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IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 19 (PAGES: 28) | 15 TO 21 MAY 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

IDMA & APTAR Pharma Webinar on
Container Closure Systems Testing: Leak detection and Extractable/ Leachable studies in an age of complex drug formulations
to be held on 26th May 2022, 5.00 pm to 6.30 pm
(Details on Page No. 4)

HIGHLIGHTS

★ **India's pharma business is valued above $50 billion for FY 2020-21: Mandaviya** *(Page No. 21)*

★ **Sri Lanka reaches out to Indian drug makers for supply of lifesaving medicines** *(Page No. 22)*

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SSB PHARMA (Shellac)
SSB AQUAGOLD
(Shellac Aqueous Coating System)

Signet

The Complete Excipients Company

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Indian Drug Manufacturers' Association
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Dr. A.B. Road, Worli, Mumbai - 400 018
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Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 53 **Issue No. 19** **15 to 21 May 2022**

IDMA ACTIVITIES:

INDIAN PHARMACOPOEIA COMMISSION:

GOVERNMENT COMMUNICATIONS:

GOVERNMENT NOTIFICATIONS:

SEBI MATTERS:

PARLIAMENT NEWS:

NATIONAL NEWS:

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

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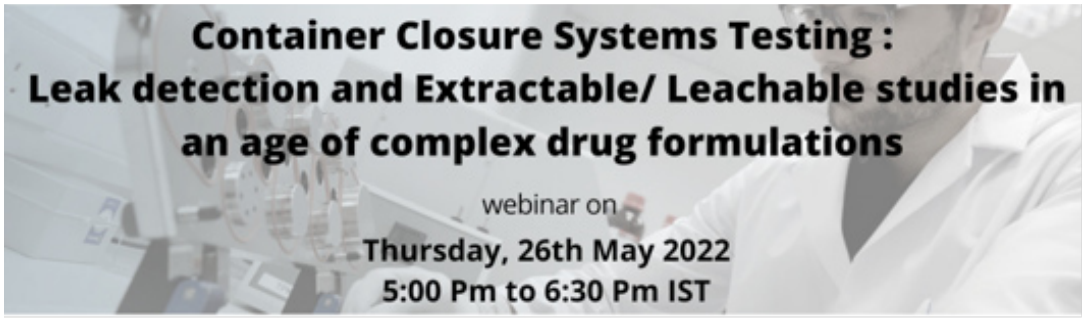
IDMA and APTAR Pharma Webinar on Container Closure Systems Testing: Leak detection and Extractable/ Leachable studies in an age of complex drug formulations

Dear Members,

Aptar Pharma and Indian Drug Manufacturers' Association (IDMA) is organizing a webinar the above mentioned subject on Thursday, 26th May 2022 at 5:00 PM to 6:30 PM.

The Moderator of the Webinar : Dr. Prasant Bodhe, Principal Consultant CliniSearch.



Speakers for the Webinar

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

Here is your Registration link : **REGISTER NOW**

Webinar Registration page link :
https://teams.microsoft.com/registration/PkrXX3rVDkGNfALE3wYiNA,M8Y2FUhaNEmpIW5AtPPojg,H699HZJvpke-twCuPK6LVQ,dJMYtvVs10KGt_1wa0oyEw,fS6EUT-ZhUGV3xnAIRR95Q,JqdA01ckPEmRn9JyQ4nClw?mode=read&tenantId=5fd74a3e-d57a-410e-8d7c-02c4df062234&skipauthstrap=1

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

Thanks & regards,

Daara B Patel, *Secretary – General*
Indian Drug Manufacturers' Association
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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*

Invitation to Beijing International life and health expo

Dear Members,

In response to the further deployment of the Ministry of Commerce and the National Health Commission of China, jointly "Contribute to a Global Community of Health for All" and strengthen global cooperation in the field of life sciences, the Opening Ceremony of the Beijing International Life and Health Industry Expo will be held online on May 26th, 2022, Beijing time. Meanwhile, the Project Docking Fair will be held both online and offline from May 26th to July 16th, 2022, depending on the pandemic situation.

Time: Opening Ceremony: May 26th, 2022, Beijing time

Project Docking Fair: May 26th to July 16th, 2022

Exhibition Categories: Medical Equipment, biological medicine, epidemic prevention, traditional Chinese medicine, medical cosmetology, health care, Pharmaceutical equipment, raw material, digital healthcare, etc.

Organizers: Trade Development Bureau of the Ministry of Commerce of China, World Federation of Chinese Medicine Societies, Chinese Research Hospital Association, China Chamber of International Commerce

Organizing form: [http://www.360clhe.com] +ZOOM

The exhibitors of the Expo are all from the white list of the Ministry of Commerce and have all necessary certifications. The fair will provide Chinese and foreign enterprises with a safe and efficient platform for communication, exchange, cooperation and negotiation through online and offline joint offices.

For more details, please contact us
Organizing Committee:
Secretary General: Mr. Qiu +86 15801079798
Exhibition Director: Mr. Liu +86 15294617556
Email:pxchina@126.com
Website: http://www.360clhe.com

Thanks & regards,

Daara B. Patel,
Secretary – General

The Opening Ceremony and the Online Press Conference of Beijing International Life and Health Industry Expo and World Life Science Project Fair

1、 Time: May 26th, 2022

2、 Agenda:

08:40-09:20	Guests Register (online and offline);
09:20-09:40	The announcement of start of the Ceremony and Introduction to the Guests and Representatives by the host: Chinese and foreign officials, heads of the United Nations agencies, representatives of leading companies in the global pharmaceutical industry, well-known experts and scholars in the field of Life Science, etc.;
09:40-09:50	Speech by the Representative of Trade Development Bureau of the Ministry of Commerce;
09:50-10:40	Speeches by Public Health Officers and Experts around the world;
10:40-11:00	Introduce the significance and goals of Beijing International Life and Health Industry Expo and World Life Science Project Fair, exhibitors and progress, etc.;
11:00-12:00	Answer to the questions of the reporters；
12:00	End of the Ceremony.

Health Sector Meeting at IMC

IMC organized a Health Sector meeting with the senior officials of U.S. Development Finance Corporation (DFC) from Washington on May 13, 2022 at IMC, Mumbai. IDMA was represented by Ms Sapna Patil, Deputy Secretary - General.

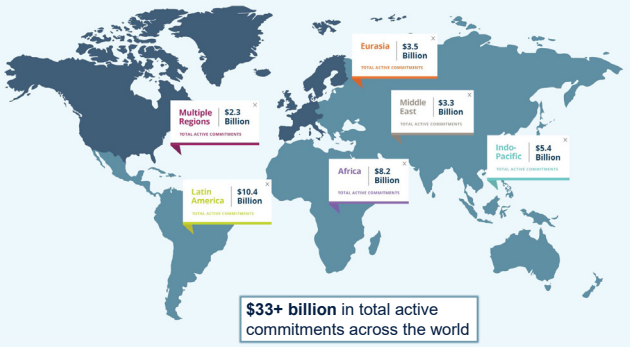
DFC's discussed Health and Prosperity Initiative Investment Guidelines at the meeting. DFC's focused on the health sector and to help low-income and middle-income countries attain a prosperous future by developing robust, sustainable health systems led by private sector innovators. As countries in the developing world faced immense challenges of the COVID-19 pandemic, addressing both communicable and the increasing prevalence of non-communicable diseases (NCDs) created a new strains on emerging market health systems.

Mr. Ajay Rao, Regional Managing Director for South Asia, U.S. International Development Finance Corporation made an excellent presentation on 'Global Health and Prosperity Initiative'. The presentation is reproduced below.

Members can reach out to Mr. Ajay Rao, Regional Managing Director for South Asia, U.S. International Development Finance Corporation on ajay.rao@dfc.gov for any further information or assistance with regard to the U.S. DFC tools to expand healthcare sector support in India.

PRESENTATION

Where We Work



$33+ billion in total active commitments across the world

DFC has a $3.2 billion of active investments in India

- DFC, and its predecessor, OPIC have been open in India since 1974, with over 200 projects and over $5 billion of Commitments
- Sectors include Clean Energy Finance, Agriculture, Affordable Housing, Healthcare and Micro and SME Financing

DFC is rapidly expanding its health portfolio

A few examples include:

First project in Ecuador – Axxis Hospital

First equity project – Kasha

First local currency loan project – Aspen Pharmacare

One of **DFC's Largest** projects – Gavi Liquidity Facility

First PRI project for vaccine access – Gavi PRI

DFC continues to expand investments and impact in the health sector across geographies and business lines

DFC is supporting vaccine access and manufacturing capacity

1.55 billion vaccine related investments:

- **$1b loan to Gavi** for liquidity to **purchase 160m doses** of COVID-19 vaccines and ancillary supplies for COVAX AMC countries
- **To date, $383m PRI to Gavi** has **shipped nearly 30m doses** of COVID-19 vaccines for 9 self-financed countries
- **$118m working capital loan to Aspen Pharmacare** in South Africa helped build a manufacturing **capacity of 450m doses** annually of COVID-19 or other routine vaccines by 2022
- **$50m loan to Biological E LTD** in India to build a manufacturing **capacity of 1b doses** annually of COVID-19 or other routine vaccines by the end of 2022
- **$3.3m TA to IPD** in Senegal to potentially build a manufacturing **capacity of 300m doses** annually of COVID-19 or other routine vaccines by 2023 or later
- **$200k TA to Biovac** in South Africa to potentially build a manufacturing **capacity of 500m doses** annually of COVID-19 or other routine vaccines by 2023 or later

DFC is also strengthening health systems

A few examples include:

A **$31m direct loan** to Femme in Brazil is supporting expansion of diagnostic facilities focused on underserved women. This will enable access to improved gynecology, obstetric, reproductive, and primary care for women in Brazil.

A **$150m investment** in Quadria Capital's Fund in India is supporting investments in the healthcare value chain, including hospitals and other treatment facilities, medical laboratories, medical equipment, and pharmaceutical manufacturers.

A **$17.5m loan guarantee** to Medical Credit Fund (MCF) is enabling working capital to health SMEs to continue providing essential health services during the pandemic, aiming to reach over 150,000 facilities across Sub-Saharan Africa.

A **$5m direct loan** to Africa Healthcare Network (AHN), the largest operator of dialysis centers in East Africa, is supporting expansion of chronic kidney care facilities. It is estimated that there are over 1 million patients with chronic kidney disease in sub-Saharan Africa.

DFC is committed to health investments in India

A few recent examples include:

$50M loan to **Biological E** to expand vaccine manufacturing capacity for COVID-19 and other routine vaccines for India and South Asia

$7.7M loan to **Portea Medical** to expand in-home healthcare services, including for COVID-19, in India

$20M equity investment in **Chiratae Ventures International Fund** to invest in early-stage tech companies, including in digital health in India

$15M loan to **Sabre Partners Fund** to invest in healthcare and financial services in India

Looking ahead, DFC is committed to further expanding its health pipeline

DFC U.S. International Development Finance Corporation

DFC's **three** key health sub-sector priorities are:

1) **Health services & infrastructure**
   - Hospitals
   - Health clinics
   - Specialty care (e.g., chronic kidney care, eye care)
   - Pharmacies
   - Diagnostic centers

2) **Health commodity manufacturing & supply chain**
   - Vaccines, diagnostics, therapeutics, and ancillary supplies production
   - Delivery & logistics

3) **Digital health & health information**
   - Provider or patient digital health applications
   - Electronic health records and other data systems

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Project Life Cycle

DFC U.S. International Development Finance Corporation

Sourcing	Prescreening	Application	Due Diligence	Approval	Project Close	Monitoring
DFC conducts outreach in the U.S. and host countries to identify potential partners that could make use of DFC investment tools to achieve or expand a developmental impact in an emerging market.	Potential clients and their projects are prescreened based on the strength of the business plan, alignment with agency priorities and resources, and compliance with DFC's investment standards.	Businesses and investors can complete the application on www.dfc.gov/apply.	DFC conducts a detailed assessment of the potential client's business plan, financial model, historical financial statements, expected project impact, legal compliance, and character risk.	The project is reviewed by DFC management, credit and investment committees for final approval. Loans and investment guarantees above $50 million as well as all equity transactions require approval from DFC's Board of Directors.	Transaction documentation is negotiated and executed. DFC can begin disbursing once the client has complied with the pre-disbursement requirements listed in the transaction documentation.	DFC monitors the credit, policy compliance, and developmental impact of all projects.

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Please reach out to us!

DFC U.S. International Development Finance Corporation

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Rashanda.Johnson@dfc.gov

Ajay Rao
Managing Director, South Asia
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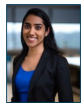

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Salient features of IP 2022

Indian Pharmacopoeia 2022

Published By

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health and Family Welfare
Government of India
Sector 23, Raj Nagar, Ghaziabad 201 002, India
Website: www.ipc.gov.in; **Email:** lab.ipc@gov.in

Effective Date

1ST DECEMBER 2022 (Tentative)

Salient Features

- New Monographs: 92
- APIs: 27
- Dosage Forms (Chemicals): 33
- Vitamins, Minerals, Amino acids, Fatty Acids etc.: 21
- Herbs & Herbal Products: 02
- Vaccines and Immunosera for human use: 04
- Biotechnology Derived Therapeutic products: 03
- Blood & Blood Related Products: 02
- General Chapters: 12

Note: For more details, Members are requested to visit IPC website www.ipc.gov.in

New decree (No. 593) for expedited procedure for registration of drugs in Russia

PXL/HO/Cir-014/2022-23, date 13th May 2022

Pharmexcil is in receipt of communication from the Department of Commerce, Government of India wherein our Indian mission in Moscow has shared the new decree towards expedited procedure for registration of generic and new medicines in Russia.

The Russian Government has adopted Decree No. 593(enclosed) dated April 05, 2022, which introduces temporary rules (till the end of year 2023) for registration of drugs facing shortage in the Russian market.

The major points of the decree are as below:

- A special interdepartmental commission will be created by the Ministry of Health that will determine a list of medicines, shortage of which are faced or might be faced in the Russian market.
- If this special interdepartmental commission acknowledges the shortage of a certain drug, the therapeutic analogue of the drug in short supply can be registered as part of an accelerated procedure. This is expected to take up to 60 business days, instead of 1-2 years earlier. [The concept of a therapeutic analogue established by the document is wider than the concept of a generic (copies of the original drug), and may include not only drugs registered under one international non-proprietary name (INN) with different trade names, but also drugs with other INNs].
- Producers of such medicines are allowed not to hold separate clinical trials of such medicines in Russia. Instead of this, they can present results of trials conducted in other countries. In addition, remote mode of lab testing of medicines is also allowed including through audio or video communication, the procedure and forms of which are determined by an expert institution in agreement with the said applicants. However, producers of medicines that will be registered according to this new facilitated procedure may be obliged to conduct post-clinical studies after the release of the drug into circulation.
- In addition, this decree allows newly registered medicines to the Russian market even in non-Russian packaging (till now Russian packaging was mandatory), provided that they have a sticker in Russian language (till end of 2022).

Member companies with business operations in the market and the ones planning for business expansions are advised to take note of this important information.

With regards,

Udaya Bhaskar,
Director General
Pharmexcil

Amendment in the Methylene Chloride (Dichloromethane) (Quality Control) Order, 2021

Chemicals & Fertilizers Order S.O.2224(E), dated 13th May 2022

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government hereby makes the following amendment in the Methylene Chloride (Dichloromethane) (Quality Control) Order, 2021 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

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

"(2) This order shall come into force on the 20th November, 2022."

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

N K Santoshi,
Deputy Director General,
Ministry of Chemicals and Fertilizers,
Department of Chemicals and Petrochemicals,
New Delhi.

Note : *The principal order for Methylene Chloride (Dichloromethane) was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide notification number S.O. 2032(E) dated the 25th May, 2021 and subsequently amended vide notification number S.O.4913(E) dated the 29th November, 2021.*

● ● ●

Amendment in the Ortho Phosphoric Acid (Quality Control) Order, 2021

Chemicals & Fertilizers Order S.O.2225(E), dated 13th May 2022

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government hereby makes the following amendment in the Ortho Phosphoric Acid (Quality Control) Order, 2021 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

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

"(2) This order shall come into force on the 10th December, 2022."

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

N K Santoshi,
Deputy Director General,
Ministry of Chemicals and Fertilizers,
Department of Chemicals and Petrochemicals,
New Delhi.

Note : *The principal order for Ortho Phosphoric Acid was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide notification number S.O.2335(E) dated the 15th June, 2021 and subsequently amended vide notification number S.O. 4914(E) dated the 29th November, 2021.*

● ● ●

Amendment in the Polyphosphoric Acid (Quality Control) Order, 2021

Chemicals & Fertilizers Order S.O.2226(E), dated 13th May 2022

In exercise of the powers conferred by section 16 of the Bureau of Indian Standards Act, 2016 (11 of 2016), the Central Government hereby makes the following amendment in the Polyphosphoric Acid (Quality Control) Order, 2021 published by the Ministry of Chemicals and Fertilizers, Department of Chemicals and Petrochemicals, namely:-

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

"(2) This order shall come into force on the 22nd December, 2022."

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

N K Santoshi,
Deputy Director General,
Ministry of Chemicals and Fertilizers,
Department of Chemicals and Petrochemicals,
New Delhi.

Note : *The principal order for Polyphosphoric Acid was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-Section (ii) vide notification number S.O.5388(E) dated the 24th December, 2021.*

● ● ●

Medical Devices Rules, 2017 amended - reg.

Drugs & Cosmetics Notification G.S.R.356(E), dated 18th May 2022

Whereas a draft of certain rules further to amend the Medical Devices Rules, 2017, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R.23(E), dated the 18th January, 2022, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of fortyfive days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 19th January, 2022;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Medical Devices Rules, 2017, namely:-

1. (1) These rules may be called the **Medical Devices (Third Amendment) Rules, 2022.**

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

2. In the Medical Devices Rules, 2017, after rule 43, the following rule shall be inserted, namely:-

"43A. Suspension and cancellation of licence.- (1) If the manufacturer or licensee fails to comply with any of the conditions of an import license, or any provisions of the Act and these rules, the Central Licensing Authority may after giving the manufacturer or licensee an opportunity to show cause why such

an order should not be passed, by an order in writing stating the reasons therefor, cancel a license issued under rules, or suspend it for such period as it may thinks fit either wholly or in respect of any of the part of medical device to which it relates or direct the licensee to stop import, sale or distribution of the said medical device and, thereupon, order the destruction of medical device and the stock thereof in the presence of an officer authorised by the Central Licensing Authority, if in its opinion, the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Act or the rules made thereunder:

Provided that a person who is aggrieved by the order passed by the Central Licensing Authority under this rule may, within thirty days of the serving of the order, file an appeal to the Central Government, and the Central Government may, after such enquiry into the matter, as it considers necessary and after giving the said appellant an opportunity of being heard, pass such order as it thinks fit.".

F.No.X.11014/4/2019-DR

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

***Note** : The Medical Devices Rules, 2017 was published in the Official Gazette vide notification number G.S.R.78(E), dated the 31st January, 2017 and last amended vide notification number G.S.R.174(E), dated the 4th March, 2022.*

● ● ●

Drugs Rules, 1945 amended - reg.

Drugs & Cosmetics Notification G.S.R.357(E), dated 18th May 2022

Whereas a draft of certain rules further to amend the Drugs Rules, 1945, was published as required under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R.75(E), dated the 1st February, 2022, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas, copies of the said Official Gazette were made available to the public on the 2nd February, 2022;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs Rules, 1945, namely:-

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

(2) They shall come into force with effect from the **1st day of November, 2022.**

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

"552. Acitretin".

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. 158(E), dated the 24th February, 2022.*

● ● ●

Relaxation from compliance with certain provisions of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015

CIRCULAR SEBI/HO/CFD/CMD2/CIR/P/2022/62, dated 13th May 2022

To
All Listed entities,
All Recognized Stock Exchanges.

1. MCA vide Circular dated May 05, 2022 has extended the relaxations from dispatching of physical copies of financial statements for the year 2022 (i.e. till December 31, 2022). In view of the same, SEBI has also been receiving multiple representations from listed companies, seeking dispensation from requirements of sending hard copy of annual reports to shareholders.

2. Considering the above, it has been decided to provide relaxation upto December 31, 2022, from Regulation 36 (1) (b) of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 ("LODR Regulations") which requires sending hard copy of annual report containing salient features of all the documents prescribed in Section 136 of the Companies Act, 2013 to the shareholders who have not registered their email addresses. Further, the notice of Annual General Meeting published by advertisement in terms of Regulation 47 of LODR Regulations, shall contain a link to the annual report, so as to enable shareholders to have access to the full annual report.

3. It is however emphasized that in terms of Regulation 36 (1) (c) of LODR Regulations, listed entities are required to send hard copy of full annual report to those shareholders who request for the same.

4. Further, the requirement of sending proxy forms under Regulation 44 (4) of the LODR Regulations is dispensed with upto December 31, 2022, in case of general meetings held through electronic mode only.

5. This Circular shall come into force with immediate effect. The Stock Exchanges are advised to bring the provisions of this circular to the notice of all listed entities and also disseminate on their websites.

6. The Circular is issued in exercise of the powers conferred under Section 11(1) of the Securities and Exchange Board of India Act, 1992 read with Regulation 101 of the LODR Regulations.

Yours faithfully,

Amy Durga Menon,
Deputy General Manager,
Compliance and Monitoring Division,
Corporation Finance Department,
New Delhi.

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In Rajya Sabha & In Lok Sabha

In Rajya Sabha

Labelling of Food Products

Rajya Sabha Starred Question No.351

Shri Harshvardhan Singh Dungarpur:

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

(a) whether steps have been taken to make interpretive food labels mandatory so that consumers are guided to make healthier choices, if so, the details thereof;

(b) whether the Ministry has evaluated global best practices on what symbols on labels are proving to be the most effective to convey the health harms of packaged foods and showing positive results of decline of purchases of unhealthy packaged foods by consumers; and

(c) whether such measures will ensure that the Indian food industry follows global standards and is encouraged to reformulate unhealthy food products in the interest of public health?

Answered on 5th April, 2022

A. (a) to (c) A Statement is laid on the Table of the House.

Statement Referred to in Reply to Rajya Sabha Starred Question No. 351* For 5th April, 2022

(a) to (c): Food Safety and Standards Authority of India (FSSAI) has notified Food Safety and Standards (Labelling and Display) Regulations, 2020 regarding requirements for labelling of packaged food. As per this Regulation's section related to nutritional information requires display of nutrients and their contribution to Recommended Daily Allowance (RDA) in percentage to enable consumers to make informed choice. It is mandatory for Food Business Operators (FBOs) to label the food package in accordance with these Regulations.

The Minister of Health and Family Welfare (Dr Mansukh Mandaviya)

Fake and Adulterated Medicines

Rajya Sabha Unstarred Question No.3695

Dr. Vikas Mahatme:

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

(a) whether Government has undertaken any survey to determine the prevalence of fake, subpar and adulterated medicines in the Indian market, if so, the details thereof;

(b) whether Government has formulated any policy for the regulation of fake, subpar and adulterated medicines in the pharmaceutical industry in the country, if so, the details thereof, if not, the reasons therefor; and

(c) the actions taken by the various State Governments and Union Government in dealing with the issue of fake medicines in the country?

Answered on 5th April, 2022

A. (a): A Nation-wide survey (2014-16) was conducted to assess the extent of Not of Standard Quality (NSQ)/ Spurious drugs. Out of a total 47012 drug samples drawn from both Governments and private sources, the estimated percentage of NSQ and spurious drugs from Retail outlets was 3% and 0.023% respectively, while that from Government sources was 10.02% and 0.059% respectively.

(b): 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.

(c) : The Government has taken a series of 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 five 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 prosecu-tions	No. of persons arrested
2016-17	76,721	2,780	123	186	106
2017-18	82,599	2783	236	131	163
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)

WHO'S Recommendation for the Implementation of front of Package Labelling

Rajya Sabha Unstarred Question No.3790

Shri A. D. Singh:

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

(a) the effort Government is taking to regulate the quality of the products with the increase in packed food being consumed by a large section of our population;

(b) whether World Health Organisation (WHO) recommends the implementation of Front of Package Labelling as one of the best buy measures as it shows the contents used in the making of the said packed food; and

(c) by when does Government plan to universally implement WHO's advice on the packed products?

Answered on 5th April, 2022

A. (a): Food Safety and Standards Regulations notified under Food Safety and Standards Act, 2006 prescribe necessary quality and safety parameters of food products, including packaged food. These Standards have been specified in alignment with Codex & other international standards. All Food Business Operators have to ensure adherence to these standards.

(b) & (c): Food Safety and Standards Authority of India (FSSAI) has informed that it has notified Food Safety and Standards (Labelling and Display) Regulations, 2020 regarding requirements for labelling of packaged food. Section related to nutritional information requires display of nutrients and their contribution to Recommended Daily Allowance (RDA) in percentage to enable consumers to make informed choice. It is mandatory for Food Business Operators (FBOs) to label the food package in accordance with these Regulations.

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

In Lok Sabha

Crowdfunding for Rare Diseases

Lok Sabha Unstarred Question No. 3867

Shri Feroze Varun Gandhi:

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

(a) the total number of patients registered on the Digital Portal for Crowdfunding and Voluntary donations for Patients of Rare Diseases;

(b) whether the total number of registration is very low when compared to the sizable number of people suffering from rare diseases, if so, the details thereof and the reasons therefor;

(c) the measures taken to create awareness about the said portal to ensure that patients and the families of those suffering from rare diseases avail the benefits;

(d) the total amount of donations that have been channelled to the portal along with the fund benefits accrued to the beneficiaries through this portal, case/ amount-wise; and

(e) whether the accrued amount in the fund portal remains unutilized, if so, the details thereof and steps taken to channelize these fund for treatment?

Answered on 25th March, 2022

A. (a) & (b) The total number of patients registered on the Digital Portal for Crowd funding and voluntary donations for patients of Rare Diseasesis 253 till date.As per the National Policy for Rare Diseases, 2021, the rare diseases have been categorized into 3 groups and the digital platform is especially for Group 3 rare disease patients.Hence, the data available on the digital portal is of the Group 3 rare disease patients only.

(c) to (e) The National Policy for Rare Diseases (NPRD), 2021, which has the provisions for financial assistance through crowd funding to the patients suffering from the diseases for which definite treatment is available but involves very high cost and lifelong therapy (listed under Group 3), has already been in public domain since March 2021. The Department of Health and Family Welfare has launched a Digital Portal for Crowd Funding and Voluntary Donations for Patients of Rare Diseases in accordance with the mandate of the Policy. The Digital Portal may be accessed through https://rarediseases.nhp.gov.in/. The total amount of donations that have been channeled to the portal is Rs.1,18,016 (Rupees One Lakh Eighteen Thousand Sixteen Only) till date.The Donors have a choice to make donations to different Centres of Excellence(CoEs) and for the patients' treatment by these CoEs. The Centres of Excellence (CoEs) have their own Rare Disease Fund which is utilized with the approval of their competent authority.

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

Misleading Advertisement by Pharma Companies

Lok Sabha Unstarred Question No. 3874

Shri Nihal Chand:

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

(a) whether the Government has taken into cognizance the misleading advertisements of pharmaceutical companies on television, if so, the details thereof;

(b) the norms formulated by the Government for the drug sellers in relation to the sale of medicines;

(c) the measures taken by the Government for ensuring compliance of the above norms by the drug sellers;

(d) whether the Government has received complaints against the drug sellers in this regard; and

(e) if so, the details thereof along with the action taken thereon?

Answered on 25th March, 2022

A. (a) to (e): Advertisements concerning drugs are regulated under the provision of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, which is administered by the State Governments. The Drugs & Cosmetics Rules, 1945 were amended in 2015 and a provision was made to the effect that no advertisement of drugs specified in Schedule H, Schedule H1 and Schedule X (i.e. Prescription drugs) shall be made except with the previous sanction of the Central Government. State Licensing Authorities are empowered to take action in case of non-compliance.

Ministry of Information & Broadcasting, on the basis of information provided by Ministry of AYUSH, in order to protect the citizens from misleading advertisement and health risk, issued an advisory on 12.07.2017 in which all TV channels were advised to advertise only products that have valid licence issued by Ministry of AYUSH or State Drug Licensing Authorities.

The sale and distribution of drugs in the country are regulated by the State Licensing Authority (SLAs) through a system of inspection and licensing under the provisions of the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945. The said Rules prescribe conditions to be satisfied before grant of licence for sale of drugs. These include adequacy of the premises, proper storage facilities for preserving the properties of drug, requirement of competent person to supervise and control the sale of drugs, etc. SLAs are legally empowered to take action in case violation of the condition of license.

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

Pricing Policy of Medicines

Lok Sabha Unstarred Question No. 3878

Shri Devendra Singh Bhole:

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

(a) whether the Government has announced a pricing policy of expensive medicines in the country in view

of the huge gap between the cost of manufacturing of medicines and their market price; and

(b) if so, the details thereof?

Answered on 25th March, 2022

A. (a) to (b): The extant National Pharmaceutical Pricing Policy (NPPP), notified on 7th December, 2012, has been formulated with an objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of essential medicines at reasonable prices while providing sufficient opportunity for innovation and competition to support the growth of pharma industry. The policy made a shift from earlier 'cost based' pricing under the Drug Policy, 1994 to 'market based' pricing.

In pursuance of NPPP, 2012, the Government notified the Drugs (Prices Control) Order, 2013 (DPCO-2013). As per the provisions of DPCO, 2013, the National Pharmaceutical Pricing Authority (NPPA) 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.

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

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NATIONAL NEWS

India's pharma business is valued above $50 billion for FY 2020-21: Mandaviya

India's pharmaceutical business is witnessing exceptional development. It's valued above $50 Billion (2020-21), with a development fee of 10-12%, mentioned Dr Mansukh Mandaviya, Union Minister of Chemical & Fertilisers on Sunday.

"PM @Narendra ModiJi's Govt has taken many initiatives to unlock the big potential of the pharma business," mentioned Mandaviya on twitter.

Indian pharma business identified globally for its reasonably priced and high quality medicine. India has fulfilled 50 per cent of the demand in lots of the low-income economies in addition to within the superior market by supplying good high quality generic medicines regularly.

In line with the Centre authorities, India has constructed up a fame for having the ability to ship good high quality generic medicines at excessive manufacturing scale and at reasonably priced costs.

Not too long ago, the chemical & fertilisers minister had mentioned that pandemic state of affairs has proven the resilience of the pharma sector.

"We should work in direction of strengthening this additional. We are going to have interaction with business and academia to chalk roadmap for pharma & medical units for the subsequent 25 years. We will quickly get the aggressive edge in medical units too with analysis & innovation", he added.

The federal government has authorized greater than 22,000 crores have already been authorized for bulk medicine, APIs and so forth beneath Manufacturing Linked Incentive (PLI) scheme.

Source: Live Mint, 16.05.2022

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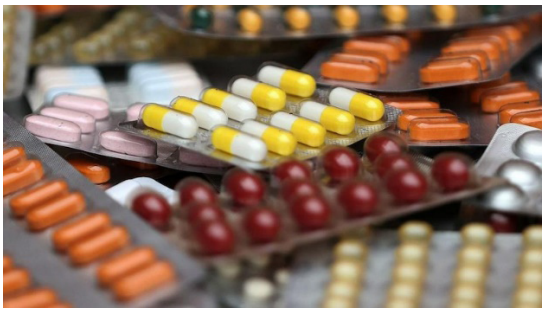
Pharmaceutical industry hit hard by Sri Lanka's economic crisis

Sri Lanka's economic crisis is causing a shortage of medicine in the country.



Sri Lanka's economic crisis is affecting the pharmaceutical industry and the country is facing a shortage of essential medicines. Local pharmacies have run out of medicine with patients leaving empty-handed.

A doctor at the Sri Lanka medical association, Ishan, said, "All kinds of medicines - general medicines and those that are specific to a certain health condition - are in shortage due to the economic crisis. A list is continually circulated by the authorised organisations to give a picture of the missing medicines and also to seek assistance for others."

A local pharmacist said, "Many over-the-counter medicines like paracetamol and antibiotics are not available. Heart medicines and anaesthetic medicines are unavailable because of which surgeries have been temporarily stopped in many places." Another pharmacist added, "The economic crisis has also led to the increase in prices of medicines. We have observed people travelling long distances to get medicine. Sometimes, they don't buy the medicine they need because of the price. It is a terrible situation."

Last week, a two-year-old child fell sick and the family could not arrange medicine for her. Her mother said they had to travel very far just for general medicine.

According to Dr Ishan, the next step forward is for other countries to provide help. He said, "India has given a helping hand and we are thankful for it. But we will need more assistance when it comes to medicine."

Since January, the Indian government has given US $ 3.5 billion in aid to the island nation. Earlier, external affairs minister S Jaishankar had also said that India will also assist Sri Lanka with its medicine shortage problem.

Source: India Today, Akshaya Nath, 15.05. 2022

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Sri Lanka reaches out to Indian drug makers for supply of lifesaving medicines

Sri Lanka, which is reeling under severe financial crisis, has urged the Indian drug manufacturers to supply vital lifesaving medicines to it on humanitarian and compassionate grounds.

The forex reserve of the island nation which imports 85 per cent of its drug requirement stands at less than US$ 1 billion. The country exhausted dollars to pay for the drug import, leading to crumbling of its healthcare infrastructure.

Sri Lanka's state ministry of production, supply and regulation of pharmaceuticals has released a list of 273 urgent pharmaceuticals. The list includes Streptokinase injection, anti-rabies serum & vaccine, disposable IV giving sets, dantroline sodium injection, suxamethonium chloride injection, morphine sulphate tablet & injection, cefuroxime tablet, meropenem injection, flucloxacillin syrup, pethidine hydrochloride injection, remifentanil injection, gentamicin sulphate injection, clofazimine, netilmicin injection.

The list further includes ofloxacin, amphotericin injection, esmolol HCl injection, fluconazole injection, levofloxacin, carvedilol, colistimethate sodium injection, metoprolol tartrate injection, heparin injection, diazepam, enoxaparin injection, tramadol injection, omeprazole, oxytocin injection, linezolid tablet & injection, salbutamol injection, nicorandil, ranitidine HCl injection, acetylcysteine injection, diclofenac sodium etc.

The state ministry of production, supply and regulation of pharmaceuticals and its institutions are completely responsible for procuring, distribution and regulation of pharmaceuticals, consumables and all kinds of medical supplies for all healthcare institutions in Sri Lanka.

Said Dr RMSK Rathnayake, secretary, state ministry of production, supply and regulation of pharmaceuticals, "We are utilizing the maximum production capacity of the local production and have also initiated to utilize the Indian credit line to the maximum effect to purchase medical supplies for Sri Lanka. But due to the prevailing foreign

reserve crisis it has been extremely difficult to maintain the supply chain of most lifesaving drugs which are not produced at Sri Lanka and could not be imported through the Indian credit line."

A separate working committee has been appointed to coordinate this activity, to direct foreign drug suppliers and to utilize donations to the maximum effect. The working committee is chaired by the director of the medical supplies division, Dr Rathnayake informed.

"There is a considerable amount of vital medical supplies such as orthopaedic implants, anti-cancer drugs, reagents and consumables used at blood banks, HLA (human leukocyte antigen) testing, HIV-AIDS testing reagents and laboratory reagents that are imported from the US, Europe and Australia. Due to the prevailing foreign reserve crisis, it has been extremely difficult to maintain the supply chain of above-mentioned extremely important medical supplies imported from Europe," he stated.

The state ministry is awaiting official approval of the finance ministry to open a foreign currency account to collect donations to support the medical supply chain. A separate online payment gateway is also requested, he added.

Dr.Lohitha Samarawickrema, president of National Chamber of Pharmaceutical Manufacturers (NCPM) at the behest of Sri Lankan authorities has reached out to Indian Drug Manufacturers' Association (IDMA) seeking supply of lifesaving drugs.

Confirming this, Daara Patel, secretary general, IDMA said "We have received a request from Sri Lankan authorities courtesy Dr Lohitha Samarawickrema for supplying emergency medicines for the people of Sri Lanka. We requested all our members who have the required approvals to be generous and help for this noble cause."

Dr.Lohitha Samarawickrema, president of NCPM, Sri Lanka and IDMA signed the MoU along with Deepnath Roy Chowdhury, national president, IDMA (Year 2017-2018) and Daara B. Patel, secretary general, IDMA on May 18, 2018.

Besides this, the State Pharmaceuticals Corporation of Sri Lanka has also sent a communication to the Pharmaceuticals Export Promotion Council of India (Pharmexcil) in this regard.

The State Pharmaceuticals Corporation has appealed to Pharmexcil to ask its member companies to supply lifesaving medicines to the island nation in the wake of the economic crisis faced by it.

Indian drug manufacturers whose products have been approved by National Medicinal Regulatory Authority, Sri Lanka or US FDA, EMA, UK MHRA, TGA Australia can dispatch medical supplies to the island nation.

India exported pharmaceutical products worth US$ 206.79 million to Sri Lanka in fiscal 2017-18. In FY 2018-19, India's pharma export to the island nation stood at US$ 219.19 million. The country has exported drugs worth US$ 220.30 million to Sri Lanka in fiscal 2019-20.

India's export of pharmaceutical products to Sri Lanka was US$ 221.68 million during 2021. The island nation is India's 20th export destination of pharma products.

Source: Laxmi Yadav, Pharmabiz, 12.05.2022

Dear IDMA Member,

We invite you to Cytiva Presents India Biopharma Leaders Conclave Co-powered by Rockwell Automation on 26th-27th May at Hotel Novotel Convention Centre, Hitec City, Hyderabad. The Indian biopharma industry is on a steady growth path, but the market is changing, and we need to adapt quickly. If you want to ensure your business stays ahead of the curve, it's time to join us for this event, where you can learn about the potential of Indian Biopharma.

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