (3) of rule 75 of these rules, or

(b) for grant of permission to manufacture new drug for sale or distribution under rule 80 of the New Drugs and Clinical Trials Rules, 2019, or

(c) rule 122B of these rules, as the case may be made simultaneously."

(ii) for sub-rule (6), the following sub-rule shall be substituted, namely:-

"Where an application under these rules is for the manufacture of drug formulation falling under the purview of new drug under rule 80 of the New Drugs and Clinical Trials Rules, 2019 or rule 122B of the Drugs Rules, 1945, as the case may be, the licence to manufacture for sale or distribution of the drugs shall be granted after approval of the drug as new drug."

F.No.X.11014/2/2022-DR

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

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

● ● ●

Draft rules to further amend the Drugs Rules, 1945 published (Notification G.S.R.383(E))

Drugs & Cosmetics Notification G.S.R.383(E), dated 23rd May 2022

The following draft of certain rules further to amend the Drugs Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by Sub-section (1) of section 12 and Sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published in consultation with the Drugs

Technical Advisory Board for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of seven days from the date on which copies of the Gazette of India containing these draft rules are made available to public;

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

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

DRAFT RULES

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

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

2. In the Drugs Rules, 1945, in Schedule K, in serial number 39, in column under heading "Extent and Conditions of Exemptions", at the end, the following proviso shall be inserted, namely:-

"Provided that the condition(d) shall not be applicable for the drugs manufactured on or before 30.11.2022."

F.No.X.11014/10/2021-DR

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

***Note** : The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H(1) dated 21st the December, 1945 and last amended vide notification number G.S.R.....(E), dated the.....*

● ● ●

Draft rules to further amend the Drugs Rules, 1945 published (Notification G.S.R.393(E))

Drugs & Cosmetics Notification G.S.R.393(E), dated 25th May 2022

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

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

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

DRAFT RULES

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

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

2. In the Drugs Rules, 1945, in Schedule K after serial no. 39 and entries relating thereto, the following serial number and entries shall be inserted, namely:-

Class of Drugs	Extent and conditions of Exemptions
"40. The following drugs to be sold Over-The- Counter (OTC) by retail under the valid licence: (1) Povidone Iodine 5% w/v solution Composition: Povidone Iodine 5% w/v (Antiseptic and disinfectant agent) (2) Chlorohexidine Mouth wash Composition: Chlorohexidine Gluconate 0.2% (For the treatment of gingivitis) (3) Clotrimazole cream Composition: Clotrimazole 1% w/w cream (Antifungal) (4) Clotrimazole dusting powder Composition: Clotrimazole 1%w/w powder (Antifungal) (5) Dextromethorphan Hydrobromide Lozenges (5mg) (Cough) (6) Diclofenac ointment/cream/gel Each gram of gel contains 10 mg of diclofenac sodium (equivalent to 11.6 mg of diclofenac diethylammonium) (Analgesic) (7) Diphenhydramine Capsules 25 mg (Antihistaminic/ Antiallergic) (8) Paracetamol tabs 500 mg (Antipyretic) (9) Sodium Chloride Nasal spray – 0.9% (Nasal Decongestant) (10) Oxymetazoline nasal solution 0.05% (Nasal Decongestant) (11) Ketoconazole shampoo 2% w/v (Anti dandruff) (12) Lactulose solution 10gm/15ml (Laxative) (13) Benzoyl peroxide 2.5 w/w (Antibacterial for acne) (14) Calamine Lotion (Anti septic) (15) Xylometazoline hydrochloride 0.05% w/v (Nasal decongestant) (16) Bisacodyl tablets 5mg (Laxative)	The provisions of Chapter IV of the Act and Rules thereunder to provide that these drugs can be sold by retail Over-The-Counter without prescription of a Registered Medical Practitioner (RMP), subject to the following conditions, namely:- (a) The maximum duration of treatment/use should not exceed five days. (b) If the symptoms do not resolve the patient should consult Registered Medical Practitioner. (c) Pack size may not exceed the maximum doses recommended for five days. (d) Each pack of the drug may be accompanied with Patient Information Leaflet (PIL). (e) The indication claimed should be same as already approved by the Licensing Authority under Rule 21(b) for the categories mentioned."

F.No.X.11014/27/2021-DR

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

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

Micro, Small and Medium Enterprises Development (Furnishing of Information) (Amendment) Rules, 2022

Notification dated 11th May, 2022 (Published in the Gazette of India on 19th May, 2022)

In exercise of the powers conferred by clause (e) of sub-section (2) of section 29 of the Micro, Small and Medium Enterprises Development Act, 2006 (27 of 2006), the Central Government hereby makes the following amendments in the Micro, Small and Medium Enterprises Development (Furnishing of Information) Rules, 2016, namely:-

1. Short title and Commencement. – (1) These rules may be called the **Micro, Small and Medium Enterprises Development (Furnishing of Information) (Amendment) Rules, 2022**

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

2. In the Micro, Small and Medium Enterprises Development (Furnishing of Information) Rules, 2016, in the Form, under the "Basic Details",-

   (a) For the words "Udyog Aadhaar Number" the words "Udyam Registration Number" shall be substituted;

   (b) the words "Get Udyog Aadhaar" shall be omitted.

F.No.9(8)/2016-SME

Sd/-
Mercy Epao,
Jt. Secy.
Ministry of Micro, Small and Medium Enterprises
New Delhi

Note: *The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, Sub section (i) vide number G.S.R. 750(E), dated the 1st August, 2016.*

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In Rajya Sabha & In Lok Sabha

In Rajya Sabha

Medical devices notified as drugs under the Drugs (Price Control) Order, 2013

Rajya Sabha Unstarred Question No. 3697

Shri K.C. Ramamurthy:

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

(a) whether it is a fact that Medical devices/equipments have been notified as Drugs and are governed under the provisions of the Drugs (Price Control) Order, 2013;

(b) if so, the reasons and objective for which the medical devices/equipments have been included in the Legal Metrology (Packaged Commodities) (Amendment) Rules, 2017; and

(c) the steps taken by Government to address this anomaly?

Answered on 5th April, 2022

A. (a): As per the Gazette notification S.O. 648(E) dated 11.02.2020 issued by the Ministry of Health & Family Welfare, all medical devices have been notified as Drugs under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940) w.e.f. 01.04.2020. Pursuant thereto, National Pharmaceutical Pricing Authority (NPPA) vide notification dated 31.03.2020 has ordered that all medical devices shall be governed under the provisions of the Drugs (Prices Control) Order, 2013.

(b) & (c): Prior to declaration of all medical devices as drugs, the Department of Pharmaceuticals had requested the Department of Consumer Affairs in the Legal Metrology (Packaged Commodities) (Amendment) Rules, 2017 to have Maximum Retail Price (MRP) as part of fixed sticker on medical device packaging and to make the unit of packaging match the unit of prescription /use to avoid any ambiguity of unit costs to the end user/patient.

Subsequent to the notification of Medical Devices as Drugs and notification of Medical Devices Rules, 2017, wherein elaborate rules are available for labelling requirements of Medical Devices and based on the representation from the Industries, the Department of Pharmaceuticals has since prepared the proposal to Department of Consumer Affairs to exempt the licensed Medical Devices from the Legal Metrology (Packaged Commodities) Rules 2011 in February 2022.

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

Increase in the prices of raw material of medicines

Rajya Sabha Unstarred Question No. 3700

Ms. Indu Bala Goswami:

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

(a) whether Government is aware of the fact that the reckless increase in the prices of raw materials of medicines has made a huge impact on the pharmaceutical industry;

(b) if so, the measures being taken by Government to control it, the details thereof;

(c) whether due to the unexpected increase in the price of auxiliary components used in the manufacturing of medicine, the crisis of shortage of essential medicines in the country may also deepen; and

(d) if so, the details thereof?

Answered on 5th April, 2022

A. (a) & (b): As per provisions of Drugs (Prices Control) Order, 2013 (DPCO-2013), the National Pharmaceutical Pricing Authority (NPPA), an attached office of the Department of Pharmaceuticals fixes the ceiling price of all scheduled formulations appearing in National List of Essential Medicines (NLEM). All the manufacturers of these drugs are required to sell their product equal to or lower than the ceiling price. Further, NPPA monitors the prices of non-scheduled drugs so as to ensure that the increase in their Maximum Retail Price (MRP) is not

more than 10% of what was prevalent during the preceding twelve months.

Representations from manufacturers of drugs are received from time to time by National Pharmaceutical Pricing Authority (NPPA) for upward revision of prices of the drugs on account of increase in raw material, transportation and other input costs, etc. These representations are examined and considered by NPPA after scrutiny. NPPA has invoked extraordinary powers in public interest under para 19 of the Drugs (Prices Control) Order, 2013 (DPCO, 2013) for upward revision of the ceiling prices of 30 scheduled formulations of 15 drugs by giving one time increase of 50% from the extant ceiling price in December 2019 and July 2021 respectively. Details of the revision of ceiling prices of drugs by NPPA are available on its website at www.nppaindia.nic.in.

(c) & (d): The manufacturers of scheduled formulations are required to submit quarterly returns of production/ import of scheduled formulations and their bulk drugs/active pharmaceutical ingredients to NPPA. Whenever shortage is reported by the State Drug Controllers or when the matter comes to the notice of NPPA, remedial steps are taken for ensuring availability of drug by impressing upon manufacturers to rush the stocks to the places of shortage.

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

Unethical practices being adopted by Pharma companies

Rajya Sabha Unstarred Question No. 3708

Shri Brijlal

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

(a) whether Government is aware of the nexus such as adopting unethical modes of marketing and luring doctors to increase the sale of medicines by the Pharma companies;

(b) if so, the details thereof, along with the steps taken by Government to stop such unethical practices and nexus; and

(c) whether Government is also considering to make any law in this regard and if so, the time by which it is likely to be implemented?

Answered on 5th April, 2022

A. (a) & (b): The Department has formulated the Uniform Code of Pharmaceutical Marketing Practices (UCPMP), w.e.f 1.1.2015, which is a voluntary code to be adopted by the pharmaceutical companies. Under this, all the associations of pharmaceutical and medical devices companies shall constitute committees viz, Ethics Committee for Pharma Marketing Practices (ECPMP) and Apex Ethics Committee for Pharma Marketing Practices (AECPMP) to enquire complaints received against a pharmaceutical company and have to host the actions taken on such complaints in their websites, besides sending the quarterly reports in this regard to National Pharmaceutical Pricing Authority (NPPA) under the department.

NPPA prepared a proforma for furnishing quarterly return as per para 8 of the UCPMP; the same has been circulated on 24.07.2021 to associations for submission to NPPA within 30 days at the end of each quarter via email. Further, Department and NPPA on various instances have reviewed implementation of the voluntary code.

Further, the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 formed under Indian Medical Council Act, 1956 (102 of 1956), provides for conduct for doctors and professional association of doctors in their relationship with pharmaceutical and allied health sector industry. Under this, any complaint of professional misconduct of a medical practitioner or professional is to be addressed by the respective State Medical Councils. Ethics and Medical Registration Board is the appellate authority for medical practitioner or professional against decision of the State Medical Council.

(c): The Department is not considering to make any law in this regard.

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

In Lok Sabha

Use of Expired Medicines

Lok Sabha Unstarred Question No. 3835

Kunwar Danish Ali:

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

(a) whether the Government is aware that expired medicines are re-used by erasing original manufacturing details and re-stamping them by the pharmaceutical companies;

(b) if so, the details thereof and the threat posed to people's health due to use of expired medicines; and

(c) the measures taken by the Government to curb such practice?

Answered on 25th March, 2022

A. (a) to (c): The manufacturing, 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 drugs in the country is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs) appointed by the respective State Governments. Manufacturers are required to comply with the conditions of Licence granted under the said Act and Rules to manufacture any drugs for sale and distribution in the country.

One of the conditions for licensing is regarding withdrawal/recall/take back of drugs which is reproduced below:

"the licensee shall on being informed by the Licensing Authority or the Controlling Authority that any part of any batch of the drug has been found by the Licensing Authority or the Controlling Authority not to conform with the standards of strength, quality or purity specified in these rules and on being directed so to do, withdraw the remainder of the batch from sale, and, so far as may in the particular circumstances of the case be practicable, recall all issues already made from that batch."

The SLAs are empowered to take action on violations of any of the conditions of Licence including directing the concerned manufacturer to take back expired drugs.

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

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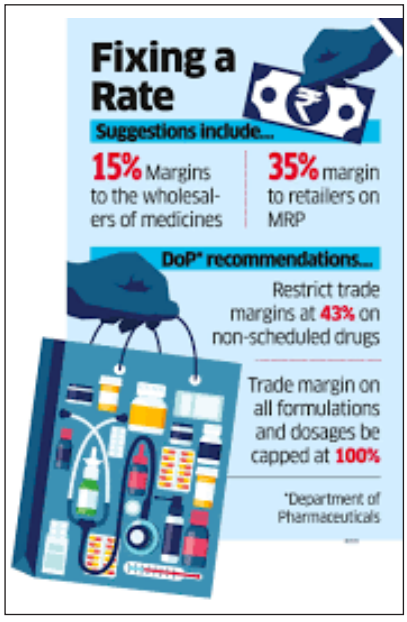
Government may 'rationalise' drug trade margins in a bid to reduce costs

One suggestion was to restrict trade margins at 43% on non-scheduled drugs, as was done in case of cancer drugs.

The government is geared up to apply the trade margin rationalisation (TMR) formula to drugs in order to bring down their prices. At the National Pharmaceutical Pricing Authority's (NPPA's) meeting with stakeholders on the issue last week, the stakeholders were asked to give their suggestions by the end of this week, people in the know told ET.

The meeting was attended by representatives from the Indian Drug Manufacturers Association (IDMA) and Indian Pharmaceutical Alliance (IPA), The Organisation of Pharmaceutical Producers of India (OPPI), and All India Drug Action Network (AIDAN), among others. The All India Organisation of Chemists and Druggists (AIOCD) has suggested a 10% trade margin for wholesale dealers on PTR (price to retailer) and 20% for retailers on MRP.



"The AIOCD has suggested that the government should come out with a clear-cut definition for generic medicines. For generic medicines we have suggested a trade margin of 15% to wholesalers and 35% to retailers on MRP," Rajiv Singhal, general secretary of AIOCD, told ET.

The department of pharmaceuticals (DoP) had earlier proposed a few options to rationalise the trade margins on drugs to policy think-tank Niti Aayog. One suggestion was to restrict trade margins at 43% on non-scheduled drugs, as was done in case of cancer drugs.

The DoP had also suggested that trade margin on all formulations and dosages be capped at 100%. It also proposed that lower-priced medicines - those in the Rs2-5 per unit range - may be exempted from TMR. "We appreciate NPPA on capping the cancer drugs with provision of 30% margin to the trade channel. Similar formula may be applied for capping prices," said Singhal. At present, the NPPA fixes the price of scheduled drugs.

Source: Teena Thacker, Economic Times, 26.05.2022

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WHO Launches New Guidance On Integrating Eye Care Into Health Systems

Geneva: The World Health Organization (WHO) launched a new eye care guide at an event – Universal Health Coverage and Eye Care: Promoting Country Action – attended by government officials, representatives WHO and eye care nongovernmental organizations.

The Eye Care in Health Systems: Guide for Action provides practical, step-by-step advice to help Member States plan and implement the recommendations of the World Vision Report with the aim of providing integrated eye care services person-centred.

This new resource leads Member States through a four-step process: situation analysis; developing an eye care strategic plan and monitoring framework; development and implementation of an operational plan; and establish and maintain ongoing review processes.

Currently, more than two billion people live with visual impairment and of these, at least one billion people live unnecessarily with poor vision due to lack of access to eye care services. This burden is not borne in the same way since 90% of visually impaired or blind people live in

low- and middle-income countries. Often all that is needed is a cost-effective intervention, such as a pair of glasses or cataract surgery.

Implementing integrated, people-centred eye care has the potential to improve the lives of millions of people around the world and yield enormous benefits for the economy, gender equity, inclusion, education and the workplace.

Source: ET HealthWorld, Health News, 25.05.2022

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Centre proposes over-the-counter sales of 16 classes of drugs

The change will potentially allow retail shops to sell such OTC formulations without the need for buyers to show prescriptions from doctors

The Union health ministry has proposed over-the-counter sales of 16 classes of medicines, including the anti-fever paracetamol, an anti-bacterial acne formulation, anti-fungal creams, nasal decongestants, an analgesic cream formulation and anti-allergy capsules, among others.

A gazette notification released by the ministry on Wednesday sought public responses to a proposed amendment to the national drug rules to allow the 16 formulations "to be sold over-the-counter (OTC) by retail under valid licence".

The change will potentially allow retail shops to sell such OTC formulations without the need for buyers to show prescriptions from doctors. These medicines are currently available mainly through retail chemists or hospital pharmacies.

But the OTC sales will be allowed only under the conditions that the maximum duration of treatment or use should not exceed five days and that if the symptoms do not resolve, the patient should consult doctors. The pack size should not exceed the maximum doses recommended for five days and each packet should be accompanied by a patient information leaflet.

The move to introduce an OTC class of medicines in India comes in a landscape where many chemists and pharmacies continue to sell restricted medicines, including antibiotics or fixed-dose combinations of medicines, without insisting on prescriptions despite government strictures.

The Indian Association of Dermatologists had over four years ago complained to the central drug regulatory agency about dangerous skin creams laced with steroids being sold without doctors' prescriptions that had contributed to "an epidemic of superficial fungal infections".

"But nothing has changed on the ground — steroid-containing creams continue to be sold without prescriptions," said Abir Saraswat, a Lucknow-based dermatologist and a member of an association panel that had urged a government crackdown.

But, Saraswat said, the plan to introduce OTC formulations could help as it might allow consumers to learn to differentiate between drugs that can be bought without doctors' prescriptions and those that require prescription.

"We never had anything labelled as OTC. Let us hope the introduction of some OTC medicines is followed up by authorities on getting tough on medicines that need to be sold only on prescriptions," Saraswat told **The Telegraph**. "The rules already exist — they just need to be enforced."

The proposed OTC formulations include providone iodine, an antiseptic disinfectant, chlorohexidine mouthwash, clotrimazole antifungal cream and dusting powder, dextromethorphan hydrobromide cough lozenges, diclofenac analgesic cream, benzoyl peroxide anti-acne cream, diphenhydramine anti-allergic capsules, paracetamol 500mg tablets, three nasal decongestants, two anti-dandruff formulations, calamine antiseptic lotion and two laxative formulations.

Source: G.S. Mudur, Telegraph online, 28.05.2022

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India to prepare detailed guidelines, SoPs for testing medical devices

According to the CDSCO, from October 1, 2021, manufacturers of category A & B medical devices (low risk devices) were told to come under a compulsory registration scheme up to September, 2022 and manufacturers of category C & D medical devices (high risk medical devices) were directed to do so up to September 2023.

The government is preparing detailed guidelines and SoPs for laboratories testing medical devices. These measures are being taken to strengthen the testing infrastructure for licensing medical devices.

As of now, state regulators randomly take samples and conduct verification without any compulsory regulations in place on the lines of drugs and pharmaceuticals. The state drug regulator picks the sample with its batch number and conducts verification in its own laboratories. All the states have developed labs so that they are able to take action as and when required.

A task force has been set up for the exercise to map the existing labs available for such certification and testing.

"A meeting was held last month on the measures to be taken towards strengthening testing infrastructure to enable smoother transition to licensing for medical devices under the chairmanship of secretary, department of pharmaceuticals (DoP). A task force has been constituted to prepare a road map for mapping and augmenting the laboratory resources required under medical device regulations. The committee has to submit its report to the DoP within two months," said an official in the know of the matter requesting anonymity.

"There's a minimum mandatory requirement for the state regulator that every month how many such samples they have to pick and verify. Once the medical devices regulation comes into place, testing of medical devices will become compulsory. So now, this task force is to identify facilities within government and independent ones available in the country for testing of medical devices," said the official.

These labs could be NABL accredited labs, IIT Labs or National Institute of Pharmaceutical Education and Research (NIPER) labs.

In India, medical devices are a category of almost 5,000 products. Different categories of medical devices may require different kinds of testing infrastructure.

The committee will also tell us which category of product which lab may be able to test. We have brought in multiple stakeholders from Central Drugs Standard Control Organisation (CDSCO), industry, DoP, NIPER to do this exercise and give its report," said the official.

According to the CDSCO, from October 1, 2021, manufacturers of category A & B medical devices (low risk devices) were told to come under a compulsory registration scheme up to September, 2022 and manufacturers of category C & D medical devices (high risk medical devices) were directed to do so up to September 2023. After the compulsory registration period, these classes will respectively move to the licencing regime.

"The purpose is to prepare the industry for a smooth transition regulatory regime. The testing has been mandated by the CDSCO as per the norms; besides, random samples are also being done. This exercise will create an enabling environment and fill the existing gaps.

Queries mailed to the department of pharmaceutical spokesperson were unanswered at press time.

Source: Priyanka Sharma, Live mint, 27.05.2022

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Tracing the cure

As the monkeypox outbreak brings the focus back on smallpox vaccines, the critical question is — which countries have the stock?

The recent monkeypox outbreaks have brought before a pandemic-struck world the question: How to guard against this new pathogen attack? The smallpox vaccine has emerged as a key contender. But who has it?

The smallpox vaccine, which is 85 per cent effective against monkeypox, should be reserved for the vulnerable population because the availability is low and not everyone needs it, said Maria Van Kerkhove, the World Health

Organization's (WHO) leading epidemiologist on zoonotic diseases.

The scientist said this on May 23, 2022 during a WHO interaction amid a monkeypox outbreak in at least 17 countries, in most of which the disease is not endemic.

The smallpox vaccine can prevent monkeypox if given within four days of exposure and limit symptoms if given within two weeks.

It remains unclear what the mitigation strategy will be. Governments are mulling administering the vaccine to healthcare workers and close contacts of those infected.

But which countries still stock it, since vaccination was discontinued after smallpox was eradicated in the 1980s?

The US reportedly has 100 million doses of two Foods and Drugs Authority (FDA)-approved vaccines as part of the Strategic National Stockpile. These include the ACAM 2000 and the Jynneos shot developed for smallpox by Sanofi Pasteur Biologics and Danish vaccine maker Bavarian Nordic A / S respectively.

Only the latter has been FDA-approved for monkeypox as well. ACAM 2000 has severe side effects since it uses a live virus. Canada also has a stockpile of smallpox vaccines but the figure is unknown. The country's chief public health officer Dr Theresa Tam stated on May 20 that the smallpox vaccine is being considered for the outbreak. In April 2022, Public Services and Procurement, Canada, put up a tender to buy 5,00,000 doses of the Jynneos shot (locally called Imvamune) under the Public Health Agency of Canada from 2023-2028.

It read: "Although smallpox disease is currently considered to be eradicated, the Public Health Agency of Canada (PHAC) is procuring a stockpile of the vaccine to immunise Canadians against smallpox disease, should a risk ever arise where smallpox is intentionally or unintentionally released."

The European Centre for Disease Prevention and Control (ECDC), home to the largest monkeypox cluster outside Africa, urged healthcare officials May 23 to begin assessing smallpox vaccine availability. It can be considered for "close contacts at increased risk for severe disease" following risk assessment, the body stated.

The UK has begun offering smallpox vaccines to those who require it, a UK Health Security Agency spokesperson was quoted as saying to the news agency Reuters. How many people the vaccine has been offered to remains unclear.

The Spanish government is planning to buy thousands of doses of the Jynneos shot, called Imvanex in the country, and in other European countries. "This vaccine is not intended to be administered to the general population, but only to contacts of confirmed cases, in a so-called 'ring' strategy that was already used successfully to eradicate smallpox in 1977," a report in the El Pais newspaper noted.

Paul Chaplin, chief executive of the Bavarian Nordic, was quoted as saying in the Wall Street Journal that several countries have inquired about the Jynneos vaccine. "Immediate demand from governments around the world could be met with stocks that Bavarian Nordic has in storage, which he expects to send out over coming days," the report quoted Chaplin as saying.

Those doses, Chaplin told the newspaper, were surplus stock from earlier production runs. He didn't specify how many doses were already available.

WHO has pledges of donors including France, Germany, Japan, New Zealand and US of 31 million doses "for use in time of international need upon request by WHO".

"The smallpox vaccines described are those that are part of, or intended to be donated to, the (physical and virtual) WHO stockpile," the global health body noted in a 2019 operational framework document.

Smallpox vaccines donated for the virtual WHO stockpile are also intended for use in the donor countries in case of an outbreak, it added. DTE

Source: Taran Deol, Editorial, Millennium post, 27.05.2022

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India-Canada second round free-trade agreement talks start next week

Canada is expected to seek greater market access for agricultural products such as pulses. Both nations may steer away from including sensitive items such as dairy in the trade deal

Officials from India and Canada are expected to meet virtually next week to commence the second round of negotiations for a free-trade agreement (FTA) that aims to strengthen economic ties between the two countries.

India is expected to push for greater market access for pharmaceutical products, readymade garments, agriculture

Canada was India's 36th largest trading partner in FY22. India exported goods worth $3.76 billion to Canada, while importing goods worth $3.13 billion in the financial year 2021-22

goods and easier movement of skilled workers, to create more jobs for its IT professionals, people aware of the matter said. Canada is expected to seek greater market access for agriculture products such as pulses. Both nations may steer away from including sensitive items such as dairy in the trade deal, they said.

"The first round of negotiations happened soon after the fifth Ministerial Dialogue on Trade and Investment, where broader issues were discussed. There will be more clarity on the way forward as something more concrete is expected after the second round of discussions," one of the officials cited above said.

India and Canada had launched negotiations towards a comprehensive economic partnership agreement (CEPA) in 2010. However, no headway was made even after the 10th round nearly five years ago.

A joint statement released by India and Canada in March stated that both the countries are looking to finalise an interim or an early progress trade agreement (EPTA). A spokesperson from the High Commission of Canada said that while India has rolled out various reform measures over the last few years, uncertainty caused due to unpredictable tariff rates in India's agriculture sector are some of the hurdles faced by the exporters from Canada. "Canada is happy to note that India is steadily moving up the ranking of the World Bank's 'Ease of Doing Business'. This has been possible, in part, as a result of some Government of India initiatives such as the establishment of the National Investment Promotion and Facilitation Agency, Similarly, the amalgamation of various taxes into one GST has been welcomed by the business community and has facilitated trading across state borders. The debt and insolvency law, as well as implementation of the PLI, are being used by some Canadian producers in India," the spokesperson told Business Standard.

"However some challenges still exist, mostly at the local and state level, such as permit approvals, land acquisition, supply-chain unpredictability, and high tariffs. And in the agricultural sector, unpredictable tariff rates and quantity restrictions can cause uncertainty," the spokesperson said.

Canada was India's 36th largest trading partner in FY22. India exported goods worth $3.76 billion to Canada, while importing goods worth $3.13 billion in the financial year 2021-22.

Source : Shreya Nandi, Business Standard, 25.05.2022

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2021-2022 & 2022-2023

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102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai 400 018. Tel: 022-2494 4624/2497 4308 Fax: 022-2495 0723
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