PRICE
PER COPY
₹25/-

LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/TECH/WPP-337/WEST/2021-23
RNI REGN. NO. 18921/1970
REGN NO. MCW/95/2021-23

IDMA BULLETIN

VOL. NO. 53 | ISSUE NO. 37 (PAGES: 20) | 01 TO 07 OCTOBER 2022 | ISSN 0970-6054 | WEEKLY PUBLICATION

INDIAN PHARMA - GLOBAL HEALTH CARE

INDIAN DRUG MANUFACTURERS' ASSOCIATION

HIGHLIGHTS

UNMATCHED RIGOUR AND DEDICATION. THAT LEADS TO INCOMPARABLE **EXPERIENCE**

Dear Partner,

For over 30 years, Signet has brought the world's best excipients to Indian shores, by partnering with global firms that boast immeasurable experience. One such company is Innophos.

Innophos began it's journey in 1902 and has spent over a century advancing their phosphate technology. Today, their management systems, quality standards and formulation versatility are unmatched. They are the leading provider of high quality calcium phosphates and other minerals, having pioneered the process of manufacturing excipients in both anhydrous and dihydrate forms, with extremely low lead content.

By choosing to associate with experience, we have been able to not just keep up with our customer needs, but race far ahead, with knowledge and time on our side.

Signet-ure Experience

Innophos

DICALCIUM PHOSPHATE ANHYDROUS
- A-TAB - Granular, Directly Compressible
- CALIPHARM A - Milled Powder

DICALCIUM PHOSPHATE DIHYDRATE
- DI-TAB - Granular, Directly Compressible
- CALIPHARM D - Milled Powder

TRICALCIUM PHOSPHATE ANHYDROUS
- TRI-TAB - Granular, Directly Compressible
- CALIPHARM T - Milled Powder
- VERSACAL MP - Micronized Powder

CO-PROCESSED CALCIUM PHOSPHATES
- NUTRA TAB - Granulated TCP with Guar Gum
- A-TAB MD - DCP Anhydrous with Maltodextrin
- TRITAB PVP - TCP Anhydrous with Povidone

MINERAL AMINO ACID CHELATES

Signet

The Complete Excipients Company

A Publication of
Indian Drug Manufacturers' Association
102-B, 'A-Wing', Poonam Chambers,
Dr. A.B. Road, Worli, Mumbai - 400 018
Tel : 022-2494 4624 / 2497 4308 **Fax:** 022-2495 0723
e-mail: publications@idmaindia.com/
actadm@idmaindia.com/ website: www.idma-assn.org

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

Annual Subscription
₹ 1000/- *(for IDMA members)*
₹ 2000/- *(for Government Research/Educational Institutions)*
₹ 4000/- *(for non-members)* **US$ 400** *(Overseas)*
Please send your payment in favour of
Indian Drug Manufacturers' Association

IDMA BULLETIN

Vol. No. 53 **Issue No. 37** **01 to 07 October 2022**

IDMA ACTIVITIES:

DPIIT MATTERS:

INDIAN PHARMACOPOEIA COMMISSION:

NATIONAL NEWS:

IDMA Secretariat (Mumbai) Celebrates Dussehra

IDMA Secretariat Mumbai office celebrate Dussehra with Pooja and Get-together on 4th October 2022

• • •

IDMA-GSB Jointly with IPA-GSB and LMCP Organized Program on Hindi Pakhwada

IDMA-GSB jointly with IPA-GSB and LMCP organized program on Hindi Pakhwada on 17th September 2022 following Hindi Diwas which is celebrated in India on 14th September. On this day Hindi language was accorded the status of National Language in 1949 by the Constitution of India.

The specific topic of discussion for this event was पानी, प्रदूषण और प्रगति (Water, Pollution and Progress)

Dr. Jayant Dave welcomed the guests and conveyed the importance of the day. He also briefed about the **'World Patient Safety Day'** which is celebrated on 17th September and theme at this day was Medication safety.

Dr. Shrenik Shah appreciated and thanked the speakers and Organizers. He said that this is the first time when the program is entirely conducted in Hindi.

Prof. Ramgopal Singh gave an exhaustive account of Hindi language with reference to Constitution of India and related enactment by State assemblies.

Shri Jagat Kinkhabwala made an interesting presentation on world of birds particularly sparrows and coexistence of species on Earth planet.

Shri Mahesh Pandya threw light on technical aspects of common effluent treatment plants and ecological fallouts of large dams.

Shri Tushar Pancholi gave practical tips on water conservation and small check dams.

Shri Gaurang Oza, Rajnibhai Mehta, Shri Sumit Agrawal and Dr. Mahesh Chhabria were also among the speakers who addressed the program.

The event was attended by the good number of students, faculty and industry personnel and who were benefited from the deliberations.

Dr. Sunita Goswami presented a cordial vote of thanks and she also appreciated and thanked Ms Sakshi and Ms Jsitri, (M-Pharm students) who helped in organizing the program.

● ● ●

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)
102, Poonam Chambers, A Wing, 1st Floor, Dr. Annie Besant Road, Worli, Mumbai - 400 018. Maharashtra, India. Tel: +91-22-24974308 / 24944624 Email: actadm@idmaindia.com Website: www.idma-assn.org

REGISTER NOW

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

REGISTER NOW

Organizes

Symposium on Nasal and Pulmonary Drug Delivery

Hotel Sofitel, BKC, Mumbai,
November 10 & 11, 2022

Indian Drug Manufacturers' Association (IDMA) is proud to present the Two-Day **"Symposium on Nasal and Pulmonary Drug Delivery"** on Thursday, 10th & Friday, 11th November 2022 at Hotel Sofitel, BKC, Mumbai.

The Indian Pharmaceutical Industry is showing increasing interest in developing **orally inhaled and nasal products (OINDP)** compared to conventional dosage forms as they provide significant benefits to patients, including minimal systemic exposure, faster onset of action, and broader options for disease management. New therapeutic agents such as proteins, peptides and nucleic acid based agents are being developed every year, making it vital to find a non-invasive route such as nasal or pulmonary for their administration.

These developments represent significant opportunities for pharmaceutical companies, provided they choose delivery systems that adequately "partner" each drug during its development.

Nasal and pulmonary delivery are non-invasive routes of administration that target the delivered dose directly to the site of drug action. Drug delivery to the respiratory area can also be used for systemic delivery of peptides and proteins due to the large surface area for drug absorption.

Nasal and pulmonary drug delivery systems are used for local and systemic treatment of diseases such as asthma, chronic obstructive pulmonary disease (COPD), rhinitis, migraine and many more. New inhalation products are being developed for non-respiratory disease indications, e.g. diabetes, which would allow patients to avoid more intrusive medical treatments. Drug delivery device used in these products is far more than an instrument for the administration of the formulation.

The device is part of the primary packaging, is part of the container closure, and is the vehicle to transport successfully the active medicine to the target. During the dispensing act the responsibility of the effect of the therapy switches to the device. Delivery devices for nasal and pulmonary applications require additional particular attention during development and production as their performance characteristic and reliability has a crucial impact on the efficiency of the nasal or pulmonary delivery to the target site.

Request members to kindly register and attend this Symposium along with their concerned personnel.

The Registration fee for the same would be as follows: -

- **Delegate - Rs.12,000 + GST @ 18% per Delegate**
- **Student - Rs.6,000 + GST @ 18% per Student**

** Early bird discounts - Before 21st October 2022:* ***10% discount***
** Group registration benefits (for 3 or more):* ***15% discount***

RTGS Details:
Account Holder's Name: **Indian Drug Manufacturers' Association**
Current Account Number: **76080200000242**
Bank: **Bank of Baroda**
IFSC Code: **BARB0DBWORL**
Branch: ***Worli, Mumbai 400 018***

For any further clarifications / assistance, please feel free to call :
Ms. Sapna Patil - (9619802299 / **admin@idmaindia.com**) &
Mr. Melvin Rodrigues (9821868758 / **actadm@idmaindia.com**)

We would be forwarding more information on this symposium at the earliest.

Thanks & regards,
Daara B Patel
Secretary – General

REGISTRATION FORM

To,
The Secretary General
Indian Drug Manufacturers' Association
102/B, A Wing, Poonam Chambers, Worli, Mumbai 400 018.
Tel. # 022 - 24974308 / 24944624
E-mail: admin@idmaindia.com / actadm@idmaindia.com

Date:

Dear Sir,

Symposium on Nasal and Pulmonary Drug Delivery
Hotel Sofitel, BKC, Mumbai | November 10 & 11, 2022

Kindly register the name/s of the following person/s from our company to participate in the above programme: -

SR. NO.	NAME	DESIGNATION	MOBILE NOS.	EMAIL
1				
2				
3				
4				
5				

Our Cheque/ DD / RTGS details :_____ dated _____for

Rs._____ is enclosed.

Thanking you,

Yours faithfully,
(Name & Designation)

Name of the Company_____

Address _____

_____

Tel No. :_____ Fax No. : _____ E-Mail:_____

The Registration fee for the same would be as follows: -
- **Delegate - Rs.12,000 + GST @ 18% per Delegate**
- **Student - Rs.6,000 + GST @ 18% per Student**

** Early bird discounts - Before 21st October 2022:* ***10% discount***
** Group registration benefits (for 3 or more):* ***15% discount***

RTGS Details:
Account Holder's Name: **Indian Drug Manufacturers' Association**
Current Account Number: **76080200000242**
Bank: **Bank of Baroda**
IFSC Code: **BARB0DBWORL**
Branch: **Worli, Mumbai 400 018**

DPIIT invites suggestions to enhance Ease of Doing Business and Ease of Living

Sahaj Karobar avam Sugam Jeevan Hetu Sujhav

About

Government of India is committed to improve Ease of Doing Business and Ease of Living across the country. Multitude of reforms have been implemented over the last few years to improve Government's interface with businesses and citizens. In the Amrit kaal of Independence, Government is marching ahead rapidly to create a transparent system, efficient process and smooth governance to make development all-round and all-inclusive.

Objective

DPIIT is inviting suggestions from businesses and citizens to enhance Ease of Doing Business and Ease of Living focusing on what kind of problems are faced in starting and running a business. Also, minor violations under which Provisions/Sections of the Acts/Rules are to be decriminalized. The aim is to make 'New India' a preferred investment destination across the globe and ensure hassle-free service delivery to the ultimate beneficiary.

Participating Guidelines

Participants have to share suggestions, related to issues faced by businesses or citizens, across categories. Information across fields is to be provided by selecting correct option from drop-down menu, wherever available. Suggestions are to be submitted in a clear and concise manner along with selection of correct Department of a Central Ministry or a State/ Union Territory. Participants need to fill separate forms for submitting different suggestions across different categories or Government Departments.

Problem Domains

Following are the broad areas for which suggestions may be submitted to improve *Ease of Doing Business and Ease of Living:*

- Getting Certificates, Licenses, Permissions, Approvals
- Renewal of Certificates, Licenses, Approvals
- Decriminalization of minor offences
- Filings/Returns
- Inspections/Audits
- Online systems/process
- Maintaining Registers & Records
- Applying for Incentives
- Payment of Incentives
- Procedural/Guidelines related
- Payment mechanism
- Others

Timelines

Start Date	29th September 2022
Last date	15th October 2022

Terms and Conditions

- All businessmen and aspiring entrepreneurs, who have invested in India or planning to invest in India, and Indian citizens may participate
- **Incomplete and incorrect** forms will not be considered
- All entries obtained through unauthorized sources or which are incomplete, illegible, mutilated, altered, reproduced, forged, irregular, or fraudulent in any way or otherwise not in compliance with the rules are automatically void
- Once a suggestion is submitted, DPIIT may correspond with the participant for supplementary information, if necessary
- Organizers reserve the right to cancel the campaign or modify the rules, dates of the campaign anytime. The Organizers shall have no liability whatsoever for any inconvenience/loss directly or indirectly caused to any Participant due to such modification of rules/cancellation of campaign and the participants

shall accordingly not be entitled to raise any claims pertaining to the same

- The organizers reserve the right to select or reject any submission without assigning any reasons whatsoever and without thereby incurring any liability to the participant(s) whatsoever.
- Once the participants have made submissions on the platform, they shall have no claim even in the event of stoppage/cancellation of the competition.
- If any question, dispute or difference arises between the applicant and DPIIT, then the decision of Secretary, DPIIT is final and binding

Note: Members are requested to visit ***https://innovateindia.mygov.in/suggestion-box/*** *for detail information*

● ● ●

IDMA BULLETIN SUBSCRIPTION FORM

Date : _____

To
The Subscription Department
Indian Drug Manufacturers' Association ,
102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai – 400 018, India.
Email: admin@idmaindia.com /accounts@idmaindia.com / Web: www.idma-assn.org

Kindly enter my subscription to **"IDMA Bulletin".**

The details are as follows:

Name of the subscriber ……

Current institutional attachment ……

Designation ……

Delivery Address ……

City …… Pin code ……State ……

Country ……Phone no. (with STD/ISD code) …… E-mail address ……

Subscription details

Subscription Period: One year

Subscription Type: India / Foreign

Subscription starts from: Month …… Year……

Payment details

Cheque No …… Dated …… Drawn on ……Amount ……Date: ……

Signature of the subscriber

Annual subscription rates:

India (INR)

Members	Government Research/Educational Institutions	Non-Members
1000	2000	4000

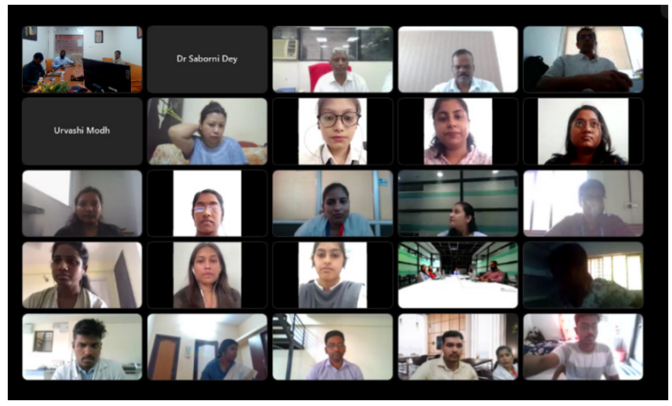
Overseas (US$) :-

Individual
USD 400

Kindly note: *IDMA Bulletin* is Published on 7th, 14th, 21st and 30th of every Month.
(IDMA GSTIN:27AAATI3594D1ZO)

- Subscriptions are for calendar year only
- Please return the filled form to the above mentioned address.
- Cheque should be issued in favour of "Indian Drug Manufacturers' Association", payable at Mumbai.
- Please allow at least two weeks for commencement of new subscription.
- Claims for missing issues can be made only within fifteen days of publication

22nd Skill Development Programme on Pharmacovigilance of Medical Products



The National Coordination Centre for Pharmacovigilance Programme of India (NCC-PvPI) located at Indian Pharmacopoeia Commission Ghaziabad, organized the 22nd Skill Development Programme on Pharmacovigilance for Medical Products from 12th to 16th September, 2022 through virtual mode. The training started with welcome address by Dr. Jai Prakash, Officer-in-Charge, PvPI. He extended his warm greetings and best wishes to all the participants on behalf of IPC.

A total of 131 registered participants from Bihar, Andhra Pradesh, Assam, Chandigarh, Chhattisgarh, Gujarat, Delhi, Haryana, Karnataka, Kerala, Madhya Pradesh, Maharashtra, Puducherry, Punjab, Tamil Nadu, Telangana, Uttar Pradesh, Uttarakhand, West Bengal, Jharkhand, Rajasthan, Sikkim participated in this training programme. The participants included Associate Professor/ Assistant Professor/ HOD's, Students (B Pharm, Pharm D, MBBS), Industry Professionals, Doctor/ Dental Surgeon, Pharmacist across the country. Dr. Shashi Bhushan, Dr. R. S Ray, Mr. Hammad Ali, Mr. Akash Deep Rawat, Mr. Tarun Kumar from NCC PvPI supported during the workshop.

During the 5 days Skill Development Programme, 19 technical sessions were conducted on various topics of Pharmacovigilance including Basics of Pharmacovigilance to in-depth Signal detection method and Regulatory intervention/outcomes in an understandable language to the participants. All participants appreciated the Skill Development Programme.

Note: Please visit IPC website (www.ipc.gov.in) for regular updates.

● ● ●

NPPA fixes prices of 40 new drugs

The National Pharmaceutical Pricing Authority (NPPA) has fixed the retail price of 40 new drugs including generic fixed dose formulations of diabetes drugs dapagliflozin and sitagliptin, among others.

Some of these drugs include those used to treat high blood pressure, certain kinds of cancers, bacterial infection and bone pain and joint pain.

The Authority discussed retail price fixation of 42 new drugs and approved 40 of them, except for two formulations on which the marketers made representation on the retail price recommended by the Multidisciplinary Committee of Experts. The products, for which the retail prices were fixed include dapagliflozin and metformin hydrochloride (extended release) tablets marketed by Macleods Pharmaceuticals, Glenmark Pharmaceuticals and Abbott Healthcare, as per the notification issued by the NPPA.

Retail price for sitagliptin and metformin hydrochloride (as extended release) tablets marketed by MSN Laboratories, Sun Pharma Laboratories, Macleods Pharmaceuticals, and Wockhardt Ltd have also been fixed. Out of the 42 formulations, pantaprazole powder for oral suspension (sodium bicarbonate as buffer) from Alkem Laboratories and lidocaine patch 5 per cent from Hetero Healthcare were not fixed by the Authority during the meeting, sources said.

Alkem Laboratories and Hetero Healthcare made representations to the Authority on the retail price recommended by the Multidisciplinary Committee of Experts (MDC) in its last meeting held on September 13, 2022, and the Authority deliberated upon the matter in detail and decided to refer the matter to the MDC for examination of the representation, said the sources.

The Authority meeting held on September 27, also fixed the retail price of dextrose injection 25% w/v in 100 ml in specific container, mannitol injection 20 gm per 100 ml in 100 ml pack in special package, Metronidazole Injection IP 500 mg/100 ml in 100 ml pack with special packaging and from Axa Parenterals.

It has also extended the ceiling price of sodium chloride injection 0.9 per cent in 500 ml with special feature packaging, glucose injections 5 per cent in 500 ml non glass with special features with euro head, and ringer lactate injection in special packaging among others for Puerto Life Sciences Pvt Ltd, dextrose injection 5 per cent in 500 ml pack with packaging in non glass with special features with brand 'Safe Port' from Sachin Parenteral, among others, during the meeting, said the sources.

Source: Pioneer News Service, 05.10.2022

● ● ●

Should free medicine samples be kept outside the purview of Income Tax?

Pharma companies have some valid points to argue to CBDT to exclude free medicine samples from ambit of Section 194R of I-T Act; Govt should consider them with deserving seriousness

If it is brought under tax net, the doctors may refuse to provide their PAN number to the pharmaceutical companies or even receive any such free samples from the companies. If the doctors refuse to receive free medical samples from the pharmaceutical companies, it will be extremely challenging for any company to introduce new drugs into the market or test its efficacy or even increase knowledge about their products in the market

The pharmaceutical companies in the country have recently knocked at the door of the Central Board of Direct Taxes (CBDT) to keep free medicine samples provided by them to the medical practitioners and hospitals outside the purview of Section 194R of the Income Tax Act-1961 as the same does not benefit them. Section 194R, which came into effect from July 1, 2022, provides for tax deduction at the rate of 10 per cent of the value or aggregate of value of any benefit or perquisite, whether convertible into money or not, provided to a resident arising from carrying out of a business or exercising of a profession by such resident.

The pharmaceutical companies are arguing that the free medical samples provided to hospitals or doctors are not benefits or perquisites in the hands of doctors. Such free medical samples are statutorily required to be used by the doctors for clinical evaluation purposes or testing the efficacy of the medicines by giving them to patients free of cost and cannot be sold or monetized by them.

Accordingly, such free medical samples are not consumed by the doctors for any personal benefit nor they can earn any income by selling such samples to the patients. Such free medical samples are passed on to the patients free of cost and the benefit, if at all any, is accruing to the patients which cannot be subjected to TDS under Section 194R as such benefit is not arising to the patients from any business or profession.

Of course, the pharmaceutical companies have made some valid points to drive home some hard facts. The receipt of free medicine samples is not treated as taxable income under Section 28(iv) of the Income Tax Act for the doctors as the said samples are not consumed by them and in fact is passed on to the patients or discarded in other cases. Besides, providing samples of pharmaceutical products is not prohibited under either the Indian Medical Council (Professional Conduct, Etiquette and Ethics), Regulations 2002 (MCI Code) or the Uniform Code of Pharmaceutical Marketing Practices (UCPMP) released by the Department of Pharmaceuticals in 2014. So, if it is brought under tax net, the doctors may refuse to provide their PAN number to the pharmaceutical companies or even receive any such free samples from the companies. If the doctors refuse to receive free medical samples from the pharmaceutical companies, it will be extremely challenging for any company to introduce new drugs into the market or test its efficacy or even increase knowledge about their products in the market. Such measures in turn will impact the patients and humanity at large and therefore should be addressed at the earliest. Alternatively, if the TDS is grossed up by the pharmaceutical company, then it will significantly increase the additional cost burden on the industry which may in turn lead to increase in the price of the medicines and therefore again have an impact on the patients and humanity at large. It is common knowledge that free sample of medicines supplied to doctors is done for promotion of the product of the pharmaceutical company. When a new product is launched, the doctors through the free sample provided, test the efficacy of the new drug launched in the market, give necessary inputs regarding the use and effectiveness etc. of the product. Provision of free samples help impart knowledge to other doctors about the new medicine/product coming into the relevant practice of their profession.

Therefore, distribution of free samples is directly related to business promotion activity of the pharmaceutical company and no benefit or perquisite arises to the doctors from such samples. Another valid point is that UCPMP prescribes guidelines under which medical samples should be dispensed which ensure that they are used strictly for clinical evaluation purposes and each sample shall be marked "free medical sample – not for sale".

Even the draft Uniform Code for Medical Device Marketing Practices (UCMDMP) published for stakeholder consultation on March 16, 2022 lays down guidelines to ensure that medical devices are distributed as samples for evaluation purposes only. The Drugs and Cosmetics Rules, 1945 also recognizes the practice of providing drugs for distribution to medical professionals as a free sample by providing specific labelling requirements, requiring such samples to be labelled with the words 'Physician's Sample – Not to be sold." Now that the pharmaceutical companies have driven home their points, the government should consider them with the deserving seriousness.

(The author is freelance journalist with varied experience in different fields)

Source: Sreeja Ramesh, Bizz Buzz, 05.10.2022

● ● ●

Govt may form dedicated units to build expertise in FTA areas

India is in trade talks with the UK and EU. Bloomberg

NEW DELHI : Taking a more aggressive approach to free trade deals, the department of commerce is considering setting up 'subject matter divisions' to develop expertise in areas like services, agriculture, pharmaceuticals, trade remedies and digital trade. The move is aimed at enabling India to negotiate deals from a position of strength with partner countries and at the World Trade Organization.

It is also looking at bringing on board sector specialists, including from the private sector, who will give their insights and expertise during negotiations. The outline of

the proposal is to strengthen the negotiation infrastructure with right the expertise, robust end-to-end processes and clearly defined focus. "The aim is to participate in negotiations fully prepared. With the free trade agreements being comprehensive nowadays, it is important to have experts from different domains, who have insights. So it is important to bring in people, if required, from outside the bureaucracy," said a government official.

"Whichever is the country, especially if you talk of developed countries, they bring specialists to the negotiation table. They have experts in services, goods or agriculture coming for talks. There is a realization that it shouldn't be the case that an officer is negotiating a deal for India who has no subject knowledge," said the official.

While India has signed a free trade agreement with the UAE and an interim deal with Australia, it is in talks with the UK, EU, and Canada for a comprehensive FTA.

Experts welcomed the move but said it could only work if there's a clean break with business-as-usual. "Getting subject-matter experts is a step in the right direction, but the problem is, will it be implemented? Private sector experts will always give practical approaches but bureaucracy always tends to complicate things. And they are people who will take the decision," said Vijay Kalantri, chairman, MVIRDC World Trade Centre, Mumbai.

"The crucial thing is that the people who will be brought should be independent. World over—in US, UK—economic reforms took place and young experts from the industry were made heads of the regulatory body. In India retired bureaucrats are made heads of the regulatory body. How will a person from the same system bring change?" The ministry is also looking at evolving separate negotiating teams for bilateral and multilateral agreements. Queries emailed to the department of commerce remained unanswered.

Source: Dilasha Seth & Ravi Dutta Mishra, HT Mint, 06.10.2022

● ● ●

Healthtech by the Horns


David J Shulkin

With India's leadership in technology-based companies, abundant talent in medical science and the growing number of healthcare startups — now numbering over 7,000 it is poised to become a world leader in digital health and medical innovation. GoI's plans to establish a national digital health ecosystem holds real promise for significant impact in both the domestic and world-wide markets.

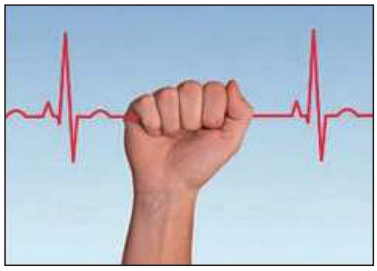
The National Health Authority (NHA) has set out to create an open, interoperable platform to allow government and private health providers to contribute digital resources. The objective of this effort is to allow the sharing of clinical data, use of information being input from new medical technologies, integration of payments and the ability to address identity, privacy and security concerns for sensitive data. The potential significance of such a system is large. India could further its progress in decreasing health disparities in rural parts of the country; address future public health emergencies, support additional efforts in preventive care and allow for more integrated care delivery across diverse groups of healthcare providers.

It is also likely that this interoperable platform will advance efforts in drug discovery and add to our knowledge with real-world evidence and outcomes data. Also, such a robust source of data could support discovery, innovation and commercial development within the healthcare and life sciences industries. Commercial innovation is often as important as introducing new medical products when it comes to improving healthcare accessibility and affordability.

Yet, the challenges are real. As the ninth US secretary of the Department of Veterans Affairs (VA), I oversaw the largest integrated health system for our country's war heroes. One of the biggest challenges I faced was establishing the interoperability for medical records of veterans who sought care both within and outside VA. Even while overseeing VA, as a practising physician, I would care for veterans in rural parts of the US using telehealth equipment from my office in WasIthigton DC.

The US Department of VA has invested significantly in virtual care, digital health and an interoperable health system. During the height of the pandemic, VA was seeing more than 40,000 veterans using telehealth. It has an electronic health record system that supports more than 9 million veterans. VA has also used its data systems to enable predictive analytics, remote monitoring and artificial intelligence (AI)-based tools.

Yet, even with a budget of close to $300 billion a year, VA has often struggled in achieving its goal of interoperability of data. The US Congress first directed the Departments of VA and of Defence to create an interoperable electronic health record system in 2007 as part of the National Defence Authorisation Act.



Seamless opportunity

Fifteen years later the departments are still struggling to achieve this.

Recently, the offices of the inspector general of both agencies released a report detailing many remaining challenges. VA's planned goal to achieve a fully integrated electronic health record is not until 2028. Even that date seems daunting to some stakeholders.

The challenges of building interoperability and optimising digital health data at scale in VA should provide lessons for India. We learnt that it is important to determine upfront the data elements and healthcare information that constitutes a complete set of health data. We also learnt that there must be detailed plans to deal with legacy systems and in creating functioning interfaces with disparate medical devices.

Finally, some of the most daunting challenges do not involve technology as regulatory issues are often as significant. Balancing the need for access to data with security and privacy needs, and establishing regulatory approvals for digital health tools and professional standards for medical practice across regions should not be overlooked.

Cooperation between the US and India should be of significant benefit to both countries. The US has had significant experiences in the development of large data infrastructum projects and in public-private partnerships. India has the advantage of being able to learn from what worked for the US and other countries that have made considerable progress, but have also identified real barriers.

A successful effort by India will require collaboration between government, regulators, pharmaceutical manufacturers, payers and providers that create new public-private partnerships. Mostly, however, this will require India's commitments and the understanding that this is going to be a marathon and not a sprint.

The writer is former secretary of veteran affairs, US.

Source: ET, 04.10.2022

● ● ●

These scientists found a way to join molecules like building blocks

Barry Sharpless, Morten Meldal & Carolyn Bertozzi Won the 2022 Chemistry Nobel Prize for Their Work on Click Chemistry, A Simple And Efficient Way to Create Complex Molecules

MAKING CHEMISTRY MORE FUNCTIONAL

In pharmaceutical research, making complicated molecules can be an expensive and time-intensive process. Building molecules in a lab can require many steps, produce unnecessary by-products, and waste precious materials. Conventional methods can work at smaller scales for testing or clinical trials but become inefficient in largescale manufacturing.

To solve this problem, Karl Barry Sharpless, an American chemist at Scripps Research, developed a minimalistic form of chemistry in which molecular building blocks can quickly and efficiently snap together — he called it “click chemistry”.

Sharpless, who also won the prize in 2001 and is the fifth person to win twice, found that instead of forcing carbon atoms — the building blocks of organic matter — to bond with each other in the process of building molecules, it’s easier to link smaller molecules with complete carbon frameworks.

The central idea is to choose simple reactions between molecules that have a “stronger intrinsic drive” to bond together, resulting in a faster and less wasteful process. Even if click chemistry is unable to perfectly imitate naturally occurring molecules, it can still build modular molecules that serve the same purpose.

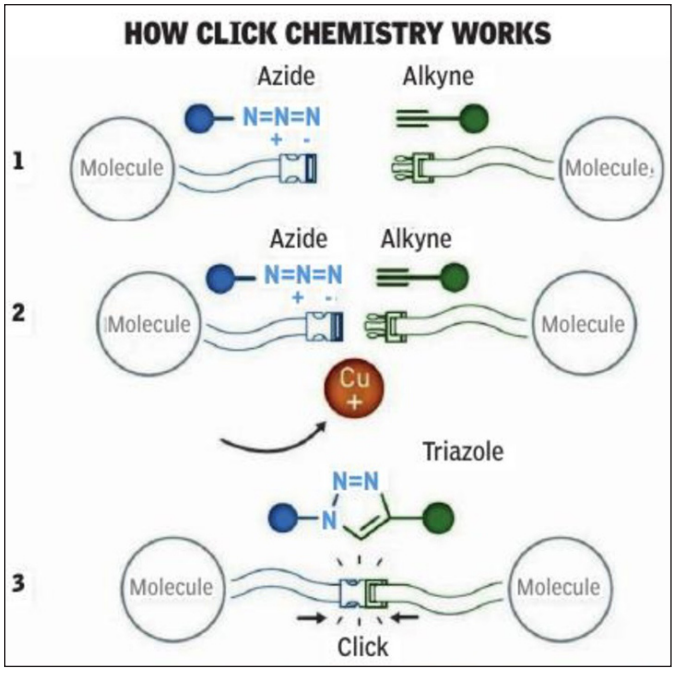
At around the same time in the early 2000s, Danish chemist Morten Meldal and Sharpless developed a technique that is now the “crown jewel” of click chemistry — the copper catalysed azide-alkyne cycloaddition. While investigating new pharmaceutical materials, Meldal found that adding copper ions to a reaction between an alkyne and an acyl halide unexpectedly created atriazole, a stable ring-shaped chemical structure that’s a common building block in pharmaceuticals, dyes and agricultural chemicals.

The alkyne ended up reacting with the wrong end of the acyl halide molecule, creating a chemical group known as

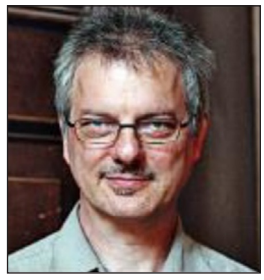
azide at the other end. Together, the alkyne and the azide combined to make a triazole.

Until then, researchers had been unable to manufacture triazoles without creating unwanted by-products. But Meldal found that the addition of copper ions helped control the reaction and create just one substance. Sharpless called it the "ideal" click reaction.

Now, when chemists want to combine two different molecules to make a new one, they only need to attach an azide molecule to one and an alkyne molecule to the other, which then snap together in the presence of copper ions. Click chemistry's applications go far beyond research labs — its industrial potential is immense. Already, click chemistry is used to manufacture new, purpose-built materials. For instance, adding a clickable azide to a plastic or fibre could allow manufacturers to later "click in" substances that can conduct electricity or fight bacteria.



Carolyn Bertozzi



Morten Meldal

Barry Sharpless

CLICK CHEMISTRY CAN HELP FIGHT CANCER

While researching glycans, an elusive type of carbohydrate found on the surface of cells that is crucial to the immune system, Stanford University's Carolyn Bertozzi — the eighth woman to win the prize — found that she did not have the right tools to study them. Bertozzi wanted to attach fluorescent molecules to glycans so they could be easily spotted.

She found a way to attach "chemical handles" to glycans for the fluorescent molecules to latch on to. But she needed a "bioorthogonal reaction" in which the handle did not react with any other part of the cell. Bertozzi turned to the same azide used by Sharpless and Meldal to serve as the handle. The azide not only avoids interacting with other parts of the cell, but it's also safe to introduce in living beings. As the importance of azides grew with the prominence of click chemistry, Bertozzi realised that her bioorthogonal reaction had more potential. In 2004, she developed an alternate click chemistry reaction that worked without toxic copper, making it safe for living cells.

Bertozzi's work is already being used to identify glycans on the surface of tumour cells and block their protective mechanisms that can incapacitate immune cells. This method is currently in clinical trials for people with advanced cancer. Researchers have also begun developing "clickable antibodies" that can help track tumours and accurately deliver doses of radiation to cancer cells.

Source: The Times of India, 06.10.2022

● ● ●

IDMA PUBLICATIONS RATE CARD

Sr. No.	Name of Publications	Cost in ₹
1.	**IDMA BULLETIN (Annual Subscription – 48 Issues)** *(Published on 7th, 14th, 21st and 30th of every month)*	
	• Members	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
2.	**INDIAN DRUGS (Annual Subscription – 12 Issues)** *(Published on 28th of every month)*	
	• Members	1000/- p.a
	• Students	1000/- p.a.
	• Government Research / Educational Institutions	2000/- p.a.
	• Non-Members	4000/- p.a.
3.	**IDMA APA Forum**	
	• Annual Membership	500/-
	• Life Membership	5000/-
4.	**TECHNICAL MONOGRAPHS**	
	NO. 1: STABILITY TESTING OF EXISTING DRUG SUBSTANCES AND PRODUCTS	400/-
	NO. 2: PRIMARY & SECONDARY CHEMICAL REFERENCE SUBSTANCES	400/-
	NO. 3: INVESTIGATION OF OUT OF SPECIFICATION (OOS) TEST RESULTS	400/-
	NO. 4: PHARMACEUTICAL PREFORMULATION ANALYTICAL STUDIES	400/-
	NO. 5: ENVIRONMENTAL MONITORING IN CLEANROOMS	400/-
	NO. 6: CORRECTIVE/PREVENTIVE ACTIONS (CAPA) GUIDELINE	400/-
	NO. 7: DATA INTEGRITY GOVERNANCE	400/-
5.	**TECHNICAL DOCUMENT** QUALITY 4.0 DIGITAL TECHNOLOGY OF THE FUTURE	500/-
6.	**IDMA MEMBERSHIP DIRECTORY**	1,500/-
7.	**IDMA ANNUAL PUBLICATION**	1,500/-

KINDLY NOTE:

- *Mailing of IDMA Bulletin and Indian Drugs by Post will commence prospectively only after receipt of payment.*
- *All payments may be made in advance by Cheque / DD / RTGS / NEFT only in favour of:* ***"Indian Drug Manufacturers' Association".***

  For RTGS/NEFT: Name: BANK OF BARODA, **Branch:** Worli, **Name of Account Holder:** INDIAN DRUG MANUFACTURERS' ASSOCIATION, **Account No.** Current A/c 76080200000242, **IFSC :** BARB0DBWORL, **MICR CODE :** 400012332
- Courier charges for Publications under Serial Nos. 4 to 7 will be extra as applicable.
- Please intimate us details through email immediately after making the remittance through RTGS/NEFT, so as to enable us to do the needful promptly.
- GST will be charged extra, as applicable.

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, "A"-Wing, Poonam Chambers, Dr A B Road, Worli, Mumbai 400 018.Tel: 2494 4624 / 2497 4308 Fax: 022- 2495 0723
Email: admin@idmaindia.com/publications@idmaindia.com, Website: www.idma-assn.org / www.indiandrugsonline.org

IDMA BULLETIN

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

ADVERTISEMENT TARIFF

(Effective from 01.11.2017)

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

Position		Rate per Insertion ₹	
		B/W	Colour
Full Page (18 cm wd x 23.5 cm ht)	:	9,000	12,500
Half Page (18 cm wd x 11.5 cm ht) (Horizontal)		5,000	8,500
Half Page (8.5 cm x 23.5 cm) (Vertical)	:	5,000	8,500
Quarter Page (8.5 cm wd x 11.5 cm ht)	:	2,500	6,000
Strips Advts (4 cm ht x 18 cm wd)	:	2,500	-
Inside Cover Pages	:	-	18,000
Back Cover	:		25,000
Centre Spread (double spread) Print area (40cm wd x 27cm ht)	:	25,000	30,000

Terms and Conditions:

- All payments by **Cheque/ Demand Draft/RTGS** in advance only to be made in favour of **"Indian Drug Manufacturers' Association", Payable at Mumbai**

  The RTGS details are as follows:- BANK: BANK OF BARODA

  Account Name : ***Indian Drug Manufacturers' Association,*** *Bank A/c No. : Current A/c* ***76080200000242***

  Bank : ***BANK OF BARODA,*** *Branch Address : Worli Branch, Mumbai-18,* ***IFSC : BARB0DBWORL***

  MICR CODE : 400012332
- GST will be charged extra, as applicable. *(Current Rate is @5%)*
- SPECIAL DISCOUNTS for Series Advertisements
- For colour advertisements, positives to be supplied otherwise processing charges to be paid.
- **Advertisement material must reach us 7 days before the date of publication.**
- Positioning of the Advt other than Cover Positions will be at our discretion.
- Only Colour Advts will be entertained on Cover Positions.

Classified Advertisements

- Upto 80 words — ₹2,000/-
- 50% extra for Advt Box Number
- 50% extra for indent/layout spacing, bold captions, etc.
- ₹50/- extra for voucher copy
- Series discount not applicable for classifieds

For further details such as series discounts etc, please contact:
Melvin Rodrigues — Cell: +9821868758 (Email: actadm@idmaindia.com)/
Geeta Suvarna — — Cell: +9820161419 (Email: publications@idmaindia.com)

PUBLICATIONS DIVISION

INDIAN DRUG MANUFACTURERS' ASSOCIATION

102-B, Poonam Chambers, Dr. A. B. Road, Worli, Mumbai 400 018. Tel: 022-2494 4624/2497 4308 Fax: 022-2495 0723
Website: **www.idma-assn.org/www.indiandrugsonline.org**

LICENSED TO POST WITHOUT PREPAYMENT
LICENCE NO. MR/Tech/WPP-337/West/2021-23
RNI REGN. NO. 18921/1970, REGN.NO.MCW/95/2021-23
Published and Posted on 7th, 14th, 21st and 30th of every month
This issue posted at Mumbai Patrika Channel Sorting Office on 07.10.2022

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