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Impact of Digitization on the Pharmacy Practice Settings on the International Landscape ...... II

Transformation of Herbal Drug Discovery and Development Progression by Joining the Hands 





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# Editorial Calendar for 2021 -22

Theme Based Special Issues	Month
Nutraceuticals	March 2021
Ethnomedicine	July 2021
Excipients	November 2021
Health Economics & Outcomes Research	February 2022







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# Contents





	Impact of Digitization on the Pharmacy Practice Settings on the International Landscape Amy Hai Yan Chan School of Pharmacy, University of Auckland, New Zealand Professional Development and Research lead, Commonwealth Pharmacists Association, London, UK	.11
Ð	Emerging Roles of Sports Pharmacist in the Health Management of Athletes Sivakumar Kannan <sup>1</sup> , Anup Naha <sup>1*</sup> , Robindra Ramnarine Singh <sup>2</sup> , Punit Bansal <sup>3</sup> , Vinod C Nayak <sup>4</sup> , Sandeep Goud <sup>5</sup> Department of Pharmaceutics, Manipal College of Pharmaceutical Sciences, Manipal, Karnataka	.13
)	Transformation of Herbal Drug Discovery and Development Progression by Joining the Hands with Artificial Intelligence Neelesh Malviya <sup>1</sup> , Rajiv Saxena <sup>1</sup> , Ruchi Gupta <sup>1</sup> , Archana Patidar <sup>1</sup> , Yashu Chourasiya <sup>1</sup> , Smriti College of Pharmaceutical Education, Indore	.18

# **Regular Features**

5
7
5, 47
17
26
26
n 27
29
30
31
36
38
39
45
47



### Pharma Times

Official Publication of The Indian Pharmaceutical Association

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# From the Editor's Desk...



Simultaneous and universal access to COVID vaccines is essential; only then can the virus be effectively wiped off the globe. India too, has been playing its part and has committed supplies of the precious life- saving doses to friends and neighbour countries.

### **Dear Readers**,

2021 began with positive news trickling in from many quarters! With nations initiating vaccination drives against the dreaded virus that brought the entire world down onto its knees the entire last year, 'vaccine nationalism' and 'vaccine diplomacy' have occupied centre- stage; hectic parleys for reserving and procuring the vaccine doses have made top-billings in all international dialogues. Just as were getting into press, there was this announcement from Pfizer and BioNTech SE about an advance purchase agreement with COVAX for up to 40 million doses of their vaccine that will be supplied at not-for-profit prices, through 2021. COVAX, as you know, is a global initiative coordinated by the Global Alliance for Vaccines and Immunization (GAVI), the Coalition for Epidemic Preparedness Innovations (CEPI) and the World Health Organization (WHO), to ensure equitable access to COVID-19 vaccines for all countries, regardless of their income levels. COVAX includes an Advanced Market Commitment (AMC) financial mechanism that aims to ensure that the 92 low- and lower-middle-income countries will be able to secure access to COVID-19 vaccines at the same time as higher-income countries, so as to counter the pandemic more effectively. Simultaneous and universal access to COVID vaccines is essential; only then can the virus be effectively wiped off the globe. India too, has been playing its part and has committed supplies of the precious life- saving doses to friends and neighbour countries. Recent reports about the marked surge in COVID-19 infection cases due to the new UK & South African strains has set the alarm bells ringing, especially when effectiveness of the approved vaccines in conferring immunity against the mutant strains remains a big question mark. The mutant strains said to be responsible for the 'second wave' in these regions are reportedly 50 - 75% more infectious, but with no apparent increase in severity of infection, though some recent reports suggest otherwise, with early evidence of possibly increased mortality index.

The much awaited list of companies that have been approved under the Production linked Incentive (PLI) Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs), was released by the Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, last week. The companies that made the cut include Aurobindo Pharma, Karnataka Antibiotics & Pharmaceuticals and Kinvan, with a total committed investment of Rs. 3.761 crore from their end. The government on its part will extend the production- linked incentive for a maximum of Rs. 3,600 crore that will disbursed over a period of 6 years, beginning from April 2023. This tranche is the first of four such packages that are expected to be announced soon. The PLI Scheme mooted in March 2020, with a total government outlay of Rs. 6,940 crore, envisages securing selfreliance in production of KSMs and APIs for pharmaceutical products for domestic as well as export markets.



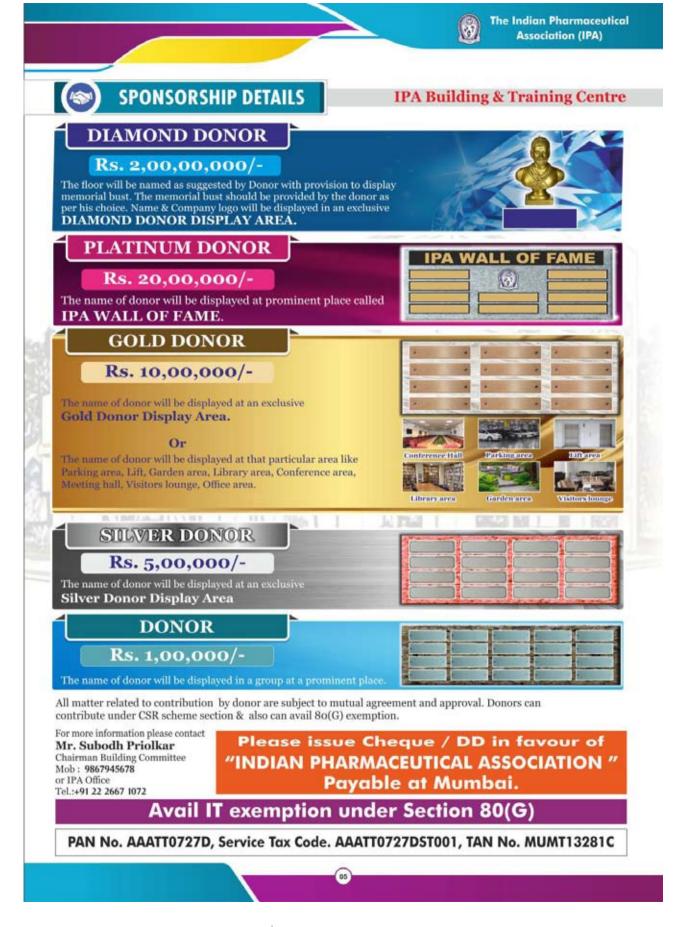
	Editorial Calen	dar for 2021 - 22	
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### **Our Mission**

The Indian Pharmaceutical Association (IPA) is the national professional body of pharmacists engaged in various facets of the profession of Pharmacy. The IPA is committed to promote the highest professional and ethical standards of pharmacy, focus the image of pharmacists as competent healthcare professionals, sensitize the community, government and other on vital professional issues and support pharmaceuticals education and sciences in all aspects.

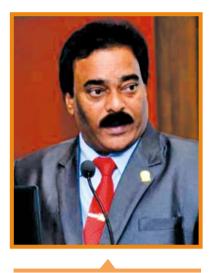
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# **IPA BUILDING SPONSORSHIP OPPORTUNITIES**



# President Speak...





It is imperative for countries to expand their infrastructure and diversify their pathways for vaccination and for pharmacies to commit to playing a central role in vaccination strategies.

### Dear Members,

"Leaders will focus on what's in front of them rather than scrabbling about for what they're searching for"

On behalf of IPA and its members our salutations to Bharat Biotech and Serum Institute for their innovative development of vaccine for COVID-19. IPA salutes the teams who have worked hard to make it possible and incredibly impressed with the tremendous potential and immense contribution in these challenging circumstances. IPA specially congratulates Dr Krishna Ella, CMD of Bharat Biotech for the commendable contribution with his resilient, professional, scientific approach in developing first indigenous vaccine to COVID-19 at affordable cost. During this COVID-19 pandemic period, though our resources showed dependency on imports for masks, PPE Kits, ventilators, testing kits, etc., Bharat Biotech accepted the challenge and developed fully indigenous - COVID 19 vaccine and made a break through despite the short time frame of nine months. I am happy to recollect that the Typhoid Conjugate Vaccine first developed in the world by Bharat Biotech is now saving lives in various countries against the extreme-drug-resistant typhoid bacteria. I wish this pharma and biotech industry will lead the world in new molecule discovery and innovative therapeutic and prophylactic interventions for public healthcare in future. IPA feels that it is extremely proud moment for the entire nation and motivation for many young researchers and scientists.

I am happy to share with our members that our official Magazine, Pharma Times, now a day's e-version coming out with special issues has received several applauds and recognition from all walks of Pharma Profession. I am also happy to share with our members that several organisations are approaching IPA with proposals to organise various collaborative activities and recently IPA has signed several MOU's with different organisations and one such important one is with Logistics Insider as Associate Partner. Logistics Insider is an agency established to bring fresh approach to the news, updates and happenings in the logistics industry. Logistics Insider is coming up with a detailed and researched Knowledge Report on the Indian Cold Chain Market in order to provide logistics industry insights on Indian Cold Chain Market in terms of growth prospects, challenges before the industry in the post-COVID era and how Government is taking initiative to bolster growth and much more. My thanks to Mr. Gaurav Dubey, Co-founder & Lead - Business Development for the collaborative initiative and my compliments to Dr. Alka Mukne, Editor, Pharma Times for bringing the proposal.

It is imperative for countries to expand their infrastructure and diversify their pathways for vaccination and for pharmacies to commit to playing a central role in vaccination strategies. Because of poor cold chain infrastructure, the mock drill of vaccination has to be conducted in phases rather in parallel fashion. The main reason is lack of cold chain warehousing / logistics in sufficient numbers to cater to the nook and corner of the entire nation at large. If the Cold chain infrastructure is not corrected imminently there will be huge

challenges during the actual vaccination process. Management professionals who're specialized in Supply Chain Management and Chemical engineering professionals who're adept in Thermodynamics, Heating Ventilation & Air-Conditioning. Brine Technology, Humidification / Dehumidification process have to work hand-inhand with core pharma professionals while dealing with Cold storage warehousing of pharmaceuticals so that there will be positive transformation in overall infrastructure of Cold Storage throughout the entire country in coming years.By having a good infrastructure of Cold storage warehousing. supply chain / logistics, we can assure quality vaccines and also will be able to achieve 100% effective vaccination of people in a single-stretch instead of phases / priorities and will help to maintain the potency and stability of the drug products throughout the shelf life. Definitely we can see exponential improvements in infrastructure of Cold storage warehousing, supply chain / logistics throughout the country. Since there are multiple players involved with their own vaccine to introduce into the country, it's a boon for the growth of Indian cold chain market.

I am happy to share that all the divisions of IPA are contributing to maximum extent with various collaborative projects, fund raising activities throughout India and contributing immensely to build the brand image of IPA and also contributing towards the dream project of IPA building. I request the members to support the activities of IPA and its divisions and make IPA more visible in their respective state and local branches.

The construction of long awaited IPA building has been completed and only interior work is pending. If everything goes well, the inauguration of the IPA Building will be done in March 2021. I extend my deep sense of gratitude to Pharma institutions, Pharma industries for their voluntary contribution and sponsorship. My sincere appeal to all the IPA members, IPA state and local branches, donors to come forward and contribute towards the fixtures and furniture of the IPA office and building.

thangund.

Dr. T. V. Narayana

# Digital transformation at ACG – smart manufacturing and connected products

ACG, an integrated pharma manufacturer, caters to the complex and evolving needs of the pharmaceutical industry. Its competitive portfolio is built on fostering a culture of digital transformation and innovation with the support of emerging technologies.

ACG proactively tracks latest trends in technology application covering the entire scope of the drug supply chain. As a key intermediary in producing safe and quality medicines, it is looking for ways to conserve investment and manhours spent on removing unpredictable roadblocks, maintenance, human errors and improving overall pipeline and efficiency for its customers.





We're proud to be one of the first adopters of industry 4.0 technology and advocate its applications with our customers and value chain partners. Apart from improving manufacturing efficiency, we are investing in new applications to provide quality and safe drugs. Today, new age technologies like AI, IoT, ML are well integrated into the DNA of all ACG's businesses.

Karan Singh, Managing Director, ACG

# Transforming into a futuristic smart factory

In 2018, new-age technology platforms were introduced at multiple touch points in ACG's biggest capsule site in Shirwal, Maharashtra.



Network of IoT sensors track 'Critical to Quality' parameters such as temperature, volume, speed, etc.



Real-time data from machines and human inputs were collated on a cloud platform



An interoperable technology stack connected data points from different assets and legacy enterprise applications on one platform



Artificial Intelligence (AI) and Machine Learning (ML) technology used to provide insights on multitude of performance factors



Digital platform enabled data visualizing – fluctuations, delays and errors, appeared as red flags



Predictive analytics used to prevent any unplanned downtime

reduction in

energy cost

### **BX** improvement in quality monitoring by instant detection of anomalies

**30%** improvement in On-time

**Business Value** 

Delivery in Full (OTDIF)

increase in capacity utilization driven by

predictive maintenance



process optimization during COVID-19

## Future areas of application:

- Extending industrial IoT platforms to other production lines
- New products by analysing production data and machine utilization
- Trend analysis and predictive analytics to provide guaranteed results

While the current focus is on driving operational efficiencies and building connected products and services, ACG is expanding into building delightful customer experiences and digital led business models. The future is bright. The future is digital.



# PHARMA INDUSTRY'S OVERDUE TECH BOOSTER SHOT

Karan Singh

Managing Director, ACG

It has been a rollercoaster ride for India's pharmaceutical industry in 2020. While the entire globe continues to deal with the pandemic's impact, companies in this sector have undergone an upheaval marked by the disruption in global supply chain network. From raw materials to final drugs and vaccines, the industry is looking to re-invent themselves for the post COVID era.

Over the last year, businesses have been buffeted by upwards of 50% increase in raw material costs imported from China, leaving the industry hobbled by shrinking margins and questions of long-term viability. This distress even caused them to appeal to the NPPA for price increases.

Indian pharma today continues to find itself in a bind. Unlike mature markets such as USA, where drug prices are controlled by market forces; in India government and regulators play a pivotal role in the entire process. Regulators fix the price companies pay for bulk drugs and the price they sell their products in the market without controlling the prices of KSMs and APIs which have increased by over 25-30%, primarily on account of import dependence and sharp rupee depreciation against dollar. This leaves little leeway to build profitable businesses which could then invest in technology, sustainability and R&D. The list of price-controlled drugs, by the Department of Pharmaceuticals under Ministry of Health and Family Welfare, has swelled from 74 in 1995 to almost 860 in 2019.

For Indian pharma this is a double-edged sword. Companies have discovered to maximise efficiency by squeezing every ounce in their processes. However, with slim margins, they have little incentive to upgrade and modernize their manufacturing capabilities. On the world stage, this places us at a distinct disadvantage. Most don't invest in R&D to develop breakthrough high-margin drugs and thus can't compete with their rivals worldwide. **This pressure has become only more severe as the cost of bringing a drug candidate to the market has increased sharply—from nearly \$1.1 billion in 2010 to over \$2.1 billion in 2018, according to Deloitte.** 

I ascertain that India's pharma industry has built a myth that it cannot competitively manufacture essential medicines under these restricted circumstances. While I agree with the industry's stance that the current base prices for excipients and APIs are not in line with what the government has listed and have further grown, let me also argue that this calls for a fundamental shift in operating processes. With the massive volumes required these firms can yet build viable businesses here. With technological developments such as Industry 4.0 and digital manufacturing, I believe that Indian drug makers can harness these tech enhancements to rejuvenate their outmoded businesses. According to an estimate from a recent paper from consultancy EY, half the drugs still fail in Phase 2 and 3 of the development cycle, due to lack of efficacy or safety signals. Using AI, drug makers could identify better compounds four times faster, with the potential to reduce the late stage drug failure rate by as much as 20%, this report states.

In recent times, the pharma industry has begun to belatedly embrace new technologies such as mobile, cloud, analytics and the internet of things, just like companies in more techadvanced sectors such as financial services, consumer goods and telecom. Notably we are amongst the last few industries to migrate towards industry 4.0.

I believe this calls for us to rethink the way we do business. Today, 90% of our medicines are manufactured using a batch process, which is wasteful and inefficient. Pharmaceutical companies need to consider shifting to a process of continuous manufacturing. Traditionally, once a company decides to commercially manufacture a medicine - they reject hundreds if not thousands of trial batches, before they can zero in on what is termed a golden batch. In an era of digitization this process can be hastened by using AI to rapidly identify this one ideal batch and manufacture it continuously.

While technology allows these manufacturers to operate far more efficiently, this aggressive investment in building advanced digitally led manufacturing operations also enables drug makers to be more compliant, since multiple manual checks and balances these companies had in place are being replaced by faster Al and ML-driven processes.

The onset of new age technologies, especially artificial intelligence and the Internet of Things has allowed companies to build factories of the future that are ready to compete on the world stage. This will optimize costs, drive efficiencies in the manufacturing process and help pharma companies build sounder businesses.

While a recent EY report places manufacturing utilization at 75% actuals are estimated at even less. These facilities are so underutilized that there is scope to even double production and therefore tap effectively into the large volume game. To really make this booster shot stick, the government has a role to play too: it needs to incentivize companies making this upgrade with financial sops to ensure they invest in building a more robust and viable industry, primed to compete in the global stage.

# IMPACT OF DIGITIZATION ON THE PHARMACY PRACTICE SETTINGS ON THE INTERNATIONAL LANDSCAPE

### Amy Hai Yan Chan

School of Pharmacy, University of Auckland, New Zealand Professional Development and Research lead, Commonwealth Pharmacists Association, London, UK

In the past 20 years, digitization has had a significant impact on all aspects of healthcare from medicines access, supply, administration to monitoring. The effects of digitization are cross-disciplinary, influencing the practice of nursing, medical clinicians, allied health and pharmacy, and across borders, allowing pharmaceutical care to be standardised and streamlined across different regions, countries, and cultures. Pharmacy was one of the first health professions to truly embrace digitization, with the implementation of electronic dispensing and stock management systems to facilitate medication supply and production, ensure safe administration of medicines to patients and effective management of patient medication records. These new technologies and innovations for pharmacy practice are particularly pertinent in the current pandemic times, where globally, there are increasing pressures to explore contactless and remote ways of delivery of healthcare. Digitization provides many opportunities to consider new and innovative ways of delivering pharmaceutical care - including enabling routine repetitive tasks to be automated and standardised to improve care, efficiency and allow personalisation of care according to the needs of the local population. Looking at the medicines pathway, the impacts of digitization are seen throughout the entire medicines product life cycle, starting from the medicines development stage right through to the point of delivery of medicines to the patient. The effects of these at the different stages of the medicines pathway are discussed below, in the context of the international landscape.

### **Medicines development**

The identification and development of new medicines has historically been a process that takes many years, involving iterative cycles of molecule testing, development and refinement. New innovations and technologies have revolutionised this process of new molecule identification and production, effectively shortening the time taken for new medicines to be discovered and developed. We have seen this in the development of the coronavirus vaccine, where globally there has been a coordinated response towards vaccine development involving countries from different parts of the world. This has been facilitated by digitization which has supported the establishment of global collaborations to accelerate the coronavirus vaccine development, such as the Access to COVID-19 Tools (ACT) Accelerator - a ground-breaking global collaboration to accelerate development, production, and equitable access to COVID-19 tests, treatments and vaccines. With the support of digitization, the ACT Accelerator has brought together governments, scientists, businesses, civil society, philanthropists and global health organisations. Specifically, digitization has helped key stakeholders share resources and new knowledge more easily, standardise ways of working, and support local production and manufacturing of tests and vaccines. A case example of how digitization has shaped pharmacy practice internationally in the context of the pandemic is the Commonwealth Pharmacists' Association needs assessment work. This involved surveying 31 Commonwealth countries as part of a needs assessment to identify and explore the issues facing pharmacy teams during the COVID-19 pandemic. Digitization allowed dissemination of the survey across different countries across Africa, Asia, America, Europe and the Pacific.

### **Medicines distribution and delivery**

Digitalization of the medicines distribution process has allowed automation of many steps of the distribution process. Globally, the medicines manufacturing and subsequent distribution process typically involve multiple countries, with raw materials being sourced from one country, and manufacturing and distribution occurring in other regions and countries. This process involves billing, invoicing, tracking, transport, and monitoring with multiple quality assurance controls in place at every step. Digitization has allowed data associated with each of these steps to be recorded and shared seamlessly between systems, for example through the use of digital barcoding systems e.g. the serialisation of medicines, electronic feedback documents such as electronic delivery notes (e.g. electronic packing slips with delivery and shipment information - DESADV), identification of logistic units (e.g. serial shipping container codes - SSCC), and electronic invoices based on global GS1 standards - a global common language used to identify, capture and share supply chain data, in a way that is accessible, accurate and easy to understand. Digitization has helped to achieve uninterrupted endto-end supply chain processes that cover the different aspects of medicines distribution and delivery. Internationally, many countries legally require pharmaceutical companies to use serial numbers and unique identifiers to comply with their national standards and/ or regulations - for example in the United States or in Turkey, where the "Track & Trace" system must be used for medicines by law.

### Quality control and quality assurance

The rise of substandard and falsified (SF) medicines is of particular concern in low- and middle-income countries, where rates of SF medicines have been reported to be as high as 1 in 10 medical products. Digitization has played a key role in protecting patients from SF medicines. The legal requirements in the European Union (EU) for serialisation of medicines (the EU Falsified Medicines Directive) represents a significant advancement in supporting traceability from medicines manufactured through to the patient, forecasting, and efficiency when it comes to tracking and monitoring. Mackey et al. conducted a review of existing and emerging digital technologies to combat the global trade in SF medicines, and identified examples of 'mature' anti-counterfeit digital technologies such as mobile and RFID-based solutions which have been used internationally to facilitate SF medicines detection, authentication and track and trace. Newer, less 'mature' technologies that are being explored include the use of machine learning to detect and prevent the sale and distribution of SF medicines such as via online means. The authors also identified 'blockchain' as a potential revolutionising technology framework that may be used to modernise and digitise the medicines supply chain in a trustworthy, accountable, and transparent manner that is protected from the infiltration of SF medicines. The blockchain technology allows a dependable record of all transactions within the supply chain process to be recorded digitally and permanently when the medicine moves between stakeholders, making it difficult for thirdparties to introduce fraudulent materials or steal pharmaceuticals from the supply chain. The technology also supports faster tracking and tracing, and investigations, if any disruptions occur.

### Monitoring and pharmacovigilance

Monitoring and tracking of medicines and their effects is a pivotal part of pharmaceutical care, at both an individual level and population basis nationally and globally. Key to the process of pharmacovigilance and pharmacoepidemiology - defined as the study of the uses and effects of medicines in populations - is data. To achieve effective medication monitoring, a strong data ecosystem is needed to provide the infrastructure to identify medicine effects; track patterns and trends over time, within and between individuals; and monitor the results of any interventions to reduce adverse effects or optimise treatment efficacy. Digitization enables the collection and sharing of high-quality data to facilitate this process; without digitization, many of the current pharmacovigilance systems would not be able to function. Data by itself without systems to support data reporting and connectedness between health systems leads to disorganised data collection and inconsistencies that prevent effective pharmacovigilance and monitoring. Timeliness is also key; the availability of accurate data helps to ensure better patient safety and health outcomes.

### **Connectivity between health systems**

Digitization has enabled connectivity between health systems within and between countries; improving communication between different health providers across different sectors to streamline patient care and share information that is current and up-to-date. The transition between different care settings – for example, when a patient transitions from primary care (community) into hospital or into a residential facility – is often a high risk point for potential medication discrepancies and medication errors to occur. This often arises from a lack of a common interface between different health systems, for example, different prescribing and medication administration systems and methods of documentation.

Digitization has allowed seamless and timely transfer of information, enabling data to be transferred between care settings either through a secure server or through digital print-outs from electronic systems. Digitization also empowers patients to take ownership of their own medication records and self-management of their health conditions – through tools such as adherence monitoring devices, telehealth, medication tracking apps, and patient portals that allow patients to access their own health data. These technologies serve as an extra 'checkpoint' for patients to facilitate better quality care and patient safety, with sophisticated systems being able to apply artificial intelligence and machine learning to understand and foresee the patient's needs as they move through different points along the medicines pathway.

Local examples include online medicines ordering, management of repeat prescriptions, text reminders to support adherence and medicine brand switches, and 'click and collect' systems. Global examples of medicines management include the WHO essential medicines list, and associated information portal, which contains the medications considered to be most effective and safe to meet the most important needs in a health system, and is typically used by countries to develop their own local lists of essential medicines; and Healthcare Information for All (HIFA), a global campaign and community of practice improve the availability and use of healthcare information in low- and middle-income countries.

### **Continuing professional development**

In the context of an evolving pandemic, there is an urgent need to stay up-to-date with new knowledge and innovations. Digitization has

played a key role in the communication of information internationally, for example through knowledge sharing webinars developed by the Commonwealth Pharmacists' Association and the International Pharmaceutical Federation, and online digital resources to support best practice and address knowledge gaps such as the Commonwealth Partnerships for Antimicrobial Stewardship (CwPAMS) app. This app was originally launched as part of the CwPAMS programme to inform appropriate antimicrobial use and support antimicrobial stewardship (AMS) initiatives, to address a gap in access to clinical tools. The app includes national treatment guidelines for Ghana, Tanzania, Uganda and Zambia, as well as that from WHO AWaRE. The digital format enabled a 'one-stop-shop' information resource, where information on national standard treatment guidelines, the WHO essential medicines list, AMS training resources, infection prevention and control resources, and point prevalence survey (PPS) tools for antimicrobial use and AMS surveillance were able to be housed in one place. As countries had access to the app already during the COVID-19 pandemic, the CwPAMS app was also used as a means of delivering COVID-19 related information to pharmacy workers.

Digitization can also facilitate information delivery by crossing language and cultural barriers when disseminating information. An example of this is the Commonwealth Pharmacists' Association training resource for health professionals to guide them on the manufacture of WHO's alcohol hand rub in pharmacy manufacturing units. The video uses animations to convey the instructions in a clear, practical and readily accessible format. The digital online format has enabled a broad reach of this resource globally.

### **Digitisation considerations**

The advent of digitization provides great opportunities for improving care efficiency and facilitating easier access to health information internationally between parties and sectors. However, with great opportunities also come great responsibility. Data governance, patient privacy and confidentiality and the impact on health inequities require consideration. There is a need for robust processes to be developed to safeguard the data and ensure that digitization does not further exacerbate existing inequities due to differences in access between populations. How data is used is also a key consideration - access to data is only the first step - being able to achieve change and use the data in a way that influences care is the true demonstration of value. The use of common data protocols, shared digital interfaces, and standardisation of data processes facilitates effective data sharing and reduces the risks of information loss from inefficiencies between different systems and care settings; on the flipside, connectivity and linked systems may be more prone to greater data loss if the system and cybersecurity are compromised as the stakes are even higher, particularly if the entire global supply chain of medicines is connected for example using blockchain. In such cases, a cyber-attack that impacts any part of the chain, be it the manufacturer, distributor, or health provider, could lead to adverse medicines mismanagement and consequently significant impacts on patient outcomes further down the supply chain. To counteract this, any digitised systems need to consider multi-level security settings to reduce the risks of data sharing across different systems and nations. At the same time, whilst digitization holds great promise in revolutionising the pharmacy practice setting internationally, there remains a need to use non-digital mechanisms and systems as a back-up to support any digital processes. As with all advances that human society has seen till date, no level of digitization or smart technology can completely replace in-person care; to that end as digitization evolves and becomes more complex and sophisticated, so too should the role that humans play in managing these innovations.

# EMERGING ROLES OF SPORTS PHARMACIST IN THE HEALTH MANAGEMENT OF ATHLETES

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### Abstract:

Pharmacists represent the third-biggest healthcare professional group in the world who contribute to the health of people by imparting the safe use of medicines. The health of athletes in sports is at high risk with the increasing incidences of doping. Anti-doping agencies like the World Anti-Doping Agency (WADA) are working together to prevent doping from sports, listing prohibited performance-enhancing substances, creating awareness, thereby providing an equal chance to each sportsperson and protect their health. Pharmacists with their existing knowledge about drugs and with the training in the basics of sports can play vital roles in preventing doping in sports. Sports Pharmacists can be involved in imparting education to the sportsperson, conducting drug research and testing to control doping in sports, thereby creating a culture of 'Play Safe' in sports.

Keywords: Athletes, doping, nutrition, prohibited substances, Sports Pharmacists.

### Subject:

### 1. Background:

- In sports, doping incidences are increasing at an alarming rate and a large number of athletes are being banned due to this.
- Several drug formulations and dietary supplements contain banned substances and the consumption of the same results in doping.

### 2. Finding:

- Pharmacists have in-depth knowledge of drugs and with acquired knowledge of sports can play an important role to prevent doping.
- Sports Pharmacists can play role in Education, Research, Testing in Doping Prevention and can create a culture of 'Play Safe' in sports.

### **1. Introduction**

Pharmacists are healthcare professionals who help people in utilizing the best use of medicines<sup>[1]</sup>. Over 65% of World Health Organization affiliate reports have less than five pharmacists for each ten thousand people, and about 35% reports to have less than one pharmacist. Other than selling drugs at the pharmacy, pharmacists role to play in the healthcare system. Pharmacists play an integral role in patient care and can perform a variety of functions ranging from its procurement and supply of products to pharmaceutical care facilities, as well as the rationale for ensuring patients get the best treatment<sup>[2]</sup>. Pharmacists represent the third-biggest healthcare professional group in the world<sup>[3]</sup>. Today pharmacist services are focused more on Patient Care, Regulatory and Public Health. There are several fundamentals of public health that can be profitable by having a pharmacist with their professional ability to incorporate pharmacotherapy, access to care and prevention services<sup>[4]</sup>. Pharmacist involvement is a practical approach to decrease medication faults in patients undergoing the transition from hospital back to the community.

Also, pharmacist involvement reduces subsequent emergency room visits after hospital discharge<sup>[5]</sup>. Pharmacists with their existing knowledge about drugs and with training in the basics of sports can play vital roles in the safe use of medicines in sports.

### 1.1 Sports and doping

The International Olympic Committee (IOC) conferring sports is worldwide, crossing societies and laws, yet there is just one culture in sports, i.e., the culture of respect<sup>[6]</sup>. In sports, the use of prohibited methods or prohibited substances or breaking Anti-Doping Rules Violations (ADRV) is called doping<sup>[7]</sup>. In modern sport, doping has been reported since the 19<sup>th</sup> century (middle), and IOC mentions doping control since the Mexico Olympics of 1968. From Mexico-1968 Olympic to Pyeongchang-2018 Olympic, one hundred forty medals have been stripped from athletes due to positive doping at various sports<sup>[8]</sup> (Athletics, Biathlon, Boxing, Cycling Road, Swimming and Weightlifting). Worldwide doping has become a high risk for athlete health and all sports. In the past ten years in India, the National Anti-Doping Agency (NADA) has banned 1038 athletes due to the positive test for using prohibited substances<sup>[9]</sup>.

Anti-Doping organizations are working together to prevent doping from sports, providing an equal chance to each sportsperson and to protect athlete health. Those kinds of substances or methods that have the potential to increase sports performance, potential health risks for athletes, and violations of the spirit of sport, are named as prohibited substance or method means<sup>[7,10]</sup>.

### 2. Drug Substances used in Sports

WADA prohibited performance-enhancing substances include non-approved substances, Anabolic agents, Peptide hormones and Growth factors, Beta-2 agonists, Hormone and Metabolic modulators, Diuretics, Stimulants, Narcotics, Cannabinoids, Glucocorticoids and Beta-blockers. Performance-enhancing methods include chemical and physical manipulation, cell and gene doping and manipulation of blood and its components<sup>[11]</sup>.

### 2.1 Non-Approved substances

Substances that are under discovery stage, research and development, pre-clinical trial and human clinical trials, and also products non-approved by any government, are prohibited all times of sports<sup>[11]</sup>, both in-competition and out-of-competition (IC and OOC).

### 2.2 Anabolic agents

Anabolic agents corresponding to Anabolic Androgenic Steroids (AAS) administered through an exogenous route prohibited at all times in sports. AAS are synthetic male sex hormone-like testosterone derivatives that play a significant role in the rise of protein synthesis<sup>[12]</sup>. AAS are wildly taken by powerlifters and bodybuilders to increase their muscle mass and performance. Adverse effects of AAS include cardiovascular alteration, changing behavior, sexual problem, liver damage and renal disorders<sup>[13,14]</sup>.

### 2.3 Peptide hormones and growth factors

Peptide hormones and Growth factors were also prohibited at IC and OOC sports by WADA. Erythropoietin (EPO) hormone plays an essential role in the production of red blood cells<sup>[15,16]</sup>. EPO increases the oxygen-carrying capacity that could enhance the performance of athletes. Common adverse effects of EPO use include myocardial infarction, vascular thrombosis and congestive heart failure<sup>[16]</sup>. Human Growth Hormone (HGH) is a peptide hormone secreted by the anterior pituitary gland<sup>[17]</sup>. HGH increases the absorption of amino acids into the muscle, which leads to faster gain in muscle mass and strength<sup>[18]</sup>.

### 2.4 Beta-2-Agonists

Orally administration of Beta-2-Agonists is also used to increase performance in sports<sup>[19]</sup>. Beta-2-Agonists substances (Example: Salbutamol, Terbutaline) are prohibited at all times in sports by WADA, except inhaled Salbutamol (maximum dose 1600 micrograms/ 24 hours, maximum dose 800 micrograms/ 12 hours). The most common side effect of Beta-2-Agonists is skeletal muscle tremor and tachycardia<sup>[20]</sup>.

### 2.5 Hormone and metabolic modulators

Hormone and metabolic modulator products modify the hormone effects by blocking, activating the enzyme, one way or the other. Athletes take the hormone and metabolic modulators to beat the anabolic agents' adverse effects<sup>[21]</sup>. Hormone and metabolic modulators substances are banned; IC also OOC sports events by WADA.

### **2.6 Diuretics**

Diuretics are a group of drugs that increases urine flow and helps in the elimination of sodium to regulate the volume and composition of body fluids. Diuretics are frequently used by athletes to excrete water to reduce weights and hide the presence of prohibited substances<sup>[22,23]</sup>. Diuretics are not permitted at IC and OOC by WADA.

### 2.7 Stimulants

Stimulants with all-optical isomers are prohibited at IC sports by WADA. Stimulant drugs activate the Central Nervous System (CNS) during the competition, and so athletes misuse the stimulant drugs to increase their performance level<sup>[24]</sup>. More usage of stimulants causes cardiac arrest, stroke, abnormal heartbeat and high blood pressure<sup>[24,25]</sup>.

### 2.8 Narcotics

Narcotic drugs act on CNS to decrease pain, reduce fear and anxiety. Higher consumption of narcotics leads to a challenging respiratory system<sup>[26]</sup>. WADA has prohibited the use of narcotics drugs during the IC sports events.

### 2.9 Cannabinoids

Except for Cannabidiol, wholly natural and modified cannabinoids are banned by WADA throughout IC sports. Specific other natural plants also produce banned substances<sup>[27]</sup>. Cannabis sativa contains Tetrahydrocannabinol and Ephedra plant contains Ephedrine. Cannabinoids are used to reduce anxiety but do not increase athlete performances, and in some cases, it drops the athlete's performance. It causes severe adverse effects such as amnesia, anxiety and tachycardia<sup>[28]</sup>.

### 2.10 Glucocorticoids

Glucocorticoids are banned in IC sports, particularly when administrated by the Intramuscular route, intravenous route, oral route and rectal route. Generally, athletes are using this to treat asthma and musculoskeletal injuries<sup>[29,30]</sup>.

### 2.11 Beta-Blockers

Beta-Blockers (BB) are used to treat cardiovascular disorders, and the critical functions of these drugs will reduce heart rates<sup>[31]</sup>. Athletes consume BB to lessen the anxiety and relaxing purpose of sports, for example during shooting events<sup>[26]</sup>. BB drug substances are banned at IC particular sports, and also it has been prohibited OOC specific sports events (Shooting and Archery).

### 3. Prohibited substance statistical report

Due to positive doping cases, several athletes were banned from different sports. Figure 1 Anti-Doping Administrative Management System (ADAMS) has reported prohibited substance uses in overall sports from various nations from the year 2003 to 2018<sup>[32]</sup>.

### 4. Sports Pharmacist

The International Pharmaceutical Federation (FIP) has decided to recognize the Pharmacist's role in the fight against sports doping (see Figure 2). The FIP recommends that Pharmaceutical

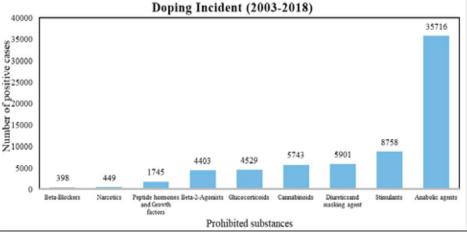


Figure 1. Statistical Reports of Prohibited Substances.

associations should participate in awareness campaigns on the dangers of doping, in cooperation with national anti-doping agencies, national Olympics committees and relevant government departments. Pharmacists should keep the contents of the WADA code up-to-date and advise those engaged in athletic sports about Anti-Doping education more than once have more accurate Anti-Doping knowledge than those who are less educated about this<sup>[37]</sup>. Pharmacists can play a vital role in imparting anti-doping education to athletes and are needed to assist athletes in their medication needs and join in the cause against doping. The roles

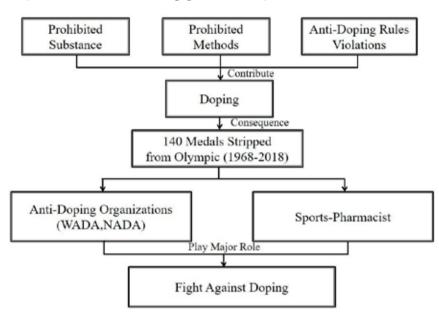


Figure 2. Significance of Sports-Pharmacist in Sports.

the benefits of supplements and the health problems associated with using them. Pharmacists can support WADA by informing the marketing company of any new medicinal product which can be used to enhance performance in sport<sup>[10]</sup>. To create an environment of clean sport, the first international conference was held in Paris in November 2012, which brought several Biopharmaceutical companies and their representative associations together<sup>[33]</sup>. Before taking medications or supplements, WADA also recommends that athletes can consult a Pharmacist<sup>[34]</sup>. Japan Anti-Doping Agency (JADA) in 2009 established a Sports Pharmacist system for training pharmacists. Education is one of the main pillars of the anti-doping community. If the pharmacists can train in the best anti-doping practice along with some basics of sports, then they can contribute immensely to the good of athletes and sports as a whole<sup>[35]</sup> and will lead to the development of Sports Pharmacy professionals.

### 4.1 Roles and responsibility

Pharmacists know about drug profile, mechanism of action in the body, half-life, therapeutic windows, side effects, drug/food interactions, disease/drug interactions, drug/drug interactions, and much more about drug actions in the body. Pharmacists can play vital roles in sports in the following domain

- a) Education
- b) Research
- c) Testing

### 4.1.1 Education

In PyeongChang 2018, pharmacists at the Olympic and Paralympic Winter Games played a crucial role in delivering safe and effective pharmacy services based on their experience in anti-doping and clinical drug use in sport<sup>[36]</sup>. Athletes who receive of pharmacists include creating awareness on doping, counseling athletes, advising physicians, and athletic personnel and educating the public effect of performanceenhancing drugs<sup>[38]</sup>.

### 4.1.2 Research

Anti-Doping organizations have been promoting research. Since the year 2001, WADA has spent USD 80 million on research, increasing the volume of research devoted to emerging new and improved methods of detection of banned substances and methods<sup>[39]</sup>. Pharmacists can play significant roles in research to find the effects of a prohibited substance and their actions.

### 4.1.3 Testing

In 1968 IOC introduced drug testing mandatory for all types of sports<sup>[26]</sup>. ADAMS has reported an increase of 9.81% overall sample analyzed in WADA approved laboratories between 2018 and 2017<sup>[32]</sup>. Pharmacists can be involved in drug testing

and analysis as they have the necessary professional knowledge and expertise  $^{\rm (40)}\!.$ 

### 5. Sportsperson lifestyle and Pharmacist interventions

Athletes are having a high chance of consuming prohibited substances in their day-to-day life. Fig.3 has described sportsperson routine activity and health problems. Consumption of banned substance causes severe adverse effects on an athlete's health. Pharmacists have a potential role in advising athletes because of their advanced knowledge in the medication profile<sup>[41]</sup>.

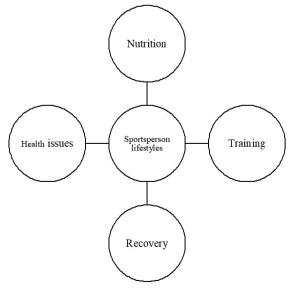


Figure 3. Sportsperson Lifestyles.

### 5.1 Nutrition

Nutrition plays a significant role in a sportsperson's daily lifestyle, starting from energy production to produce new cells and proteins. Sportspersons are consuming nutrition through dietary supplements in their day-to-day life to achieve the target level. Joint sports supplements used by athletes are protein supplements, energy drinks, sports confectionery, sports drinks, sports bars, electrolyte replacement and liquid meal supplements<sup>[42]</sup>. The results of performance-enhancing drugs and dietary supplements are less known to sportspeople<sup>[43]</sup>. Substances banned by WADA have been found in most nutritional supplements marketed<sup>[44]</sup>. A study reported before consuming supplements takes advice from anti-doping organizations regarding recent information on contaminated or hazardous products to understand the positive and negative results<sup>[45]</sup>. If the dietary supplement label lists contain unknown substances or terms, the athletes should seek professional advice. [46] In such cases, pharmacists can play a significant role.

### 5.2 Training

As per the ADAMS anti-doping testing report of worldwide sports, the usage of anabolic agents is higher than other prohibited substances<sup>[32]</sup>. During the selection time or competition, athletes are taking dietary supplements to increase their performance<sup>[42]</sup>, which lands them knowingly/unknowingly into doping. Pharmacists, with their detailed knowledge about the drugs and its pharmacological aspects, can guide the athletes to take safe food supplements.

### 5.3 Recovery

Recovery is an essential element for athletes during sports and post-exercise<sup>[47]</sup>. Protein drinks are widely used to recover faster<sup>[42,48]</sup>. Several marketed nutrition supplements are mislabeled and or contain the WADA prohibited substances<sup>[49]</sup>. Pharmacists can provide necessary ethical guidance to the athletes for faster healing and recovery.

### 5.4 Injury

The most common post-injuries are sprains and strains. Pharmacists suggested the RICE method (Rest, Ice, Compression and Elevation) to treat these injuries. Most of the pharmacists are aware of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), which are not to be recommended for the first 48 hours<sup>[50]</sup>.

### 5.5 Health issues

Most of the Over The Counter (OTC) products contain prohibited substances<sup>[46]</sup>. Pharmacists deployed and engaged in significant sports have been involved in the dispensing of more than 5000 prescriptions, endorsing the Therapeutic Use Exemption (TUE) and IOC rule procedures and supplying clinical information to athletes and prescribers on sports drugs and the WADA guidance on drugs banned in sports<sup>[36]</sup>.

### 6. Conclusion

Worldwide doping has become a high risk for athlete's health and well-being in all sports. Sportsperson has less knowledge about performance enhancement effects and dietary supplements. Athletes were also taking prohibited substances to increase or reduce weights, get recovery faster, mask other prohibited substances. Sports pharmacists can play a vital role in sports by providing information about substances and their effects, protecting athlete health and preventing doping from sports, and ultimately to create a culture of 'Play Safe.'

### References

- Code of Ethics | American Pharmacists Association [Internet]. [cited 2020 May 24]. Available from: https://www.pharmacist.com/codeethics
- Pharmacists (per 10 000 population) [Internet]. [cited 2020 May 23]. Available from: https://www.who.int/data/gho/data/indicators/ indicator-details/GHO/pharmacists-(per-10-000-population)
- 3. Global Pharmacy Workforce Report G. 1 . 1 Global Overview : Pharmacists density. Health Policy (New York). 2005;11-6.
- 4. The Role of the Pharmacist in Public Health [Internet]. The American Public Health Association. 2006 [cited 2020 May 24]. p. 1–8. Available from: https://www.apha.org/policies-and-advocacy/publichealth-policy-statements/policy-database/2014/07/07/13/05/ the-role-of-the-pharmacist-in-public-health
- de Oliveira GS, Castro-Alves LJ, Kendall MC, McCarthy R. Effectiveness of Pharmacist Intervention to Reduce Medication Errors and Health-Care Resources Utilization After Transitions of Care: A Meta-analysis of Randomized Controlled Trials. J Patient Saf. 2017;00(00):1–6.
- Support and protect clean athletes [Internet]. [cited 2020 May 25]. Available from: https://www.olympic.org/safe-sport
- 7. WORLD ANTI-DOPING [Internet]. [cited 2019 Jun 18]. Available from: www.wada-ama.org
- List of athletes stripped of their medals PyeongChang 2018 Rio 2016 Sochi 2014 London 2012. 2018;
- National Anti Doping Agency Anti Doping Disciplinary Panel candidate list [Internet]. [cited 2020 May 3]. Available from: https:// www.nadaindia.org/en/anti-doping-disciplinary-panel-candidatelist
- FIP Statement of Professional Standards. J Pain Palliat Care Pharmacother. 2005;19(2):55–7.
- World Anti-Doping Agency. Prohibited List [Internet]. World Anti-Doping. 2020 [cited 2020 May 25]. p. 1–116. Available from: http:// www.wada-ama.org
- 12. Yesalis CE, Bahrke MS. Anabolic-Androgenic Steroids: Current Issues. Sport Med. 1995;19(5):326–40.
- Nieschlag E, Vorona E. Doping with anabolic androgenic steroids (AAS): Adverse effects on non-reproductive organs and functions. [cited 2020 May 30]; Available from: www.wada.org
- van Amsterdam J, Opperhuizen A, Hartgens F. Adverse health effects of anabolic-androgenic steroids. Regul Toxicol Pharmacol. 2010;57(1):117-23.
- Sgrò P, Sansone M, Sansone A, Romanelli F, Di Luigi L. Effects of erythropoietin abuse on exercise performance. Phys Sportsmed [Internet]. 2018;46(1):105–15. Available from: http://dx.doi.org/ 10.1080/00913847.2018.1402663
- Salamin O, Kuuranne T, Saugy M, Leuenberger N. Erythropoietin as a performance-enhancing drug: Its mechanistic basis, detection, and potential adverse effects. Mol Cell Endocrinol [Internet]. 2018;464:75–87. Available from: http://dx.doi.org/10.1016/j. mce.2017.01.033
- Sereikaite J, Statkute A, Morkunas M, Borromeo V, Secchi C, Bumelis V-A. Production of recombinant mink growth hormone in E. coli. Microb Cell Fact. 2006;5(Suppl 1):P15.
- Roemmich JN, Rogol AD. Exercise and growth hormone: Does one affect the other? J Pediatr. 1997;131(1 II SUPPL.):75–80.
- 19. Collomp K, Le Panse B, Candau R, Lecoq AM, De Ceaurriz J.

Bêta-2 agonistes et performance sportive. Sci Sport [Internet]. 2010;25(6):281-90. Available from: http://dx.doi.org/10.1016/j. scispo.2010.08.002

- Lulich KM, Goldie RG, Ryan G, Paterson JW. Adverse Reactions to β2-Agonist Bronchodilators. Med Toxicol. 1986;1(4):286–99.
- 21. S4 Hormone and metabolic modulators | antidoping.ch [Internet]. [cited 2020 May 29]. Available from: https://www.antidoping.ch/en/ prevention/education/mobile-lesson/s4-hormone-and-metabolicmodulators
- 22. Caldwell JE. Diuretic Therapy and Exercise Performance. Sport Med An Int J Appl Med Sci Sport Exerc. 1987;4(4):290–304.
- Cadwallader AB, De La Torre X, Tieri A, Botrè F. The abuse of diuretics as performance-enhancing drugs and masking agents in sport doping: Pharmacology, toxicology and analysis. Br J Pharmacol. 2010;161(1):1–16.
- Avois L, Robinson N, Saudan C, Baume N, Mangin P, Saugy M. Central nervous system stimulants and sport practice. Br J Sports Med. 2006;40(SUPPL. 1):16–20.
- 25. Reardon CL, Factor RM. Considerations in the Use of Stimulants in Sport. Sport Med. 2016;46(5):611–7.
- 26. K R, Narendranath.S, HS S, Navin.A.Patil, Reshma S, A V. Drug abuse in sports. J Pharm Res. 2012;5(1):593–603.
- Four Reasons Why 'All-Natural' Supplements Might Still Be Risky for Athletes | USADA [Internet]. [cited 2020 May 28]. Available from: https://www.usada.org/spirit-of-sport/education/reasons-naturalsupplements-risky-athletes/
- 28. Campos DR, Yonamine M, De Moraes Moreau RL. Marijuana as doping in sports. Sport Med. 2003;33(6):395–9.
- Collomp K, Arlettaz A, Buisson C, Lecoq AM, Mongongu C. Glucocorticoid administration in athletes: Performance, metabolism and detection. Steroids [Internet]. 2016;115:193–202. Available from: http://dx.doi.org/10.1016/j.steroids.2016.09.008
- Vernec A, Slack A, Harcourt PR, Budgett R, Duclos M, Kinahan A, et al. Glucocorticoids in elite sport: current status, controversies and innovative management strategies - a narrative review. Br J Sports Med. 2020;54(1):8–12.
- Dézsi CA, Szentes V. The Real Role of β-Blockers in Daily Cardiovascular Therapy. Am J Cardiovasc Drugs. 2017;17(5):361– 73.
- 32. Anti-Doping Testing Figures Report | World Anti-Doping Agency [Internet]. [cited 2020 May 29]. Available from: https://www.wadaama.org/en/resources/laboratories/anti-doping-testing-figuresreport
- 33. The Pharmaceutical Industry and the Fight Against Doping: New Partnerships for Clean Sport [Internet]. [cited 2020 May 25]. Available from: https://en.unesco.org/events/pharmaceuticalindustry-and-fight-against-doping-new-partnerships-clean-sport
- WADA WA-DA. Anti-Doping: important facts and highlights from WADA's Athlete Guide. 2015 [cited 2020 May 26]; Available from: www.wada-ama.org
- 35. SPORTS PHARMACIST □ PLAY TRUE 2020 [Internet]. [cited 2020 May 23]. Available from: https://www.playtrue2020-sp4t.jp/static/ sportspharmacist/
- Stuart M, Kwon YI, Rhie SJ. Pharmacy services at the PyeongChang 2018 Olympic and Paralympic Winter Games. Br J Sports Med. 2019;53(17):1105-10.
- Murofushi Y, Kawata Y, Kamimura A, Hirosawa M, Shibata N. Impact of anti-doping education and doping control experience on antidoping knowledge in Japanese university athletes: A cross-sectional study. Subst Abus Treat Prev Policy [Internet]. 2018 [cited 2020 Mar 3];13(1). Available from: https://doi.org/10.1186/s13011-018-

0178-x

- Ambrose PJ. Educational opportunities and anti-doping roles and responsibilities for pharmacists. Yakugaku Zasshi. 2011;131(12):1761-4.
- Research | World Anti-Doping Agency [Internet]. [cited 2020 May 27]. Available from: https://www.wada-ama.org/en/what-we-do/ science-medical/research
- 40. Ambrose PJ. An advanced pharmacy practice experience in sports pharmacy. Am J Pharm Educ. 2008;72(1).
- 41. Yee KC, De Marco M, Salahudeen MS, Peterson GM, Thomas J, Naunton M, et al. Pharmacists as a Source of Advice on Medication Use for Athletes. Pharmacy [Internet]. 2020 [cited 2020 May 28];8(1):10. Available from: www.mdpi.com/journal/pharmacy
- 42. Maughan RJ, Burke LM, Dvorak J, Larson-Meyer DE, Peeling P, Phillips SM, et al. IOC consensus statement: Dietary supplements and the high-performance athlete. Br J Sports Med. 2018;52(7):439–55.
- Morente-Sánchez J, Zabala M. Doping in Sport: A Review of Elite Athletes' Attitudes, Beliefs, and Knowledge. Vol. 43, Sports Medicine. 2013. p. 395–411.
- 44. Martínez-Sanz JM, Sospedra I, Ortiz CM, Baladía E, Gil-Izquierdo A, Ortiz-Moncada R. Intended or unintended doping? A review of the presence of doping substances in dietary supplements used in sports [Internet]. Vol. 9, Nutrients. 2017 [cited 2020 Mar 20]. Available from: www.mdpi.com/journal/nutrients
- 45. Maughan RJ, Shirreffs SM, Vernec A. Making decisions about supplement use. Int J Sport Nutr Exerc Metab. 2018;28(2):212-9.
- Helle C, Sommer AK, Syversen PV, Lauritzen F. Doping substances in dietary supplements. Tidsskr Nor Laegeforen. 2019;139(4).
- Peake JM. Recovery after exercise: what is the current state of play? Curr Opin Physiol [Internet]. 2019;10:17–26. Available from: https:// doi.org/10.1016/j.cophys.2019.03.007
- Orrù S, Imperlini E, Nigro E, Alfieri A, Cevenini A, Polito R, et al. Role of functional beverages on sport performance and recovery. Nutrients. 2018;10(10):1–21.
- Van der Merwe P, Grobbelaar E. Inadvertent doping through nutritional supplements is a reality. South African J Sport Med. 2004;16(2):3.
- 50. Braund R, Bannerman SL, Lim C, Moon J, Nicholls J, Straight P, et al. Recommendations of community pharmacists for the treatment of sprains and strains. Int J Pharm Pract. 2006;14(4):271-6.

### Advertisement Index

Sr.	No. Company Name	Pg. No.
1.	Workstore	3
2.	ACG	8-9
3.	IPA-MSB, ACE	28
4.	Gracure Pharmaceuticals Ltd.	
5.	Elmach Packages (India) Pvt. Ltd	24, 25, 48

# TRANSFORMATION OF HERBAL DRUG DISCOVERY AND DEVELOPMENT PROGRESSION BY JOINING THE HANDS WITH ARTIFICIAL INTELLIGENCE

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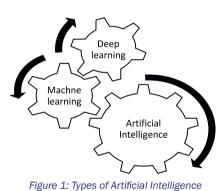
### Abstract:

Drug discovery and development with the use of new technological inputs are taking new shapes and dimensions and proving its benefits over traditional drug discovery methods. Artificial intelligence (AI) applications in Pharmaceutical sciences are coming up as a potential tool in solving many complex problems in discovering a new drug molecule and also at the preclinical drug development level. Since herbal medicines are also an integral part of the disease management system, scientists are working on bringing Artificial Intelligence concept in herbal medicine discovery and development through machine learning and analysis of big phytochemical data through machine learning and deep learning processes. Researchers are taking the help of AI to predict the biological function of natural products by the use of its 2D structure. This review focuses on the various Artificial Intelligence-based systems and multidisciplinary approaches for herbal medicine discovery, use and importance of automation techniques and data mining in the natural product discovery. Overall the use of Artificial Intelligence and its based techniques in different fields and steps in different aspects of drug discovery are mentioned with their important roles.

Key Words: Artificial Intelligence, natural products, machine learning, drug discovery.

### Introduction

Artificial intelligence (AI) can be defined as intelligence exhibited by the help of machines more specifically by computers and robots. Artificial Intelligence technique can learn from the data provided and is termed as 'Machine Learning.' With the applications



of AI, deep learning can be achieved with the help of statistical techniques applied to the numerous data.

Artificial Intelligence is human intelligence in the form of machine format. Here, the computer programs on the basis of data provided take decisions as of humans.

Machine learning is an advancement of AI in such a way that algorithms are designed and programmed to learn without the human data input.

Deep learning is the advancement of machine learning that introduces many layers of learning from the massive datasets<sup>[1]</sup>. (Fig:1).

Al had been adapted in many industries along with the healthcare system. With the use of large data and machine learning, Al can improve the diagnostic power in severe disorders like cancer, dermatological and psychological disorders. The applications can result in more accurate disease diagnosis and thus, better and faster treatment approaches can be implemented at a cheaper cost.

The drug discovery with the aid of AI is coming up with the revolution in the Pharmaceutical sector and people are working on:

 Generation of mobile platforms to collect real-time data to improve patient health.

- 2. Application of cloud computing to develop personalized medicines.
- 3. To nurture new and innovative needs of biopharmaceutical industries.
- 4. Reducing the cost of the drug discovery process<sup>[2]</sup>.

The deep learning process on the basis of existing knowledge can be able to make a smart prediction of biological functions from the 2D structure of natural products. Al gives a new opportunity to provide a connecting link between the metabolite structures of natural compounds and the probable functions (Fig:2).

Al can handle two basic aspects in terms of herbal drug discoveries:

- A. Phenotype Prediction: The deep learning and pattern analysis using the physicochemical properties along with the phenotypic function of already studied and explored metabolite can result in the creation of data and opportunity to learn models as well as mine patterns.
- B. Metabolite-Protein Interactions: The artificial neural networks can be trained with the help of large datasets available on metabolites with their known ligand-protein binding pairs.

The big challenge in this process is the collection of data on metabolites and interactive patterns. The collected data then needs to be cross annotated and assembled and further multiplexed for the creation of Al algorithms. The role of chemogenomics and chemoproteomics, here is very significant and, if we can make our machines learn these patterns, then surely we can develop precision herbal medicine in the near future<sup>[3]</sup>.

The success of artificial intelligence especially in the field of herbal medicines is largely based on the exploration of data obtained after the scientific study on medicinal plants. Traditional Chinese medicines have developed knowledge discovery in database obtained from traditional Chinese medicines<sup>[4]</sup>. Wide information on traditional medicines is included in the database, like the names of the active chemical properties, pharmacological action, toxicity, etc.

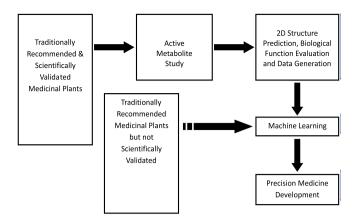


Figure 2: Biological function identification through 2D structure data

In order to synchronize traditional knowledge with its application in modern medicines, again AI is playing a very important role. Apart from traditional Chinese medicine, many other systems like African traditional medicines are working on refining the traditional knowledge of herbs that can help in policymaking and to take corrective action with the use of conceptual graph-based knowledge representation and AI<sup>(5)</sup>.

The quality of herbal medicine and identification of the marker compounds are controlled and estimated by the use of the latest analytical techniques like UPLC quadrupole and time-of-flight with Partial Least Squares-Discriminant Analysis and near IR spectroscopy. The Artificial Intelligence algorithms are used to suggest the complex relationship amongst the quality markers and integral functions. This exercise helps in the identification and distinguishment of substandard and superior quality goods<sup>[6]</sup>.

# Drug discoveries from Natural Resources and Artificial Intelligence

New drug discoveries are very costly (1 billion US\$), timeconsuming (12 years approx) and complex processes. But this process develops new chemical entities that are involved in medicinal chemistry inventions, combination libraries and drug molecule studies in the natural products. A lot of examples shows that new drugs can be developed from plants or natural resources like morphine isolated from seed pods of poppy plants of Opium, Erythromycin, Tetracycline, Penicillin (antibiotic), Avermectin (antiparasitics), Quinine, Artemisinin (antimalarials), Lovastatin and its analogs (lipid control agents), Cyclosporine (immunosuppressants) and Paclitaxel, Irinotecan (anticancer drug)<sup>[7]</sup>. Artificial intelligence (AI) has been recently developed and overcome all drawbacks of new drug discoveries in biopharmaceutical industries, medicinal chemistry invention and drug molecular studies. In recent years, an evolution of Albased start-up companies focused on drug discovery is seen due to the accessibility of immense statistics in life sciences and speedy development in machine learning algorithms<sup>[8]</sup>. In Artificial Intelligence, algorithms can be used in which six datasets offer a combination of information related to natural products to molecular target, structure similarity/dissimilarity, scaffolds and phenotypic cellular activity. Its time for AI to forecast the function of natural products which could be biological, ecological, pharmacological or metabolite production (the result of the interaction with macromolecule and protein) on the basis of its 2D structures which are provided by natural products (isolated after screening against

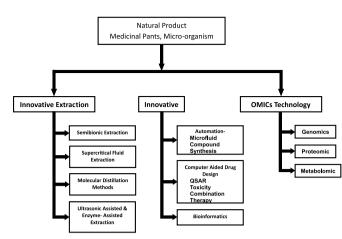
molecular target). For example, Sideroxylonal C<sup>[9]</sup> isolated from *Eucalyptus albens*. It is an inhibitor of human Plasminogen Activator type-1 and resulted from the screening of 21328 extracts. The osteoclast vacuolar H<sup>+</sup>-ATPase proton pump in hen bone-derived membrane vesicles is inhibited by Adociasulfate 1<sup>[10]</sup>. 25-Hydroxy-13IJ24),15,17-cheilanthatrien-19,25-olide<sup>[11]</sup> inhibits mitogen and stress-activated kinase (MSK1). Dysinosin A<sup>[12]</sup> from a marine sponge (family *Dysideidae*) acts as a potent inhibitor of the blood coagulation cascade factor VIIa<sup>[13]</sup>.

# 2.1. Innovations for novel drug discovery using natural products in the current era

Since ancient times we know that plants have therapeutic values. Formerly, extracts of plants were used in medicine without isolating the active constituents. In modern times medicines are prepared by extraction, isolation, purification and analysis of active constituents present in the plants or natural sources. These plantderived medicines are used in communicable or non-communicable disease treatment but the challenge is to reduce their side effects. A lot of medicines are used in the treatment and management of diseases like cancer, hypertension, malaria, diabetes and HIV/AIDS, etc. But sometimes these medicines are associated with mortalities. So such challenges can be overcome by using innovative drug discoveries from natural sources that are different from the current 'blockbuster' Pharma R&D strategies. Currently, drug discovery from natural products by using novel drug discovery strategies reduce these issues. Anti-malarial drugs such as Quinine (Cinchona), Artemisinin (Artemisia annua) and anticancer drugs such as Taxol (Taxus brevifolia), Vinblastine (Catharanthus roseus) are discovered from natural products and are effective in the treatment and management of these diseases. Research and pharma R&D of natural products play a potential role in innovative drug discovery for tackling global public health challenges<sup>[14]</sup>. Paclitaxel and Morphine are the drugs that are isolated from the plants which are approved by FDA (Food and Drug Administration) and EMA (European Medical Agency)<sup>[15,16]</sup>. During the screening of Penicillin antibiotic from the fungus, other microorganisms were screened which have potential antibiotic activities<sup>[17]</sup>. The discovery of drugs from natural products revolutionized medicine which led to the development of Doxorubicin from Streptomyces peucetius, Cyclosporine from Tolypocladium inflatum, Tetracycline from Streptomyces aureofaciens and Artemisinin from Artemisia afra<sup>[18,19]</sup>. Lack of standardization procedures, lack of isolation of pure chemical products, lack of elucidation of biological mechanisms and documented clinical trials according to 'standards' are some of the current challenges in using natural products. The complexity of the molecular mixtures made it difficult to search for new drug candidates from natural products<sup>[20]</sup>. Since cancer and degenerative disease are complex diseases, a combinatorial approach is used during plant-based drug discovery. A combinatorial approach is possible due to novel technologies such as quantum Computing, Profiling Techniques, Computational Biology Techniques, Big Data, Microfluidics and Artificial Intelligence. This approach harnesses the therapeutic properties of plant-based natural products and helps to study their molecular effects in physiological conditions<sup>[21,22]</sup>.

### Novel Technologies in Multidisciplinary Approach to Natural Products Drug Discovery

Various technologies are used in the development of nextgeneration drugs to overcome the current health challenges (Figure 3).



### Figure 3: Innovative technology for natural product drug discovery

Medicinal extract components often work in a synergistic manner. The isolation of individual components may be counterproductive. Innovative approaches are needed to study such compounds that can lead to the development of innovative drugs<sup>[23]</sup>. This transcends looking for a specific molecule with a specific target and espousing the complete equilibrium of a physiological system undergoing synchronized mechanisms on multiple molecular targets. Better drug candidates can be developed by a systems biology approach coupled with the application of various modern technologies (Genomics, Transcriptomics, Proteomics, Metabolomics/Metabonomics, Automation and Computational strategies). A non-reductionist strategy is required for innovative drug discovery from natural products to understand their complex mechanisms of action at the molecular level.

### 3.1. 'NIWARANA' - An Artificial Intelligence Based System For Traditional Medicine

Currently, the traditional system of medicine is becoming important as compared to modern medicine because traditional medicine has less risk of side effects, effective in chronic disease, low cost and widespread availability<sup>[24]</sup>. So we can benefit from these advantages by using traditional medicine. But currently, suitable sources are not available for getting their information to be used for patients. These problems can be overcome by using 'NIWARANA.'

NIWARANA system is a web-based system (machine learning methodology) and which provides effective and efficient service to users. It consists of 4 modules and 3 research parts under its submodules. NIWARANA system is described below (Figure:4).

### **Automation in Natural Product Drug Discovery**

Automation is the technique that offers to make better decisions as well as work faster. Automated systems already have a long and fruitful history in drug discovery. In pharmaceutical industries, robotic screening for specialized assays and testing has become standard at medium to high throughput levels<sup>[25]</sup>. Other applications of automated systems are elaborated from decision support systems to computational molecular design reaching upto a fullyfledged robotic synthesis and hit finding<sup>[26]</sup>. Applications include model-based and traditional rule-based approaches, several software tools and prototypical robotic systems. Model-based and traditional rule-based approaches include archetypal DENDRAL system used for analyzing mass spectra, LHASAs software similar to Amgen's AADAPT system used for synthesis planning and several in-house tools that are used to access and analyze biological

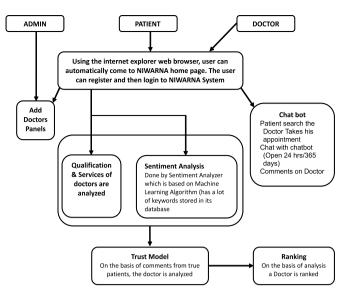


Figure 4: System diagram of NIWARANA

and chemical data. Several software tools are used for *de novo* molecular designing and prototypical robotic systems used for hit finding and automated targets include ADAM and EVE software systems<sup>[27]</sup>.

Automation techniques are similarly used in drug discovery of natural products to reduce human mistakes and bias that are commonly made during the drug designing and drug optimization, reduce the number of candidate compounds required for the testing, reduce the time required for the testing and do allow summarization of disease biology much more effectively than that in in-vitro testing<sup>[28]</sup>. These techniques have made testing of several hypotheses easier and faster i.e. within a few days. More advanced technologies are also completely integrated with natural drug discovery through the use of Artificial Intelligence and organ-on-chip technologies. Integrated microfluidics systems are designed by the laboratories and pharmaceutical companies for use in natural drug discovery to handle liquids and heat together that is necessary for the analysis during synthesis and purification that are required for screening and synthesis of compounds<sup>[29,30]</sup>.

In a drug discovery process during molecule and compound designing, several factors are taken into consideration which includes both pharmacokinetic and pharmacodynamic factors, i.e. Absorption, Distribution, Metabolism, Excretion and Toxicity properties and final biological activity of the compound<sup>[31]</sup>.

Automation helps to make a better decision regarding appropriate compound designing with required biological activity and desired ADMET properties too. Several concepts to aid compound or molecule designing and increase collection of compounds with new chemical formula, structure and constituents have been developed which include biology-oriented synthesis (BIOS) and diversity-oriented synthesis (DOS). Function-oriented synthesis concept is even more advanced than may seek to mimic the functions of a particular promising compound to achieve simple scaffolds and also make the synthesis of such compounds simple and easier<sup>[32,33]</sup>.

# Artificial Intelligence-based technology in herbal medicine discovery and development

In natural drug discovery, various automated compound

generators are also used which use deep learning techniques and obtain better designs of the required compounds with relevant biological activity and other properties by allowing the automated analysis of generated compounds. These models with deep learning techniques are also used to predict ADMET properties of the designed compound, drug-target interactions and binding affinity of the designed compound during the new drug discovery process<sup>[34,35]</sup>. For designing a compound library and building block selection virtual library enumeration is used parallelly with target panel prediction. Integration of microfluidics-assisted synthesis and computational activity prediction helps in the identification of ligands with different binding profiles. Hence, computer-aided target prediction and microfluidics synthesis together can be used for the rapid and efficient formation of bioactivity-focused compound libraries<sup>[36,37]</sup>.

### 5.1. Data Mining in herbal research

Data mining is a computational process of searching and discovering the knowledge and patterns in the large reported data sets which involves methods correlating to Machine Learning, Artificial Intelligence, Statistics and Database Systems. Data mining is done to collect valuable information for further research in various fields. Data collection, data shrink and valuable data quest are the three major steps involved in the data mining process to achieve valuable information from large data sets<sup>[38]</sup>. Various approaches of data mining including Extrapolative Modeling, Association Analysis, Divergence Detection and Database Fragmentation are being adopted by various researchers as per the requirements<sup>[39]</sup>.

Plant-based products are the most important source of ingredients for the new drug discovery. More than 80% of drug substances are obtained or inspired by plant sources. In order to discover the new drug or an active substance that can be used as the main ingredient in medicines, various screening approaches are developed<sup>[40]</sup>. Plant-based products i.e. herbal products along with those screening approaches can be used in the drug discovery process which includes data mining and virtual screening techniques. Data mining and virtual screening techniques can be applied to database sets of herbal products. These screening approaches are important to obtain more efficient and effective applications of herbal products by comparing to different sources which may lead to the improvement of the drug discovery process and may also reduce the cost of drug development<sup>[7]</sup>. Data Mining, Virtual Screening Techniques and other similar techniques including Artificial Intelligence are also being used to replace the ethnomedicinal herbs with herbs having similar efficacy when the availability of some herbs may decline due to their widespread utilization<sup>[41]</sup>.

From the mid-1970s, Government of India started humongous attempts in order to standardize the Ayurvedic system of medicine by forming a number of qualifications as well as accreditation policies for the institutions and taking various other initiatives. Few initiatives designed to pursue herbal and ayurvedic researches are the Ministry of Health and Family Welfare-framed to monitor higher education in Ayurveda and Central Council for Research in Ayurvedic Sciences (CCRAS), Indian Medical Central Council Act-framed in 1970, and Central Council of Indian Medicine (CCIM) under the Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) established in 1971<sup>[42]</sup>.

### 5.2. Machine learning algorithm: for Plant Recognition

The term 'Ecopharmacognosy' is the philosophic consideration for biological outcomes of traditional medicinal plants which ensures the integral aspects of quality of traditional medicine. This term offers the study of viable, biologically vigorous natural means, i.e. therapeutically active secondary plant metabolites<sup>[43]</sup>. There are huge number of plants available on Earth, which carry essential nutritional supplements and most of them have medicinal properties to cure and attenuate acute and chronic illness at a certain level. For the identification of the foremost therapeutic properties of a plant, recognition of the plant is necessary. As the number of plant species is varied on earth, manual recognition is difficult. Solutions to these problems arise in terms of Artificial Intelligence which is a digital characterization of plant species more promptly without the need of the expertise of a botanist<sup>[44]</sup>.

Artificial intelligence revealed the data integration and spectral consolidation of data in the form of Automated Structure Elucidation. The Botanical, Chemical, Biological and Quality Control databases are modified intensely and genuinely by these techniques to identify the role of the natural compounds. The AI/ Multi-faceted Big Data bank creates a beneficial knowledge of data integrated affiliation and logic associations between the metabolite structures and functions. The autoencoders (data learning facility) will give a new archetype for data amalgamation. These data integration achieved by Machine Learning algorithms that acquire identified data and produce robust extrapolation for the function of novel compounds. The machine learning algorithm involves six logical steps that identify and classify the plant automatically from its knowledge bank<sup>[45]</sup>.

Thus, machine learning algorithms have executed the strategies of plant analysis approaches. In combination with Mass Spectroscopy, the plant species identification is much possible but with GC-MS the individual component identification has been done. If a small number of new sample datasets are provided to the algorithm, then it will fail to process it and thus creates a high variance problem, which means it generates inferior recital on cross-validation statistics. This problem could be overcome by the regularization process and constricting feature space<sup>[46]</sup>.

### 5.3. Chemometric utilization in Multivariate Analysis

To explore the multi-component analysis from limited original information data is difficult to access. To overcome this crucial problem the scientist introduced chemometrics with mathematical and statistical techniques that can retrieve more processed information from available data. It proves a great invention in the field of herbal drug standardization to provide faster analysis results with less product development time. Chemometrics could be categorized into pattern recognition (supervised and unsupervised) and exploratory data analysis. The implementation of several tools such as PCA, FA (Factor Analysis), and PP (Projection Pursuit) gives meaningful information on multivariate analysis of plant recognition. The unsupervised pattern recognition is different from exploratory data analysis in terms of similarities detection. The unsupervised pattern recognition techniques involve Similarity Analysis (SA) and Clustering Analysis (CA). In both the techniques, SA is most widely used for the evaluation of similarity of processed data and it provides consistency by adopting the correlation coefficient and resemblance coefficient. The CA again classified into Fuzzy Clustering (FC) and Hierarchical Clustering Analysis (HCA), which is used for preliminary evaluation of information content.

Although the supervised pattern recognition tool can be classified into discriminating technique and class modeling method, the discriminating technique is further categorized in PLSDA (Partial Least Squares Discriminant Analysis), KNN (K-Nearest Neighbors), CCA (Canonical Correlation Analysis), LDA (Linear Discriminant Analysis), LS-SVM (Least Square- Support Vector Machine), ANN (Artificial Neural Network), etc. Ultimately, the Chemometric techniques determine the Efficacy, ascertain Bioactive components and Quality Control evaluation by applying above stated tools to provide more chemical information at a micro level<sup>[47]</sup>.

# 5.4. Identification of Indian medicinal plants by artificial neural network

The machine learning algorithm identifies the plant by leaf features like leaf contour, centroid, solidity and eccentricity, etc., and some sophisticated classifier models are developed by researchers are morphological feature-based analysis models designed for the automatic plant identification to give a highly efficient and accurate quality control tool for plant recognition<sup>[48]</sup>. The artificial neural network model is utilized for leaf vein extraction. Gabor filter banks are designed for the identification of bark texture features<sup>[49]</sup>. The other identification classifier tools are improved Edge Detection Algorithm (EDA) that detect the image corners of leaf edge, the Spider optimization of Neural Network (SONN) that detect the segmentation process, Symbolic Accurate Approximation (SAX) model determine the color feature and two-Dimensional Binary Phase Encoding (2DBPE) tool determine the tooth features. The whale optimization with deep neural network classifier determines the type of plant with greater competencies and precision<sup>[50]</sup>.

The artificial neural network called perceptron is a group of interrelating process (neurons) divided into three main layers. The input layer receives information in the form of sigmoidal or Gaussian signals which transmits the information to the intermediate layer. This layer passes the processed and modified information by an algorithm in the form of new gaussian signals to the output layer. The ANN prevailing data modeling tool optimizes the scale functions, learning rate factor, momentum factors and initial weights. The BP-ANN (Back Propagation-ANN) is the most popular feedforward multilayer network. Apart from that, the determination of total flavonoid content and antioxidant activity can be done by various multivariate calibration models such as Stepwise Multiple Linear Regression (Step-MLR), Principle Component Regression (PCR), Partial Least Squares (PLS), Partial Robust M-regression (PRM), uninformative variable elimination PLS, and UVE genetic algorithm PLS<sup>[51]</sup>.

### **Summary and Conclusion**

Artificial Intelligence is already successful in the field of drug discoveries and has also received much attention in other fields too. A number of techniques based on Artificial Intelligence are being established including Machine Learning Techniques, Automation Techniques, Data Mining, various Software, etc. and utilized in the drug discovery processes. All these techniques are at the same time playing a huge role in the discovery of natural compounds that initiate herbal medicine discovery and development. Further improvements in the property predictions of a compound are observed when deep learning techniques are compared to the classical machine learning techniques as a result of neuronal network-based novel algorithms such as deep neural networks. Applications of techniques based on Artificial Intelligence in natural drug discovery are being demonstrated to predict the compound design, physicochemical properties, biological activity, ADMET properties, etc. Along with this, it is also helpful in mining the data in search of a compound with similar properties and biological activities as required when there is a lack of the original compound. From an open-source implementation, Artificial Intelligence benefited drug discovery strongly by providing access to software libraries and allowing the implementation of complex neural networks. The extent of applications of Artificial Intelligence in drug discovery has been largely increased and may also increase its branches in natural drug discovery and development. Along with *de novo* designing, retrosynthetic analysis, etc., Artificial Intelligence is also spreading the applications in other areas where large datasets can be made available easily. With such progress, a tendency towards more automated natural drug discovery can be expected leading to large robotics which may accelerate the development to a large extent.

### References

- H.C. Stephen Chan, Hanbin S, Thamani D, Horst V, Shuguang Y. (2019). Advancing Drug Discovery via Artificial Intelligence. Trends in Pharmacological Sciences, 40, 8.
- Agrawal P. (2018). Artificial Intelligence in Drug Discovery and Development. Journal of Pharmacovigilance, 06, 10.4172/2329-6887.1000e173.
- Liu B.(2009). Handbook Chapter: Sentiment Analysis and Subjectivity. Handbook of Natural Language Processing. Marcel Dekker, Inc. New York, NY, USA.
- Yi F, Zhaohui W, Xuezhong Z, Weiyu F. (2006). Knowledge discovery in traditional Chinese medicine: State of the art and perspectives. Artificial Intelligence in medicine, 38(3),219-236.
- Bernard KF, Gayo D, ClovisF. (2013). Conceptual graph-based knowledge representation for supporting reasoning in African traditional medicine. Engineering Applications of Artificial Intelligence, 26(4),1348-1365.
- Gang B, Tiejun Z, Yuanyuan H, Guoyu D, Min J, GuoanL. (2018). From quality markers to data mining and intelligence assessment: A smart quality-evaluation strategy for traditional Chinese medicine based on quality markers. Phytomedicine, 44, 109-116.
- Harvey AL. (2008). Natural products in drug discovery. Drug discovery today, 13, 894-901.
- Neve J, Leone PDA, Carroll AR, Moni RW, Paczkowski NJ, Pierens G, Björquist P, Deinum J, Ehnebom J, Inghardt T, Guymer G, Grimshaw P, Quinn RJJ. (1999) Nat.Prod, 62, 324–326.
- Hong F, Zheni C. (2003). A two-stage approach for leaf vein extraction. Proceedings of International Conference on Neural Networks and Signal Processing, 1, 208–211.
- Kalaitzis JA, Leone PDA, Harris L, Butler MS, Ngo A, Hooper JNA, Quinn RJ. (1999) J. Org. Chem, 64, 5571–5574.
- Buchanan MS, Edser A, King G, Whitmore J, Quinn RJ. (2001), J. Nat. Prod,64, 300–303.
- Carroll AR, Pierens GK, Fechner G, De Leone P, Ngo A, Simpson M, Hyde EJNA, Hooper JN, Bostroem SL, Musil D, Quinn RJ. (2002). J. Am. Chem. Soc. 124, 13340–13341.
- 13. Carroll AR, Buchanan MS, Edser A, Hyde E, Simpson M, Quinn RJ.(2004) J. Nat. Prod,67, 1291–1294.
- Nicholas E, Thomford D, Dimakatso AS, Arielle R, Daniella M, Palesa S, Alfred M, Kevin D.(2018). Natural Products for Drug Discovery in the 21<sup>st</sup> Century: Innovations for Novel Drug Discovery Int. J. Mol. Sci., 19, 1578.
- Patridge E, Gareiss P, Kinch MS, Hoyer D. (2016). An analysis of FDAapproved drugs: Natural products and their derivatives. Drug Discov. Today, 21, 204–207.
- Wani MC, Taylor HL, Wall ME, Coggon P, McPhail AT. (1971). Plant antitumor agents. VI. The isolation and structure of taxol, a novel antileukemic and antitumor agent from Taxus brevifolia. J. Am. Chem. Soc. 93, 2325–2327

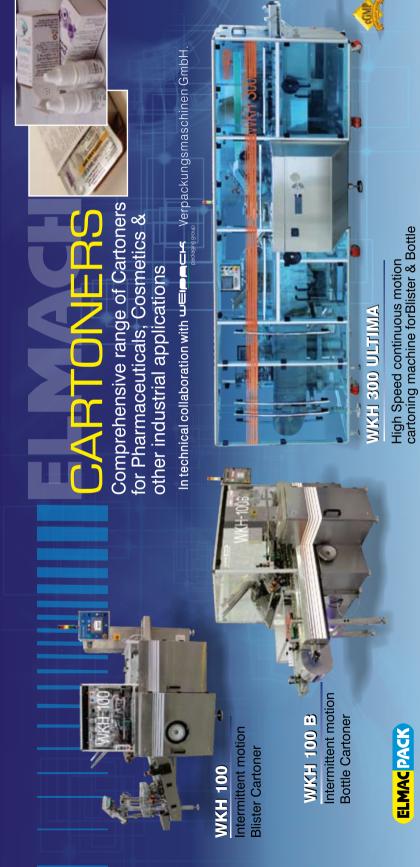
- 17. Li JW, Vederas JC. (2009). Drug discovery and natural products: End of an era or an endless frontier. Science, 325, 161–165.
- Newman DJ, Cragg GM. (2012). Natural products as sources of new drugs over the 30 years from 1981 to 2010. J. Nat. Prod, 75, 311–335.
- Li FS, Weng JK. (2017). Demystifying traditional herbal medicine with modern approach. Nat. Plants, 3,17109.
- Leonti M, Verpoorte R. (2017). Traditional Mediterranean and European herbal medicines. J. Ethnopharmacol, 199, 161–167.
- Ozdemir V, Hekim N. (2018). Birth of industry 5.0: Making sense of big data with artificial intelligence, "the internet of things" and nextgeneration technology policy. Omics , 22, 65–76.
- Ozdemir V. (2015). An accelerator for global science, systems medicine and responsible innovation. Omics, 19, 579–580.
- Buriani A, Garcia-Bermejo ML, Bosisio E, Xu Q, Li H, Dong X, Simmonds MS, Carrara, M, Tejedor N, Lucio-Cazana J.(2012). Omic techniques in systems biology approaches to traditional Chinese medicine research: Present and future. J. Ethnopharmacol, 140, 535–544.
- Dissanayake A, Gunathilaka G, Dias M, Jayasinghe G, Kasthurirathna D. (2018). "Niwarana"-An Artificial Intelligence Based System for Traditional Medicine. 10.13140/RG.2.2.19949.23522.
- Schneider G. (2018). Automating drug discovery. Nature reviews drug discovery, 17, 97.
- 26. Sanderson K. (2015). March of the synthesis machines. Nature Publishing Group.
- Sparkes A, Aubrey W, Byrne E, Clare A, Khan MN, Liakata M, Markham M, Rowland J, Soldatova LN, Whelan KE. (2010). Towards Robot Scientists for autonomous scientific discovery. Automated Experimentation, 2, 1.
- Eglen RM, Randle DH. (2015). Drug discovery goes three-dimensional: goodbye to flat high-throughput screening. Assay and drug development technologies, 13, 262-265.
- Macconnell AB, Price AK, Paegel BM. (2017). An integrated microfluidic processor for DNA-encoded combinatorial library functional screening. ACS combinatorial science, 19, 181-192.
- Tomov TE, Tsukanov R, Glick Y, Berger Y, Liber M, Avrahami D, Gerber D, Nir E. (2017). DNA bipedal motor achieves a large number of steps due to operation using microfluidics-based interface. Acs Nano, 11, 4002-4008.
- Meanwell NA. (2016). Improving drug design: an update on recent applications of efficiency metrics, strategies for replacing problematic elements, and compounds in nontraditional drug space. Chemical research in toxicology, 29, 564-616.
- Adami C. (2015). Artificial intelligence: Robots with instincts. Nature, 521, 426-427.
- Rafferty MF. (2016). No Denying It: Medicinal Chemistry Training Is in Big Trouble: Miniperspective. Journal of medicinal chemistry, 59, 10859-10864.
- Mondal M, Hirsch AK. (2015). Dynamic combinatorial chemistry: a tool to facilitate the identification of inhibitors for protein targets. Chemical Society Reviews, 44, 2455-2488.
- 35. Peplow M. (2014). Organic synthesis: the robo-chemist. Nature News, 512, 20.
- Vermesan O, Friess P. (2013). Internet of things: converging technologies for smart environments and integrated ecosystems, River publishers.
- Carroll GP, Srivastava S, Volini AS, Piñeiro-Núñez MM, Vetman T. (2017). Measuring the effectiveness and impact of an open innovation platform. Drug discovery today, 22, 776-785.
- Han J, Pei J, Kamber M. (2011). Data mining: concepts and techniques, Elsevier.
- 39. Amin H, Sharma R. (2016). How Data Mining is useful in Ayurveda. Journal of Ayurvedic and Herbal Medicine, 2, 61-62.
- Yea SJ, Seong B, Jang Y, Kim C. (2016). A data mining approach to selecting herbs with similar efficacy: Targeted selection methods based on medical subject headings (MeSH). Journal of ethnopharmacology, 182, 27-34.

- 41. Ang-Lee MK, Moss J, Yuan CS. (2001). Herbal medicines and perioperative care. Jama, 286, 208-216.
- 42. Patwardhan B. (2012). The quest for evidence-based Ayurveda: lessons learned. Current science, 1406-1417.
- Cordell GA. (2017).Sixty Challenges A 2030 Perspective on Natural Products andMedicines Security.Natural Product Communications, 12 (8), 1371 – 1379.
- 44. Satty V, Satya A, Sharma S. (2013). An automatic leaf recognition system for plant identification using machine vision technology. International Journal of Engineering Science and Technology, 5, 874-879.
- 45. Liu M, Karuso P, Feng Y, Kellenberger E, Liu F, Wang C, Quinn RJ. (2019). Is it time for artificial intelligence to predict the function of natural products based on 2D-structure. Med chem. Comm, 1-11.
- Nazarenkoa DV, KharyukbPV, Oseledets IV, RodinalA, ShpigunaOA. (2016). Machine learning for LC–MS medicinal plants identification. Chemometrics and Intelligent Laboratory Systems, 156, 174–180.
- Huanga Y, Wua Z, Sua R, Ruana G, Dua F, Li G. (2015). Current application of chemometrics in traditional Chinese herbal medicine research. Journal of Chromatography B,1-9.
- Sharma S, Gupta C. (2015). A Review of Plant Recognition Methods and Algorithms. International Journal of Innovative Research in Advanced Engineering, 6, 111-117.
- Zheru C, Li H, Wang C. (2003). Plant species recognition based on bark patterns using novel Gabor filter banks", Proceedings of International Conference on Neural Networks and Signal Processing, 2, 1035 – 1038.
- Keskar M, Maktedar D. (2019). Enhancing Classifier Accuracy in Ayurvedic Medicinal Plants using WO-DNN. International Journal of Engineering and Advanced Technology, 9 (1), 6705-6714.
- Gopal A. (2014). Near infra-red spectroscopy for quality assessment of Indian traditional herbal medicines: a review. International Journal of Pharmaceutical Sciences and Research, 5(8), 3133-3143.

### **APP 9th Annual Virtual International Convention**

Association of Pharmacy Professionals (APP) Rajasthan State Branch and APP American International Branch jointly organized two-days APP 9<sup>th</sup> Annual Virtual International Convention on 'Recent Advances in Pharmaceutical Sciences, Potential Role of Herbs and Health Challenges' at Faculty of Pharmaceutical Sciences, SunRise University, Alwar, Rajasthan on 19<sup>th</sup> to 20<sup>th</sup> December, 2020 in collaboration with APP MolPharm Division. During the Convention, Dr. Rajiv Dahiya, Founder President APP and Director, School of Pharmacy, The University of the West Indies, Trinidad & Tobago acted as 'Organizing Chairman' and Prof. G. Jeyabalan, Principal, Alwar Pharmacy College, Alwar, Rajasthan and Ex-Dean, Faculty of Pharmacy, Rajasthan University of Health Sciences, Jaipur, Rajasthan, India acted as 'Convener.' International & National renowned experts delivered talks during the conference.

During the convention, E-posters were presented by staff and students of various pharmacy institutions and the event was witnessed by the Vice Chancellors of four Indian Universities *viz*. Prof. Ramesh Goyal, VC, Delhi Pharmaceutical Sciences and Research University, New Delhi, India; Prof. Madhabhai M. Patel, VC, Sabarmati University, Ahmedabad, Gujarat, India; Prof. Indrajeet Singhvi, VC, Sai Tirupati University, Udaipur, Rajasthan, India; Prof. Anup Diwan, VC, SunRise University, Alwar, Rajasthan, India and the Deans of Indian Universities *viz*. Prof. B.N. Suhagia, Dean, Faculty of Pharmacy, DD University, Nadiad, Gujarat, India and Dr. Saurabh Kumar Banerjee, Dean, School of Pharmaceutical Management, The IIHMR University, Jaipur, Rajasthan, India.



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### Obituary



Prof. K.P.R. Chowdary, a Pharma legend and lifelong resident of Visakhapatnam died unexpectedly on 27<sup>th</sup> December, 2020 at the age of 70 due to a massive heart stroke.

K.P.R Chowdary is survived by his parents, his wife Annapurna and his children Janakidevi and Kusumadevi, the two beautiful daughters who were the most important part of his life.

K.P.R. Chowdary was born on 25<sup>th</sup> December, 1950. He did his graduation and post-graduation from Andhra University in 1972 and 1974 respectively. He also completed his doctoral degree from the same Andhra University in 1979. His dedication and destiny made him work as the Principal of the same University of

Pharmaceutical Sciences, Andhra University, Visakhapatnam. He was serving as the President– IPA Rajahmundry Local Branch, IPCA- SSC Convener and also Research Director of Vikas Institute of Pharmaceutical Sciences, Rajahmundry, Andhra Pradesh.

K.P.R. Chowdary was a devoted teacher and an avid Researcher. His passionate teaching and outstanding knowledge dissemination have paved the way for many students to expertise in their relevant fields. He often wrote too many articles in most of the journals and was a great scientist in the Pharma field who mastered around 100 Ph.D Scholars with his vast research experience in Pharmacy. His notable achievements include many awards like Best Principal Award, Best Teacher Award and Eminent Pharmacist Award, etc. He has written the most important aspects of Pharmaceutics in the form of books which are always available in every institution. His contributions to the Pharma sector are inspirational to many students and staff. He will be deeply missed by his students, friends, family and all who knew him.

On behalf of IPA, we express our deepest condolences to the bereaved family for his heavenly abode.



### WORK STATUS AS ON JANUARY, 2021 & PROPOSED ACTIONS FOR THE IPA BUILDING PROJECT

- 1. The External Plumbing work is over.
- 2. The Internal Plumbing work is going on.
- 3. The Fire Fighting work has begun and the wiring for the heat detectors is done.
- 4. The core cutting required for the Firefighting work is going on. The mock up has been done.
- 5. The terrace waterproofing work along with the china mosaic flooring is over.
- 6. The marking for the road around the building & the excavation for the same has been done.

### Donations received in December – January 2020-21

1. A.S.N. Pharmacy College - 1,00,000/-

### Mean, Means and Meaning A Column by Ajaz Hussain, Senior Regulatory Professional



# Making Meaning of Sustainable Human, Professional and Corporate Development in the 2021 to 2030 Years

We are in an epoch of unprecedented changes in the ways we work and live, and we are experiencing worry and unease about uncertain outcomes. As pharma professionals, we practice building quality in ensuring safety and efficacy. How our experience sustains our professional development, and more broadly, human and corporate development is a topic that interests me. Writing this column reflects and introspects how we

experience unprecedented changes and learn from our experiences to sustain our professional growth and development. Grounded in regulatory science and good practices, knowing how to share assurance to be at ease where we work and live is the purpose of these writings—this column place in the context of mind and matter, a simple tool, the PDCA Cycle.

### When time flys a week passes by like a day, and the World changes.

In being connected to a smartphone, working in smart factories with smart devices, and living in smart cities, information inundates us. We are in a race to "smart" maturity in the unfolding "Great Reset" of systems we are born, live, and die [1-3]. We can observe this race in real-time, and know-how consequential falling behind is when the USA's President can be casually de-platformed from social media corporations mining maturity poverty for profit. The words smart and maturity together signify development because smartness without maturity is just witty, clever, rude, or impolite, boldly disrespectful.

The gap in our smartness is in the meaning we make as the World changes, increasing complexity, and ambiguity in ways that we can not estimate the probability of an outcome. Being human is a journey. From 2021 to 2030, one roadmap for this journey is outlined by the United Nations [5,6] and supported by the elites leading the World Economic Forum [7].

Suppose you have read my previous contribution to Pharma Times [1-4]. You may recall or remember my proposal on how to mature our smartness. Observing and learning in real-time to notice emotions we feel (i.e., experience), be mindful of expanding the space between stimuli and response can be the way forward to make sense of our knowledge and move from being predictably irrational to a rational being.

We attempted to take a migratory bird's eye view for charting a path forward [1-4]. Since these writings, a lot has changed around us, but often it is masked and not in our awareness while many of us remain confined to lockdowns. When time flys a week passes by as a day accelerating change. So let us take flight again, like a migratory bird, to view what has changed in the past few weeks.

Like a migratory bird, I am taking a flight again, more confidently.

Speaking of a migratory bird, I noted a new research article with great interest that describes a key biochemical reaction of a cryptochrome protein sensitive to the Earth's magnetic fields. Spooky experience, indeed. Yet this emerging evidence of quantum physics directly affecting a biochemical reaction in cells underpins birds', and many other creatures,' talents for sensing the direction of the planet's poles [6]. So then, the experience of seeing the World through the eyes of a migratory bird (pinpoint focus, panoramic view, and sensing the invisible magnetic fields) shouldn't be spooky. But what does it mean, how do we perceive it, and what meaning do we make of sustainable development?

I am returning to India's wisdom traditions to explore a way forward. With all due respect to Cartesian mind-body dualism, I posit, the prescription in changing how we interact with smartphones and other tools is to erase this dualism and note that "*I feel; therefore, I am,*" then "I am; therefore, I think" [1,4]. In practical terms, this means a reinterpretation of the verb "experience," telling to feel, in the professional context such as the US CGMP regulations at 21 CFR 211.25 (which pertains to education, training, and experience) and being more sophisticated to describe and measure our experience beyond counting time in a job.

The meaning we make depends on the maturity of our development.

The meaning we make of our observations begins in our subconscious mind and multiple definitions of words we hear and read, and we rarely consult a dictionary. It is emotionally and rationally entwined; as professionals, we seek to be good at practicing being rational. Under "normal" circumstances, we can misunderstand each other, but in complex and chaotic scenarios, we must rely on the sharpness of our skills of sensemaking; a process of making sense of or giving meaning to something, especially new developments and experiences (see Figure 1 in [1]).

Do we come to our senses when we lose our minds? In psychology, the term "Theory of Mind" encompasses our ability to attribute mental states, including emotions, desires, beliefs, and knowledge. Note the emphasis on theory is important as in an opinion and hypothesis.

Mind Matters: Converting the "plan, do, check and act cycle" to a Spiral

As professionals, we begin with an idea, but we don't stop until we test its validity. Our passion and interests focus our attention, and we observe what interests us. We must expand our interests and be passionate about our development. Most of us should be familiar with the Deming - Shewhart PDCA cycle, so why not use it more broadly for our minds to sustain our growth and development? If so, how might we do so?

What in mind are the analogs to a plan in materiality and the do, check, and act? Figure 1 is an image of an analogous process 4 Cs process in mind. Conception, cognition, clarity, and communication, via our voice or authorship, to the world. Conceptualization (in information science) is an abstract, simplified view of some selected part of the world, containing the objects and ideas of

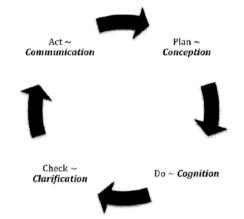


Figure 1. Mind matters: The 4 Cs and PDCA Cycels

interest (to us). Cognition is the mental process of acquiring knowledge and understanding through thought, experience, and the senses. Clarity of our mind forms our intention, which is our informal decision. We communicate to seek agreement with others to formalize decisions that drives the PDCA Cycle in professional practice.

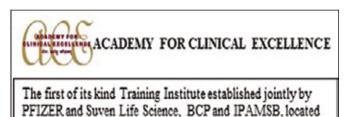
Only in the reality of evidence we assure others, we must know what interests others, particularly the patients who will use the pharmaceuticals we make. To give assurance, we first must be self-assured. To be self-assured, we must seek to be internally validated and not be dependent on or seeking external validation. In an environment of increasing complexity and uncertainty, we must continually test the validity of what has informed our beliefs and opinions.

With effort, I practice in mind as in the real world, the 4 Cs and PDCA Cycles, respectively. Between cycles, I take time to collect and review lessons learned, introspect to expand my awareness. It is a way to experience how to step-by-step understand what

it means to fly like a migratory bird. To see opportunities and risks in uncertainty, gauge my suitability and capability, and be internally validated. Will reading this column help some reflect on their current practice for managing tensions and dangers they confront in their environments? Uncertain until I receive feedback. So until the next column or cycle explores further the UN's "sustainable development" [5,6] and "The Great Reset [7], an open question for introspection.

### References

- Hussain, AS Digitization in Pharma and Digital Therapeutics: A Migratory Birds Eye View for Charting a Path Forward. Pharma Times - Vol. 52 - No. 12, December 2020 - Vol. 52 - No. 12.
- Hussain, A, S. Mean Meaning Making and Manufacturing Maturity. Pharma Times - Vol. 52 - No. 10 - 11, October - November 2020.
- Hussain, A. S. Mean "Therapeutic Equivalence" and a population in which it is common to think one is better than average. Pharma Times - Vol. 52 - No. 09 - September 2020.
- Hussain, A. S. Pharmaceuticals Beyond 2020: Professionals and Artificial Intelligence. Pharma Times - Vol. 52 - No. 06 - June 2020.
- United Nations. Agenda 21. Sustainable Development Goals. Knowledge Platform. <u>https://sustainabledevelopment.un.org/outcomedocuments/agenda21</u> (Accessed 13 January 2021)
- United Nations. Transforming Our World: The 2030 Agenda for Sustainable Development. <u>https://sustainabledevelopment.</u> <u>un.org/content/documents/21252030%20Agenda%20for%20</u> <u>Sustainable%20Development%20web.pdf</u> (Accessed 13 January 2021)
- 7. The World Economic Forum. The Great Reset. <u>https://www.weforum.org/great-reset</u> (Accessed 13 January 2021).



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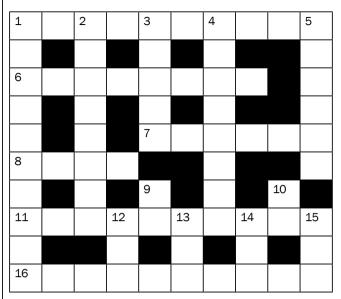
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# PHARMA WITS AND LEISURE

# - Raj Vaidya PHARMA CROSSWORD 61



### CLUES ACROSS

- 1. Diclofenac not permitted for \_\_\_\_\_ use (10)
- 6. Basic units of our bean organ (8)
- 7. The prefix referring to our guts (6)
- 8. Torsemide acts on the \_\_\_\_\_(4)
- 11. Drug blocks alpha, eases urination (10)
- 16. Device turning liquid to vapour [in reverse order] (10)

### DOWN

- 1. The breathing machine (10)
- 2. Its larvae can migrate and forms cysts in brain (8)
- 3. Calibrate regularly to minimize \_\_\_\_\_[in reverse order] (5)
- 4. Acetaminophen is a \_\_\_\_\_ painkiller [1st 8 of 12 letters] (8)
- 5. A vaccine with a fever in it (6)
- 9. The light which disinfects [in reverse order] (1,1)
- 10. Attack on the heart (1,1)
- 12. System that unconsciously regulates body functions [in reverse order]  $(1,\!1,\!1)$
- 13. Internal phase in milk [in reverse order] (3)
- 14. High altitude sickness for hikers [in reverse order] (1,1,1)
- 15. Indian tree, antiseptic, blood purifier [1st 3 of 4 letters] (3)

### **PHARMA CROSSWORD - 60**

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Т		С			N		Р		A
<sup>6</sup> 0	A	Т	S		<sup>7</sup> K	I	N	I	N
L		Е			Y				N
8	L	R		۶B	L	A	<sup>10</sup> T	Т	A
Z		U		В			Н		В
<sup>11</sup> U	N	S	<sup>12</sup> A	Т	<sup>13</sup> U	R	A	Т	I
М			S		Т		L		S
A			0		U		A		
<sup>14</sup> B	A	С	Т	E	R	E	М	I	A

### PHARMA MUMBO-JUMBO - 61

Unscramble each of the following 6 sets of letters to form pharma related words. Then select the letters in the circles, and use each letter once, to make another pharma related 14 –letter word taking clue from the hint provided.

Clue: I am age to largest human gland Master Word

### This Quiz is open to IPA members only.

You need to send your completed entries, along with your name, designation/affiliation, address, contact details, and IPA membership number to **pharmatimesquiz@ipapharma.org**. You can complete the quiz on this page itself & scan the page & mail it to us. Alternatively, you can download the quiz from the IPA website at **www.ipapharma.org** & send it across.

The first 3 correct entries (a correct entry is one in which both the quizzes -crossword and unscramble - are all correct) would be declared winners of the quiz.

### Last date for receiving entries : 15th February, 2021

Read the March 2021 issue for the quiz results & the names of the winners !!

Unscramble each of the following 6 sets of letters to form pharma related words. Then select the letters in the circles, and use each letter once, to make another pharma related 14 –letter word taking clue from the hint provided.

PHARMA MUMBO JUMBO 60

0			•						
LETAD	(X)	Х	Х	(X)	Х			DELTA	
ASMS	X	Х	Х	(X)				MASS	
GEENYR	X	Х	Х	(X)	Х	$\otimes$		ENERGY	
ΟΟΙΜΝΤ	Х	(X)	Х	(X)	Х	(X)		MOTION	
RFOEC	Х	X	Х	(X)	$(\mathbf{X})$	-		FORCE	
RHTEAML	Х	(X)	Х	Х	$(\mathbf{X})$	(X)	Х	THERMAL	
Clue: Branch of Physics. Heat, temp, work, physical properties • Master word : THERMODYNAMICS									

# LEADERSHIP BYTES

### S.V. Veeramani

### Chairman & Managing Director, Fourrts (India) Laboratories Pvt. Limited



Digitalisation in Research & Development and Drug Discovery has been in vogue for quite some time internationally in the pharmaceutical industry. But, subsequently, the Digital application has gone up in manufacturing, supply chain, marketing and probably every facet of pharmaceutical industry. Today, it is estimated that around 5% of the total work force in pharmaceuticals worldwide are IT Professionals.

The advent of Covid has further accelerated digital application. With social distancing, work from home and restriction on transport and courier as well as personnel, digitalization has taken off greatly of-late. Covid has thought us on how to carry on business without much human interaction and the great need for digital marketing. I will confine myself to pharmaceutical marketing in India, although there has been an increased digital application in manufacturing and supply chain.

Digital marketing has taken off in a big way in the Indian Pharmaceutical Industry. And they are likely to stay even after Covid will be gone.

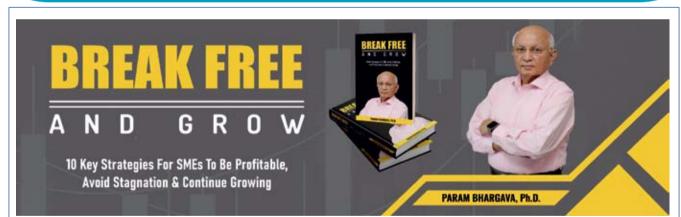
With restrictions on movement of sales personnel, a need arose for reaching Doctors digitally. With the result, there has been an increased activity of marketing on E-mail / Whatsapp and Videos. Further, customers are reached through social medias like Facebook, Youtube, E-CRM, Interactive & Educational Videos. There is an omni-channel communication depending on the digital aptitude of customers. Doctors are also using tele-consultation and e-practice platform.

There is an increased use of Webinars than ever before in the pharmaceutical industry. With reduced travel, sales persons meetings are conducted on zoom. There is also a surge on e-commerce in pharmaceuticals, as people would like to reduce visits to Pharmacies. One good aspect is that they are all mobile friendly. In product management, there is conceptualization and content creation going on digitally. There is also a need for better key accounts management digitally, considering that we are not able to meet all the Doctors. There is a need for digital literacy and digital etiquette to field force in marketing. There is also a need for up-skilling, cross-skilling and re-skilling in digital application today. There is a need to rework the media to reach customers and adopt a suitable media-mix and promote the brands in new normal.

In general, we seem to be entering into the exciting world of digital in marketing.

In the post covid era, we will not go back 360° to old normal. Many digital learnings will remain in the new normal.

Pharmaceutical industry has started exploring on "How to deliver customers experience with digital marketing".



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### **IPA Bengal State Branch**



Indian Pharmaceutical Association Bengal Branch celebrated National Pharmacy Week by virtually paying homage through a display in two reputed newspapers namely 'Times Of India' and 'Ei Samay', to martyred pharmacists and the ones still working in different hospitals throughout the world for their service to the people in COVID-19 situation.

The inauguration program was conducted virtually on 16th November, 2020. The program was initiated by Dr. Subhash C. Mandal, Vice President & Chairman Regulatory Affairs Division. Indian Pharmaceutical Association, Kalina, Santacruz, Mumbai and Moderator of the program, stating the objectives of celebration this week during the past 58 years. Mr. Prabir Banerjee, President, IPA Bengal Branch extended a hearty welcome to the guests and participants. The Guest of Honour was Dr. T.V. Narayana, National President of IPA & President of SEARPharm Forum. The Chief Guest of the program was Prof. Saikat Moitra, Vice-Chancellor of Maulana Abul Kalam Azad University of Technology (MAKAUT). Prof. Moitra expressed his satisfaction with the activities of the Indian Pharmaceutical Association. The program was conducted jointly with Eminent College of Pharmaceutical Technology, BCDA College of Pharmacy and Technology, JIS University and Bharat Technology, Uluberia.

### **Eminent College of Pharmaceutical Technology**

IPA Bengal Branch in collaboration with Eminent College of Pharmaceutical Technology celebrated the 59<sup>th</sup> National Pharmacy Week, through a live online session on 19<sup>th</sup> November, 2020. The program was inaugurated by Mr. Samir Chakraborty, Chairman and Mr. Swapan Karak, Managing Trustee, Nirmala Foundation Trust. Dr. Amitsankar Dutta, Principal, Eminent College of Pharmaceutical Technology; Mr. Surajit Goon, Principal, Eminent College of Management graced the occasion. Esteemed speakers were Mr. Prabir Banerjee, President, IPA, Bengal Branch and Dr. Jayanta Chatterjee, President, All India Drugs Control Officers' Confederation. With a cultural performance by the students, the program was concluded.

### **BCDA College of Pharmacy and Technology**

The 59<sup>th</sup> NPW Students Day was celebrated on 20<sup>th</sup> November, 2020 through online Zoom & YouTube platform jointly with IPA, Bengal

Branch & BCDA College of Pharmacy and Technology, Hridaypur campus, Kolkata. Dignitaries from IPA & BCDA Organizations and Directors, Principals, Faculty members & Students from all WB Pharmacy Colleges making a total of 1363 Youtube viewers & 172 Zoom viewers participated in the above-said program. An Inter-College Quiz Competition was also held among the students of 8 participant colleges. The winners were Eminent College of Pharmaceutical Technology, Barasat; Dept. of Pharmacy, North Bengal University, Siliguri; and Dr. B.C. Roy College of Pharmacy and AHS, Durgapur. Dr. Soumendra Darbar and Dr. Amal Dhara conducted the online quiz successfully.

The eminent speakers were Prof. Pranabesh Chakraborty, Dr. Subhash C. Mandal from Regulatory Affairs, Mr. Monoj Gupta, Mr. Sankha Roy Chowdhury, Mr. Pralay Kumar Mondal. Mr. Prabir Kumar Banerjee, President, IPA Bengal Branch & Prof. Dr. N.N. Bala, Principal, BCDA College of Pharmacy and Technology were the Joint Organizers. The program was co-ordinated by Dr. Nityananda Mondal, Associate Professor, BCDA College of Pharmacy and Technology.

### **JIS University**

The 59<sup>th</sup> National Pharmacy Week was celebrated by the Department of Pharmaceutical Technology, JIS University in association with IPA Bengal branch on 21<sup>st</sup> November, 2020 via Zoom. The celebration session started with the welcome address by the Vice-Chancellor of JIS University Prof. (Dr.) Biman Chandra Mal. Dr. A.B. Bhattacharya, Pro Vice-Chancellor of JICS University; Prof. (Dr.) Tapan Kumar Chatterjee, Dean of the University; Mr. Prabir Kumar Banerjee, President of Indian Pharmaceutical Association, Bengal Branch and Dr. Divakar Goli, Editor of Indian Journal of Pharmaceutical Sciences (IJPS), graced the occasion by delivering inspiring talks. Departmental Head Prof. (Dr.) H.S. Maji expressed his views by quoting why till date the pharmacist does not get the deserved recognition in the Indian society. The last part of the session was the poster-making competition on 'Innovation or Research to counteract COVID-19.' More than 50 participants participated from which, 17 participants were shortlisted. The three best students were given recognition certificate signed by Dean and HOD. The whole session was live from the departmental YouTube Channel 'JISU-PHARMA' and was co-ordinated and anchored by Mr. Sakshar Saha.

### Bharat Technology, Uluberia, Howrah

59<sup>th</sup> National Pharmacy Week was celebrated by Bharat Technology, Uluberia, Howrah & IPA, Bengal Branch jointly on 24<sup>th</sup> & 25<sup>th</sup> of November 2020. Keeping in mind the present COVID-19 scenario, the institute organized a COVID-19 awareness rally which witnessed active participation from the students and teaching, non-teaching staff members and IPA members of the organization in the surrounding areas, to distribute the masks and sanitizer among the locals on 24<sup>th</sup> November. On 25<sup>th</sup> November, a webinar arranged on the theme, 'Pharmacist: Frontline Health Professionals' was inaugurated by the Hon'ble Chairman of the Institute Prof. (Dr.) Rabindra Debnath, followed by Dr. Kuntal Hazra, Principal of the Institute; Dr. Biplab Debnath, Vice Principal of the Institute and Mr. Prabir Banerjee, President, IPA, Bengal Branch

The eminent speakers, Dr. Richa A. Dayaramani and Dr. B.B. Barik delivered their speeches on the same. The entire programme was moderated by Mr. B. Biswal, Assistant Professor of the Institute and the Vote of Thanks was addressed by Mr. S. Dutta, Assistant Professor of the Institute. Durgapur chapter of IPA Bengal Branch celebrated NPW at DSP Main Hospital Pharmacy premises. Around 50 Pharmacists participated in this programme. Dr. Joy Mukherejee, Joint Director of DSP Hospital inaugurated the programme. Invited Pharmacists spoke on the theme of NPW celebration- 2020.

### **IPA Bihar State Branch**

Indian Pharmaceutical Association (IPA) Bihar State Branch celebrated the 59<sup>th</sup> National Pharmacy Week virtually on 23<sup>rd</sup> November, 2020. Sri. Sanjiv Rai, President of the branch presented the welcome address. Sri. R. Bandyopadhyay, Hon. Secretary of the branch delivered the keynote address on the theme of 59<sup>th</sup> NPW. Online Intercollege Essay Competition



2020 was organized and the winners were– Anuradha Kumari, MIT Muzaffarpur, Jaya Singh and Pranab Vivek. The recipient of this year's S. Laskar Memorial Pharma Excellence Award- 2020 was also declared during the event. Dr. R.N. Gupta, Professor, BIT Mesra, Ranchi and Vice-President cum Chairman of the Hospital Pharmacy Division, IPA was awarded this prestigious award for his outstanding contribution in the development of different spheres of the pharmacy profession. Dr. L.K. Chaudhary, past President, Sri. Binod Kumar, Council member of the branch, Azad Bharti, IPA-SF GPI, Anjali of IPA-SF MIT spoke on the occasion. 59<sup>th</sup> National Pharmacy Week Celebration was concluded with a Vote of Thanks by Sri. Satish Shankar Pathak, Jt. Secretary of the branch.

### **IPA Delhi State Branch**

The Indian Pharmaceutical Association-Delhi State Branch (IPADSB) in collaboration with Delhi Pharmaceutical Trust (DPT) celebrated the inaugural function of the 59<sup>th</sup> National Pharmacy Week (NPW) on 15<sup>th</sup> November, 2020 at Hotel Legend Inn, New Delhi. The theme of the NPW the year was 'Pharmacists: Frontline Health



Professionals' and was celebrated throughout the country from 16<sup>th</sup> to 22<sup>nd</sup> November, 2020. The inaugural session started with the traditional lamp lighting ceremony. Kalhan Bazaz, President of IPADSB, welcomed the guests. The Chief Guest of the inaugural function was Prof. Bejon Kumar Misra, International Consumer Policy Expert and Founder Director of Patient Safety & Access Initiative of India Foundation (PSAIIF). The Guest of Honour, Smt. Yogita Singh, President, BJP Mahila Morcha, Delhi Pradesh extended support for the various initiatives taken by IPADSB to combat COVID-19. Dr. Naresh Sharma, Immediate Past President, IPADSB gave a keynote address. Prof. Roop K. Khar, Director, B.S. Anangpuria Institute of Pharmaceutical Sciences (BSAIPS), Faridabad delivered an informative talk. Dr. T.V. Narayana, National President, IPA, inaugurated the website of IPADSB. On the occasion, Prof. Bejon Misra and Prof. Roop Khar released posters of the 59<sup>th</sup> NPW. Smt.

Yogita Singh and Prof. Farhan Ahmad released a Handbook on Pharmacy Management-Standard Operating Procedures authored by Dr. Sangeeta Sharma, Professor and Head, Department of Neuropsychopharmacology, Institute of Human Behaviour & Allied Sciences (IHBAS) and President of Delhi Society for Promotion of Rational Use of Drugs. During the inaugural session, a stock of N95 mask (6-layered) was donated to IPADSB by Mr. Anjani Kumar Mishra, Managing Director (MD), Irvine Lifesciences for the campaign 'Do Gaj Ki Doori Aur Mask Hai Zaroori' and the masks were distributed to the needy people throughout the Week. Other dignitaries present were Prof. Farhan Ahmad, Dean, School of Interdisciplinary Sciences & Technology & Professor of Pharmaceutics at School of Pharmaceutical Education & Research, Jamia Hamdard, New Delhi; S.L. Nasa, President, Indian Hospital Pharmacists Association (IHPA); Dr. Mymoona Akhter, Treasurer, IPADSB; and Rajesh Agarwal, Dr. Javed Ali, Dr. Siddharth Sahai Malhotra, Dr. Saurabh Dahiya & Dr. Ankur Kaul, Executive Council Members of IPADSB. The inaugural function ended with the presentation of mementos to the dignitaries and a Vote of Thanks was proposed by Dr. Neeraj Kumar, Hon. Secretary, IPADSB.

Webinars were organized on the main theme of NPW that will cover topics like Role of Pharmacist in COVID-19 Crisis in India, Pharmacovigilance in COVID-19 Pandemics, Recent Developments in COVID-19 Drugs or Vaccines & their Challenges, Good Storage Practices, Telemedicine in India: its Regulation & Challenges, and last but not least, a topic on IPR. IPADSB Student's Forum had a roster of online competitions including photography battle, video shooting, article writing, poster making, leaflet making, cartoon making, movie maniac quiz competition, etc. Finally, the week ended with a valedictory function on 22<sup>nd</sup> November where the dignitaries declared the results of various competitions held.

### **Jharkhand State Branch**

IPA Jharkhand state branch celebrated National Pharmacy Week on 22<sup>nd</sup> November, 2020 in collaboration with the Department of Pharmaceutical Sciences and Technology, Birla Institute of Technology Mesra, Ranchi. Dr. Hari Kumar, Registrar, Central University of Jharkhand was the Chief Guest. Dr. S. Samanta, HOD Pharmacy department; Mrs. Ritu Sahay Director, Drugs Control, Jharkhand, Dr. S.S. Mahli, Commissioner (Retd), IRS, Dr. B.N. Sinha, Vice President of IPA Jharkhand State branch and Dr. M.P. Chopra, Secretary of Branch, spoke on the occasion. Dr. R.N. Gupta, President of the branch delivered the welcome address. Video and essay competitions were organized. Mr. Harish Kumar Singh was the Co-ordinator. About 140 members of the branch, faculty members and Hospital Pharmacists participated in the NPW. The winners of the video making competition were Miss Surbhi Sharma, Amit Kumar and Gaurav Rakshit. The winners for Extempore talk were Rayesha Das, R. Padmavati and Md Misbah.

### **IPA Punjab State Branch**

University Institute of Pharmaceutical Sciences under the aegis of MHRD Institution's Innovation Council and IPA, Panjab Branch celebrated 59<sup>th</sup> National Pharmacy Week on the theme 'Pharmacists: Frontline Health Professionals' from 17<sup>th</sup> to 21<sup>st</sup> November, 2020. Online events and webinars were organized under the leadership of Prof. 0.P Katare, President IPA; Prof. Bhupinder Singh Bhoop, Vice President IPA and Prof. Indu Pal Kaur, Chairperson, UIPS & Secretary, IPA, Punjab branch. The event was held under the vigilance of Dr. Anurag Kuhad. Dr. Vandita Kakkar and Dr. Amita



Sarwal organized the quiz and interactive debate competition in collaboration with Dr. Eswar Rao from MyBO group on 18th and 19th November respectively. More than a hundred candidates from institutes like NIPER Mohali, NIPER Hyderabad, Jamia Hamdard and Lovely Professional University registered and events observed exemplary performance by all the students. Webinar on 'Skills, Values and Sustainability in the Face of COVID 19 Crises' by Prof. Nandita Singh Dean, International Students, Panjab University was held on 20<sup>th</sup> November. Prof. V.R. Sinha, Dean Research, Panjab University, Chief Guest of the day, emphasized the role of pharmacists not only as a frontline warrior but also as a fabricator and manufacturer of the vaccines and medicines. The week ended with a valedictory function on 21st November and an expert talk on 'National Innovation & StartUp Policy (NISP) & Healthcare Startup Opportunities' by Mr. Sachin Rajaram Kumbhoje, CEO and & Co-Founder, OpEx Accelerator Pvt. Ltd. Felicitation of the winners of various competitions was done with certificates and cash prizes during the concluding event.

### **IPA Anantapur Local Branch**

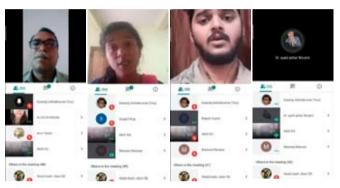
The Indian Pharmaceutical Association (IPA) Anantapur Branch celebrated the IPA National Pharmacy Week (NPW) 2020 on the theme 'Pharmacists: Frontline Health Professionals' from 16<sup>th</sup> to 21<sup>st</sup> November, 2020 at Raghavendra Institute of Pharmaceutical Education and Research (RIPER), Autonomous jointly in association with University College of Pharmaceutical Sciences, Sri Krishnadevaraya University; and Oil Technological and Pharmaceutical Research Institute, JNT University Anantapur; Ananthapuramu, Andhra Pradesh, India.

The IPA Anantapur Branch NPW 2020 celebrations at RIPER Autonomous was chaired by Prof. Dr. Y. Padmanabha Reddy, Immediate Past President, IPA Anantapur Branch/Principal RIPER Autonomous, and coordinated by Dr. P. Ramalingam, President IPA Anantapur Branch/Director R&D RIPER Autonomous; Dr. Mohanraj Rathinavelu, Hon. Gen. Secretary IPA Anantapur Branch/Associate Professor RIPER Autonomous; Mrs. K. Varalakshmi Devi, Vice President IPA Anantapur Branch/ Assistant Professor UCoPS SKU and LEC members IPA Anantapur Branch Dr. U. Veerendra, Mr. G. Narayana, Mr. A. Sudheer, Dr. M. V. Jyothi, Dr. B. Pradeep Kumar, Dr. C. Haranath and Mr. B. Kishore Kumar Reddy.

IPA Anantapur Local Branch organized an Elocution Competition, Virtual Drawing Competition, and Slogan Writing Competition on the NPW 2020 Theme. A National Webinar on the NPW theme and a RIPER Alumni Webinar on 'Prism of Career Opportunities for Millennial Pharmacists' was organized. The resource persons were Dr. Vivekanandan Kalaiselvan Principal Scientific Officer, Indian Pharmacopeia Commission, MoHFW, Gol, Ghaziabad, India and Dr. Dipak Bharambe, Clinical Pharmacologist, Sahyadri Super Speciality Hospital, Pune; Dr. S. Suvarchala, Patient Safety Pharmacovigilance Associate, (IPC-PVPI), MoHFW, Gol, VIMS, Bangalore; Mr. Kommanuru Teja, Senior Associate Manager Pharmacovigilance, Eli Lilly, Bangalore, respectively.

Valedictory and Prize Distribution

### **IPA Channapatna Local Branch**



Dr. H.L. Thimmegowda College of Pharmacy, Channapatna, Karnataka in association with Indian Pharmaceutical Association (IPA) Channapatna Local branch celebrated 59<sup>th</sup> National Pharmacy Week on 18<sup>th</sup> November, 2020 on the theme of NPW 'Pharmacists: The Frontline Health Professionals.' The students actively participated and shared their views on the theme. The Elocution and Poster Making Competitions were organized. Ms. Shifa Afreen welcomed the participants and delegates. Dr. R. Ramesh, President, Dr. Ashok Kumar D, Secretary, IPA Channapatna branch and Dr. M. Gurumurthy, Head, Dept. of Pharmaceutical Chemistry addressed the audience. Ms. Kavya K. proposed the Vote of Thanks. Dr. Syed Azhar Nizami, Mr. Abhilash R, Ms. Sumitra Devi and Mr. Md. Shadab Pasha were the Co-ordinators. Mr. Akhil K A, Assistant Professor, Dept. of Pharmacology, served as Moderator.

### **IPA Enikepadu Local Branch**

Vijaya Institute of Pharmaceutical Sciences for Women, Enikepadu, Vijayawada in association with IPA Enikepadu Local Branch and VIPW-IPASF, organized the 59<sup>th</sup> National Pharmacy Week Celebrations 2020 from 16<sup>th</sup> to 22<sup>nd</sup> November, 2020 on the theme, 'Pharmacists: Frontline Health Professionals' in both online and offline modes. Online competitions on video-making, E-Poster and E-Card making were conducted from 2<sup>nd</sup> to 4<sup>th</sup> November. The inaugural talk was given by Dr. Karthik Rakam, President, Pharmacon Society for Pharmacy Practice on the topic 'Inspiring Professional Journeys.' Students along with the faculty members visited the Pharmacy stores in the rural areas of Enikepadu and Ramavarappadu to educate the personnel about the significance of a pharmacist in a medical store. They



also delivered PowerPoint presentation to the employees of the neighbouring industries of Prakasa Spectro Cast Pvt. Ltd. & Kristna Engg. Works, on COVID-19-Precautions. An awareness webinar was organized, as part of the Student Exchange Programme. The student speakers, Ms. Babitha. K. of Pharm D and Ms. Divya Sree. Ch, B. Pharmacy, presented a talk to the ICC women students of PSCMR College of Engineering & Technology, Vijayawada on 'COVID-19: Advice to Protect Yourself.' The NPW concluded with the valedictory talk and announcement of prizes by Dr. H. Khizer Basha, Consultant Paediatric Intensivist and Neonatologist, Capital Hospitals, Vijayawada. The winners of the competitions with first, second & third in different events respectively were: Video making: Ms. Ch. Amrutha, Ms. S. Lakshmi Devi; E- Poster: Ms. S. Divya, Ms. Sumaiyya Saleem and E-Card: Ms. Sumaiyya Saleem and Ms. S. Divya.

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### **IPA Gudlavalleru Local Branch**



Indian Pharmaceutical Association (IPA) Gudlavalleru Local Branch celebrated the 59<sup>th</sup> National Pharmacy Week by organizing Essay Writing, e-Poster and Video Competitions, wherein students from various colleges participated. Pamphlets were distributed among the public in Gudlavalleru local area to create awareness about COVID-19 and precautions to be taken. As a part of NPW



celebration, a Webinar was organized titled 'You Can Win' by Dr. M. Eswar Guptha, Principal, Sir C.R. Reddy College of Pharmaceutical Sciences, Eluru on 18<sup>th</sup> November, 2020. E-certificates were issued to all the participants.

### **IPA Lam Local Branch**





Indian Pharmaceutical Association (IPA) Lam local branch organized National Pharmacy Week 2020 was celebrated at Chalapathi Institute of Pharmaceutical Sciences (Autonomous), Lam, Guntur from 16<sup>th</sup> to 19<sup>th</sup> November, 2020 under the Theme- 'Pharmacist: Frontline Health Professionals.' Prof. Rama Rao Nadendla, President IPA Lam Local branch and Principal, Chalapathi Institute of Pharmaceutical Sciences (Autonomous) detailed about the celebration week. Several events were conducted such as Pharma Quiz, Essay Writing, Elocution and Extempore. Total 113 students participated from B. Pharmacy, M. Pharmacy and Pharm D. The winners of Pharma Quiz amongst 41 participants were K. Aryani, M. Hema and D. Sai Shanmuk Srinivas. Out of 35 competitors, the first prize in the Essay Writing Competition was bagged by E. Anusha; the first runner-up was M. Lavanya and the third prize was achieved by V. Yoga Sri. in Elocution. In Extempore, out of 37 candidates, the best three participants were G. Preethi, V. Karthikeya and K. Chinni Krishna. The event facilitators were Dr. G. Madhu, Hon'ble Secretary, IPA-Lam, Sk. Munwar, Dr. J. Venkateswar Rao, Mrs. K. Swathi. The college acknowledged Sri Y.V. Anjaneyulu, President, Chalapathi Educational Society for support and patronage of this event.

### **IPA Narsapur Local Branch**



Vishnu Institute of Pharmaceutical Education & Research (VIPER), in Association with IPA Narsapur local Branch, IPGA TS, NSS Unit celebrated the National Pharmacy Week 2020 on the theme 'Insights on Pharma Trends & New Drug Discovery' from 9<sup>th</sup> to 11<sup>th</sup> November, 2020. VIPER organized Webinars, Essay Writing and E-Poster Competitions. Over 837 delegates from across the country participated in the above events. Curtain raising for NPW 2020 was held on 9<sup>th</sup> November, 2020. The Chief Guest of this event was Dr. T.V. Narayana, President, IPA. Dr. Rao Vadlamudi, President CPA, Guest of Honour, updated



on approaches for antiviral drugs for SARS-CoV-2 and clinical developments in COVID-19 vaccine research in various countries including India. The best E-poster presentations were selected and awarded with a cash prize.

Dr. G. Koteshwar Rao President IPGA, Telangana State, was Chief Guest for the valedictory function of NPW 2020 celebration. The Plenary Speaker C.S. Mujeebuddin, Founder & CEO Clinisol Research lab inspired the participants to develop leadership qualities, good communication skills, teamwork, professionalism, decision-making abilities, entrepreneurship. The celebrations were brought to end after the announcement of the winners of the competitions by Dr. G. Koteshwar Rao.

The first position in the Essay competition was achieved by Abi Monika AP, Swamy Vivekanda College of Pharmacy Tamilnadu. The second position was achieved by Sofia Khanam, CIPT&AHS, West Bengal and the third position by Anish Cherian from Dr. L.H. Hiranandani College of Pharmacy, Maharashtra. The winner of the E-poster competitions was K. Sai Vineela from G. Pulla Reddy College of Pharmacy, Hyderabad, Telangana. The second position was bagged by Tamalika Chakraborty, Guru Nanak Institute of Pharmaceutical Science and Technology, West Bengal and the third position was achieved by Subhadip Bhoushik from the Neotia University, West Bengal. This event was successfully hosted and conducted under the guidance of Dr. Ramesh Alluri President and co-ordinated by Mr. Rajashekar Perusomula, Secretary, IPA Narsapur Branch Telangana state. The Convener was Dr. Vanitha Kondi and Co-ordinator was G. Suryam. The organizers of the program were MD. Faheemuddin, Durga Bhavani, B.P. Alta, Nameera Jabeen.



Eminent scholar Prof. Dr. Dhrubo Jyoti Sen bagged 'Iconic Educationist Award' for the year 2020 from the Glorious Organization for Accelerated to Literacy of Goal Society, Delhi on 27<sup>th</sup> December, 2020 for the hallmark of excellence and outstanding achievements

in the field of Pharmaceutical Science. Total 30 eminent personalities from India in the field of Education, Medical Services, Engineering, Infrastructure, Astrology, Mechanical and Social Development have been awarded this honour and he is the only person in the Pharmacy field from West Bengal among the total four selected persons in Pharmaceutical Sciences from the country. GOAL honoured him with an Award and Certificate of Excellence for his outstanding leadership in the Pharmaceutical field with an exceptional performance of high order and salutes his extravaganza curriculum. At present, he is working as a Professor of Pharmaceutical & Medicinal Chemistry in School of Pharmacy, Techno India University, Kolkata, West Bengal.

### **Awards and Honors**

### Ph.D. Award



Name: Dr. Sreekanth Dittakavi

**Title:** Development and validation of LC-MS/MS methods with DBS technique on drugs acting as kinase inhibitors and its application to pharmacokinetic study

University: Shri Jagadishprasad Jhabarmal Tibrewala University

**Guide:** Dr.Rakesh Kumar Jat, Principal and head of college of Pharmacy, Shri Jagadishprasad Jhabarmal Tibrewala Unieristy, Rajasthan.



# 59th National Pharmacy Week Celebration-2020

### **A.S.N Pharmacy College**

A.S.N Pharmacy College, A.P. celebrated the 59<sup>th</sup> National Pharmacy Week 2020 in association with Indian Pharmaceutical Association IPA-AP state branch, IPA Education Division, Mumbai and IPA Student's Forum, ASNPC-Tenali from 16<sup>th</sup> to 22<sup>nd</sup> November, 2020, on the theme 'Pharmacists: Frontline Health Professionals.' On 16<sup>th</sup> November, the inaugural function was done by Sri A. Siva Kumar, Chairman by organizing Essay Writing Competition on the current



year theme of NPW. On 17<sup>th</sup> November, a Debate was conducted on COVID-19. On 18<sup>th</sup> November, a Quiz was conducted and on 19<sup>th</sup> November, an Awareness Camp was held on COVID-19 and pamphlets were distributed at Chakrayapalem village. On 20<sup>th</sup> November, a plantation program was organised with Mr. M. Yesu Ratnam, Co-ordinator, NSS UNIT and students. On 21<sup>st</sup> November, the SWATCHA BHARAT program was held at BC colony, near Tenali wherein more than 100 students participated. On 22<sup>nd</sup> November, the valedictory function of NPW 2020 was held where, Sri. A. Satyanarayana, founder of ASN group of institutions; Principal Dr. K. Venkata Ramana, A.S.N. Pharmacy College & CEC Member, IPA and other dignitaries graced the occasion. Dr. A. Samba Siva Rao, Dr. Sd. Abdul J. Basha and other faculty members, students participated in the program. Vote of Thanks was given by Mrs. T. Sri Lakshmi, Associate Professor, A.S.N College of Pharmacy.

### **GITAM School of Pharmacy**

National Pharmacy Week 2020 was celebrated by GITAM School of Pharmacy, Hyderabad. International Webinar was organized jointly by GITAM School of Pharmacy, Hyderabad and University Technology Mara, Malaysia on the topic 'Challenges and Innovative Drug Delivery Approaches for the Management of Chronic Diseases.' The guest speakers for the event were Prof. Wong Tin Wui, Faculty of Pharmacy, UiTM, Malaysia and Dr. Sunitha Sampathi from GITAM Deemed to be University, India. The inaugural address was



given by Dr. Shariza Sahudin, Dean, Faculty of Pharmacy, UiTM, Malaysia. This was followed by a talk by Prof. N. Siva Prasad. Pro Vice-Chancellor, GITAM Deemed to be University. Prof. G. Shiva Kumar, Principal, GITAM School of Pharmacy also addressed the audience. Dr. Nor Hayati Abu Samah from UiTM, Malaysia gave an introduction to the Faculty of Pharmacy, UiTM, Malaysia. The first session was on the topic 'Innovative Oral, Inhalational and Skin Drug Delivery for Cancer and Diabetes Treatment' by Prof. Wong Tin Wui, Faculty of Pharmacy, UiTM, Malaysia. This was followed by the questions and answers session, moderated by Dr. Ravi Seshala, Senior Lecturer, UiTM, Malavsia, The second session was on the topic, 'Formulation Approaches to Improve the Brain Uptake by Intranasal Delivery' by Dr. Sunitha Sampathi from GITAM School of Pharmacy. The webinar was attended by more than three hundred participants from across India and other countries as well. The concluding remarks and Vote of Thanks were given by Dr. Shariza Sahudin and Prof. G. Shiva Kumar.

### Vignan Pharmacy College

Vignan Pharmacy College celebrated 59<sup>th</sup> National Pharmacy Week from 16<sup>th</sup> to 23<sup>rd</sup> November, 2020 under the theme: 'Pharmacists-Frontline Health Professionals.' The program was inaugurated by Dr. P. Srinivasa Babu, Principal with the startup of Health Camp for faculty and students of Vignan Group of Institutions organized by Mr. P. Rana Kishor, Assistant Professor, Dept. of Pharmacy Practice. Students Activities Council (SAC) organized Technical and Literary events such as Poster Design Contest, Photography, Oratorical





Competition & Essay Writing. Overall, 200 students from various States participated and won the prizes. The week concluded with the valedictory ceremony on 23<sup>rd</sup> November, 2020 by the Chief Guest, Prof. P. Rajeswara Rao, Retd. Professor, Dept. of Pharmacology, AU

and President, IPA AP State branch. Dr. P. Sowjanya, Prof. & Head, Dept. of Pharm. Biotechnology and SAC Coordinator announced the winners and runner ups of the competitions. Dr. L. Rathaiah, Chairman and Sri. Srikrishnadevarayalu, Vice-Chairman, Vignan Group of Institutions congratulated the winners and the organizing team - Dr. P. Sowjanya, Mr. D. Ashok, Mrs. J. Srividya, Ms. K. Preethi & Dr. Satyavathi.

### Delhi Pharmaceutical Sciences and Research University (DPSRU)

Delhi Pharmaceutical Sciences and Research University (DPSRU) virtually celebrated the 59<sup>th</sup> National Pharmacy week from 16<sup>th</sup> to 22<sup>nd</sup> November, 2020 under the theme, 'Pharmacists: The Frontline Professionals.' The program was coordinated by Dr. Sushama Talegaonkar. The inauguration program began with the welcome address by Prof. Geeta Aggarwal. Prof. Harvinder Popli and Prof. Ramesh K. Goyal, Hon'ble Vice-Chancellor, DPSRU also addressed the audience. Dr. D.B.A Narayana, Chief Scientific Officer, Ayurvidye Trust, Bangalore was the Chief Guest. A Flow Diagram Making competition was held where participants were asked to draw a flowchart on a randomly assigned topic. A Label Making event was also organized.

On the second day of the celebration, a Debate competition was held on the topic 'Should India adopt the Western Method of Drug Dispensing?', a Sales Pitch contest, 'Kavyanjali'- A Poetry



Competition was conducted. On Day 3, a Live Pharma Quiz, an online Article writing competition on the theme- 'Pharmacists thwarting Coronavirus' was held. The last day observed an AdMad competition and a Photography competition on the theme 'The New Normal.' On 23<sup>rd</sup> November, the valedictory function was



held wherein Dr. Pramil Tiwari, Head, Department of Pharmacy Practice, NIPER, Mohali was the Chief Guest. Prof D.P. Pathak, Director, DIPSAR highlighted the contribution of Pharmacists to the world. Prof R.K. Goyal discussed various facets of the Pharmacy profession. The Vote of Thanks was presented by Dr. Sushama Talegaonkar.

#### **Rahul Dharkar College of Pharmacy and Research Institute**

RTM Nagpur University UDPS Alumni Association in collaboration with Konkan Gyanpeeth Rahul Dharkar College of Pharmacy and Research Institute, Karjat celebrated the 59<sup>th</sup> National

Pharmacist Week in association with IPA, Raigad Branch, Pharmaceutical Society of India, Nagpur and Academy of Career Design Entrepreneurship and Start-up, on a YouTube platform on the theme 'Pharmacists: The Frontline Professionals.' On the occasion and in the memory of Late Dr. D. M. Brahmankar, Ex. HOD, the great Biochemistry Faculty member of University Department of Pharmaceutical Sciences; Dr. D.M. Brahmankar Memorial Webinar Series was organized. The program was inaugurated by Dr. C.T. Chopde, Ex. HOD UDPS, RTM University Nagpur, and co-ordinated by Mr. Ajay Kharche; Mr. Amol Borade, Assistant Professor; Mr. Sandep Waghulde, Assistant Professor; Dr. Bharat Tekade, Professor; Mrs. Vaishal Jadhav, Assistant Professor and Mr. Pritam Juvatkar, Assistant Professor. The program began with the welcome address and a brief life-sketch of late Dr. D.M. Brahmankar by Dr. Naresh Gaikwad, President, UDPS Alumni Association and Ex. HOD UDPS, RTM University Nagpur, Dr. Mohan Kale, Principal, KGRDCP and RI, and Dr. C. T. Chopde, Ex. Professor and HOD UDPS, RTM paid tribute to the pioneer of research in India, late Dr. D.M. Brahmankar. Dr. Chopde talked about pharmacy education with respect to its development in India and shared the scenario of the transforming pharma industry. The second speaker was Dr. S. N. Umathe, Ex. HOD UDPS, RTM University Nagpur. He discussed advances in healthcare access, facilities and the problems that exist in the rural areas, On 22<sup>nd</sup> November, Mr. Ravi Vishvanathan, Associate Vice-President, Production Department, Mylan pharma, Nashik delivered a talk on 'Current Good Manufacturing Practices' and discussed the basics of GMP from procedures, documentation, validation up to the audit for compliance. The entire program was compered by Mr. Ajay Kharche and Mr. Amol Borade. They also proposed the Vote of Thanks.

#### **PSG College Of Pharmacy**

The 59<sup>th</sup> National Pharmacy Week was celebrated on 27<sup>th</sup> November, 2020 by PSG College of Pharmacy through Zoom Meeting on the theme 'Pharmacists- Frontline Healthcare Professionals.' The Program started with a welcome address delivered by Dr. V. Sivakumar, Professor, Department of Pharmacy Practice. Dr. M. Ramanathan, Principal, PSG College of Pharmacy delivered the Presidential Address. The Chief Guest for the event was Dr. T. Saravanan MD., FICP, Professor & Head, Department of General Medicine, PSGIMSR Hospitals. In his speech, he emphasized the importance of clinical pharmacists in the healthcare team and also stressed upon the need for Poison Information Centre. The Guest of Honor, Dr. Aashig Ahamed Pharm. D. (PB), Clinical Pharmacist, Department of Cardiology, PSG College of Pharmacy Super Specialty Hospitals gave an informative talk on the role of Clinical Pharmacist in various areas of Healthcare. Nearly 160 students and faculties participated in the event. The one-hour session successfully ended with a Vote of Thanks and National Anthem.

#### **Sri Ramachandra Faculty of Pharmacy**

Sri Ramachandra Faculty of Pharmacy, SRIHER (DU) celebrated the 59<sup>th</sup> National Pharmacy Week virtually through Google Meet and YouTube Live Stream (https://youtu.be/XpYTeb08LEQ,https:// youtu.be/wPYrlvzanQ) on the theme, 'Pharmacists: Frontline Health Professionals' from 20<sup>th</sup> to 30<sup>th</sup> November, 2020. On 20<sup>th</sup> November, Prof. Dr. Ciddi Veeresham, Principal, welcomed the gathering and Dr. K. Chitra, Vice-Principal delivered the keynote address. Dr. Suhas Prabhakar, Medical Director, SRMC gave the inaugural address and released the Brochure. The Overview of the Program was briefed by Dr. S. Umamaheswari. Various competitions were conducted virtually from 21<sup>st</sup> to 27<sup>th</sup> November including Photography, Short Video, E-Poster Case Presentation, Clinical



Pharmacy Case Review, Poetry, etc. The valedictory function was held on 30<sup>th</sup> November and was presided by Guest speaker Dr. Sanju Dhawan, IPGAWF South Zone Coordinator, Head-Product Development IKKT, Medicinal Sciences -Pharmaceutical Sciences Small Molecule, Pfizer Healthcare India Private Limited, Tamil Nadu. This was organized by Student Club members under the guidance of Students Advisor Dr. C. Vinodhini; Dr. S. Karthik, Assistant Dean, Students Dr. J. Srikanth. Dr. K. Mangathayaru, Vice-Principal Additional, proposed the Vote of Thanks.

#### **Hindu College of Pharmacy**

59<sup>th</sup> National Pharmacy Week was inaugurated on 16<sup>th</sup> November, 2020 on the theme, 'Pharmacists: Frontline Health Professionals.' The event was inaugurated by Hon. Chairman of HCOP, Sri. Jupudi Ranga Raju, Chairman, Hindu College of Pharmacy and Dr. S. Madhusudhan Rao, Secretary and Correspondent, Hindu College of Pharmacy. Hon. Chairman of HCOP gave the welcome address. Dr. S. Madhusudana Rao in his address highlighted the role of



pharmacists in the healthcare system. Dr. S.V. Ramana, Chief Guest, Principal, Hindu College of Pharmacy presented on the topic 'Role of pharmacy graduates in Nation-building.' Dr. A. Suneetha, Vice Principal, Sr. P. Seetharamaiah, OSD and faculty members of HCOP were present.

TPA AWA	RDEES FOR 2020
www.juphama.org	
1. IRF Life Time Achievement	• Delhi
Mr. S. D. Joag	State Branches of Special Appreciation Awards
Dr. Ajit Dangi	• Bihar
2. Eminent Pharmacist	Madhya Pradesh
Dr. Subhash Mandal	6. Local Branch of Excellence 2020 Awards
3. Fellowship Awards	• Anand
Dr. Ramesh Alluri	Mangalore
• Mr. R. Bandyopadhyay	• Rajahmundry
• Dr. H. G. Koshia	IPA Local Branch of Special Appreciation
Dr. B. Prabhashankar	Awards
Dr. N. Sivaprasad	Mysore
4. Fellowships to highly accomplished foreign	Warangal City
professionals (NRIs and others)	7. Indian Pharmaceutical Industry of Excellence
Prof. Ashok Soni, UK	Micro Laboratories
• Dr. (Ms.) Chinta Abayawardana, Sri Lanka	NATCO Pharma
5. State Branch of Excellence	8. Prof. M. L. Khorana Memorial Lecture Award
Andhra Pradesh	• Dr. T. V. Narayana
Bengal	

# PHARMASCENE

#### **NEW DRUG APPROVALS**

www.drugs.com

#### Gemtesa (vibegron) Tablets

Company: Urovant Sciences Date of Approval: December 23, 2020 Treatment for: **Overactive Bladder Syndrome** 

Gemtesa (vibegron) is a once-daily beta-3 adrenergic agonist indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency in adults.

#### Ebanga (ansuvimab-zykl) Injection

Company: Ridgeback Biotherapeutics, LP. Date of Approval: December 21, 2020 Treatment for: **Zaire Ebolavirus Infection** 

Ebanga (ansuvimab-zykl) is a monoclonal antibody for the treatment of *Zaire ebolavirus* (Ebolavirus) infection in adults and children.

#### **Orgovyx (relugolix) Tablets**

Company: Myovant Sciences Date of Approval: December 18, 2020 Treatment for: **Prostate Cancer** 

Orgovyx (relugolix) is an oral gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of adult patients with advanced prostate cancer.

#### Riabni (rituximab-arrx) Injection

Company: Amgen Inc. Date of Approval: December 17, 2020

#### Treatment for: Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, Wegener's Granulomatosis, Microscopic Polyangiitis

Riabni (rituximab-arrx) is a CD20-directed cytolytic antibody biosimilar to Rituxan indicated for the treatment of adult patients with non-Hodgkin's Lymphoma (NHL), chronic lymphocytic leukemia (CLL), and granulomatosis with polyangiitis (GPA) (Wegener's Granulomatosis) and microscopic polyangiitis (MPA).

#### Margenza (margetuximab-cmkb) Injection

Company: MacroGenics, Inc. Date of Approval: December 16, 2020 Treatment for: **Breast Cancer** 

Margenza (margetuximab-cmkb) is a HER2/neu receptor antagonist indicated, in combination with chemotherapy, for the treatment of adult patients with metastatic HER2- positive breast cancer.

#### Klisyri (tirbanibulin) Ointment

Company: Athenex, Inc. Date of Approval: December 14, 2020 Treatment for: **Actinic Keratosis** 

Klisyri (tirbanibulin) is a first-in-class dual Src Kinase and tubulin polymerization inhibitor for the topical treatment of actinic keratosis on the face or scalp.

#### VACCINES AND DRUGS APPROVED AGAINST NOVEL CORONAVIRUS

Johnson & Johnson's one shot Covid vaccine grants lasting response in trial

#### www.businessstandard.com; 15th January, 2021

Johnson & Johnson's experimental one-shot Covid-19 vaccine generated a long-lasting immune response in an early safety study, providing a glimpse at how it will perform in the real world as the company inches closer to approaching U.S. regulators for clearance. More than 90% of participants made immune proteins, called neutralizing antibodies, within 29 days after receiving the shot and all participants formed antibodies within 57 days. The immune response lasted for the full 71 days of the trial. The oneshot vaccine generates more neutralizing antibodies than a single dose of other front-runner Covid-19 vaccine, all of which are twoshot regimens. But when compared with two shots of these rivals, the response to J&J's single shot is in the same range. Interim results from the phase 1/2 trial of 805 participants ages 18 and older were published in the New England Journal of Medicine. The data expanded on more limited findings J&J first published in September. J&J's progress is being closely watched by top infectious disease experts because its vaccine has the potential to become the first that can protect people after just one shot, making massvaccination campaigns much easier.

#### India's Serum Institute expects WHO emergency approval for AstraZeneca shot soon

#### www.economictimes.indiatimes.com; 15th January, 2021

The Serum Institute of India expects WHO emergency-use authorization soon for the Oxford University/AstraZeneca coronavirus vaccine, which it is producing for mid and low income countries. The emergency use licensure from the WHO (World Health Organization) should be available and coming through in the next week or two.

### German vaccine institute praises efficacy of Oxford-AstraZeneca vaccine

#### www.economictimes.indiatimes.com; 15th January, 2021

The head of Germany's vaccine regulator described the success rate of AstraZeneca's COVID-19 vaccine as excellent, after some Australian scientists voiced scepticism about its efficacy. The AstraZeneca shot, co-developed with Oxford University, was shown in a trial to have efficacy of at least 62%, with Britain's healthcare regulator identifying an efficacy of 80% under a certain administration pattern. That compares with efficacy of around 95% for vaccines developed by Pfizer and its partner BioNTech as well as by Moderna. Some Australian scientists have proposed delaying mass inoculation using AstraZeneca's vaccine and considering a different shot instead. European Union bodies assess and approve COVID-19 vaccines for use in Germany but the PEI is involved in that process, alongside other national member-state agencies. Separately, AstraZeneca's Indian partner is expecting the World Health Organization to grant emergency approval for the vaccine soon.

### **CSMIA** facilitates delivery of over 29 lakh Covishield doses across 25 destinations

#### www.pharmabiz.com; 15th January, 2021

Chhatrapati Shivaji Maharaj International Airport (CSMIA) facilitated the cumulative delivery of 29,28,000 doses of Covishield vaccine across 25 destinations in the country. CSMIA facilitated delivery of a total 244 boxes of Covisheld vaccine, carrying 28,44,000 doses, to Goa, Bagdogra, Faizabad, Rajkot, Ranchi, Imphal, Agartala, Cochin, Bhopal, Kanpur, Jammu, Srinagar, Lucknow, Chandigarh, Gorakhpur, Raipur, Dehradun, Varanasi, Indore, Trivandrum, Jabalpur on January 13. On January 14, flights to Delhi, Dimapur, Guwahati, Chandigarh and Cochin are being operated, carrying 84,000 doses of Covishield vaccine in seven boxes. The Mumbai airport said the standard operating procedures (SOPs) implemented by it in anticipation of vaccine distribution saw the terminal register a cargo processing time of just seven minutes, right from goods acceptance to dispatch at the ramp.

#### Four more COVID-19 vaccines are in pipeline: Health Ministry

#### www.economictimes.indiatimes.com; 12th January, 2021

Four more COVID-19 vaccines are in the pipeline and their manufacturers may approach the drug controller for emergency use authorisation, the Health Ministry said. Addressing a press briefing, Union Health Secretary Rajesh Bhushan said Zydus Cadila, Sputnik V, Biological E and Gennova are other companies whose vaccines are also in pipeline which are in advanced clinical trials in India. Zydus Cadilla completed Phase 2 clinical trials of its coronavirus vaccine in December of last year and has been granted approval for Phase 3. Similarly, Phase 2 clinical trials of Russia's Sputnik-V COVID-19 vaccine have also concluded and Phase 3 trials are being carried out by its Indian partner. In the case of Biological E, the Phase 1 clinical trials of its vaccine started in December and Phase 2 is expected to begin in March. Gennova's RnA-based COVID-19 vaccine is currently in Phase 1 with Phase 2 clinical trials likely to begin in March of this year.

### Dr Reddy's Laboratories gets approval for phase 3 trials of Sputnik V Covid vaccine

#### www.economictimes.indiatimes.com; 12th January, 2021

Dr Reddy's Laboratories (DRL) announced the start of its phase 3 clinical trial of Russia's Sputnik V Covid-19 vaccine after receiving clearance from the independent Data and Safety Monitoring Board (DSMB). DSMB's clearance is based on the safety data from the phase 2 clinical trial. Hyderabad-based Dr Reddy's said the phase 2 study of Sputnik V was conducted on 100 subjects as part of the randomised, double-blind, parallel-group, placebo controlled study.

#### NIBSC to carry out independent batch release testing of Covid-19 vaccines

#### www.pharmabiz.com; 11th January, 2021

The National Institute for Biological Standards and Control (NIBSC), part of the MHRA, will carry out independent testing in the UK for any potential Covid-19 vaccines. As is the case for current, licensed vaccines, the quality of each batch of any potential Covid-19 vaccine will be evaluated by an independent laboratory. The independent laboratory will also carry out a thorough review of the manufacturer batch documentation that describes the production process and quality control testing performed by the company. In the UK, this independent testing is performed by the National Institute for Biological Standards and Control (NIBSC), an expert centre of the Medicines and Healthcare products Regulatory Agency (MHRA). Before any batch can be released for deployment, the NIBSC will issue a certificate confirming that the independent testing has been performed and that the batch is compliant with the relevant specifications for the product. Batch release testing helps to ensure the safety and effectiveness of licensed biological medicines, such as vaccines and products derived from human blood products or plasma. Every batch of biological medicine produced by a

manufacturer must undergo rigorous and independent testing before it can be released on to the market for human use. The results for every batch must be consistent with those which were previously shown to be safe and effective in clinical trials or routine clinical use.

### **Covid-19 vaccine: Each vaccine vial, with 10 doses, must be used within 4 hours of opening**

#### www.economictimes.indiatimes.com; 11th January, 2021

The initial batches of Covid-19 vaccines, likely to be used beginning January 16, will have to be used or discarded within four hours of the vials being opened. The reason: non-availability of vaccine vial monitors (VVMs) because the pandemic situation has prompted the government to do away with the open vial policy that allows storage and use of vaccines for a much longer time even after the vial has been opened. For instance, some vaccines under the Universal Immunisation Programme (UIP) can be used for about four weeks after the vial is opened (for the first time). This cannot be done without VVMs, as they display key indicators, specially the storage temperature, which helps in properly stocking and transporting vials. As there will be no VVMs and expiry date on the vial of the vaccine that will be supplied, cold chain maintenance will be of prime importance. Open vial policy will not be applicable and therefore the vaccination officer should mark date and time of opening vial, all open vials need to be discarded after four hours of opening or at the end of session.

#### Bharat Biotech seeks DCGI nod to conduct trials of nasal Covid-19 vaccine

#### www.businesstoday.in; 08th January, 2021

Homegrown pharma major Bharat Biotech has sought Drug Controller General India's (DCGI) approval to conduct nasal Covid-19 vaccine trials in India. The company had received 'emergency approval' for its Covid-19 vaccine, Covaxin, on January 3, though it is still conducting phase-3 trials in India. There are no intra-nasal COVID-19 vaccines under trial in India at the moment. The company has developed a new single-dose nasal COVID-19 vaccine in a partnership with Washington University in St Louis, USA, which is touted to be 'super efficient' and a game-changer. Bharat Biotech and Serum Institute of India are the only two companies in India that have received regulatory approval to use their Covid-19 vaccines under emergency approval. Bharat Biotech has also been allowed to carry out trials on children above the age of 12 years. The company has completed its phase-1 and phase-2 human trials, wherein its coronavirus vaccine, which was already tested on children above the age of 12 years, was found to be safe. The Hyderabad-based company is presently conducting phase-3 clinical trials with 26,000 volunteers. Thus far, the government has said the coronavirus vaccination drive is intended only for adults, but this approval gives hope that it can be extended entirely to children in the future if there is sufficient and satisfactory data available.

### China grants conditional market approval for Sinopharm CNBG's COVID-19 vaccine

#### www.worldpharmanews.com; 06th January, 2021

The inactivated COVID-19 vaccine developed by Beijing Institute of Biological Products of Sinopharm CNBG has been granted conditional registration by the NMPA of China, Chinese equivalent of FDA, according to a press conference of the State Council Joint Prevention and Control Mechanism on December 31, 2020. Over 60,000 volunteers of 125 nationalities have participated in the Phase III clinical trial of Sinopharm CNBG in countries outside China including UAE and Bahrain. The vaccine's efficacy rate based on interim analysis is higher than the target set at the beginning, and its safety and effectiveness performances also exceed the standard level of both WHO for market approval and the Chinese regulatory authority for conditional market approval, which entitles the vaccine a general public use in China. Aside from China, Sinopharm CNBG's COVID-19 vaccine was announced to be officially registered in UAE and Bahrain on December 9 and 12 respectively, based on the results of Phase III clinical trials indicating 86% efficacy rate, 99% seroconversion rate of neutralizing antibody and 100% effectiveness in preventing moderate and severe cases of COVID-19. Besides, the vaccine doesn't require freezing temperatures for storage, making transport and distribution much easier for most of the countries in the world. Its capacity is also large enough for massive inoculation. The Chinese approved COVID-19 vaccine adds to the world's faith in beating the pandemic. As defined by the Chinese government to be a global public good, Sinopharm CNBG COVID-19 vaccine will make its own contribution to the global fight against the coronavirus disease in the future.

#### **REGULATORY AFFAIRS**

### Maharashtra FDA all set to launch PMRU to track drug price violations by companies

#### www.pharmabiz.com; 14th January, 2021

The Maharashtra Food and Drug Administration (FDA) is all set to kickstart operations of its Price Monitoring and Research Unit (PMRU) with a team of seven people in Mumbai headquarters to track price violations by pharmaceutical companies across the state. With the setting up of PMRUs, violations of drug ceiling pricing reported will be dealt timely with the help of the state NPPA cell in coordination with the NPPA in cases of contraventions to the provisions of Drug Price Control Order (DPCO-2013). Under the proposed scheme, the cell is to be headed by one person along with a team of NPPA officials whose strength will vary as per the size of the pharma industry in the respective states. Maharashtra falls under the category of A states and NPPA has accordingly sanctioned the budget as per the categorization. NPPA has categorised the states based on three categories, i.e. based on maximum, minimum and least number of pharma companies in the state for better division of work. As per a notification, NPPA had proposed to set up PMRUs in states and Union territories (UTs) to support state drug controllers and through initiating a Central scheme of assistance at state level and UTs. A Total 21 states had given their consent for the formation of the PMRU in the past two years.

#### Valneva in advanced discussions with European Commission to supply up to 60 million doses of inactivated, adjuvanted COVID-19 vaccine candidate

#### www.worldpharmanews.com; 13th January, 2021

Valneva SE, a specialty vaccine company focused on prevention of infectious diseases with significant unmet medical need, announced it is in advanced discussions with the European Commission (EC) for the supply of up to 60 million doses of its COVID-19 vaccine, VLA2001. VLA2001 is currently the only inactivated vaccine candidate in clinical trials against COVID-19 in Europe. Valneva's vaccine candidate is based on a proven approach and will leverage the Company's existing manufacturing platform being used for its US Food and Drug Administration (FDA) and European Medicines Agency (EMA) approved Japanese encephalitis vaccine.

VLA2001 entered Phase 1/2 clinical studies in December 2020 and Valneva expects to report initial safety and immunogenicity data in April 2021. Upon analysis of the data, Valneva will select the best dose and commence the second part of the Phase 1/2 clinical development. If clinical development is successful, an initial approval may be granted in the second half of 2021. In September 2020, Valneva announced a major COVID-19 vaccine partnership with the UK government for the supply of up to 190 million doses of its inactivated vaccine candidate, VLA2001.Under the partnership agreement, if vaccine development is successful, Valneva will provide the UK government with 60 million doses in the second half of 2021.

### Govt rules out the option to choose between vaccines, cites logistical limitations & vaccine availability

#### www.economictimes.indiatimes.com; 13th January, 2021

The Indian government has so far ordered 110 lakh doses from Serum Institute of India (SII) and 55 lakh doses from Hyderabadbased Bharat Biotech that will reach various centres by January 14. Given the logistical limitations and availability of the vaccine, individuals cannot choose the vaccine they prefer. Bhushan said SII will be providing its vaccine at ₹200 per dose and Covaxin would cost ₹295 per dose excluding taxes. Out of the total number of doses, Bharat Biotech is providing 16.5 lakh doses of Covaxin free of cost to the government. Sources said that the hope that Covaxin, the Covid-19 vaccine developed by Bharat Biotech, is more likely to act against the mutant strain and that was the major consideration for pricing it higher than Covishield. Bharat Biotech will dispatch first tranche of 2.4 lakh doses on Tuesday to 12 places including Karnataka, Andhra Pradesh, Tamil Nadu, Telangana, Odisha, Maharashtra, Bihar, Haryana, Assam, Delhi, Lucknow and Jaipur.

#### India wants Pfizer to do local study for approval: Official

#### www.economictimes.indiatimes.com; 13th January, 2021

Any vaccine maker, including Pfizer, which has sought emergencyuse authorisation for its Covid-19 shot in India, must conduct a local "bridging" safety and immunogenicity study to be considered for the country's immunisation programme. According to reports, Pfizer had sought an exception when last month it became the first company to seek emergency-use approval in India for its vaccine already in use overseas. The company has not attended subsequent meetings called by India's drugs regulator.

#### Bharat Biotech set to dispatch first consignment of Covaxin

#### www.economictimes.indiatimes.com; 12th January, 2021

Bharat Biotech, which has received Emergency Use Authorisation approval from the Drug Controller General of India for its COVID-19 vaccine Covaxin, is set to dispatch it from the Rajiv Gandhi International Airport. The senior official at the airport said they have received the first consignment of vaccines from Serum Institute at Hyderabad airport which weighed 970 kg. Bharat Biotech has also dispatched its first consignment of vaccines which would be sent to 11 destinations.

### Govt committed to buying another 4.5 crore doses of Covishield vaccine

#### www.economictimes.indiatimes.com; 12th January, 2021

The government has committed to buying from the Serum Institute further 4.5 crore doses of Oxford COVID-19 vaccine, Covishield, at a price of Rs 200 per shot plus applicable taxes by April, in addition to a firm order given to the company for 1.1 crore doses. Flights have started ferrying the vaccines to different cities from Pune. Each dose of the vaccine has been priced at Rs 200 and with GST of Rs 10, it would cost Rs 210. The first order of 1.1 crore doses of Covishield will be worth Rs 231 crore, while the total amount including the commitment for 4.5 crore doses will amount to an estimated Rs 1.176 crore at current rates.

### Cipla recalls 5.8 lakh packets of gastric ulcer treatment drug from US market

#### www.businesstoday.in; 10th January, 2021

Drug major Cipla is recalling over 5.8 lakh packets of a drug for the reduction in the occurrence of gastric ulcers from the US market. The drug major is recalling esomeprazole magnesium for delayed-release oral suspension in unit dose packets in strengths 10 mg, 20 mg and 40 mg in the US market. The drug firm has manufactured the affected lot at its Kurkumbh facility in Maharashtra and then supplied to its New Jersey-based subsidiary. The USFDA cited "cross-contamination with other products" as the reason for the company recalling the product. The excipient, Crospovidone, NF is contaminated with theophylline. As per the US regulator, the company is recalling 2,84,610 packets of 10 mg strength and 2,89,350 packets of 20 mg strength. Further, it is also recalling 6,491 packets of esomeprazole magnesium for delayed-release oral suspension in 40 mg strength. The company has initiated the countrywide recall December 17, 2020, and the USFDA has classified it as a Class II recall. As per the USFDA, a class II recall is initiated in a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. In a separate statement, the USFDA said Strides Pharma Inc, a subsidiary of Bengaluru-based Strides Pharma Science, is recalling 960 bottles of Tacrolimus capsules (100mg) due to "failed moisture limits". The company has initiated the countrywide recall of the affected lot on December 22, 2020. The USFDA has classified it as a Class III recall, which is initiated in a "situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences".

### Emergency approval in India to help supply COVID-19 vaccine across the globe: AstraZeneca

#### www.economictimes.indiatimes.com; 07th January, 2021

Terming approval of its COVID-19 vaccine in India as an important milestone, drug major AstraZeneca said the development would also help in supplying the medication to countries around the world. The company has partnered with the Serum Institute of India (SII), the world's largest vaccine manufacturer, for the supply of the vaccine to the Indian government and also to a large number of low and middle-income countries. The drug maker also stated that the vaccine has so far been granted emergency use authorisation in six countries -- India, Argentina, Dominican Republic, El Salvador, Mexico and Morocco for active immunisation of adults. The vaccine has shown in clinical trials to be safe and effective at preventing symptomatic COVID-19, with no severe cases and no hospitalisations more than 14 days after the second dose. AstraZeneca has already submitted a substantial data package to support a conditional marketing authorisation for its COVID-19 vaccine to the European Medicines Agency (EMA), as part of an ongoing rolling review

process. It will continue to work closely with the EMA to seek approval in the coming weeks. The drug firm is also seeking Emergency Use Listing from the World Health Organisation (WHO) for an accelerated pathway to vaccine availability in lowincome countries during this health crisis and has ongoing rolling reviews with many other regulatory authorities around the world. In addition to the University of Oxford-led trials, the company is conducting a trial in the US as part of a global programme. In total, the University of Oxford and AstraZeneca expect to enrol more than 60,000 participants worldwide.

#### Sun Pharma gets exemption from provisions of DPCO, 2013 for its FDC anti-infective drug

#### www.pharmabiz.com; 05th January, 2021

The National Pharmaceuticals Pricing Authority (NPPA) has granted exemption to Sun Pharmaceuticals from the provisions of DPCO, 2013 for its FDC drug silver sulfadiazine IP (Nanonized) 0.5% w/w and chlorhexidine gluconate 0.2% w/w topical cream for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country. Further, the period of five years is co-terminus with the duration of Indian patent. Now, therefore, in exercise of the powers delegated under para 32 of the Drugs (Prices Control) Order, 2013 vide S.O. 1394(E) dated 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, M/s Sun Pharmaceuticals Industries Limited is exempted from the provisions of DPCO, 2013 under para 32 (i) of the said order in respect of above said drug viz. Fixed dose combination (FDC) of silver sulfadiazine IP (Nanonized) 0.5% w/w and chlorhexidine gluconate 0.2% w/w w topical cream. Earlier, Sun Pharmaceuticals had submitted an application for exemption of this drug from the provisions of DPCO, 2013 under para 32 (i) which was duly approved by the Office of Central Drugs Standard Control Organisation (CDSCO) as 'new drug' under the Drugs and Cosmetics (D&C) Act, 1940 and Rules thereunder. The NPPA noted that Sun Pharmaceutical Industries Ltd meets the requirement of para 32(i) of DPCO 2013 and decided that exemption may be granted to Sun Pharmaceutical Industries Ltd under para 32(i) of DPCO, 2013 for their product fixed dose combination (FDC) of silver sulfadiazine IP (Nanonized) 0.5% w/w and chlorhexidine gluconate 0.2% w/w topical cream. Further, the patent office, India has granted patent certificate to Sun Pharmaceutical Industries Ltd for an invention entitled 'A stable topical pharmaceutical composition comprising nanonized silver sulfadiazine' for the term of 20 years from 27th July 2016 in accordance with the provisions of the Patents Act, 1970 (Patent No. 349599 and Date of Grant: October 20, 2020).

### Covishield priced at Rs 200 for Indian govt, one-fifth of actual price: Poonawalla

#### www.businesstoday.in; 04th January, 2021

Oxford COVID-19 vaccine, Covishield, manufactured by the Serum Institute of India, will be sold to the Indian government at Rs 200 per dose, SII head Adar Poonawalla said. The vaccine will be sold at a higher price of Rs 1,000 per dose to private buyers. The Oxford University-AstraZeneca vaccine was granted emergency authorisation by the Indian regulator on the condition that Serum Institute doesn't export the shots, to ensure the safety of the vulnerable populations in India.

#### **MERGERS, ACQUISTIONS AND COLLABORATION**

#### ESSA Pharma inks clinical collaboration with Janssen to evaluate EPI-7386 combination for patients with metastatic castrationresistant prostate cancer

#### www.pharmabiz.com; 15th January, 2021

ESSA Pharma Inc, a clinical-stage pharmaceutical company, announced that the company has entered into a clinical collaboration and supply agreement with Janssen Research & Development, LLC (Janssen) to evaluate ESSA's first-in-class N-terminal domain androgen receptor inhibitor, EPI-7386, in combination with apalutamide as well as the combination of EPI-7386 with abiraterone acetate plus prednisone in patients with metastatic castration-resistant prostate cancer (mCRPC). Under the terms of the agreement, Janssen may sponsor and conduct up to two phase 1/2 studies evaluating the safety, tolerability and preliminary efficacy of the combination of EPI-7386 and apalutamide as well as the combination of EPI-7386 with abiraterone acetate plus prednisone in patients with mCRPC who have failed a current second-generation antiandrogen therapy. Janssen will assume all costs associated with the studies, other than the manufacturing costs associated with the clinical drug supply of EPI-7386. The parties will form a joint oversight committee for the clinical studies, which are planned to start in 2021. ESSA will retain all rights to EPI-7386. EPI-7386 is an investigational, highly-selective, oral, small molecule inhibitor of the N-terminal domain of the androgen receptor. EPI-7386 is currently being studied in a phase 1 clinical trial (NCT04421222) in men with metastatic castration-resistant prostate cancer (mCRPC) whose tumors have progressed on current standardof-care therapies.

### KSQ Therapeutics partners with Takeda Pharma to develop & commercialise novel immuno-oncology therapies

#### www.pharmabiz.com; 15th January, 2021

US-based biotech company, KSQ Therapeutics has partnered with Takeda Pharmaceutical to develop and commercialise novel immuno-oncology therapies. As per the agreement, KSQ Therapeutics has granted an exclusive, worldwide, royaltybearing license to Takeda Pharmaceutical pertaining to cell and non-cell therapy products that modulate targets identified using its CRISPRomics technology. Takeda Pharmaceutical will have the rights to develop, manufacture, and commercialise the products. The agreement includes two T-cell targets that were identified and validated previously by KSQ Therapeutics. There is a possibility to add two more T-cell targets to the partnership. The both pharma companies will also work together in discovering and developing therapeutics that modulate natural killer (NK) cell targets to be identified via the collaboration. As per the terms of the deal, KSQ Therapeutics stands to earn over US\$ 100million from upfront and potential pre-clinical milestone payments. Additionally, the company will be entitled to additional option payments and also the development and commercialisation milestone payments. Depending on the target, the option and milestone payments could turn out to more than US\$ 400million per programme.

### Boehringer Ingelheim, PetMedix collaborate to develop novel and transformative companion animal antibody therapeutics

#### www.pharmabiz.com; 14th January, 2021

Boehringer Ingelheim announced a multi-year partnership with PetMedix to develop novel and transformative companion animal

antibody therapeutics using PetMedix's proprietary Ky9 platform. As part of the collaboration, PetMedix will undertake discovery activities against a number of key targets, and Boehringer Ingelheim will work to develop and bring these therapies to market. PetMedix is a Cambridge, UK based research and development stage biopharmaceutical company developing antibody-based therapeutics for companion animals. While there are many technologies that have been used to develop human therapeutic antibodies. PetMedix's breakthrough approach is equivalent to one that has resulted in a number of successful, novel therapies for humans. PetMedix is the only company in the world that has brought this innovative approach to veterinary medicine, with its Ky9 platform able to rapidly and efficiently generate fully canine therapeutic antibodies. This approach saves time and money in drug development, and reduces the risk of certain key adverse events relative to other antibody technologies.

#### Astellas signs research collaboration with Actinium Pharma for molecular targeted radiotherapy

#### www.pharmabiz.com; 14<sup>th</sup> January, 2021

Astellas Pharma Inc has entered into a research collaboration for molecular targeted radiotherapies with Actinium Pharmaceuticals Inc, a clinical-stage biopharmaceutical company. This collaboration is a component of Astellas' initiative to develop "theranostics" as part of its Rx+ business. Theranostics is a combined term of "therapeutics" and "diagnostics", defined as a treatment protocol or concept in which healthcare professionals assess lesion sites and simultaneously determine the appropriate treatment for each patient. Through utilization of a diagnostic agent developed in parallel with a therapeutic agent that shares the same target, it may be possible to identify patients in advance who would benefit from the treatment. This approach may help healthcare professionals provide more efficient and effective treatment. In this collaboration, the potential therapeutic effect will be assessed by combining certain targeted oncology drugs that were discovered by Astellas based on its drug discovery capabilities cultivated thus far with Actinium's nuclear medicine technology which utilizes an alpha particle-emitting radioisotope (Actinium-225). Astellas is already conducting pre-clinical trials of the diagnostic agents on the target molecule. When a promising therapeutic drug candidate is identified in the course of this collaboration, clinical trials for the theranostics may be initiated. Through its Rx+ business, Astellas aims to realize a society where people can live in their own way, both physically and mentally through scientifically based on scientific evidence. Astellas aims to optimize therapeutic approach by improving diagnostic and surgical accuracy and maximize patient outcomes. The development of theranostics that integrates diagnostics and therapeutics is part of this effort.

#### Pfizer invests US\$ 25 million in Vedanta Biosciences

#### www.pharmabiz.com; 14th January, 2021

Vedanta Biosciences, a leading clinical-stage company, announced that Pfizer Inc. has made a US\$ 25 million investment in Vedanta, as part of the Pfizer Breakthrough Growth Initiative. Vedanta intends to use the proceeds to fund a phase 2 study of VE202 in inflammatory bowel disease (IBD), which it plans to initiate in 2021. Topline phase 1 study data showed VE202 was generally safe and well-tolerated at all doses and demonstrated durable and dose-dependent colonization. As part of the investment, Michael Vincent, Chief Scientific Officer, Inflammation & Immunology Research Unit at Pfizer, will join Vedanta's Scientific Advisory Board. Vedanta will

retain control of all its programs and has granted Pfizer a right of first negotiation on VE202. VE202 is a first-in-class orally administered investigational live biotherapeutic product consisting of a defined bacterial consortium. It is produced under GMP conditions from pure, clonal bacterial cell banks, which yield a standardized drug product in powdered form and bypasses the need to rely on direct sourcing of fecal donor material of inconsistent composition. VE202 was designed to induce immune tolerance via the gut and thereby potentially treat inflammatory bowel disease. Results describing the biology and candidate selection of VE202 were previously published in Science and Nature.

### Bharat Biotech inks pact with Precisa Medicamentos for Covaxin supplies to Brazil

#### www.economictimes.indiatimes.com; 12th January, 2021

Bharat Biotech has signed an agreement with Precisa Medicamentos to supply its COVID-19 vaccine Covaxin to Brazil. A team from Precisa Medicamentos visited the Bharat Biotech facility last week to discuss potential export possibilities of the vaccine, the indigenous antidote for the killer virus. Supplies to the private market would be based upon receipt of market authorization from ANVISA, the Brazilian regulatory authority.

### CureVac and Bayer join forces on COVID-19 vaccine candidate CVnCoV.

#### www.economictimes.indiatimes.com; 07th January, 2021

Bayer has signed a collaboration and services agreement with CureVac N.V., a biopharmaceutical company developing a new class of transformative medicines based on messenger ribonucleic acid (mRNA). Under the terms of the agreement, Bayer will support the further development, supply and key territory operations of Cure Vac's COVID-19 vaccine candidate CVnCoV. To this end, Bayer will contribute its expertise and established infrastructure in areas such as clinical operations, regulatory affairs, pharmacovigilance, medical information, supply chain performance as well as support in selected countries. Based on the collaboration agreement, CureVac will be the Marketing Authorization Holder for the product, while Bayer will support CureVac with country operations within the European Union (EU) and selected additional markets. Bayer holds further options to become Marketing Authorization Holder in other markets outside of Europe. The companies plan to combine their strengths for CureVac to be in a position to supply hundreds of millions of CVnCoV doses around the world, once approvals are granted. Together both companies aim to play a meaningful role to contribute to stop the COVID-19 pandemic.

### Sanofi to acquire clinical-stage biopharma company, Kymab for an upfront payment of approximately \$1.1 billion

#### www.pharmabiz.com; 11th January, 2021

Sanofi and Kymab, a clinical-stage biopharmaceutical company developing fully human monoclonal antibodies with a focus on immune-mediated diseases and immuno-oncology therapeutics, have entered into an agreement under which Sanofi will acquire Kymab for an upfront payment of approximately \$1.1 billion and up to \$350 million upon achievement of certain milestones. The transaction will result in Sanofi having full global rights to KY1005, a fully human monoclonal antibody that has a novel mechanism of action. KY1005 binds to OX40-Ligand and has the potential to treat a wide variety of immune-mediated diseases and inflammatory disorders. In August 2020, Kymab announced that KY1005 met both primary endpoints in a phase 2a trial studying moderate to severe atopic dermatitis patients whose disease is inadequately controlled with topical corticosteroids. KY1005 demonstrated a consistent treatment effect versus placebo across various key endpoints, including in the Eczema Area and Severity Index (EASI) and additional objective clinical measures. Kymab's pipeline also includes the oncology asset KY1044, an ICOS agonist monoclonal antibody, currently in early phase 1/2 development as monotherapy and in combination with an anti-PD-L1. The acquisition also provides Sanofi with access to new antibody technologies and research capabilities. Sanofi plans to finance the transaction with cash on hand. The closing of the transaction is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 and other customary closing conditions. Sanofi expects to complete the acquisition in the first half of 2021.

### Aurobindo Pharma joins hands with Covaxx for coronavirus vaccine

#### www.businessstandard.com; 25th December, 2020

Aurobindo Pharma and Covaxx, a US-based company, have entered into an exclusive licence agreement to develop, commercialise and manufacture UB-612, the first Multitope Peptide-based vaccine to fight Covid-19, for India and UNICEF. Covaxx is currently conducting a Phase 1 clinical trial for the vaccine candidate. Under the signed agreement, Aurobindo Pharma has obtained the exclusive rights to develop, manufacture and sell the vaccine in India and to UNICEF, as well as non-exclusive rights in other select emerging and developing markets.

#### **TESTING KITS**

#### Abbott fulfills US Federal Government purchase of 150 million BinaxNOW Covid-19 rapid tests

#### www.pharmabiz.com; 14th January, 2021

Abbott is announcing the fulfillment of the US federal government's order of 150 million BinaxNOW Covid-19 Ag tests. These rapid tests were distributed through the Department of Health and Human Services (HHS) to states, territories and targeted entities, such as nursing homes, assisted living facilities, home health and hospice agencies, historically black colleges and universities (HBCUs), and the Indian Health Service. Abbott is also in the final stages of completing its self-funded investment in US manufacturing capacity and is now ready to make tens of millions of BinaxNOW tests available per month for direct purchase to organizations including schools, workplaces and pharmacies. The University of Wisconsin System will be the first customer in the US to secure BinaxNOW at scale, procuring 480,000 tests over six months for use at its universities and branch campuses. At the size of a credit card and with no equipment required, Abbott's BinaxNOW Covid-19 test - sold directly to qualified organizations for US \$5 per test - is already the country's most widely available and mass-produced rapid test, providing results in 15 minutes and detecting the virus when people are most infectious and therefore at the greatest risk of spreading it to others. An at-home, virtually and digitally guided version of the test is also available at US \$25 per test. The BinaxNOW Covid-19 Ag Card is an assay for the qualitative detection of specific antigens to Covid-19 in the human nasal cavity. A simple nasal swab is used to collect specimens from people suspected of having an active infection.



### Bharati Vidyapeeth College of Pharmacy, Kolhapur, Maharashtra

### Platinum Award in the AICTE-CII Industry Linked Technical Institute Survey-2020 awarded



Bharati Vidyapeeth College of Pharmacy, Kolhapur, Maharashtra secured third-time highest rank 'Platinum' Award (score above 30) in the AICTE-CII Industry Linked Technical Institute Survey-2020, across India in the self-financed category. Dr. H.N. More, Principal, Bharati Vidyapeeth College of Pharmacy expressed his satisfaction for being awarded this laurel and advocated the collective

Principal, Dr. H.N. More

efforts taken by the teaching and non-teaching staff, students, alumni, all Bharati family members, stakeholders, employers, HR Managers, Managers in the company, friends and

well-wishers. Dr. H. N. More, Principal; Dr. M. S. Bhatia, Vice-Principal; Dr. Anilkumar J. Shinde, AICTE-CII co-ordinator; all teaching & nonteaching staff members



and students were congratulated by Hon. Dr. Vishwajeet Kadam, Secretory Bharati Vidyapeeth, Pune, Hon. Dr. S. S. Kadam, Vicechancellor, Bharati Vidyapeeth University Pune and Hon. Dr. H. M. Kadam, Regional Director, Bharati Vidyapeeth, Sangli.

#### **One-week virtual Soft Skill Development Training Program**



From 4th to 9th January, 2021

Bharati Vidyapeeth College of Pharmacy, Kolhapur organized a one-week virtual Soft Skill Development Training Program in Association with Rubicon Skill Development Pvt. Ltd. Pune from  $4^{\text{th}}$  to  $9^{\text{th}}$  January, 2021 for B. Pharm and M. Pharm students.

Eminent speakers from the industry, Mr. Dhanya Narayanan, Chief Operational Manager; Mr. Pravir Kumar, Chief Executive Officer; Dipika Patil, Manager; Swati Khillare, Business Development Manager and Mr. Mukesh Kolnad, Trainer were the resource persons of the training program. The emphasis was on Expectation Setting, Ice Breaking, Organizational Structure, SWOT Analysis, Corporate Jargons, Public Speaking, Presentation Skills, E-mail Etiquette, Grooming, Body language, Telephone Etiquette, Group Discussion and Personal Interview. Experts from industry and academia were invited to speak at this program. The inauguration program on Monday 4<sup>th</sup> January, 2021 was done by Hon. Dr. H.N. More, Principal, Bharati Vidyapeeth College of Pharmacy, Kolhapur; Mr. Pravir Kumar. Chief Executive Officer and Dr. Anilkumar J. Shinde, Coordinator, Skill & Entrepreneurship Development Cell. 50 students from B. Pharm and M. Pharm actively participated. On this occasion, Memorandum of Understanding (MOU) was signed between Bharati Vidyapeeth College of Pharmacy and Rubicon Skill Development Pvt. Ltd., Pune. For the success of this program, Dr. H.N. More, Principal: Dr. M.S. Bhatia, Vice-Principal: Dr. Mrs. N.M. Bhatia, HOD; and the Co-ordinators, Dr. Anilkumar J. Shinde, Coordinator, Training & Placement Cell and, Skill & Entrepreneurship Development Cell and Swati Killare, Rubicon Skill Development, Pune were appreciated.

### University Institute of Pharmaceutical Sciences (UIPS), Panjab University

#### UIPS pays Tributes to the Pharma Legend

University Institute of Pharmaceutical Sciences (UIPS), Panjab University, Chandigarh organized a webinar on 'Pharmacy Education: Responding to NEP 2020' on 24<sup>th</sup> November, 2020 in sweet remembrance of The Pharma Legend- Padma Shri Awardee (2017) Late Professor Harkishan Singh Ji (25<sup>th</sup> November, 1928-20<sup>th</sup> March, 2020), Padma Shri Awardee (2017), who bid adieu to his wonderful life sojourn this year and whose birthday falls on 25<sup>th</sup> November. The event began with sharing of the reminiscences of



Professor Harkishan Singh Ji, a globally renowned pharmaceutical scientist and a science historian by Prof. Indu Pal Kaur, Chairperson, UIPS. The Chief Guest of the occasion, Professor Suresh Bhojraj, Pro-Chancellor JSS Academy of Higher Education & Research, Mysuru and President, Pharmacy Council of India (4 consecutive terms since 2003) dedicated his talk to the Late Professor Harkishan Singh Ji. He enlightened about the objectives of Pharmacy Act 1948, PCI Regulations since 2003, impact of New Education Policy, 2020 and emphasized the need for the healthcare system to be integrative. Eminent Pharma Professionals including Prof

S.K. Kulkarni, Former DUI & Professor Emeritus, Panjab University; Prof V.R. Sinha, Dean Research, Panjab University; Dr. Alka Mukne, Faculty, Bombay College of Pharmacy and the Editor-Pharma Times, the monthly news magazine of Indian Pharmaceutical Association; Dr. R.N. Gupta, Professor, Pharmaceutical Sciences and Technology, BIT Mesra; Dr. Amarjit Singh, an eminent Industrialist; Prof. T.R. Bhardawaj, Vice-Chancellor Baddi University; Prof. Saranjit Singh, NIPER, Mohali, shared their valuable and insightful views on National education Policy 2020. Around 280 participants which included students, researchers, UIPS faculty, joined the webinar.

#### Delhi Pharmaceutical Sciences and Research University Orientation Programme organized for the Bachelor of Pharmacy- 2020 batch

Delhi Pharmaceutical Sciences and Research University (DPSRU) organized an Orientation Programme for the Bachelor of Pharmacy-2020 batch on 8<sup>th</sup> December, 2020 through a virtual platform. Prof. Prabhat Kumar Sahoo welcomed all the students to the university. Prof. Geeta Aggarwal, Dean Academics gave an overview of syllabus, academic activities, internship and placement along with last five years statistics. Prof. Rajiv K. Tonk, Dean, Student Welfare enlightened the students about exam strategies, marking schemes and the extra-curricular activities. Prof. Harvinder Popli, Director, School of Pharmaceutical Sciences (SPS), DPSRU motivated the students and introduced SPS and the DPSRU Innovation and Incubation Foundation (DIIF). Prof. D. P. Pathak, Director, Delhi



Institute of Pharmaceutical Sciences & Research (DIPSAR) gave a brief about the legacy of DIPSAR. Prof. Ramesh K. Goyal, Hon'ble Vice-Chancellor, DPSRU, expressed his delight over achievements of the University. The esteemed Chief Guest for the program, Dr. Mahesh Burande, Hon'ble Director, Institute of Pharmaceutical Education and Research, Pune gave uplifting remarks on the topic 'Challenges and Opportunities in Pharmacy Profession Through Skill Development.' Prof. Prabodh Sharma administered the oathtaking ceremony. This was followed by a Vote of Thanks by Dr. O.P. Shukla, Registrar, DPSRU. Students were introduced to all the faculty members in the last segment. The program was coordinated by Prof. Deepti Pandita.

#### **KLE College of Pharmacy, Belagavi**

### AICTE sponsored two-week Quality Improvement Program (QIP) organized

KLE College of Pharmacy, a constituent unit of KLE Academy of Higher Education and Research, Belagavi organized an AICTE sponsored two-week Quality Improvement Program (QIP) virtually on 'Current Trends in Formulation Development and Quality Assurance' from 23<sup>rd</sup> to 8<sup>th</sup> December, 2020. Prof. (Dr.) Sunil. S. Jalalpure, Principal KLE College of Pharmacy, Belagavi welcomed everyone. Chief Guest Mrs. Amrita Parle, Coordinator QIP, AICTE New Delhi inaugurated the program virtually and briefed on various AICTE schemes available for young teachers for professional development and research. Guest of Honor Prof. (Dr.) N.S. Mahantshetti, Principal J.N. Medical College, Belagavi addressed the challenges in pediatric healthcare and the role of Pharmacists in designing Drug Development System and Healthcare. Eminent speakers from Academia Prof. (Dr.) Vandana Patravale, ICT, Mumbai and Prof. (Dr.) Chandramoulli-Krupanidi College of Pharmacy, Bengaluru emphasized on skills to be acquired in using Computational modeling in the new millennium; Dr. Sarasija



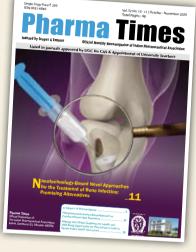
Suresh, Director, RGV Research and innovations, Bengaluru addressed on 'Translation of Nanomedicine: A Technological Perspective', Prof. (Dr.) Shrinivas Mutalik- Manipal College of Pharmaceutical Sciences highlighted on 'Lipidic nanocarriers' for Drug Delivery and Targeting'; Dr. Hema. Chaudhary-Dean, Faculty of Pharmaceutical Sciences, PDM University, Delhi spoke on 'Revolutionary Advancements in Transdermal Drug Delivery Systems'; Prof. (Dr). Sanjay Pai- Goa College of Pharmacy briefed on 'Challenges in Impurity Analysis', Prof. (Dr.) Surendra Bhat- JSS University, Mysuru presented an overview of 'Intellectual Property Rights.' Prof. (Dr.) Namdev Jadav- Bharathi Vidyapeeth, Kolhapur spoke on 'Leveraging Pharmaceutical Formulation Developments through Recycled Sericulture Waste'; Dr. S.N Meyyanathan, JSS College of Pharmacy, Ooty spoke on 'QbD and its role in Analytical Method Development.' Dr. Vijay Bambulkar, Consultant, Johnson and Johnson addressed on 'Current claim developments in Cosmetics'; Dr. Pritam Kanagale, Senior Manager, Janssen Pharma, Mumbai spoke on 'Modernizing the Formulation and Process - A Transition to Continuous Manufacturing'; Mr. Sameer Joshi, Senior scientist Sandoz development center, Hyderabad, highlighted 'Role on Analytical Development in Product Cycle and QbD Approach for Development of Robust Analysis Method'; Dr. Ankit Bahethi, Manager Product Development, Unichem Goa spoke on 'Self emulsifying Drug Delivery Systems'; Ms. Jacquline Chalissery, General Manager, Ajantha Pharma, Mumbai briefed on 'Regulatory Affairs'; Mr. Sangram Sahoo, Sr. Group Leader Accord Life Spec Pvt. Ltd. Kancheepuram talked on 'Containment Systems in Handling potent Cytotoxic Molecules'; Dr. Badrinath, Group leader F&D Syngene International Bengaluru spoke on 'Amorphous Solid Dispersion-Advances in Concept and Technology.' Skills in handling the software were demonstrated with reference to JMP, Gastroplus, Minitab, Design expert in formulation and Analytical Development. As per the statutory compliances provided by AICTE regulation 30 faculty members from different parts of Maharashtra, Goa, Karnataka attended the QIP. The program was coordinated by Prof. (Mrs). Rajashree Masareddy and Dr. V.S. Mannur, Department of Pharmaceutics and Pharmaceutical Quality Assurance.



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