ISSUE No. 48

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Happy New Year 2021

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Oct. - Nov. - Dec. 2020

Delvin Formulations

Destiny for Innovation

Moving Globally

- R & D and Manufacturing of API
- R & D and Manufacturing of Formulations
- International Marketing
- Domestic Marketing
- Medical Devices
- Surgicals

Our Group of Companies

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Tamilnadu Pharmaceutical Sciences Welfare Trust

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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Ph: 044 - 28491232
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EDITORIAL

Dear Readers,

We wish all our readers a very **HAPPY NEW YEAR 2021**

We are happy to publish the 48th issue of Pharma Web Newsletter for Oct – Dec 2020.

We are publishing this issue printed version and also inform to the readers our trust is newly elected the Hon. Gen. Secretary, Mr. J. Jayaseelan, and we thank Mr. N. Sreenivasen for tremendous 20 years of services in Hon. Gen. Secretary (2001 to 2020).

This 48th issue contains the program highlights as well as the following lectures given by various resource persons.

- **Pharmacists: Frontline Health Professionals, Dr. S. Sriram,** Prof & Head, Dept. of Pharmacy Practice, College of Pharmacy, SRIPMS, Coimbatore.
- **Recent Trends towards "Green" Chemistry HPLC, Dr. V. Manohar,** Director – Indian Institute of Chromatography & Mass Spectrometry, Chennai

We have published the various Gazette Notifications pertaining to the amendment of Drugs & Cosmetics Act & Rules and also important circulars issued by DCGI.

Important news items connected to our Pharmacy profession appeared in various national news papers are published in this issue.

We are very much thankful to M/s. Delvin Formulations, M/s. Medopharm, M/s. Tablets (India) Ltd., M/s. Acid India Ltd., for the continuous support by giving advertisement, in order to sustain the cost of publishing of this newsletter.

Our special thanks to M/s. Fourrts (India) Laboratories Pvt. Ltd., for supporting Pharma Web advertisement and also awarding meritorious award for B. Pharm Students of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai.

Hope this Newsletter will benefit our Pharma professionals. Any suggestions to improve our news letter are welcome.

With Best Regards,
R. NARAYANASWAMY
Chief Editor

ARTICLES

PHARMACISTS: FRONTLINE HEALTH PROFESSIONALS

by

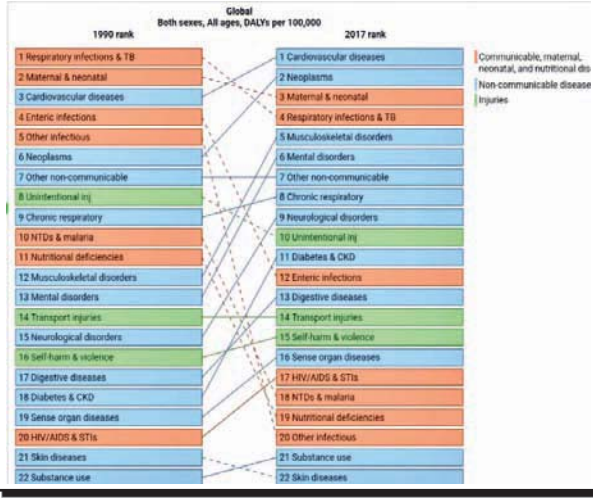
Dr. S. Sriram.
Prof & Head, Dept. of Pharmacy Practice, College of Pharmacy, SRIPMS, Coimbatore

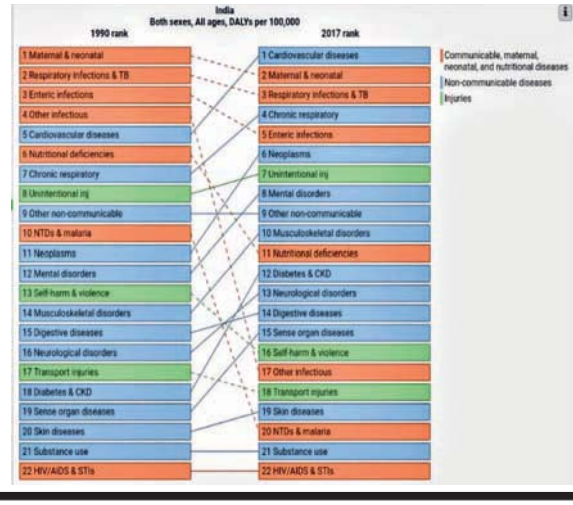
Lecture Delivered during 58th National Pharmacy Week Celebration by Faculty of Pharmacy, Dr. M.G.R. Educational and Research Institute, Chennai, in Assoication with IPA, TN Branch, (Thematic Speech) held on 21st November 2020

- The Global Burden of Disease Study (GBD), the most comprehensive worldwide epidemiological study to date, describes mortality and morbidity from major diseases, injuries and risk factors to health at global, national and regional levels.
- GBD examines the trends from 1990 to the present and make comparisons across populations enabling understanding of the changing health challenges faced by people across the world in the 21st century.

GBD studies, overseen by IHME (Institute of Health and Metrics Evaluation), Washington, USA

GBD of diseases as of 2017, GLOBALLY and specifically in INDIA.

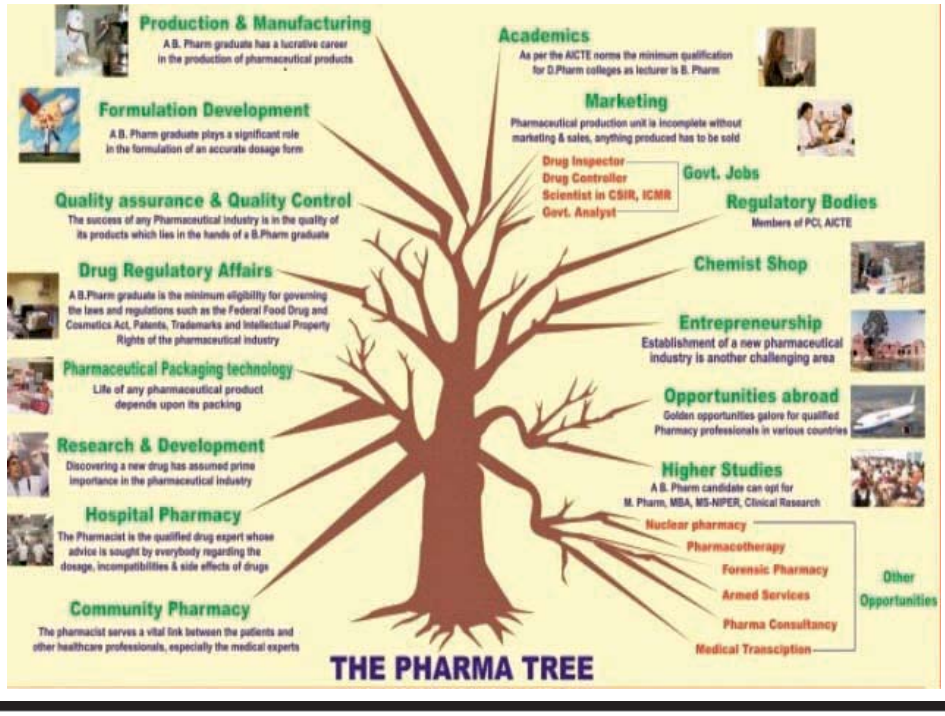




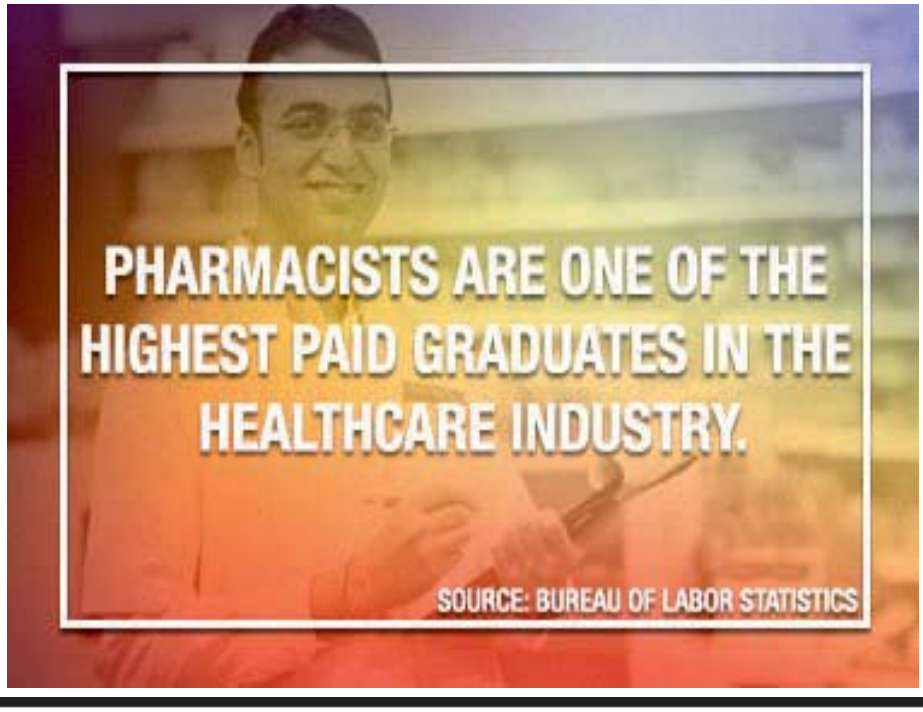

LOW QUALITY OF CARE
PROHIBITIVELY HIGH HEALTHCARE COSTS
HIGH MEDICAL RISK
MEDICAL ERRORS
RAMPANT CORRUPTION
SHORTAGE OF PHYSICIANS AND MEDICAL STAFF
GLOBAL HEALTHCARE CRISIS
SHORTAGE
LACK OF HEALTHCARE INFRASTRUCTURE
NO HEALTH INFORMATION NETWORK
LACK OF HEALTH SYSTEMS INTEROPERABILITY
LIMITED PATIENT ACCESS TO HEALTH DATA
LACK OF PATIENT ENGAGEMENT AND EMPOWERMENT

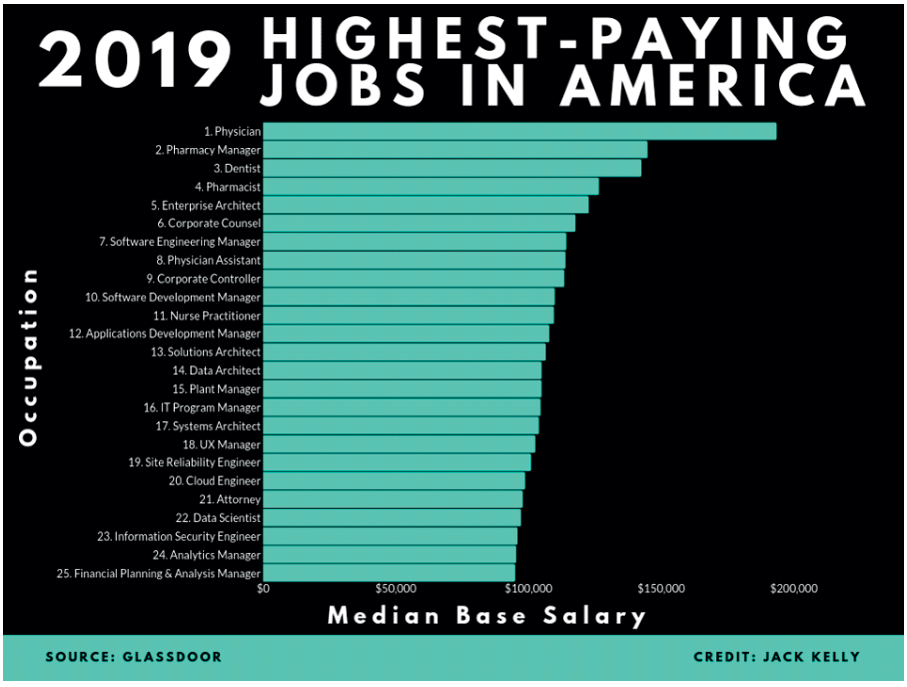

Develop Health Infrastructure
Increase Physicians & Staff
Reduce Healthcare Cost
Eradicate corruption in Health
TRANSFORM GLOBAL HEALTH
Improve Quality of Care
Develop Health Information Backbone
Reduce Global Health Risk
Empower Patient Centric Care

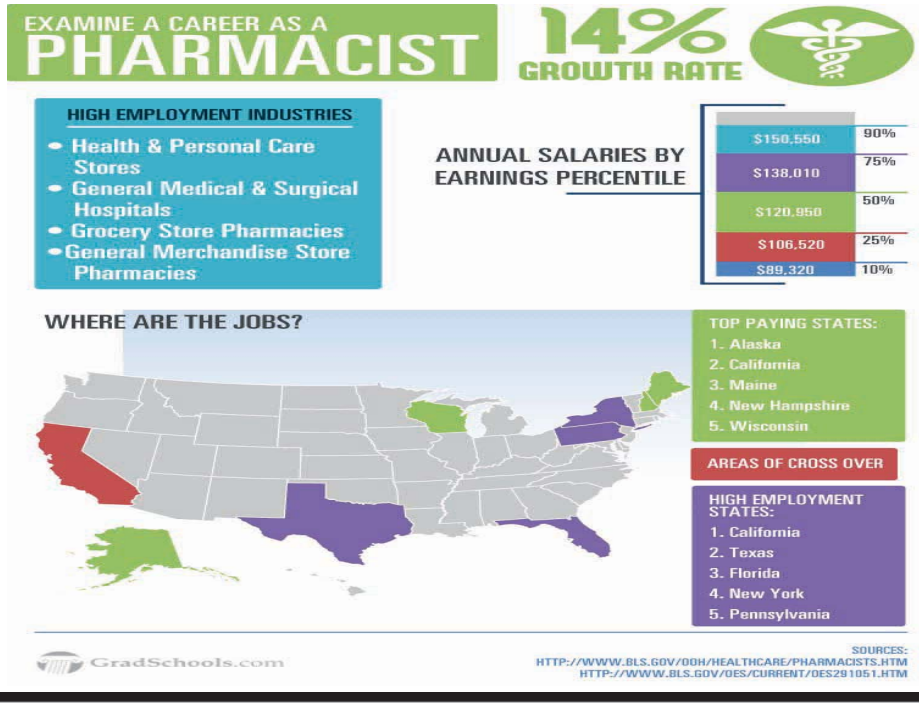
- Pharmacists - third-largest group of healthcare professionals in the world.
- Over the past 50 years, the role of pharmacists has evolved along with the health care needs of our population.
- Today, pharmacists have extended their responsibility from dispensing to pharmaceutical care, by maximizing the benefits of medications and their safety.
- In addition, pharmacists are assuming a larger role as medical counsellors, educators and advocates.
- Drug-related problems cost approximately $42 billion a year worldwide.
- Clinical Pharmaceutical services can prevent adverse reactions and decrease hospitalizations due to drug-related morbidity and can improve quality of life.
- The decrease in expenses resulting from pharmaceutical care implementation can generate savings of US$ 5377 per adverse event avoided and $421,810 per year per pharmacist carrying out clinical practice.




Community
Marketing
Clinical
Research
Manufacturing
Regulatory
Education


PHARMACISTS ARE ONE OF THE HIGHEST PAID GRADUATES IN THE HEALTHCARE INDUSTRY.
SOURCE: BUREAU OF LABOR STATISTICS


2019 HIGHEST-PAYING JOBS IN AMERICA
Occupation
1. Physician
2. Pharmacy Manager
3. Dentist
4. Pharmacist
5. Enterprise Architect
6. Corporate Counsel
7. Software Engineering Manager
8. Physician Assistant
9. Corporate Controller
10. Software Development Manager
11. Nurse Practitioner
12. Applications Development Manager
13. Solutions Architect
14. Data Architect
15. Plant Manager
16. IT Program Manager
17. Systems Architect
18. UX Manager
19. Site Reliability Engineer
20. Cloud Engineer
21. Attorney
22. Data Scientist
23. Information Security Engineer
24. Analytics Manager
25. Financial Planning & Analysis Manager
$0
$50,000
$100,000
$150,000
$200,000
Median Base Salary
SOURCE: GLASSDOOR
CREDIT: JACK KELLY


EXAMINE A CAREER AS A
PHARMACIST
14%
GROWTH RATE
HIGH EMPLOYMENT INDUSTRIES
Health & Personal Care Stores
General Medical & Surgical Hospitals
Grocery Store Pharmacies
General Merchandise Store Pharmacies
ANNUAL SALARIES BY EARNINGS PERCENTILE
$150,550 90%
$138,010 75%
$120,950 50%
$106,520 25%
$89,320 10%
WHERE ARE THE JOBS?
TOP PAYING STATES:
1. Alaska
2. California
3. Maine
4. New Hampshire
5. Wisconsin
AREAS OF CROSS OVER
HIGH EMPLOYMENT STATES:
1. California
2. Texas
3. Florida
4. New York
5. Pennsylvania
GradSchools.com
SOURCES:
HTTP://WWW.BLS.GOV/OOH/HEALTHCARE/PHARMACISTS.HTM
HTTP://WWW.BLS.GOV/OES/CURRENT/OES291051.HTM

Skill Shortage- Australia

ANZSCO 2515-11, 13
Hospital and Retail Pharmacist

Australian Capital Territory
May 2018

Current labour market rating – Shortage

This labour market has tightened in recent years and shortages are now apparent for the first time in a decade. The demand for pharmacists has strengthened in recent years, while the number of students completing relevant training in the ACT has fallen.

Key issues[1]

- Surveyed employers attracted very few applicants in 2018 and only half of their vacancies were filled.
  - Applicant numbers and the proportion of vacancies filled have declined steadily in recent years and are now at historically low levels (see figure on right).
- Employers generally had difficulty regardless of whether they were recruiting for positions in hospitals or retail pharmacies.
- One quarter of applicants did not hold the qualification required for registration as a pharmacist.
- In addition, a number of qualified applicants were regarded as unsuitable, typically because they lacked the required experience (which usually needed to be specific to the sector and role).
- Some employers had unfilled vacancies despite attracting suitable applicants due, for instance, to

2018 Survey results

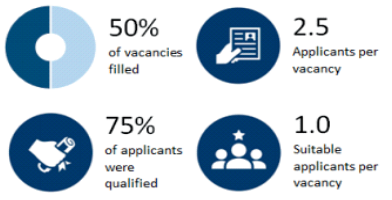
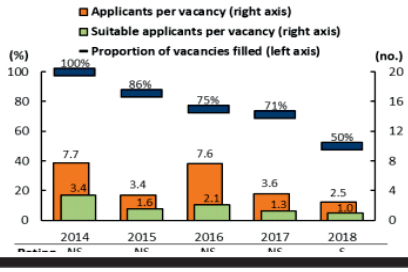
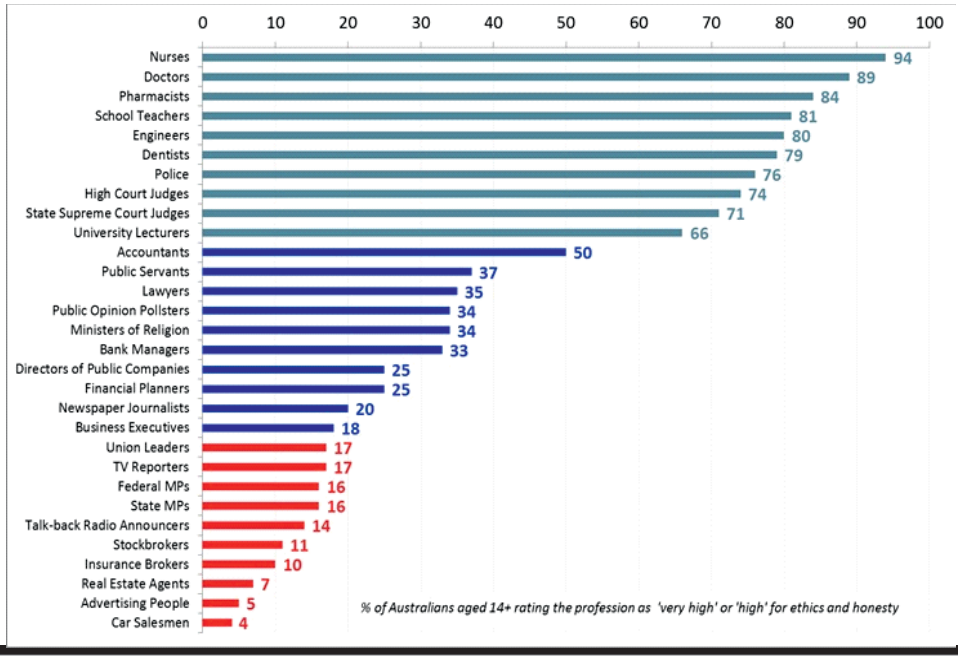
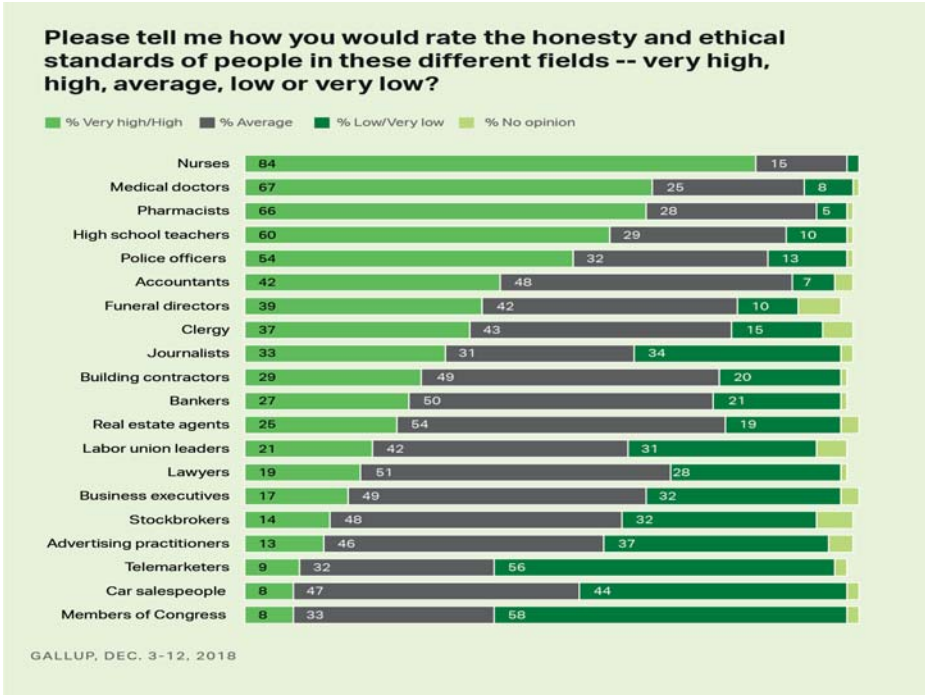


Figure 1: Survey results, Hospital and Retail Pharmacist, 2014 to 2018



Roy Morgan Image of Professions Survey - Australia



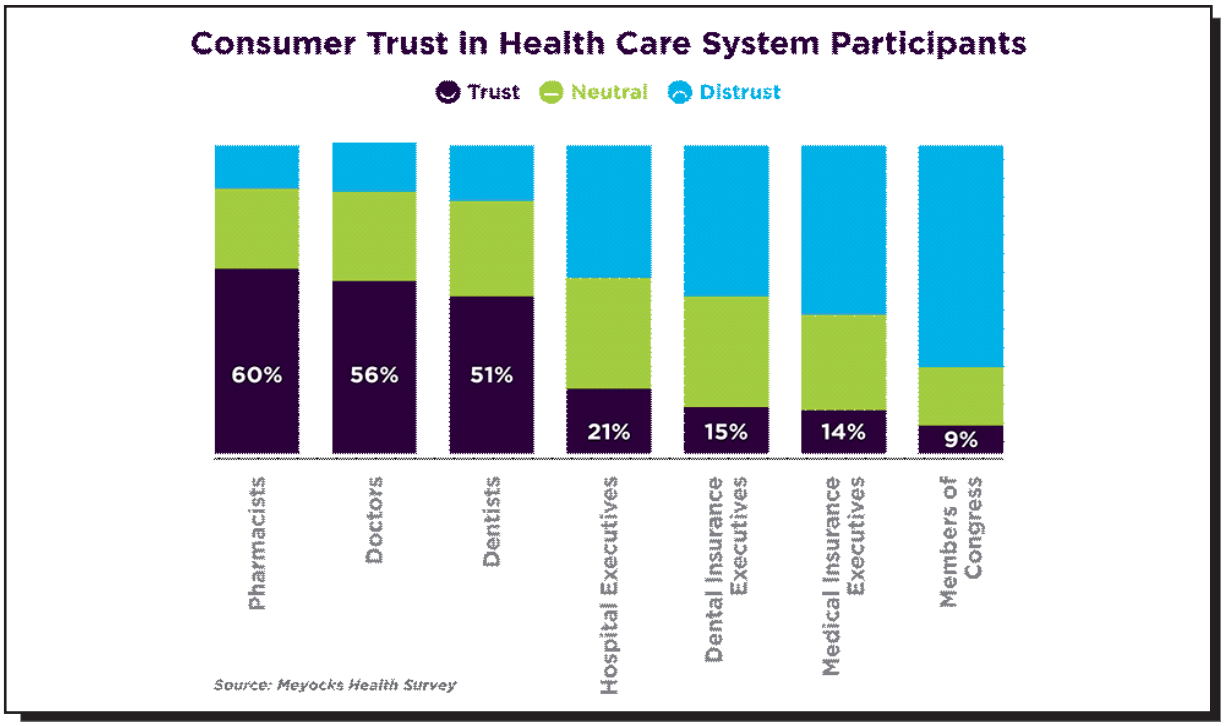


Nurses Still Rate Highest for Honesty and Ethics

Please tell me how you would rate the honesty and ethical standards of people in these different fields -- very high, high, average, low or very low. (% Very high/High)

	2019 %	2018 %	2017 %	2016 %
Nurses	85	84	82	84
Engineers	66	--	--	65
Medical doctors	65	67	65	65
Pharmacists	64	66	62	67
Dentists	61	--	--	59
Police officers	54	54	56	58
College teachers	49	--	--	47
Psychiatrists	43	--	--	38
Chiropractors	41	--	--	38
Clergy	40	37	42	44
Journalists	28	33	--	23
Bankers	28	27	25	24
Labor union leaders	24	21	--	--
Lawyers	22	19	18	18
Business executives	20	--	--	18
State governors	20	17	16	17
Stockbrokers	14	14	--	12
Advertising practitioners	13	13	12	11
Insurance salespeople	13	--	--	12
Senators	13	--	--	11
Members of Congress	12	8	11	8
Car salespeople	9	8	10	9

GALLUP



India has Achieved a Lot in Pharma Sector

- INDIA is the 3rd largest producer of medicines by volume in world.
- INDIA has 2nd largest Pharmaceutical & biotech work force in the world.
- 80% of anti-retroviral drugs used by the world is from INDIA.
- More than 40% of the drugs used in US are from INDIA.
- Highest number of USFDA approved firms (584 plants) are in INDIA
- Every third pill taken in the world is from INDIA.
- One in two vaccines used in the world is from INDIA.
- More than 20,000 Pharmaceutical firms making INDIA the Pharma Hub of the World

Strength of Indian pharmaceutical companies

- Cost advantages
- U.S. FDA approved facilities
- Strong IT skills for research data management
- Highly trained manpower
- Lower operating margins
- Largest number of DMFs
- Enrolment of adequate patients
- Strong Back-up with English communication
- Network of laboratories

Drug Discovery and Development Process

Target Selection and Validation
- Disease Mechanism Studies
- Molecular Studies
- Animal Studies

Discovery
- Target
- Lead Search
- Lead Optimization

Development
- Drug Candidate Selection
- Safety Assessment
- Toxicology
- Pharmacology – ADME
- Pharmaceutical R & D
- Formulation Development

Clinical Research
- Clinical Pharmacology
- Human Studies (Phase I, II, III)
- Statistics & Epidemiology
- Data Coordination
- Research Information Systems
- Information Services

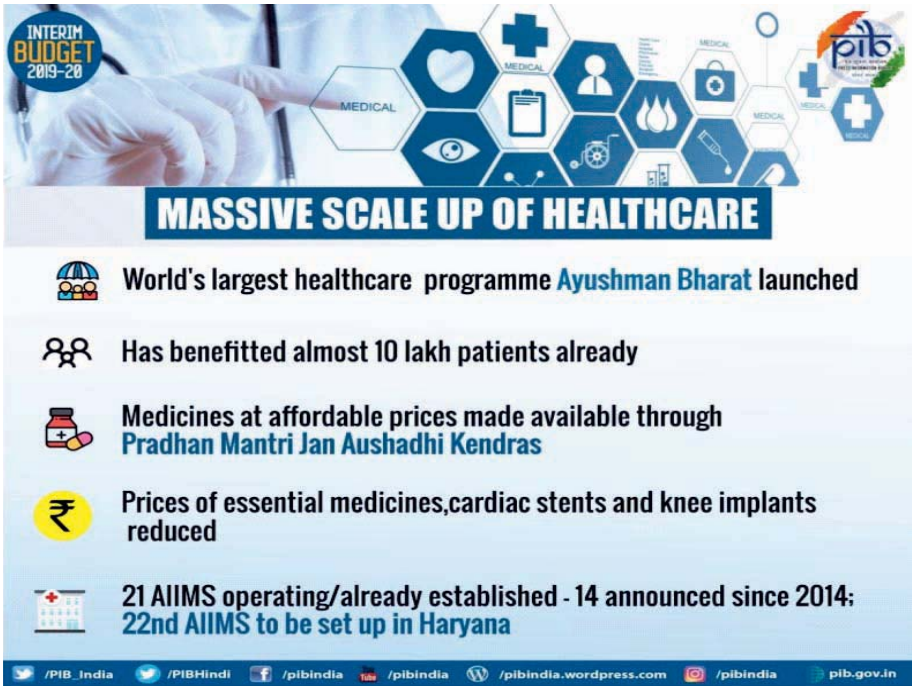
Bio Pharmaceutical Process R & D
- Process R&D
- Chem. Eng. R&D
- Manufacturing

Regulatory Affairs
- Regulatory Intelligence
- Regulatory Submissions
- Technical and Scientific Writing

Commercialization and Further Development
- Medico-Marketing
- Sales

Post Marketing Studies

Clinical Trial Execution	Laboratories	Clinical Data Management	Clinical Programming	Safety and Pharmacovigilance	Real-World & Late Phase
Phase I, II, III, IV Studies. Project Management. Clinical Monitoring. Regulatory Affairs Medical Writing.	Liquid chromatography–mass spectrometry. In vitro ADME assays and metabolite identification. Immunoassay Services. Specimen Management. Genomic Services.	Clinical Data Entry Clinical data review. Clinical Data Validation. Quality control.	Database design, development, implementation, maintenance, and user support of clinical systems	Collecting and tracking incoming Adverse Events(AE)/endpoint information;. AE Processing. Aggregate Reporting. Literature Review.	Real world and late Phase Strategy. Real world Analytics. Interventional Studies.



TIMES NATION

Drug sales reveal our lifestyle woes

Medicines For Anti-Infectives, Cardiac & Respiratory Problems See Highest Sales

Sushmi.Dey@timesgroup.com

New Delhi: Anti-infectives along with medicines for cardiac diseases, diabetes, gastro-intestinal and respiratory problems garnered the highest sales in the Indian pharmaceutical market in last one year, pointing to a rapidly growing burden of lifestyle-related ailments.

Indians spent over Rs 1,36,000 crore on medicines in last one year ending September 2019, of which 31% was spent on medicines for diabetes, heart disorders and other chronic ailments.

This is also the fastest growing segment at 13% as compared to acute therapies which accounted for 47% of the market but grew by 11.7% and sub-chronic segment at 10.7%, according to data released by All India Organisation of Chemists & Druggists (AIOCD).

1,36,802 CR SALES IN 1 YEAR

Indians bought medicines worth ₹1,36,802 crore in last one year (October 2018 to September 2019)

Maximum drug launches took place in respiratory & cardiovascular therapy

ANNUAL SALES VALUE (MAT SEPT 2019)	IN ₹ CR	GROWTH %
Respiratory	10,120.2	7.6
Vitamins/minerals/ nutrients	11,864.6	9.2
Anti-diabetic	13,369.4	14.9
Gastro-intestinal	15,472.9	8.5
Cardiac	17,076.3	12.6
Anti-infectives	18,413.8	8.4
Indian pharmaceutical market (Total)	1,36,802.2	9.8

Source: AIOCD Awacs

While anti-infectives topped the list of medicines with highest sales value, those for cardiac problems, diabetes and gastro-intestinal disorders were among the top five, with only cardiac and anti-diabetes drugs registering double digit growth of 12.6% and 14.9%, respectively, for the year. The overall drug sales grew by 9.8% during the period.

People spent over Rs 17,000 crore on cardiac drugs, around Rs 15,400 crore for gastro-intestinal disorders and over Rs 13,360 crore on anti-diabetes medicines in the last 12 months. Anti-infectives accounted for the highest sales of over Rs 18,413 crore.

"Sales of anti-diabetic drugs has increased due to multiple factors like increased number of patients, more frequent diagnosis, increasing use of more expensive drugs and insulin. Importantly, use of conventional low cost drugs/ insulin could help manage about 60-70% cases of diabetes in India, thus reducing out of pocket cost for patients," says Dr Anoop Misra, Chairman Fortis C-Doc.

Maximum drug launches were in cardiovascular and respiratory segments. Around 78 new drugs were launched in September alone. Of these, 18 were to treat cardiovascular diseases, 17 were vitamins, minerals and nutrients and 14 were in in the respiratory segment.

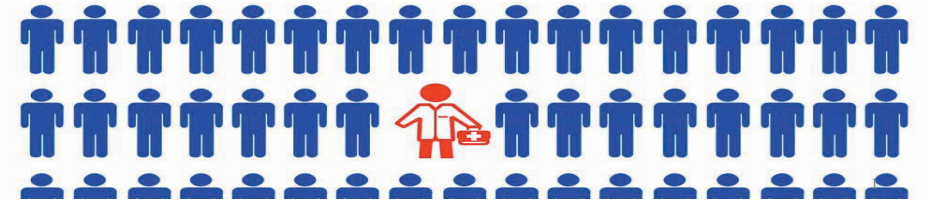
Not just in terms of value but volume growth have also gained momentum, a senior industry executive said.

"Increasing disease burden, growing awareness, availability and affordability of treatment along with enhanced insurance penetration have all resulted in higher sales of medicines. Besides, there is no doubt that the NCD (non-communicable disease) segment is growing rapidly leading to higher growth in segments like cardiac and diabetes," he said. The data also show the top ten corporates gradually increasing there market share in the chronic segment.

DOCTOR- PATIENT RATIO

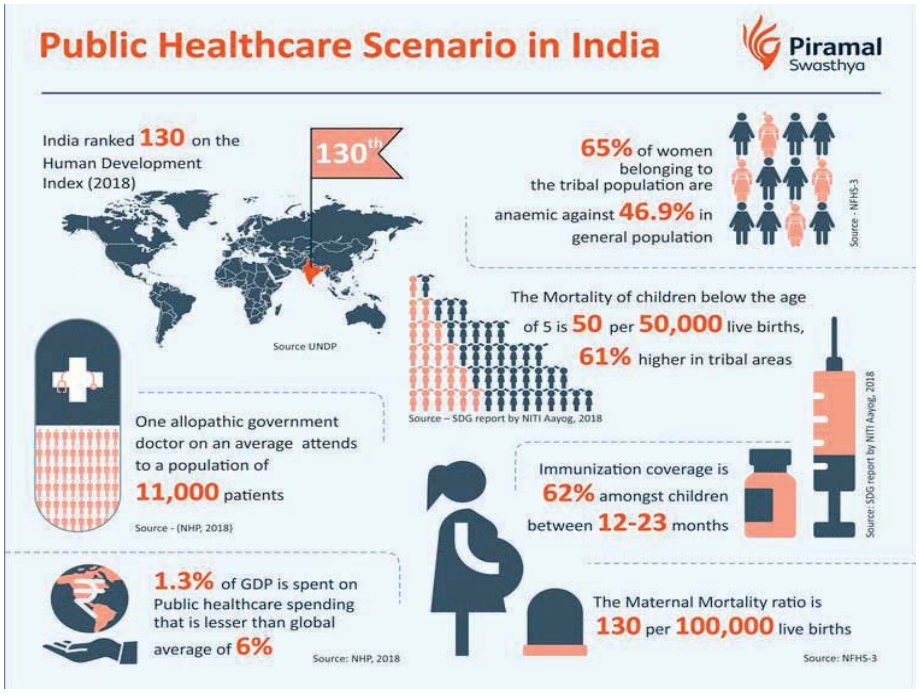
2019 statistics

Doctor : People	
Current Ratio (Current)	1:1,456
Expected Ratio (2030)	1:1000
In Most Rural Areas	1:30000 Or More



Who can play an important role in improving access to health care and in closing the gap between the potential benefit of medicines and the actual value realized?

THE PHARMACIST



World Antibiotic Awareness Wee

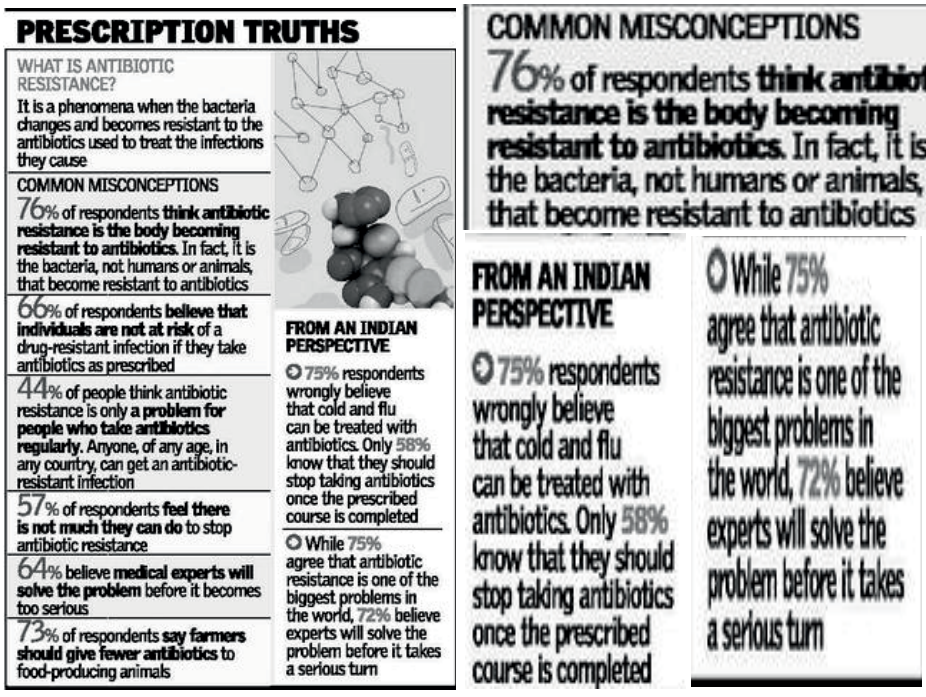
18-24 November 2020

- *"Antimicrobial resistance is not a future threat looming on the horizon. It is here, right now, and the consequences are devastating."*
  - Dr. Margaret Chan,
- Former Director-General of the WHO

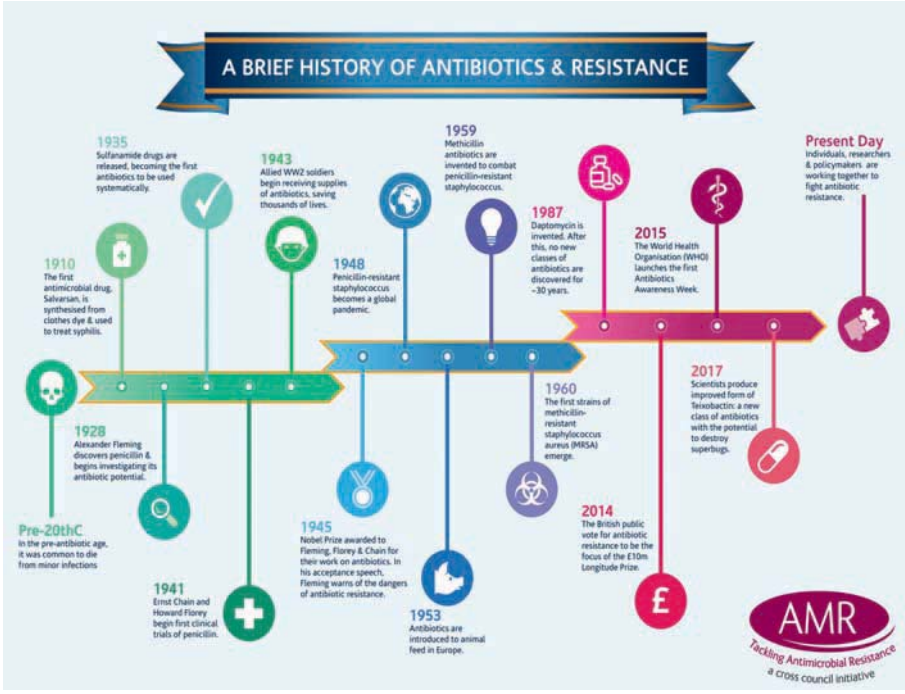
"There is no commodity in the world more precious than health"

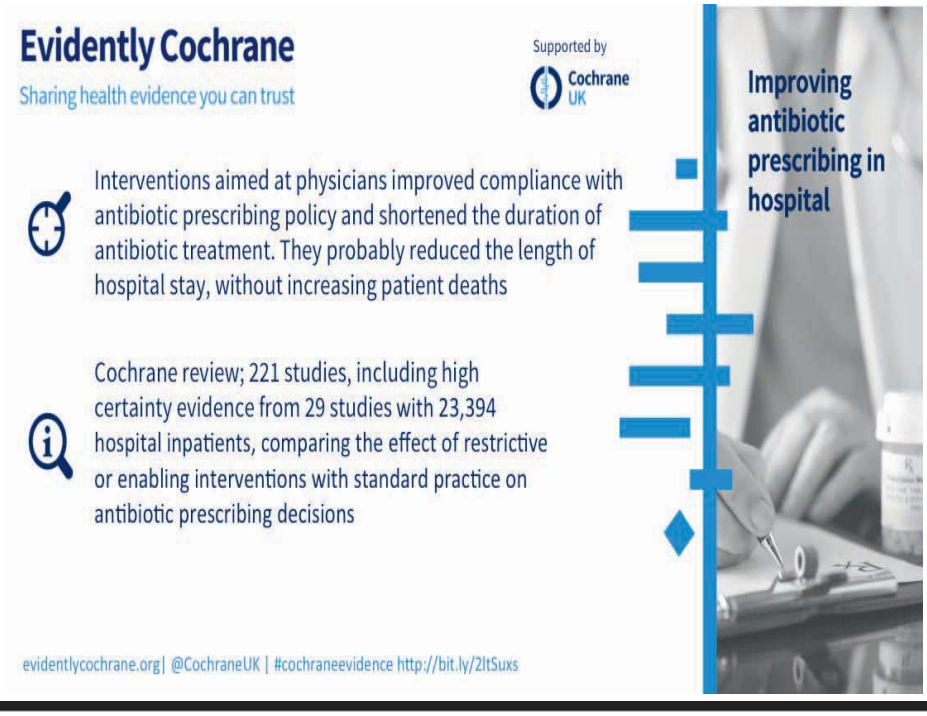
- Tedros Adhanom

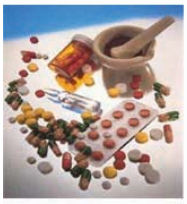
Director-General of the WHO



The new findings were published in the journal *the Lancet Infectious Diseases*. During a routine surveillance of antibiotic resistance in China, scientists discovered that a new bacterial genetic resistance mechanism called MCR-1 prevents the drug colistin from killing bacteria. (Colistin is often seen as a "last-resort" antibiotic when others aren't effective.)


A BRIEF HISTORY OF ANTIBIOTICS & RESISTANCE
Pre-20thC
In the pre-antibiotic age, it was common to die from minor infections
1910
The first antimicrobial drug, Salvarsan, is synthesised from clothes dye & used to treat syphilis.
1928
Alexander Fleming discovers penicillin & begins investigating its antibiotic potential.
1935
Sulfanamide drugs are released, becoming the first antibiotics to be used systematically.
1941
Ernst Chain and Howard Florey begin first clinical trials of penicillin.
1943
Allied WW2 soldiers begin receiving supplies of antibiotics, saving thousands of lives.
1945
Nobel Prize awarded to Fleming, Florey & Chain for their work on antibiotics. In his acceptance speech, Fleming warns of the dangers of antibiotic resistance.
1948
Penicillin-resistant staphylococcus becomes a global pandemic.
1953
Antibiotics are introduced to animal feed in Europe.
1959
Methicillin antibiotics are invented to combat penicillin-resistant staphylococcus.
1960
The first strains of methicillin-resistant staphylococcus aureus (MRSA) emerge.
1987
Daptomycin is invented. After this, no new classes of antibiotics are discovered for ~30 years.
2014
The British public vote for antibiotic resistance to be the focus of the £10m Longitude Prize.
£
2015
The World Health Organisation (WHO) launches the first Antibiotics Awareness Week.
2017
Scientists produce improved form of Teixobactin: a new class of antibiotics with the potential to destroy superbugs.
Present Day
Individuals, researchers & policymakers are working together to fight antibiotic resistance.
AMR
Tackling Antimicrobial Resistance
a cross council initiative


Evidently Cochrane
Sharing health evidence you can trust
Supported by
Cochrane UK
Interventions aimed at physicians improved compliance with antibiotic prescribing policy and shortened the duration of antibiotic treatment. They probably reduced the length of hospital stay, without increasing patient deaths
Cochrane review; 221 studies, including high certainty evidence from 29 studies with 23,394 hospital inpatients, comparing the effect of restrictive or enabling interventions with standard practice on antibiotic prescribing decisions
Improving antibiotic prescribing in hospital
evidentlycochrane.org| @CochraneUK | #cochraneevidence http://bit.ly/2ltSuxs



Product oriented approach

Patient oriented approach

- Prescription Auditing
- ADR & Drug Interaction
- Medication History Interview
- Medication Error Reporting
- Pharmaco-economic evaluation
- Formulary Update
- Patient Counseling
- Dosage Individualization
- Drug Information
- Medication Therapy Management
- Quality of Life

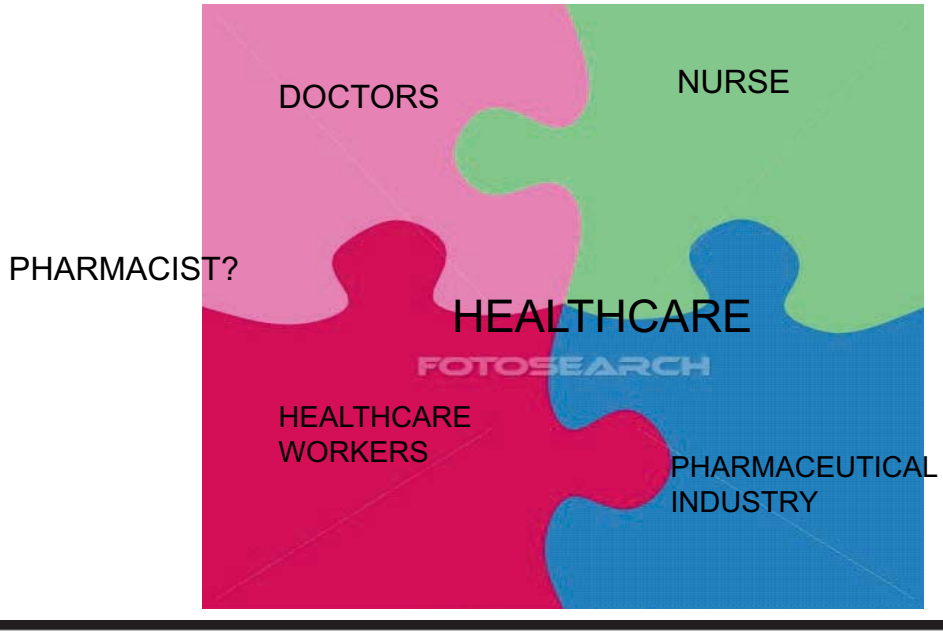
Challenges roles of Clinical Pharmacist

NABH

01.	Access, Assessment and Continuity of Care (AAC)
02.	Care of Patients (COP)
03.	Management of Medication (MOM)
04.	Patient Rights and Education (PRE)
05.	Hospital Infection Control (HIC)
06.	Continuous Quality Improvement (CQI)
07.	Responsibilities of Management (ROM)
08.	Facility Management and Safety (FMS)
09.	Human Resource Management (HRM)
10.	Information Management System (IMS)

Pharmaceutical care activities

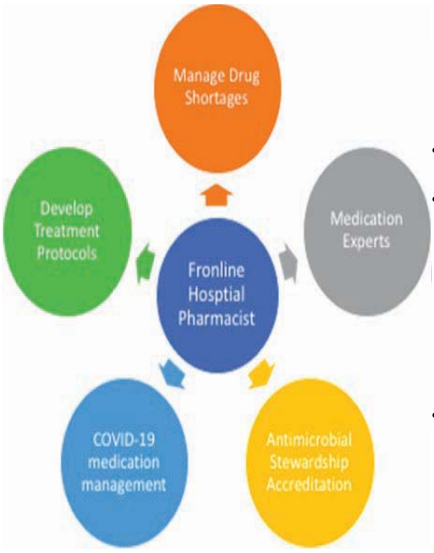
Fit as a Health Care Professional



First point of care during Covid-19: Community and Hospital setting

COMMUNITY SETTING

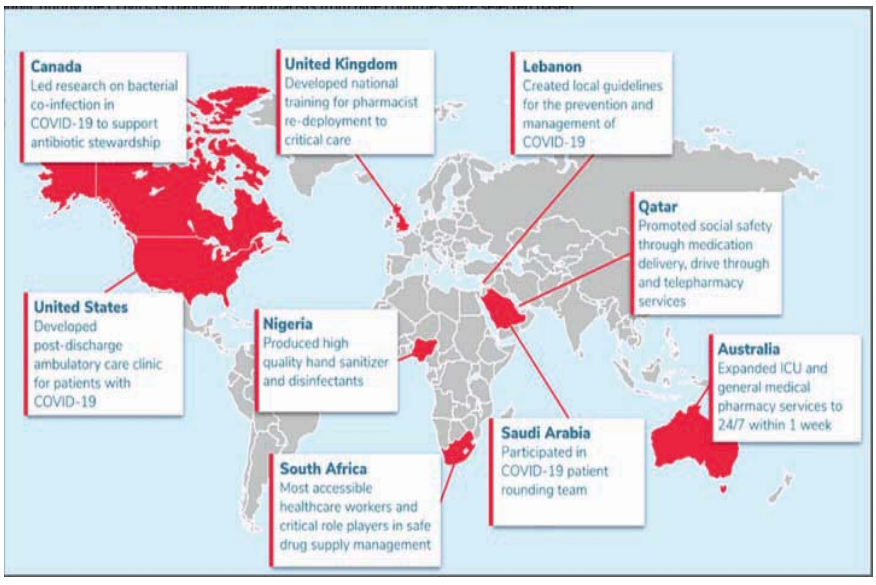
- Community pharmacists remain on the frontline of public health by serving as **direct points of access** for their patients.
- They are often the **first point of call** for patients seeking advice for infections or self-care treatments for minor ailments.
- They **can perform the triage role** and direct patients to their family doctor or to an urgent care facility.



HOSPITAL SETTING

- Hospital pharmacists participate in **inpatient rounds**.
- They participate in **antimicrobial stewardship programs;** As part of it, hospital pharmacists have been involved in **developing local treatment protocols** that repurpose antivirals and monitoring the use of antibiotics in cases of bacterial co-infections in COVID-19 patients.
- In addition, pharmacists can help interpret test results for COVID-19, explore new drug therapies or uses, and **provide medication management recommendations** to their colleagues.

Map highlighting the services rendered by pharmacists globally during the COVID-19 pandemic

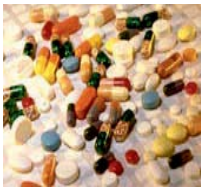


Description of the pharmacist interventions according to the DEPICT version 2.

Author	Recipient	Contact with recipient	Methods of communication	Setting of the intervention	Action(s) taken by pharmacist	Materials that support action(s)
Arain et al.[19]	Patient and HCP	One-to-one (patient and HCP) and group (HCP)	Face-to-face (patient and HCP), written (patient and HCP), and telephone (HCP)	Hospital bedside (patient and HCP), hospital pharmacy (HCP), and ambulatory setting (patient)	Drug information for HCP; patient counseling; suggestion for change in therapy; monitoring results report; drug supply management; safety measures for infection control	Discharge letter; educational materials; protocol; safety alert system
Elson et al.[20]	Patient and HCP	One-to-one (patient) and group (HCP)	Written (patient and HCP), telephone (patient and HCP), and video conference (patient and HCP)	Hospital bedside (patients and HCP), ambulatory setting (patient), and recipient's home (patient)	Drug information for HCP; patient counseling; drug supply management	NR
Fan and Kamath[21]	Patient and HCP	One-to-one (patient) and group (HCP)	Video conference (patient and HCP)	Hospital bedside (patients and HCP) and recipient's home (patient)	Drug information for HCP; patient counseling	NR
Hua et al.[22]	Patient and HCP	One-to-one (patient and HCP) and group (patient)	Written (patient and HCP), telephone (patient), video conference (patient), and radio station (patient)	Hospital bedside (patient and HCP)	Drug information for HCP; patient counseling; drug supply management	NR
Meng et al.[23]	Patient and HCP	One-to-one (patient and HCP)	Telephone and video conference (patient and HCP)	Hospital bedside (patient and HCP)	Drug information for HCP; patient counseling; drug supply management; safety measures for infection control	Educational materials
Ou and Yang[24]	NA[a]	One-to-one	Face-to-face	Community pharmacy	Safety measures for infection control	NR
Tan et al.[25]	Patient	One-to-one	NR	Recipient's home	Patient counseling; suggestion for change in therapy	NR
Ung[26]	NA[a]	One-to-one	Face-to-face	Community pharmacy	Safety measures for infection control	NR
Yemm et al.[27]	Patient	One-to-one	Telephone	Recipient's home	Application of tools to evaluated a disease	NR
Ying et al.[28]	Patient and HPC	One-to-one (patient and HPC) and group (HPC)	Face-to-face, written (patient and HPC)	Hospital bedside (patient and HCP) and ambulatory setting (patient and HCP)	Drug information for HPC; patient counseling; drug supply management; safety measures for infection control	Educational materials
Zuckerman et al.[29]	Patient and HCP	One-to-one (patient and HCP) and group (HCP)	Written (patients and HCP), telephone (patients), and video conference (HCP)	Hospital bedside (patient and HCP), hospital pharmacy (HCP), ambulatory setting (patient and HCP) and recipient's home (patient)	Drug information for HPC; patient counseling; suggestion for change in therapy; drug supply management; safety measures for infection control	Educational materials; protocols

Various vaccine trials around the world

	Candidate	Mechanism	Sponsor	Trial Phase	Institution
	Bacillus Calmette-Guerin (BCG) vaccine	Live-attenuated vaccine	University of Melbourne and Murdoch Children's Research Institute; Radboud University Medical Center; Faustman Lab at Massachusetts General Hospital	Phase 2/3	University of Melbourne and Murdoch Children's Research Institute; Radboud University Medical Center; Faustman Lab at Massachusetts General Hospital
	INO-4800	DNA vaccine (plasmid)	Inovio Pharmaceuticals	Phase 2/3	Center for Pharmaceutical Research, Kansas City, Mo.; University of Pennsylvania, Philadelphia
	VIR-7831	Plant-based adjuvant vaccine	Medicago; GSK; Dynavax	Phase 2/3	Medicago
	No name announced	Recombinant vaccine	Anhui Zhifei Longcom Biopharmaceutical, Institute of Microbiology of the Chinese Academy of Sciences	Phase 2	Various
	ZyCoV-D	DNA vaccine (plasmid)	Zydus Cadila	Phase 2	Zydus Cadila
	No name announced	Adjuvanted protein subunit vaccine		Phase 1/2	
	AG0301-COVID19	DNA vaccine	AnGes, Inc.	Phase 1/2	AnGes, Inc.; Japan Agency for Medical Research and Development



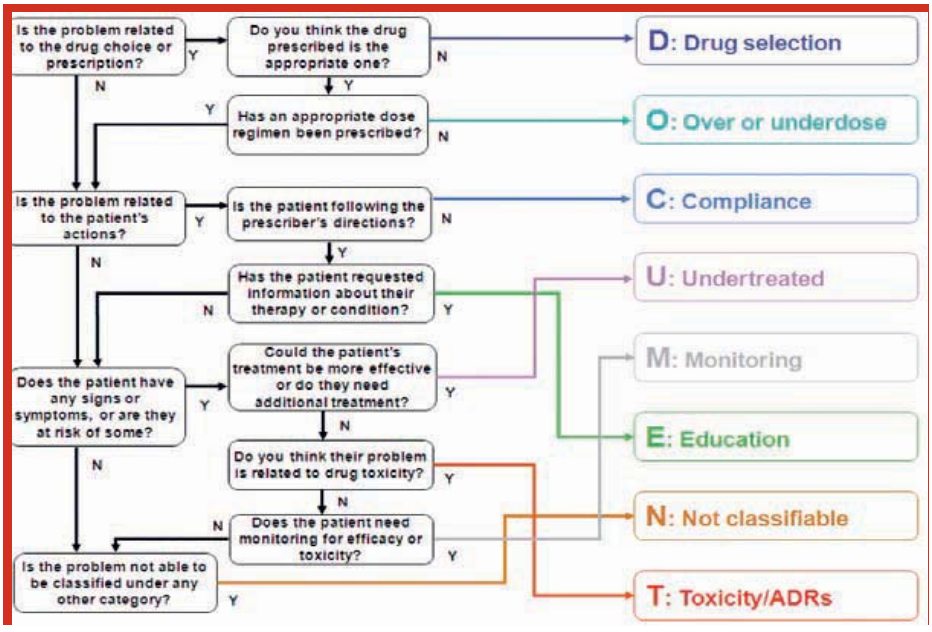
Drugs are same

But

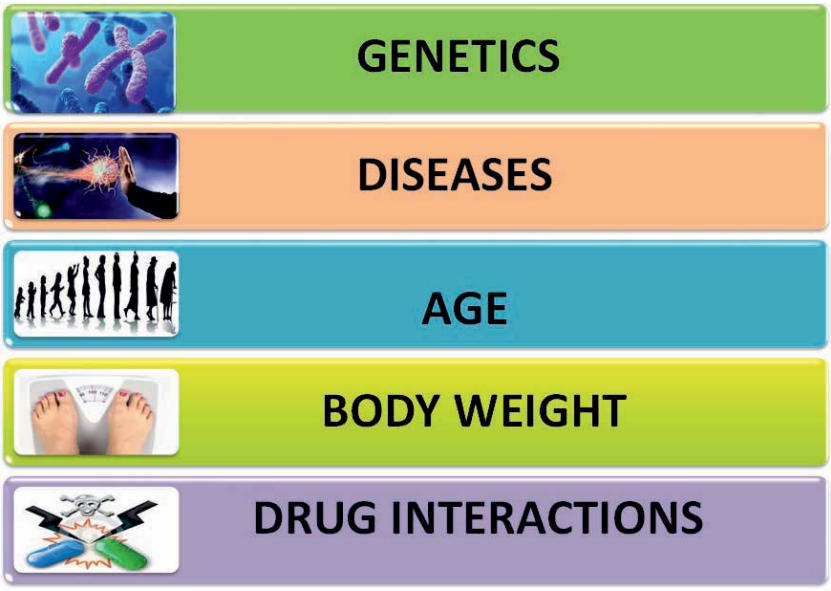
PATIENTS ARE DIFFERENT ....

PERSONALIZED MEDICINE : FUTURE

PERSONALIZED MEDICINE



Intersubject pharmacokinetic variability



Format: Abstract

J Infect Chemother. 2003 Dec;9(4):314-20.

Effects of anti-inflammatory drugs on convulsant activity of quinolones: a comparative study of drug interaction between quinolones and anti-inflammatory drugs.

Hori S[1], Kizu J, Kawamura M.

Author information

Abstract

Quinolones have been reported to possess potent convulsant activity, which is enhanced when they are administered concurrently with anti-inflammatory drugs. To define the individual drug interactions of quinolones with anti-inflammatory drugs, we studied the convulsant activity of six quinolones with or without 13 anti-inflammatory drugs and 3 analgesic/antipyretic drugs in mice. Intraventricular injections of norfloxacin (NFLX), enoxacin (ENX), ciprofloxacin, lomefloxacin (LFLX), levofloxacin, and gatifloxacin induced convulsions in mice in a dose-dependent manner. Concurrent administration of biphenylacetic acid strongly enhanced the convulsant activity of NFLX, ENX, and LFLX. Flurbiprofen also strongly enhanced the activity of NFLX and ENX, and ketoprofen strongly enhanced the activity of ENX. However, mefenamic acid, piroxicam, tenoxicam, meloxicam, etodolac, sulpyrine, isopropylantipyrine, and acetaminophen had no effect on the convulsant activity of quinolones. These results suggest that each quinolone has an individual drug interaction with each anti-inflammatory drug. It was suggested that we should know which anti-inflammatory drugs enhance the convulsant activity of individual quinolones, and which quinolone has no/weak drug interaction with different anti-inflammatory drugs when these drugs are used concurrently for the treatment of patients with infectious diseases.

Published in final edited form as:
Stroke. 2015 March ; 46(3): 722–731. doi:10.1161/STROKEAHA.114.006866.

Comparative risk of ischemic stroke among users of clopidogrel together with individual proton pump inhibitors

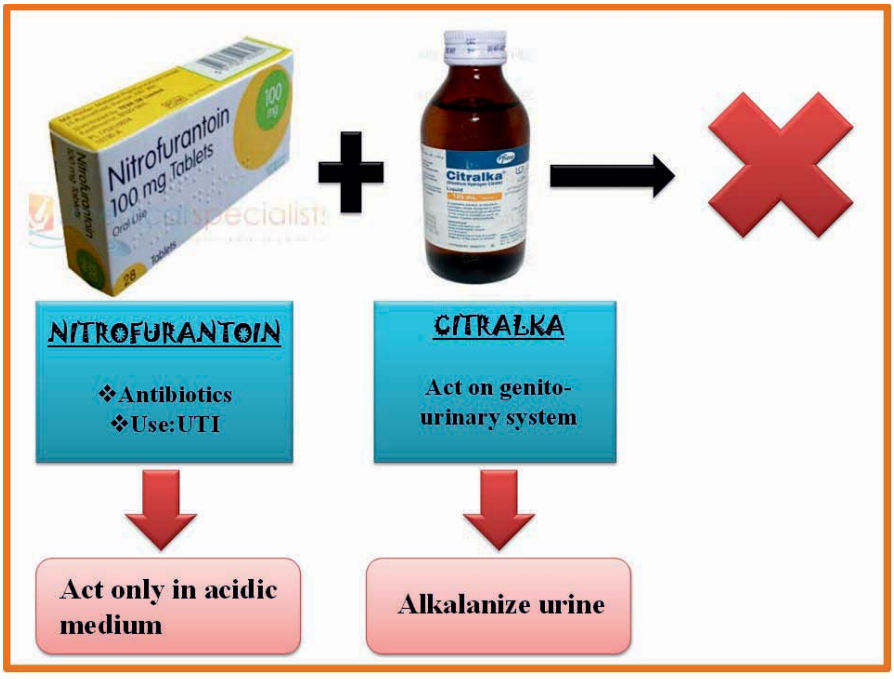
Charles E. Leonard, Pharm.D., M.S.C.E.[1,2], Warren B. Bilker, Ph.D.[1,2,3], Colleen M. Brensinger, M.S.[1], David A. Flockhart, M.D., Ph.D.[2,4], Cristin P. Freeman, M.P.H., M.B.E.[1,2,†], Scott E. Kasner, M.D., M.S.C.E.[5], Stephen E. Kimmel, M.D., M.S.C.E.[1,2,6], and Sean Hennessy, Pharm.D., Ph.D.[1,2,7]

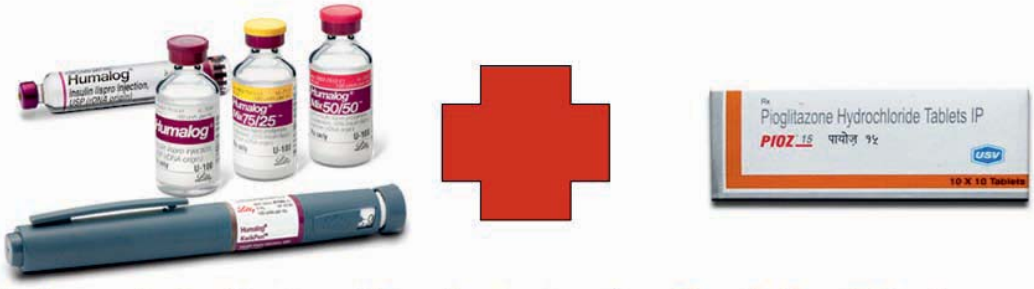
Leonard et al.

Abstract

Background and Purpose—There is controversy and little information concerning whether individual proton pump inhibitors (PPIs) differentially alter the effectiveness of clopidogrel in reducing ischemic stroke risk. We therefore aimed to elucidate the risk of ischemic stroke among concomitant users of clopidogrel and individual PPIs.

Methods—We conducted a propensity score-adjusted cohort study of adult new users of clopidogrel, using 1999–2009 Medicaid claims from 5 large states. Exposures were defined by prescriptions for esomeprazole, lansoprazole, omeprazole, rabeprazole and pantoprazole—with pantoprazole serving as the referent. The endpoint was hospitalization for acute ischemic stroke,



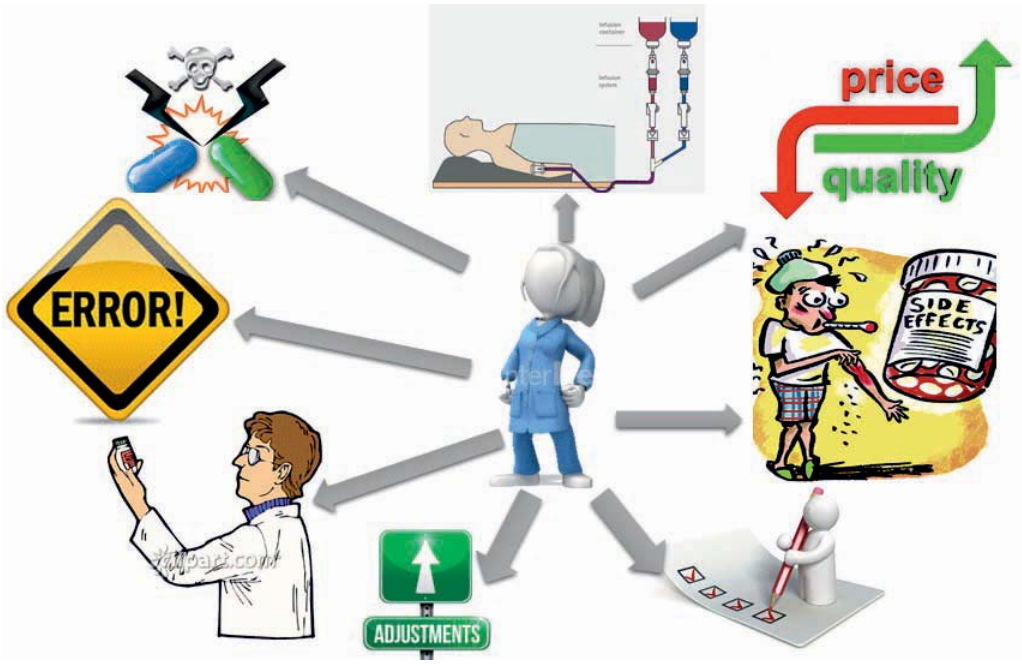


Pioglitazone in Combination with Insulin – An Overview of Results from PROactive

Bernard Charbonnel

European Endocrinology, 2011;7(1):24-9 DOI: http://doi.org/10.17925/EE.2011.07.01.24

Abstract: Abstract
Pioglitazone provides one of several add-on therapy options for patients with unsatisfactory glycaemic control treated with insulin. Although pioglitazone has the beneficial feature of low hypoglycaemia risk, it has an overlapping adverse event profile with insulin in terms of oedema (with the potential to exacerbate heart failure) and weight gain, leading to possible concern over their use in combination. Fortunately, subgroup analyses from the PROspective pioglitAzone Clinical Trial In macroVascular Events (PROactive) have provided valuable insights into the efficacy and safety profile of pioglitazone in patients on established insulin therapy. Pioglitazone improved glycaemic control and lipids, while enabling patients to reduce their insulin requirements. Oedema and weight were predictable with no excess exacerbation of heart failure with the combination. Importantly, pioglitazone had a good macrovascular safety profile (with a trend towards benefit), consistent with the overall population. This article provides an overview of the results from the insulin-treated subgroup in PROactive and highlights some of the clinical implications for pioglitazone–insulin combination therapy.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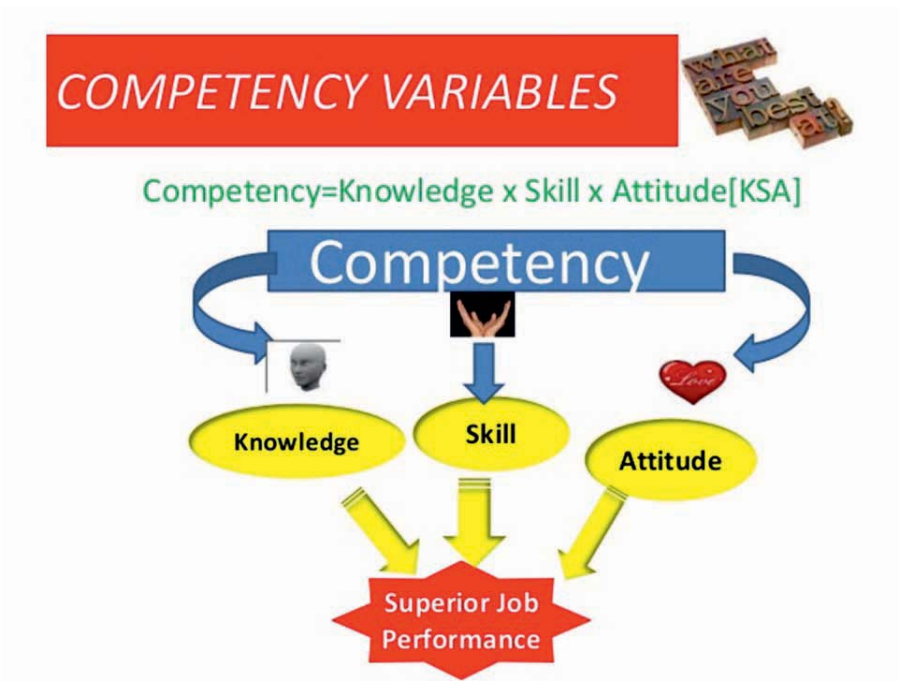
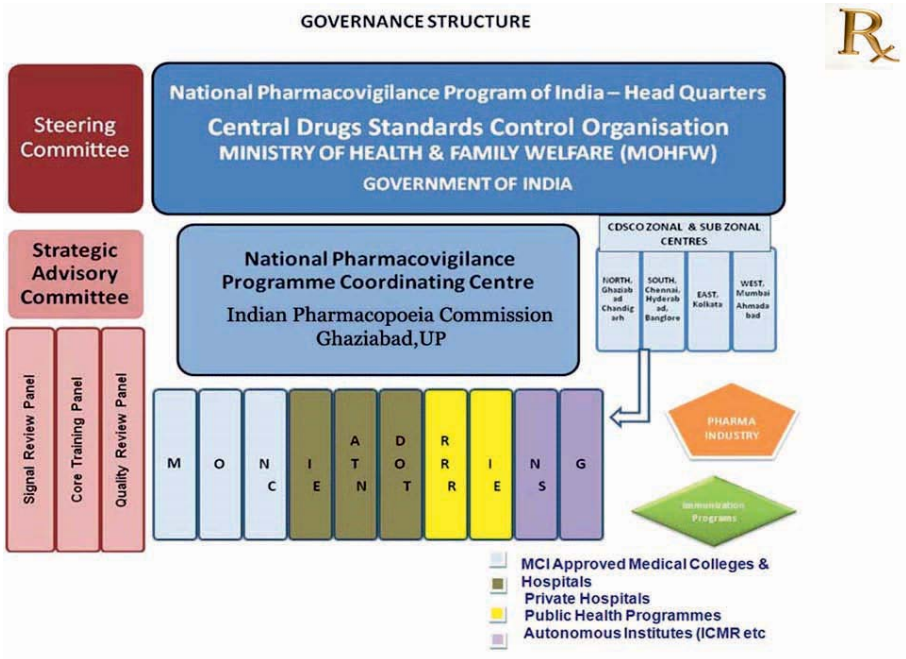
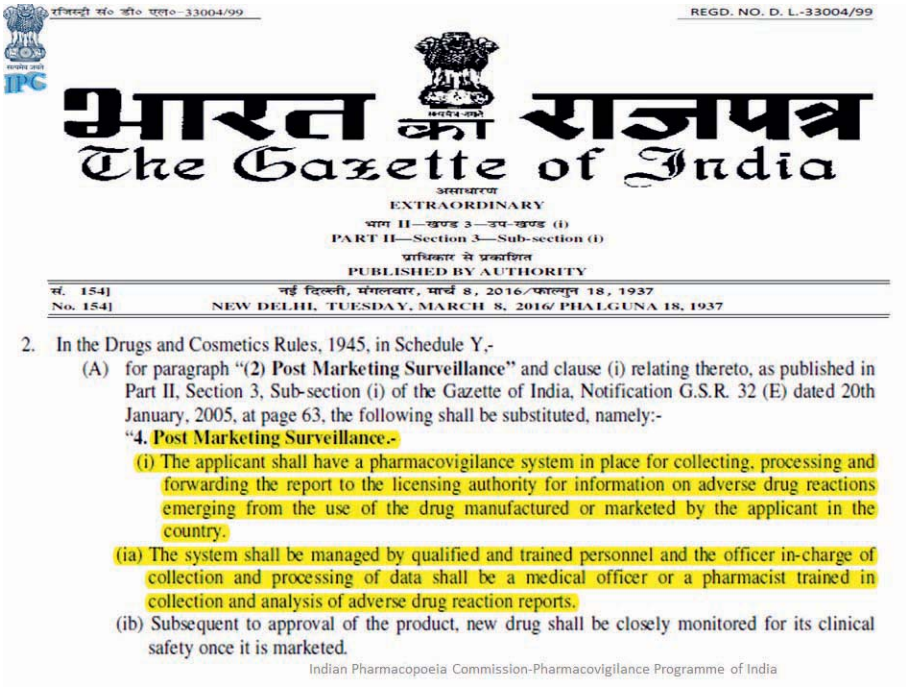
ADJUSTMENTS


COMPETENCY VARIABLES
What are you best at!
Competency=Knowledge x Skill x Attitude[KSA]
Competency
Knowledge
Skill
Attitude
Superior Job Performance





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REGD. NO. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)
प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 154] नई दिल्ली, मंगलवार, मार्च 8, 2016/फाल्गुन 18, 1937
No. 154] NEW DELHI, TUESDAY, MARCH 8, 2016/ PHALGUNA 18, 1937

2. In the Drugs and Cosmetics Rules, 1945, in Schedule Y,-

(A) for paragraph "**(2) Post Marketing Surveillance**" and clause (i) relating thereto, as published in Part II, Section 3, Sub-section (i) of the Gazette of India, Notification G.S.R. 32 (E) dated 20th January, 2005, at page 63, the following shall be substituted, namely:-

"**4. Post Marketing Surveillance.-**

(i) The applicant shall have a pharmacovigilance system in place for collecting, processing and forwarding the report to the licensing authority for information on adverse drug reactions emerging from the use of the drug manufactured or marketed by the applicant in the country.

(ia) The system shall be managed by qualified and trained personnel and the officer in-charge of collection and processing of data shall be a medical officer or a pharmacist trained in collection and analysis of adverse drug reaction reports.

(ib) Subsequent to approval of the product, new drug shall be closely monitored for its clinical safety once it is marketed.

Indian Pharmacopoeia Commission-Pharmacovigilance Programme of India

Where & How to report ?

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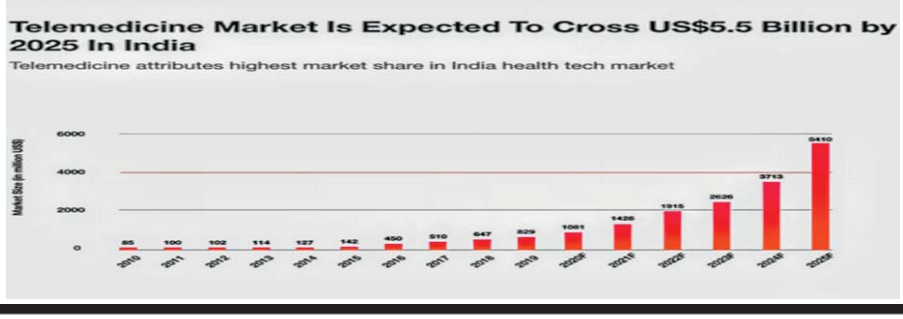
- Toll Free No. 1800 180 3024
- NCC-PvPI IPC
- @ IPC NCC-PvPI
- What-app 7042343309
- ADR Mobile-app
- pvpi.ipc@gov.in

TELEMEDICINE

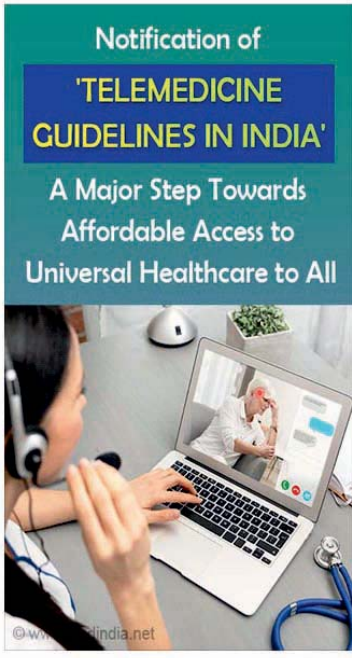
- Telemedicine, a term coined in the 1970s, which literally means "healing at a distance".
- According to WHO, Telemedicine is, "The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities"

INDIA

- India has a **shortage** of around estimated 600K doctors and 2Mn nurses, as per reports last year.
- India only has **one government doctor for every 1,456 people** whereas the World Health Organization (WHO) recommends a ratio of 1:1,000.
- The shortage of doctors is **limiting face-to-face consultations among patients.**
- Secondly, India also has a **shortage of hospital beds,** which makes hospitalization tricky, and there needs to be better facilities and infrastructure for cases where patients can be attended to via teleconsultation.
- Telemedicine will **reduce the time of consultations and improve the quality of healthcare services** in rural areas, removing many of infrastructural challenges.
- The telemedicine market in India is expected to reach $5.4 Bn by 2025 with a CAGR of 31%.



- THE GOVERNMENT OF INDIA, issued Telemedicine practice guidelines on **25th March 2020,** to encourage healthcare professionals to practice this idea in the covid 19 crises by which **efficient and prompt healthcare services** can be rendered to the public following up the social distancing norms.
- These guidelines are also **issued to bridge the gaps between the existing norms** so that various start-up's that were operating in the regulatory grey zone can operate more efficiently and more novel ideas in the domain can be encouraged.
- The link of guidelines, https://www.mohfw.gov.in/



Role of Pharmacists in telemedicine (india)

- **Jiyyo Mitra e- clinic**, is providing **online medical consultation** in rural areas of India, using telemedicine. The scheme basically involves, connecting the patient to the health care provider, once they visit the jiyyo outlet, set up in rural areas of India, primarily north India, constantly expanding to the southern parts as well. Jiyyo Lyfe app is used for this purpose.
- A pharm D professional when included in the process, can prove to provide excellent outcomes in patient as they are **qualified to provide ambulatory care**. Proper Medication History interviews can be taken, medication therapy management, patient counselling and adverse drug reaction management can be done, via telemedicine. **Currently the concern is working on incorporating pharmacists into the process.**

RECENT TRENDS TOWARDS "GREEN" CHEMISTRY HPLC!!

by
Dr. V. Manohar
Director – Indian Institute of Chromatography & Mass Spectrometry, Chennai

Introduction

The art of integration of appropriate stationary phase and the right composition of mobile phase for a specific mixture of analytes is the key for successful HPLC separation of all analytes in a mixture. The analyst has to ensure that the separation confines to chromatographic specifications such as peak shape, resolution, symmetry, tailing factor and so on. Indeed, unlike many analytical tools, HPLC is the most widely employed tool due to its versatility and compatibility with any kind of detector with appropriate interface. It is considered as universal technique and aids in the determination of purity of a product whether it is drug or a drug substance, food products, nutraceuticals, natural products, plant extracts, biological samples or cosmetics! HPLC has invaded in the analysis of every product and in every aspect of analysis, be it, purity or be it, impurity profiling. Therefore, the innovation in HPLC instrumentation continues to grow through integration of modern information technology with several automations to ease the operation and minimizing human intervention and possible ambiguities due to manual operation.

All of us know that the heart of HPLC is the column that effectively offers separation. No column is universal as it is product specific and mainly controlled by mobile phase compatibility. Due to several applications of HPLC, the consumption of solvents as mobile phase is also very high. This, invariably, leads to very high use of organic solvents such as acetonitrile (ACN) or methanol (MeOH) as most HPLC methods developed in pharmaceutical laboratories are based on the reversed-phase (RP) mode, using a hydrophobic stationary phase and a polar mobile phase. These two the solvents are by far the preferred organic solvents used in RP-HPLC because of their remarkable combination of properties favorable for RP-HPLC applications. Among them include complete miscibility with water, relatively low viscosity of their aqueous solutions (especially in the case of ACN), low UV cut-off wavelength (190 nm and 205 nm for ACN and MeOH, respectively), availability in the high purity required for HPLC, and low chemical reactivity with most sample species, as well as with HPLC instrument and column surfaces. Due to huge consumption of these organic solvents, universal concern on environmental hazard is growing and hence many scientists have begun to evaluate to introduce "green" chemistry approach in HPLC analysis [1,2].

This articles reviews the efforts on the development of aqueous phase stationary phase and its applications, high temperature liquid chromatography and other methods towards approaching "green" chemistry HPLC analysis that are environmental friendly.

Some of the approaches....

One of the simple ways of making HPLC greener is the replacement of toxic solvents such as ACN with non-toxic ones such as ethanol or acetone.

Ethanol (EtOH) [3]

The property of EtOH is chromatographically similar to the properties of ACN and MeOH. Miyabe et al. [4] have evaluated the adsorption characteristics in RP-HPLC using EtOH/water mixture on an octadecylsilyl (ODS)-silica gel column, and compared them to corresponding results obtained from MeOH/water and ACN/water mixture-based mobile phases. It has been observed that the mechanism of surface diffusion with regard to enthalpy-entropy compensation and linear, free-energy relation are similar in both the system. Shaaban, H etl.al.[5] also confirmed that satisfactory performance could be achieved with EtOH. In terms of selectivity, EtOH is in the same group as MeOH. i.e., they have a similar proton acceptor, proton donor, and dipole moments. In addition, EtOH has a higher eluotropic strength, which means that a lower percentage of EtOH than MeOH is needed in the mobile phase for comparable retention times [3].

However, EtOH has two main limitations as a mobile phase in RP-HPLC. The UV cut-off of EtOH (210 nm) is higher than that of MeOH and ACN which can result in elevated background noise and an important drift of baseline when gradient elution is used. Being intrinsic property of EtOH, one has to use choose UV wavelength accordingly. The second limitation is from the viscosity of EtOH/water mixtures, which is higher than that of MeOH/water and ACN/water mixtures for equivalent eluotropic strength at room temperature. Such high viscosity may lead to high backpressures with conventional LC systems. Thanks to the development of UH PLC system, this challenge can be overcome. Another way to overcome the high pressure generated by ethanol-based mobile phases is the use of core shell columns. Thus ethanol is one of the preferred solvent in lieu of ACN and MeOH toward green LC analysis.

Other approaches are...

One can reduce organic solvent consumption by decreasing the column dimension (especially internal diameter, and length). Elevated temperature analysis also contributes for less use of these toxic solvents. Shorter alkyl chain stationary phases can reduce the retention as well as the application of more polar RP stationary phases (polar embedded) instead of long alkyl chains,

thus less use of organic mobile phase. Application of ultrahigh performance liquid chromatography (UHPLC) with reduced column diameter, reduced column length, reduced particle size, and the application of stationary phases allowing a high water content in the mobile phases are now the most popular alternatives to classical chromatography that allow to reduce the amount of generated harmful solvents waste in liquid chromatography analyses. Conventional RP LC separation can be made attractive eco-separation technique using typical chemically bonded stationary phases hat prefers more water or using novel mixed-mode stationary phases that can operate at highly aqueous mobile phases. We shall discuss some of the properties of these mixed model novel stationary phases.

Evaluation of Stationary phases [2]

Szymon Bocian et.al.,[2] have indentified novel hybrid stationary phases to operate with purely aqueous mobile phases at normal temperature without any additives to the mobile phase. In their studies, further characteristic of the selected materials were performed. The four stationary phases they have evaluated are N,O-dialkylphosphoramidate stationary phase and three ester-bonded phases applied for successful purely aqueous separation of nucleosides, nucleic bases and purine alkaloids. The structure of the stationary phases is shown in Fig.1.

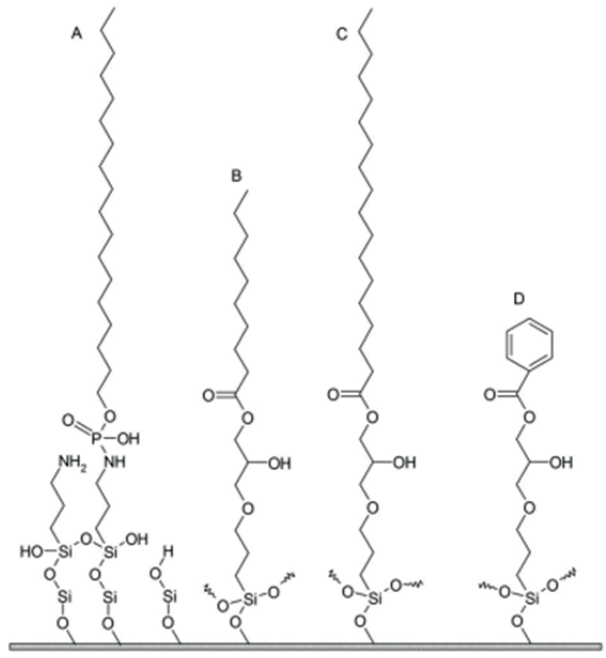


Fig.1 Structure of stationary phases [2] A – Amino-P-C18, B – Diol-Ester C10, C – Diol-Ester C18, and D – Diol-Ester Phenyl.

They have used both Shimadzu Prominence system as well as Nexera for the analysis as described below in the experimental section.

Experimental

Equipment Experiments were carried out on a Shimadzu Prominence system (Tokyo, Japan), which includes a quaternary-solvent delivery system (LC-20AD), an autosampler (SIL-20A), a column thermostat (CTO-10 AS VP), a spectrophotometric diode-array UV-Vis detector (SPDM20A), a refractive index detector (RID-20A), and a data acquisition station, as well as on Shimadzu Nexera system (Tokyo, Japan), which includes a binary solvent delivery system (LC-30AD), an autosampler (SIL-30AC), a column thermostat (CTO-30AC), a spectrophotometric diode-array UV-Vis detector (SPD-M20A), and data acquisition station. The data was collected in LabSolutions software.

Results and discussion

As discussed by Szymon Bocian et.al.,[2], the stationary phases have various functional groups, polar and hydrophobic ones. Such composition offers specific surface properties. First of all, such structures allow their solvation in a wide range of mobile phase composition, in both water-rich and organic-rich mobile phases. The hydroxyl, phosphate and ester groups can create hydrogen bond that makes these materials stable in purely water mobile phase. This is the first requirement that has to be fulfilled to apply a stationary phase for separation in purely water conditions. The second requirement is that a given material has to adsorb separated compounds and that adsorption has to be selective. The last requirement that has to be fulfilled is that the water has to be able to elute the adsorbed substances from the chromatographic column. The solvation process study demonstrates these criteria that adsorption of water is significantly higher than adsorption of acetonitrile on all the stationary phases. This indicates good wettability of the stationary phase surface in the water despite of the hydrophobic ligands present in the surface. These results confirm that the tested materials may be used in purely aqueous mobile phases. Additionally, higher adsorption of water results in its higher elution strength that allows to elute the solute from the column. As shown in Fig.2 and Fig.3 , one can achieve good separation when water alone is used as mobile phase. Thus proper choice of appropriate hybrid stationary phase helps towards moving to "green" HPLC.

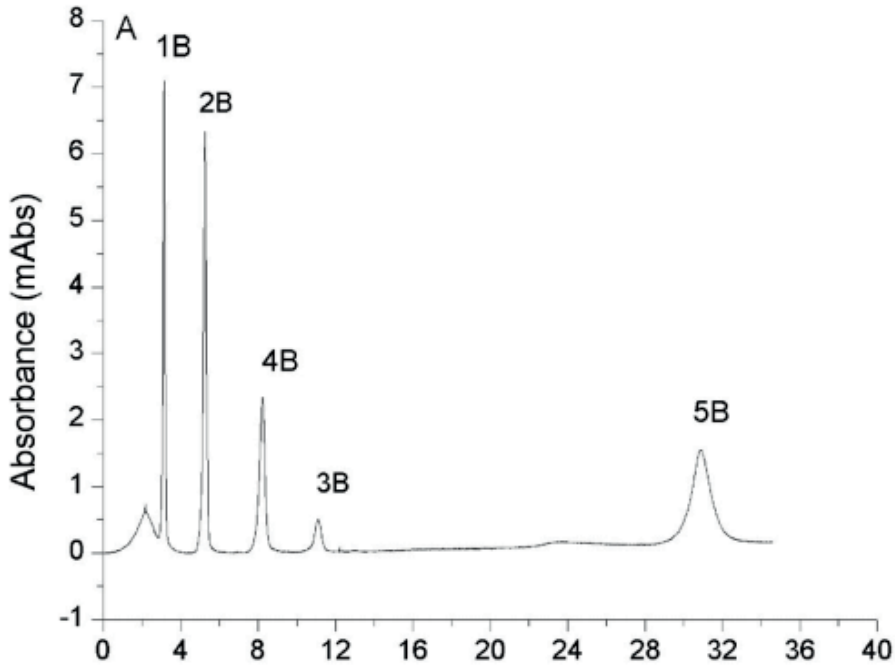


Fig.2 Nucleic bases separation on a chromatographic column A – Amino-P-C18; Phenyl, compounds: 1B – Uracil, 2B-Thymine, 3B-Guanine, 4B-Cytosine, 5B-Adenine using pure water as mobile phase [2]

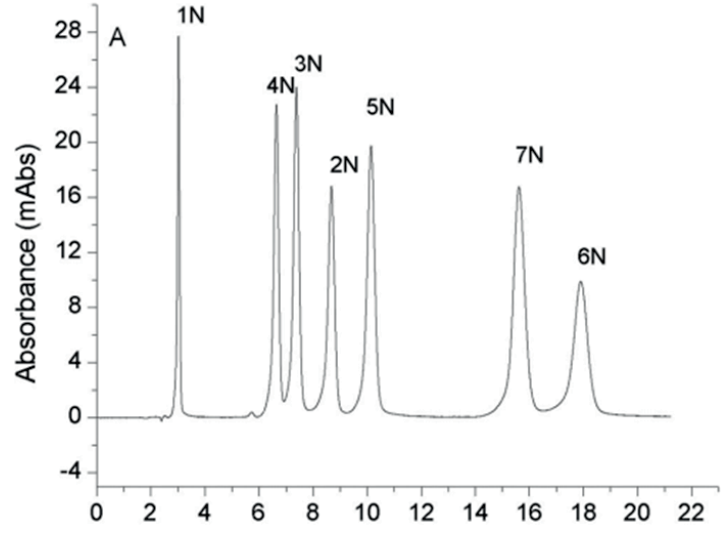


Fig.3 Nucleosides separation on a chromatographic column: A – Amino-P-C18, compounds: 1N-Uridine, 2N-Guanosine, 3N-1-methylinosine, 4N-Thymidine, 5N-1-methylguanosine, 6N – N2- methyloguanosine, 7N-Adenosine using pure water as mobile phase [2]

High Temperature HPLC[7,8]

Temperature plays an important role in the selectivity of HPLC separations. As an example, size exclusion chromatography of polymers with a low solubility such as waxes requires high temperature analysis ranging between 140 and 150 ◦C in halogenated aromatic solvents. One of the reasons that temperature is not used frequently in HPLC separations is due to the lack of stationary phases that are stable at high temperatures. The use of pure high-temperature water (HTW) as a mobile phase at temperatures above 100 ◦C brings a new dimension to chromatographic separations. The solvation properties of pressurized hot water changes compared to ambient liquid water. Hydrogen bonding by water becomes weaker as the temperature rises. Therefore, the hydrogen bond network at high temperature exists in the form of small clusters of hydrogen-bonded water molecules which changes the dielectric constant and hence polarity. At high temperature water behaves more like polar organic solvents. A more detailed theory of high temperature chromatography is discussed in detail by Clayton V. McNeff, et.al. [9]. A typical chromatogram of aromatic alcohols separated at high temperature is shown in Fig. 4.

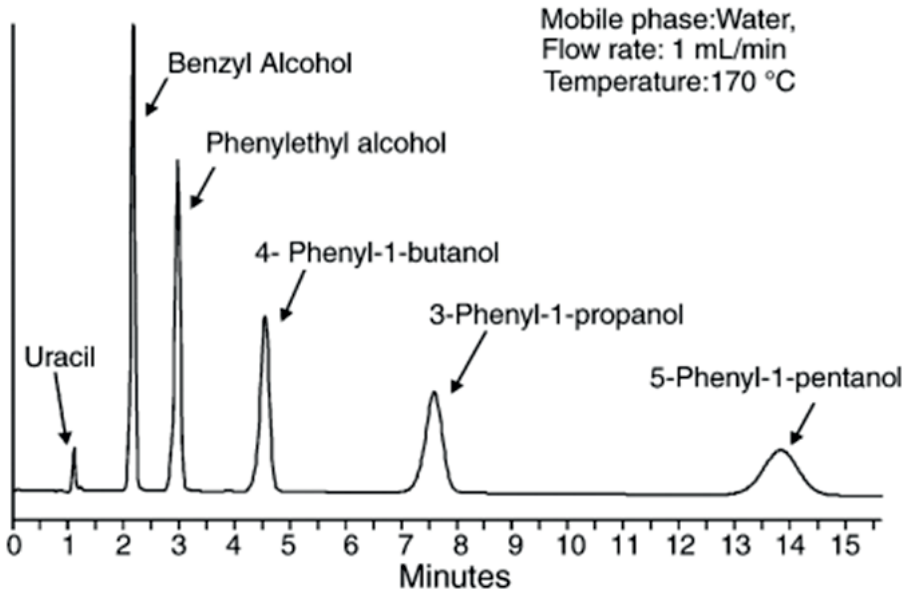


Fig. 4 Chromatogram of aromatic alcohols (mobile phase: water; temperature: 170 ◦C; flow rate: 1 mL/min)

Conclusion

In summary, this review gives a bird's eye view of how green HPLC is possible through the choice of solvents such as ethanol, use of hybrid stationary phases and careful choice of high temperature LC technique.

References

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EVENTS

59th National Pharmacy Week Celebration

i) Indian Pharmacy Graduates Association, Tamilnadu Branch

The 59th National pharmacy week celebrations was celebrated on 21st November 2020 at 5pm through Zoom meet. The theme of the year **"Pharmacist - Frontline Health care Professionals".** Shri. R. Narayanaswamy President of the Association welcomed the gathering. He emphasized the need of amendment in the recruitment rules of pharmacist in the Tamil Nadu Govt. Hospital by inclusion of pharmacy graduates . At present the recruitment rules have the qualification of only Diploma in pharmacy. He told that many state government in our country already changed the recruitment rule by inclusion of degree in pharmacy in addition to diploma in pharmacy. The quality of the medicines need to be stored properly and dispensed in right manner with counseling of the patient by employing degree holders in pharmacy. He also stress the need of amendment in the drugs and cosmetics act by repealing S.No. 23 of schedule K in order to maintain the quality of the medicine distributed to the patients / public. He welcomed Dr. Manjiri. S. Gharat Principal of K.M. Kundani College of Pharmacy, Mumbai.

Mr. M. Rajarathnam, Secretary of the association narrated about the activities of IPGA TN branch for the last one year. The major activity is giving GPAT coaching for pharmacy graduates at free of cost by online . He also enlighten the proposal of health insurance scheme to all the members of the association.

Prof. K. Elangoand and Mr. R. Vijayaraj, organized and conducted elocution competition on the theme of this year about 24 students from various colleges of pharmacy participated in the competition. The following are the winners of the competition.

PG CATEGORY

Price	Name	Institution / College
1ST PRIZE (Rs.10,000/-)	Renny Rozario Pharm D VI-year	College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore
2nd PRIZE (Rs.5,000/-)	Deepika G. Pharm D IV year	C.L. Baid Metha College of Pharmacy, Chennai
3rd PRIZE (Rs.3,000/-)	Gopikanath Pharm D III year	Vels Institute of Science, Technology and Advanced Studies, Chennai

UG CATEGORY

Price	Name	Institution / College
1ST PRIZE (Rs.10,000/-)	B. A. Tanisha, B. Pharm III year	College of Pharmacy, Dr. M.G.R. Educational and Research Institute, Chennai
2nd PRIZE (Rs.5,000/-)	A. Sonupriya, B. Pharm II year	United College of Pharmacy, Coimbatore
3rd PRIZE (Rs.3,000/-)	P. Vanitha, B. Pharm II year	College of Pharmacy, Madurai Medical College, Madurai

The amount of prizes involved for PG category and UG category donated by President and Secretary of the association.

The key note address on the theme was delivered by Mrs. Manjiri S. Gharat Principal of Kundani Colllege of Pharmacy , Mumbai.

The meeting ended with the vote of thanks by the vice president of the association Mr. M.D. Varadharajan.

ii) Faculty of Pharmacy, Dr. M.G.R. Educational and Research Institute, Chennai

Faculty of Pharmacy, Dr. M.G.R. Educational and Research Institute, in association with Indian Pharmaceutical Association (IPA) was organized 59th National Pharmacy week celebration 2020 program on 21/11/2020 with the theme **Pharmacist: Frontline Health Professionals** to focus, acknowledge and thank all the pharmacists and pharmacy sectors who are working tirelessly during the time of great uncertainty and challenges in addition to the regular responsibilities and also to honor the role of pharmacist, pharmacy profession and to spread the awareness amongst public.

The program was hosted through zoom meet on 21st November 2020 from 2:00PM to 4:00 PM for which about 500 participants had registered. The program was also live streamed via our YouTube Channel. Around 260 participants attended the program. The program commenced with Welcome address by Dr. N. Harikrishnan and the introductory address was rendered by Prof. Dr. S. Geethalakshmi, Vice Chancellor, Dr. M.G.R Educational and Research Institute.

Prof. Dr. K.Chinnaswamy, graced the occasion with his greetings and blessings. The Inaugural Speech was delivered by Dr. S. Manivannan, Deputy Drugs Controller, CDSCO, New Delhi, President, TN-IPA. Feliciation address was rendered by Prof. Dr. B. Jaykar, Registrar, VMRF, Salem, E.C. Member, PCI, New Delhi, Secretary, IACP, Shri. J. Jayaseelan, Chairman - IPA Industry division, President - Tamilnadu Pharmacy council, Chairman – IDMA and Shri. T. Sathish, Vice President – Regulatory & Corporate Support, Tablets India Limited, Hony. Secretary - IPA Tamilnadu, Hony. Secretary - IPA Industrial Division, Vice Chairman – IDMA, who all commended the role of pharmacists in the health care systems. The keynote address on the theme- 'Pharmacists- Frontline Health Professionals' was delivered by Dr. S. Sriram, Professor and Head, Department of Pharmacy Practice, Sri Ramakrishna Institute of Paramedical Sciences.

iii) PSG College of Pharmacy, Coimbatore

The 59th National Pharmacy Week was celebrated on 27th November 2020 at 3.00pm, in PSG College of Pharmacy through Zoom meet. The theme for this year is **"Pharmacists - Frontline Healthcare Professionals".** The Program started with 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 on the importance of clinical pharmacist in healthcare team and also stressed upon the need for Poison information centre. The Guest of Honor, Dr. Aashiq Ahamed, Pharm D (PB), Clinical Pharmacist, Department of Cardiology, PSG College of Pharmacy Super Specialty Hospitals gave a detailed talk on the role of Clinical Pharmacist in various areas of health care. Nearly 160 students and faculties participated and were benefited in the event. The one hour session successfully ended with Vote of Thanks and National Anthem.

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 24th November, 2020

S.O. 4206(E).—Whereas, there has been an outbreak of COVID-19 pandemic in India and worldwide;

Whereas, the Central Government is satisfied that making available suitable COVID-19 vaccines is essential to meet the requirements of emergency arising due to the pandemic COVID-19 and, therefore, in public interest, it is necessary and expedient to regulate the testing of COVID-19 vaccine for prevention and management of COVID-19 infection;

Whereas, the Central Government, in consultation with the Drugs Controller (India), is of the considered view that the supply of COVID-19 vaccine must not get affected and the vaccine must remain available to the public;

Now, therefore, in exercise of the powers conferred by sections 6 and 26B read with section 33P of the Drugs and Cosmetics Act, 1940 (23 of 1940) and rule 3 of the Drugs and Cosmetics Rules, 1945, the Central Government, hereby directs that the National Institute of Biologicals, Noida, in addition to its existing functions shall perform the function of Central Drugs Laboratory as an additional facility in respect of COVID-19 vaccine and the functions of the Director in respect of COVID-19 vaccine shall be exercised by the Director of the said Institute.

2. In case of any inconsistency between this notification and any rule made under the said Act, the provisions of this notification shall prevail over such rule in public interest so as to meet the requirements of emergency which have arisen due to COVID-19 pandemic.

3. This order shall come into force on the date of its publication in the Official Gazette.

4. The notification shall remain into force for a period upto 30th November, 2021.

[F. No. 18-35/2020-DC/DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 26th November, 2020

S.O. 4244(E).—Whereas, an outbreak of COVID -19 pandemic is prevailing throughout India and worldwide;

And whereas, several import licences in Form-10 are in existence and their validity periods of three years are likely to expire shortly;

And whereas, pharmaceutical companies and their associations have requested for extension of the validity of import licence (Form-10) for six months in the wake of COVID-19 pandemic;

And whereas, the Central Government is of the considered view that supply of drugs may not get affected and the drugs must remain available to the public;

Now, therefore, in exercise of the powers conferred by section 26B of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, hereby directs that notwithstanding anything contained in rule 28 of the Drugs and Cosmetics Rules, 1945, for import of drugs for sale or distribution, if an existing valid import licence holder under the said rules, makes an application for a fresh import licence before the expiry of the existing licence, the existing import licence shall be valid until orders are passed on the application and shall be deemed to be valid for all purposes.

2. This order shall come into force on the date of its publication in the Official Gazette and shall remain valid for a period of six months.

[F.No. X.11014/01/2020-DR]
DR. MANDEEP K BHANDARI, Jt. Secy.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 15th December, 2020

G.S.R. 763(E).—Whereas a draft of the Cosmetics Rules, 2018, was published, with a view to codify separately and to update the rules relating to cosmetics, by the Central Government in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 1153(E), dated the 29thNovember, 2018, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on 30th November, 2018;

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

Now, therefore, in exercise of the powers conferred under section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules, namely:

CHAPTER I
PRELIMINARY

1. **Short title.** (1) These rules may be called the Cosmetics Rules, 2020.

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

2. **Application.**- These rules shall be applicable to the cosmetic as defined in clause (aaa) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940).

3. **Definitions**.- In these rules, unless the context otherwise requires,-

(a) —Actǁ means the Drugs and Cosmetics Act, 1940 (23 of 1940);

(b) —Actual manufacturerǁ in relation to import of cosmetics, means a person who manufactures cosmetics at his own manufacturing site in a country other than India approved by National Regulatory Authority or any authorised competent authority in that country for that purpose, by whatever name called.

Explanation.– for the purpose of this clause, person includes a company or a unit or a body corporate or any other establishment.

(c) —Appendix‖ means the appendix appended to these rules;

(d) —Authorised agent‖ means a person in India authorised by the manufacturer. The authorised agent shall be responsible for the business activities of the manufacturer in India including compliance to the provisions of the Act and rules made thereunder.

Explanation.– For the purpose of this clause, person includes a company or a unit or a body corporate or any other establishment.

(e) —Bureau of Indian Standards‖ means the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 2016 (11 of 2016).

(f) —Central Licensing Authority‖ means the Drugs Controller General of India, appointed by the Central Government.

(g) —Change in the constitution of a licensee‖ means in relation to,-

(i) a firm, a change from proprietorship to partnership including Limited Liability Partnership or vice versa;

(ii) a company,–

(A) its conversion from a private to a public company, or from a public to a private company; or

(B) any change in the ownership of shares of more than fifty per cent. of the voting capital in the body corporate or in case of a body corporate not having a share capital, any change in its membership; and where the managing agent, being a body corporate is a subsidiary of another body corporate, includes a change in the constitution of that other body corporate within the meaning of this clause;

(h) —Director‖ means the Director of the Central Cosmetics Laboratory appointed by the Central Government under sub-rule 3 of rule 11;

(i) —Form‖ means a Form set out in Appendix to these rules;

(j) —Government Analyst‖ means, a Government Analyst appointed by the Central Government or the State Government under section 20 of the Act;

(k) —Import registration certificate‖ means a certificate issued under rule 13 by the Central Licensing Authority for registration of cosmetics manufactured for import into and use in India.

(l) —Inspector‖ means and includes an Inspector appointed by the Central Government or a State Government respectively under section 21 of the Act;

(m) —Laboratory‖ means the Central Cosmetics Laboratory established or notified for carrying out analysis or test of cosmetics by the Central Government under rule 11;

(n) —Legal manufacturer or brand owner‖ in relation to import of cosmetics, means a person, who authorise the other manufacturer from India or overseas countries for the manufacture of cosmetics, by way of an authorization referred under rule 12.

Explanation.– For the purpose of this clause, person includes a company or a unit or a body corporate or any other establishment.

(o) —Licence‖ means a licence granted by the State Licensing Authority under rule 25;

(p) —Loan licence‖ means a licence granted by the State Licensing Authority under rule 25, for manufacturing a cosmetic, to a person who intends to utilize the manufacturing site of another licensee for manufacturing the cosmetic manufactured by the licensee at that site;

(q) —Manufacturer‖ in relation to import of cosmetics means the actual manufacturer or the legal manufacturer.

(r) —New cosmetic‖ means a cosmetic which contains a novel ingredient which has not been used anywhere in the world or is not recognised for use in cosmetics in any National or International literature.

(s) —Schedule‖ means a Schedule appended to these rules;

(t) State Government in relation to a Union Territory means the Administrator thereof;

For full view of Notification, please click the below link

https://cdsco.gov.in/opencms/opencms/en/Notifications/Gazette-Notifications/

G.S.R 763(E) dated 15.12.2020_Cosmetics Rules 2020

File No: COS/MISC/12/18

Government of India
Central Drugs Standard Control Organization (HQ)
Directorate General of Health Services
Ministry of Health and Family Welfare
(Cosmetic Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated:- 19/1/2021

Notice

Subject: - Frequently Asked Questions (FAQ)/Guidance Document for grant/retention of registration certificate/license for import or manufacture of cosmetics in India under the Cosmetics Rules, 2020-reg

The Cosmetics Rules, 2020 have been published vide GSR No. 763(E) dated 15.12.2020 with effect from 15.12.2020. Therefore, in order to streamline the process of import registration of cosmetics and for ease of doing business, Frequently Asked Questions (FAQ) & Guidance Document have been prepared in light of the Cosmetics Rules, 2020 and uploaded on CDSCO website.

The approvals/licences/permissions/certificate, issued under the provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 in respect of cosmetics prior to commencement of these rules, shall be deemed to be valid for all purposes till its expiry or for a period of eighteen months from the date of notification of these rules, whichever is later, under the corresponding provisions of the said Rules.

This is for your information please.

V.G.S.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

All stakeholders/Zonal/Sub Zonal/Port Offices

F.No. 29/Misc/03/2020-DC (297)
Central Drugs Standard Control Organisation
Government of India
Ministry of Health and Family Welfare

****

FDA Bhawan, New Delhi
Dated the 28th December, 2020

ORDER

Subject: Regulation of Blood Glucose Monitors, Blood Pressure Monitors, Nebulizers, and Thermometers as Drugs with effect from January 1st, 2021.

Ministry of Health & Family welfare, Government of India has notified the following devices as per S.O. 4671(E) dated December 27, 2019 which will be effective from 01.01.2021.

1. Nebulizer
2. Blood Pressure Monitoring Devices
3. Digital Thermometer; and
4. Glucometer

2. Accordingly, as per the said order the importers/manufacturers are required to take import/manufacturing licence from Central Licencing Authority or State Licencing Authority, as the case may be, for import/manufacture of above devices, w.e.f. 01.01.2021.

3. In the meantime, a representation has been received, requesting to extend implementation of the notification for another 3 to 6 months because a lot of procedural work is to be done such as resolution of queries, audit of facilities by the regulators and notified bodies, as the case may be, testing of products at the requisite testing labs etc.

4. In this regard, it may be pertinent to mention that Rule 97 of Medical Device Rules (MDR) 2017 provides details about applicability of the said rules in respect of various actions/ operations undertaken under Drugs & Cosmetics Rules for the substances and devices referred to in rule 2 of the MDR, 2017 prior to commencement of MDR 2017.

5. In view of the above, it has been decided that in case an existing importer/manufacturer who is already importing /manufacturing any of these devices, has submitted application to Central Licencing Authority or State Licencing Authority, as the case may be, for grant of import /manufacturing licence in respect of the said device(s) under the provisions of MDR, 2017, the said application shall be deemed valid and the importer/manufacturer can continue to import /manufacture the said device(s) up to 6 months from issue of this order or till the time, the Central Licencing Authority or State Licencing Authority, as the case may be, takes a decision on the said application, whichever is earlier.

V.G.Somani

(Dr. V. G. Somani)
Drugs Controller General (I)

To,
All Stakeholders

Copy to:
1. All State Drugs Controllers
2. All Zonal Sub-Zonal & Port Offices of CDSCO

Tamilnadu Pharmaceutical Sciences Welfare Trust – Governing Body Members

The Governing Body meeting of Tamilnadu Pharmaceutical Sciences Welfare Trust, held on 11th January 2021, it was discussed about the appointment of Chairman, Vice Chairman, and Hon. Gen. Secretary. On the request of Chairman, Prof. K. Chinnaswamy suggested the present office bearers may continue for one more term. However, Mr. N. Sreenivasen, informed, because of his age and restriction due to pandemic, he is unable to continue as secretary. He said that his support will always be there for the trust, and suggested, better to appoint younger person as Secretary.

Based on the discussion and suggestion by Prof. K. Chinnaswamy, Mr. J. Jayaseelan, has been appointed as Hon. Gen. Secretary of Trust, and Mr. Rajesh H Bhadari as Joint Secretary. The current Council and Governing body members are as follows.

Governing Council Members

Mr. S.V. Veerramani - Chairman

Mr. A. Krishna Dev – Vice Chairman

Mr. J. Jayaseelan – Hon. Gen. Secretary

Mr. R. Thiruvengadam – Treasurer

Mr. R. Narayanaswamy – Joint Secretary

Mr. Rajesh H. Bhandari – Joint Secretary

Mr. M. M. Yousuf – Joint Treasurer

Governing Body Members

Mr. N. Sreenivasen - Ex officio Secretary

Dr. K. Chinnaswamy

Mr. K. Prafulla Chandra

Mr. R. Sabapathy

Dr. V. Ravichandran

Mr. S.S. Vanangamudi

Mr. M. Kannan

Mr. T. Ravichandran

Mr. T. Sathish

Dr. R. Ilavarasan

Mr. G. Anandaselvam

We like to inform the readers that Mr. N. Sreenivasen, held the post of Hon. Gen. Secretary for the last 20 years (2001 to 2020). He has successfully administered the trust function during his tenure. Many activities such as starting of library, scheme of awarding scholarships, training scheme for pharmacy students, proper administration of accounts etc. are done by him. We congratulate him for the successful tenure as Hon. Gen. secretary.

We also congratulate the new incumbent Mr. J. Jayaseelan is a Pharmacy graduate from Madras Medical College. He is a successful young entrepreneur in pharmaceutical industry by establishing various companies such as Saimirra Innopharam Pvt. Ltd, Nuray Chemicals Pvt. Ltd, Delvin Formulations Pvt. Ltd. and Dr.Kalam College of Pharmacy, Tanjore etc. . He is well known in various Pharmaceutical association by holding various important and key posts. He is also Chairman of IDMA Tamilnadu, Puducherry and Kerala State Branch. He is a very active and social person in our field. He is also President of Pharmacy Council of Tamil Nadu. We hope under his secretaryship our trust activities will improve and activate the pharmacy profession.

by
R.NARAYANASWAMY
Chief Editor, Pharma Web News Letter

NEWS

Pharma Mkt Posts 10% Growth in Oct

Building on gains made in September, the domestic pharmaceutical retail market marched ahead with a near 10% growth in October. This was led by a higher number of prescriptions, OPD (outpatient department) visits, and an increased sales and marketing push by pharma companies after 'unlocking' in most parts of the country.

The robust October growth was double that of September, which had seen a 4.5% jump. The market grew 9.6% year-on-year (YoY) during October, led by a volume growth of 0.9% YoY (September was -4%), price growth of 5% (4.6%) and increase in product launches at 3.7% (3.8%). On a moving average total (MAT) basis for the past 12 months, the growth was 3.9% for October. The revival was on the back of therapies, including cardiac and anti-diabetic, which grew by 19.5% and 9.7% respectively in October (over September), according to data from research firm AIOCD Awacs. Respiratory medicines showed marginal improvement at -6.6% in October as against -10.5 % in September.

The market, valued at nearly Rs 1.5 lakh crore, has been sluggish since March, when the lockdown was announced. The sector, however, did not face restrictions since it's categorised as an essential service. In fact in April and May, the market had dropped into the negative territory due to the absence of prescriptions and lower OPD visits.

Revenue in acute therapies grew 6% YoY, while that in chronic and sub-chronic therapies rose 13% YoY each in October. On a MAT basis, revenue in acute therapies grew 1%, while chronic and sub-chronic therapies 9% and 3% YoY, respectively, according to India Ratings and Research.

Anti-infective sales showed a positive trend, growing by 6.6% in October as against 1.4% in September, while associated therapy like gastro reported a growth of 13.6% (5.5% in September), and vitamins at 22.6% (16.3%). Pain and analgesics grew at 2.8% during the month from -4.3 % in September.

On an annual basis, acute therapies such as vitamins and gastro witnessed a healthy revenue growth of 22.6% and 13.6% respectively during October. Chronic therapies continued their strong growth outperformance with cardiac, anti-diabetic and central nervous system (CNS) reporting YoY 19.5%, 9.7% and 9.6% respectively.

Within vitamins, high growth was reported in anti-oxidant products (48% YoY, 15% of segment sales) and protein supplements (30% YoY, 7% of segment sales). In the cardiac segment, heparin product sales showed a huge growth (128% YoY, 4% of segment sales), according to the analysis.

Source: *The Times of India*, 16th November 2020

Court rejects AstraZeneca's Plea on Diabetes Drug Patent

The Delhi high court has rejected global pharma major AstraZeneca's application seeking a restraining order against marketing of a blockbuster anti-diabetes drug Dapagliflozin by domestic companies, including Torrent, USV, Micro Labs, Eris Life Sciences and Zydus, thus paving the way for affordable diabetes drugs in the Indian market. With nearly a dozen companies launching generic versions at competitive prices, the stage is set for a price war between the players to get a slice of the growing Rs 15,000-crore diabetes market. AstraZeneca had sued several generic companies for the infringement of patents covering Dapagliflozin. In a keenly watched court battle, the high court in a hearing, concluded that its patent is "prima facie invalid as it lacks inventive merit", legal sources told TOI. AstraZeneca holds two patents for Dapagliflozin in India — the first expired in October, while the second will expire in May 2023. Simply put, the second patent was not found to have inventive merit over what was already existing in prior art (earlier patent

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In a keenly watched court battle, the high court in a hearing, concluded that its patent is "prima facie invalid as it lacks inventive merit", legal sources told TOI. AstraZeneca holds two patents for Dapagliflozin in India — the first expired in October, while the second will expire in May 2023. Simply put, the second patent was not found to have inventive merit over what was already existing in prior art (earlier patent).

The order by Justice Mukta Gupta, accessed by TOI, said "since the defendants have prima facie laid a credible challenge to the validity of suit patent on the ground of obviousness and for non-compliance of section 8(2) of the Act, this court finds that the plaintiffs have not made out a prima facie case for grant of interim injunction which is declined".

AstraZeneca's Dapagliflozin is sold under the brand Forxiga, and is part of a popular class of drugs called SGLT2 inhibitors, valued around Rs 4,500 crore (MAT October 2020), approved for use in type 2 diabetes. It is also distributed by Sun Pharma and Abbott Healthcare under the brands Oxra, Oxramet, Oxramet XR and Gledepa, Gledepa MET IR and Gledepa MET XR respectively. Recently, certain generic versions have entered the market, nearly halving the therapy cost for patients.

"The court also found that failure to share vital information under section 8 (2), with the Indian Patent office was a breach enough to deny an interim order to the patent holder", S Majumdar, counsel on behalf of Torrent, said. The company has faced patentability

objections in the US, which it failed to disclose here.

When contacted, an AstraZeneca spokesperson said, “The order contains several positive findings in its favour, especially on those issues which formed the main thrust of the attack. AstraZeneca has been informed that findings mainly on two issues have been rendered against it. We are currently studying the order of the high court, and are committed to taking all steps which are necessary in law in order to protect and enforce its patent for Dapagliflozin, which it believes to be a world-class invention.”

Majumdar added, “For a suit patent to be revoked under section 64(1)(a) no prior publication is required. However, if there is a prior patent for the same invention, no second patent can be granted. Even the definition of invention under section 2(1)(j), the Act provides that invention means a new product or process involving an inventive step and capable of industrial application.”

Source: *The Times of India, 1*9th November 2020

E-Pharmacies V. Retail Pharmacies: The Honest Truth

More than half of India's population doesn't have access to health care. Situation is more acute in small towns and villages where physicians don't want to practice, and subsequently, there are no pharmacies. In our discussions with MOH, it clearly emerges that use of digital platforms is essential for India's unique problems.

E-Pharmacies are emerging as an important part of the solution for the Indian situation. E-pharmacies offer several advantages to Indian citizens, which are even more desired during situation due to Covid-19 related issues.

Apart from providing access to even the remotest part of the country and making medicines affordable, E-pharmacies also ensure complete authenticity of medicines with full 'track and trace' capability, ensuring integrity of medicines right from manufacturers up to patients' homes.

All over the world, wherever e-pharmacies operate, they co-exist peacefully with retail pharmacies. While e-pharmacies are viable due to their focus on chronic therapies, retail pharmacies are necessary for immediate requirement of acute medicines such as pain killers and antibiotics.

However, there is an unnecessary and vicious campaign that has been launched in India by the retail pharmacies' association viz. AIOCD due to reasons beyond comprehension.

The retail pharmacy sector in India is a broken, porous system that suffers from systemic failure. AIOCD, instead of working with the Govt and public to improve the system, is focused on a fruitless attack on e-pharmacies.

The ills that prevail the Indian retail pharmacy systems are too numerous to count.

Lack of trained pharmacists: It has been documented as well observed by the courts that in several states, such as UP, number of pharmacies far exceeds the number of registered pharmacists in the state. As reported by Outlook India, the Allahabad High court's Lucknow bench in 2017 said

"A large number of either fictitious and unqualified persons or one person using his registration certificate in several shops, are looking after such shops but the state government has not taken any effective preventive steps," in response to PIL filed in the honourable court.

AIOCD, instead of trying to correct the situation, has been trying to put the blame on regulators and trying to lobby that pharmacist should not be mandatory at retail pharmacies. This is dangerous for the patients and is a precedent not seen anywhere else in the world. In 2013, as reported by Pharmabiz, they even went on a nationwide strike and wanted the government to permit the partner or the proprietor of a drug store as a qualified person to dispense the medicines taking into account the shortage of qualified pharmacists. 'Renting' a pharmacist license, without having an actual pharmacist actually dispensing has become the standard and acceptable practice in retail pharmacies. Progressive trade associations like AIOCD should pro-actively address such pertinent sector issues as it compromises the safety of the patient.

Technology driven learning solutions can be deployed to meet the specific and lifelong learning needs of individual pharmacists, ultimately improving patient and public health outcomes.

E-Pharmacies, on the other hand, are meticulous in employing pharmacists for validating the prescriptions and dispensing medicines in tamper proof containers as per Pharmacy Act 2015.

Sale without prescription: It is a known fact, and has been observed by judiciary and bureaucrats too, that one just need to call a retail pharmacy, or send a driver, and medicines are delivered at home. No prescription required. The Hon'ble Delhi High Court in 2019 had directed the Centre and State Government to act against those pharmacies selling prescription medicine without prescription.

E-pharmacies, on the other hand, systematically record each prescription digitally, and have offered to the Govt to be audited by any competent regulatory agency.

Storage and Logistics: Given that India is the most fragmented and scattered pharmaceutical market in the world, making fresh medicines available that retain their full potency, is also a challenge. We all know that India falls under WHO zone 4 for storage and stability of medicines. Medicines in India must be stored below 30*C and 70% relative humidity, to retain full potency over the entire shelf life. This would require constant air-conditioning of products. Unfortunately, majority of retail pharmacies are not air-conditioned, putting stability of medicines at risk. E-pharmacies are perhaps the only ones that follow WHO 'model guidance for storage and transport' of medicines and ensure that patients get the medicines with intact integrity at their homes.

Track and trace: We all know that pharmaceutical distribution system in India is totally porous. Places like Bhagirath Place in Delhi, Agra ki Mandi and Bagri Market in Kolkata are periodically raided unearthing trading of counterfeit or stolen medicines as well as trading of samples. Before GST, when sales tax rates were different across states, there are examples of traders from Agra and Gwalior coming to Delhi to buy insulin, when sales tax on insulin in Delhi was 0, and was in double digits in UP and MP. These unscrupulous traders would carry refrigerated products like insulin in gunny sacks, and retailers in UP and MP would buy these without bills, just to make few extra bucks.

We all experience that even today, majority of retailers do not provide invoice bearing correct batch numbers and expiry dates. The amount is written on the back of the envelope and payment is made. Law requires not only details of batch and expiry to be mentioned on the invoice, each invoice must be signed by a Pharmacist. Not really possible when Pharmacists are not even present at the Pharmacy.

Counterfeiting and substandard medicines have been an industry problem with estimated percentage of 'Not of Standard quality' medicine in the retail channel accounting for approx. 3% of the total, as per the National Drug Survey 2014-2016.

After the survey it was recommended to "Facilitate regulation for transparent and secure drug distribution system which results in product traceability and reconciliation throughout the supply chain in case of quality issue or nation-wide recall."

It also said "Retailers and distributors should modernize and digitize the mechanism of procurement and inventory control of all their operations and ensure presence of qualified pharmacists to dispense Drugs as required by law."

On the other hand, e-pharmacies scrupulously record batch and expiry of each unit as it proceeds in the logistics chain, protecting the customer.

Anti-Competitive Behavior of AIOCD: In case no 30 of 2011, Competition Commission of India clearly labeled AIOCD as 'anti-competitive' and charged AIOCD with grossly using its dominant position and fined it heavily.

The Competition Commission of India (CCI), in its 2018 report pointed out that certain activities carried by trade associations mute the competition and result in higher prices of medicines for Indian citizens. It mentioned that "Self-regulation by trade associations also contributes towards high margins as these trade associations controls the entire drug distribution system in a manner that mutes competition." Further it said, "The entire supply chain of drugs is self-regulated by the trade associations who regulate entry by mandating a NOC prior to the appointment of stockists, control distribution by restricting/controlling the number of stockists and influence price by deciding the wholesale and retail margins of drugs." The issue of anti-competitive behaviour by certain pharmacy trade association has been raised and discussed multiple times at the CCI.

It is important to highlight that since 2015, multiple writ petitions in several courts of the country have been filed against e-pharmacies by various groups to curb competition. Most of them have been disposed of. AIOCD and its proxies have abused the process of law and have spread misinformation.

Hon'ble Madras High Court in its 2018 order has clearly stated “that the petitioner, by instituting vexatious and obstructive action in the Court of law, is not only guilty of abuse of multiplicity of proceedings, but also guilty of suppression very and suggestion falsi.”

While the Media headline was sensationalist, and quoted the Delhi High Court order 2018 as blanket ban on the sale of drugs online across India; the fact is that the order specifically mentions that it is for online sales of medicines without license. In e-Pharmacy model, all sales happen through licensed premises under supervision of registered pharmacist. However, if any person/entity found violating any rule, drug regulator can prosecute under Section 27(b) (ii) of the drug and cosmetic Act.

Pharmacies and pharmacists do a noble job of providing medicine and health care services to population at large. The adoption of innovative technology models will make the entire process more robust, reliable, transparent, and efficient. The debate should not be about e-Pharmacies vs brick-and-mortar pharmacies, rather between complaint vs non-compliant, irrespective of the channel. The debate should be about how best these model work together to fulfill the health care requirement of 130 crore Indian citizens and create a future ready resilient health care system.

Source: *ET Healthworld,* 1st December 2020

UK Drugs Regulator Defends Fast Pace of the Pfizer-Biontech Vaccine Approval

Britain's medicines regulator insisted Friday its world-first approval of the Pfizer-BioNTech coronavirus vaccine met all safety standards, after officials in Europe and the United States queried the rapid process.

The Medicines and Healthcare products Regulatory Agency (MHRA) on Wednesday announced emergency approval for the vaccine's general use against Covid-19, and the government plans to start rolling it out next week.

Any vaccine "must undergo robust clinical trials in line with international standards", the MHRA said in a statement.

"No vaccine would be authorised for supply in the UK unless the expected standards of safety, quality and efficacy are met.”

Leading US infectious disease scientist Anthony Fauci on Thursday said the MHRA had "rushed through that approval", but later apologised.

"I have a great deal of confidence in what the UK does both scientifically and from a regulator standpoint," Fauci, who leads the US National Institute of Allergy and Infectious Diseases, told the BBC.

"Our process is one that takes more time than it takes in the UK. And that's just the reality," he said. "I did not mean to imply any sloppiness even though it came out that way."

MHRA chief executive June Raine previously insisted that "no corners had been cut" in vetting the Pfizer-BioNTech vaccine.

With Britain transitioning out of the European Union, the UK regulator obtained an exemption from the EU's medicines agency, which has stressed it prefers to wait for further review and consultations across the 27-nation bloc.

Britain plans to distribute an initial batch of 800,000 doses starting next week, prioritising care homes.

The MHRA said it was able to move quickly after launching a rolling review of data provided by Pfizer NSE -0.38 % and BioNTech as human trials proceeded, rather than waiting for all the data to be compiled at the end of the trials.

"Covid-19 vaccines, including this one, are being developed in a coordinated way that allows some stages of this process to happen in parallel to condense the time needed, but it does not mean steps and the expected standards of safety, quality and effectiveness have been bypassed," it said.

Approval is expected this month by both the US Food and Drug Administration and the European Medicines Agency.

England's deputy chief medical officer Jonathan Van-Tam has also hit back at critics, suggesting sour grapes on the part of regulators who are bound by more bureaucracy.

"If you're a regulator who's slightly further behind, what do you say to justify your position that you are further behind? Words such as the ones we've heard perhaps," he told the BBC.

Some British ministers have strayed into anti-EU jingoism after London beat Brussels to approving the Pfizer-BioNTech jab. Education Secretary Gavin Williamson said the UK was first because it was "a better country".

But Van-Tam also stressed the cross-border nature of scientific collaboration. Another government scientific adviser, Peter Openshaw of London's Imperial College, decried the "unfortunate international competition being set up".

"This is really us against the virus, it's not us against the Americans, us against the Europeans," the professor in respiratory and immunology medicine said on BBC television.

Openshaw also defended the MHRA's green light for the vaccine: "It's quite clear this has been very, very carefully scrutinised and I have no concerns about it."

Source: *The Economics Times,* 4th December 2020

Multivitamin Tops Drug Sales for First Time in October

Call it the Covid effect. Popular health supplement Zincovit, which provides essential vitamins and minerals, catapulted to the top spot in the domestic pharma retail market for the first time ever in October by becoming the largest-selling brand. Interestingly, this would also be the first instance of a multivitamin supplement overtaking sales of drugs for lifestyle ailments such as diabetes, including Human Mixtard (Novo Nordisk), Glycomet-GP (USV) and Lantus (Sanofi), which dominate the retail market.

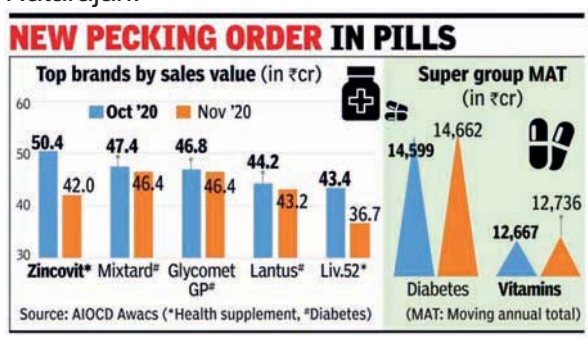
A 30-year-old brand manufactured by the little known Apex Labs, Zincovit registered sales of Rs 50 crore during October, dethroning the largest selling brand Human Mixtard (insulin) with sales of around Rs 47 crore. A multivitamin supplement topping retail sales assumes significance as it comes alongside an increase in month-on-month sales of Human Mixtard (see graphic), prompted by a strong need to prop one's immunity amid a raging pandemic, industry experts say.

Overall, the market posted a robust 10% growth in October, led by a higher number of prescriptions for anti-diabetics and cardiac drugs, coupled with a strong jump in vitamins and minerals. Zincovit — with sales averaging under Rs 20 crore — touched Rs 50 crore in October, witnessing a huge 60% jump during the six-month period of April-October, according to data culled from pharma research firm AIOCD Awacs.

Sales went up sharply over the last six months from April onwards when it was ranked 30th, then it hit the 11th position in June with sales of nearly Rs 30 crore, and was ranked second in September. In November, it dropped to the fourth position. That compares with the 53rd rank it had in January in the organised pharma retail market.

"We believed in the concept of immunity about 30 years ago and have been building the brand over the years. The category witnessed an unprecedented jump and, for us, has doubled over the 12-month ended November to Rs 340 crore. Zinc, a vital supplement, is also part of therapy for Covid-19 patients," the Chennai-based manufacturer's head (marketing) Venkatesh Mallo told TOI.

Overall, the vitamins and minerals segment — with sales of around Rs 12,700 crore (for the 12-month period ended October) — jumped nearly 23% last month, as against 16% in September. Immunity boosters continued their upward trend in purchases across India. Vitamin C and zinc -containing brands were the most in demand. These include Zincovit (Apex Labs), Bevon (Zuventus), Limcee (Abbott), Celin (Koye) and Citravite XT (Pharmed), according to research firm Pronto Consult's founder and MD Hari Natarajan.



A substantial growth was also witnessed in sales of other multivitamins which contain zinc, sold by Zuventus (Emcure) and Alkem.

Source: *The Times of India*, 17th December 2020

Medicine Dealer in Chennai Fined Rs 1.6 Lakh

The metropolitan magistrate, Egmore has imposed a fine of 1.6lakh on the proprietors of a wholesale medicine dealer for supplying stock to an unregistered pharmacy in the city. Officials of the drug control department had inspected a pharmacy in George town area and found that the proprietor was running it in a portion of his residence.

According to the prosecution, officials of the department conducted an inspection at the pharmacy in Georgetown in August 2018 following a tip. The drug inspector found the pharmacy was being run from the residence of the proprietor, who Muthukumar without any valid license as required under the Drug control act had purchased, stocked and sold medicines.

On enquiry, the Drug Inspector found an expired wholesale drug license in favour of the firm's name, the prosecution submitted. During enquiry, the officials found the stocks were supplied by Puducherry-based Medinok Healthcare Pvt Ltd and a memo was issued to the firm in October 2018, seeking response for supplying medicines to an unlicensed pharmacy. The proprietor of Medinok healthcare in a reply, admitted he had not collected the license copy from the pharmacy, the prosecution submitted.

The drug control official questioned Medinok healthcare for manufacturing and selling drugs of non standard quality and found that the firm is not permitted to manufacture the concerned drug under the license issued to them. The prosecution held that Medinok healthcare has contravened the provisions of Drug Control act and filed a case against them. The case against the pharmacy was split up and is under trial before another court. Perusing the submitted documents, X Metropolitan Magistrate, K S Arun Sabhapathy held that a hefty fine amount should be levied on them. The court imposed a fine of 1.6 lakh on the firm.

Source: *The Economics Times,* 10th December 2020

Hyderabad-Based Divi's Labs Second Pharma Company with Rs 1 Lakh Crore Market Capitalization

City-based Divi's Laboratories on Thursday became the second pharma player in the country, after Sun Pharma, to enter the elite league of companies with market capitalization of Rs 1 lakh crore or more. Led by Reliance Industries, there are just 31 companies, out of a total of about 5,000 companies in India, which can boast of this milestone.

With its entry into the big league, Divi's Labs also left behind the traditional big daddies of Dalal Street like Bajaj Auto (Rs 94,639 crore), Tata Steel (Rs 72,810 crore), Mahindra & Mahindra (Rs 90759 crore) and many more. In its sector, Dr Reddy's Laboratories is at Rs 84,384 crore, while Cipla is at Rs 63,161 crore, BSE data showed.

Pharma player beats biggies like Bajaj Auto, Tata Steel & M&M

"Divi's has set a blistering pace on the bourses in the past decade: From about Rs 8,000 crore in December 2010, the company's market value at Thursday's close was Rs 1.02 lakh crore, a jump of over 12 times. During this

period. The stock closed the day's session on BSE at Rs 3,825, more than double from its March low of Rs 1,633.

According to analysts, the key ingredient of the company's success is its positioning as the one of the key global suppliers of APIs like Naproxen (non-steroidal anti-inflammatory drug), Detromethorphan (cough suppressant) and Gabapentin (anti-convulsant), a position it attained by edging out some global pharma giants, and sharp focus on CRAMS.

The stock attracts savvy investors because of its robust and steady business model that is perceived as relatively less risky from the regulatory point of view, analysts pointed out. “It has a combination of good market share in select molecules globally and has a relatively robust business model with steady and sustainable earnings, unlike other Indian pharma companies that play in the generic formulations space and operate on the litigation led business model,” said Tushar Manudhane, lead analyst-pharma, Motilal Oswal Financial Services.

More than 650 foreign together hold 18.3% in the company while domestic mutual funds, including SBI Mutual Fund, Axis Mutual Fund and Reliance Mutual Funds, hold 14.8% while LIC holds 1.1% stake. The promoters of the company led by its founder Murali Krishna Divi hold 52% stake.

According to Surya Patra, VP-research, PhillipCapital India, the primary factor for the huge jump in market cap is the robust export opportunity that has been provided by Covid-19. “People were concerned about dependence on China due to which supplies of critical APIs were disrupted but companies like Divi's, with its positioning as a fully integrated manufacturer of APIs and custom synthesis, has delivered robust growth beyond investor expectations and has emerged as one of the most predictable firms from the investor point of view,” Patra explained.

Divi's Laboratories was set up in October 1990 by Murali Krishna Divi after he quit Dr Reddy's Laboratories, which he joined in 1984 as director and where he helped turn around ailing Cheminor Drugs that was acquired by Dr Reddy's.

Source: *ET Healthworld,* 18th December 2020

Indian Pharma Firms at High Ransomware Attack Risk in 2021

Targeted ransomware attacks on the healthcare and pharma sector will surge in India in 2021 as companies finalise their vaccines to fight Covid-19, a new report said.

Healthcare and pharma sector companies that have been in the front lines working to fight against the pandemic in the country are facing a new wave of ransomware attacks and extortion demands lately.

According to the 'threat prediction 2021' report by Seqrite, an enterprise security solutions brand by Quick Heal Technologies, although few ransomware operators agreed not to attack the healthcare sector during the Covid-19 crisis, several other attack groups have continued to use ransomware against this sector, largely because of the sensitive and personal data of patients they store.

Numerous hospitals, Covid-19 research firms, and pharma companies have fallen victim to ransomware in the last quarter of 2020, "making it necessary for them to adopt or deploy a comprehensive set of security solutions," the findings showed, without sharing the names of the victims.

"The pandemic acted as a huge opportunity for cybercriminals to innovate their attack strategies further, and steal sensitive data for their personal gain," said Himanshu Dubey, Director, Quick Heal Security Labs.

These advancements are likely to continue in the coming year as well.

"For instance, new tactics like double extortion, crypto-mining, ethical hacking, etc. are expected to be widely adopted by threat actors in 2021," he added.

There has been a massive surge in cyberattacks against the Indian vaccine makers and hospitals in the month of October and December.

According to the latest research by New Delhi-based think tank CyberPeace Foundation, nearly 80 lakh attacks were recorded between October 1 and November 25 on the healthcare sector-based 'Threat Intelligence Sensors' network specifically simulated in India.

According to the Seqrite report, the use of ethical hacking among unethical hackers will increase to inject malware into the systems in 2021.

"Threat actors will also use deep-fakes, automated phishing, red team tools, and crypto-mining to steal sensitive data," the report mentioned.

Strengthening cybersecurity hence became the need of the hour for most businesses as they gear up for 2021, the report said.

Source: *ET Healthworld,* 23rd December 2020

Pharma Exports Achieve 15% Growth, will Hit $25 bn Mark

Standing apart from all other sectors during Covid-19, pharma exports in India witnessed 15.3% so far in the financial year 2020-21 so far. According to the Pharmaceuticals Export Council of India (Pharmexcil), pharma exports are expected to touch $25 billion mark. Pharma exports recorded growth of 11.5% in November.

Pharmexcil Director General R Uday Bhaskar told TOI that more than 70% of exports are generic formulations.

R Uday Bhaskar said, “Pharma exports are doing well this financial year till November, and the same trend will continue. It is expected to do well in the next few months till March. For November, the quick estimate is around $1,989 million. The growth in November is 11.5%. So far this year, exports are around $15,868 million with a growth of 15.37%. By the end of the financial year, it will touch $25 billion.”

Pharma exports in financial year 2019-20 were $20.5 billion. Uday Bhaskar said, “More than 70%-75% of our exports are generic formulations other than APIs and vaccines. if we touch $25 billion in FY '21, we may touch $28 billion by Fy22.”

Regarding vaccines, he said, “We are capable of producing high volume of vaccines. Almost all the Indian vaccine manufacturers are tied up with overseas manufacturers / institutions in the development of Covid-19 vaccines.”

Drug formulations and biologicals contribute 76% exports followed by 16% by bulk drugs and drug intermediates. Vaccines compromise 3% of exports.

Source: *ET Healthworld,* 28th December 2020

India's First Fully Indigenous Pneumococcal Vaccine Launched

Pune-based Serum Institute of India, the largest vaccine manufacturer in the world by doses, on Monday announced the launch of India's first indigenously developed pneumococcal vaccine -- Pneumosil -- in the presence of Union Health Minister Harsh Vardhan.

Pneumosil has been developed through collaboration spanning over a decade among the Serum Institute, PATH and the Bill and Melinda Gates Foundation. This significant milestone is aimed at improving pneumococcal conjugate vaccine affordability and enabling sustainable access for low-and middle-income countries.

The vaccine will provide effective and long-lasting protection for children against pneumococcal diseases. The vaccine makes the Serum Institute the world's third supplier of pneumococcal conjugate vaccines (PCV) under the pneumococcal Advance Market Commitment (AMC), and the first developing country vaccine manufacturer to access the global PCV market.

In his address on the occasion, Harsh Vardhan said: "It is a significant milestone for the country's public health care which will ensure that children are protected better against pneumococcal disease with an affordable and high-quality vaccine.”

About the launch of Pneumosil, Serum Institute's CEO Adar Poonawalla said: "Over the years, our constant endeavour has been to provide high quality vaccines with regular supplies which ensures excellent immunisation coverage to children and families worldwide. With that thought, we have developed this PCV with a unique composition based on the serotype prevalence in India.”

"This makes our PCV an ideal choice for protecting our children from pneumococcal disease. While the vaccine itself is of the highest quality and grade available, vaccine accessibility is of utmost importance as well, and to ensure ease of access by making it available at an affordable price. With the best PCV, we hope to bring down the mortality rate significantly while also making our country self-sufficient with a robust public health care system," he added.

Pneumococcal disease is a significant contributor to the under-five mortality rate worldwide. Annually, India witnesses an estimated 71 per cent of pneumonia deaths and 57 per cent of severe pneumonia cases.

Every year nearly 67,800 children under 5 years of age die India from pneumococcal diseases in 2018. Recognising its widespread fatality, WHO recommends the

inclusion of Pneumococcal Conjugate Vaccine (PCV) in routine childhood immunisation programs in all countries. Following this, Polysaccharide Conjugate Vaccines (PCV) work directly to reduce the incidence of pneumococcal pneumonia by preventing Streptococcus pneumonia.

Serum Institute is also the pharma company that is testing and producing the Oxford-AstraZeneca Covid-19 vaccine candidate in India. The vaccine is the frontrunner in the race to find the silver bullet.

Source: *ET Healthworld,* 28th December 2020

License Required to Import, Manufacture Medical Devices

Importers and manufacturers required to take licence from the Central Licensing Authority or State Licensing Authority for the import and manufacture of nebulizers, BP monitoring devices, digital thermometers, and glucometers with effect from January 1, said Central Drugs Standard Control Organisation.

"Representation has been received requesting to extend the implementation of the notification for another three to six months because a lot of procedural work is to be done such as the resolution of queries, an audit of facilities by the regulators, and notified bodies, as the case may be, testing of products at the requisite testing labs," reads an order.

In this regard, it may be pertinent to mention that Rule 97 of Medical Device Rules (MDR) 2017 provides details about applicability of the said rules in respect of various actions/operations undertaken under Drugs and Cosmetics Rules for the substances and devices referred to in rule 2 of the MDR, 2017 prior to commencement of MDR 2017.

Source: *ET Healthworld,* 29th December 2020

Covid: Sanitation staff, pharmacists may be on 1st vax list

Amid speculation whether sanitation workers and pharmacists will be considered for vaccination against Covid-19 in the initial phase, the government has started working to include them in the 'priority' population after PM Modi lauded theirs efforts as 'frontline' corona warriors during his speech on Thursday while laying the foundation for AIIMS, Rajkot.

The government aims to inoculate 30 crore people in the first phase of Covid-vaccination which includes around 3 crore healthcare and frontline workers. Apart from doctors, nurses, ANMs and ASHAs, the plan was to include some of the allied health professionals such as those working in diagnostic labs and pharmacists. Besides, sanitation workers, scavengers and ambulance operators are also being considered to get the vaccine in the first phase.

While some of the categories lacked clarity, the mention of sanitation workers and pharmacists by the PM has stressed upon the need to include these people in the list on priority, an official said

The list of 'priority' population also includes people above 50 years of age and those below 50 years but with serious comorbidities. The PM on Thursday also cautioned people against any rumours about vaccination.

"Different people for their vested interests or due to irresponsible behaviour spread various rumours. May be rumours will be spread when vaccination begins, some have already begun," he said, asking people to be careful about such rumours and as responsible citizens refrain from forwarding such messages on social media without checking.

Source: *The Times of India,* 2nd January 2021

IIT Delhi and All India Institute of Ayurveda to Jointly Study Ayurvedic Formulations

The Indian Institute of Technology (IIT) Delhi announced in a press release that it would work with the All India Institute of Ayurveda (AIIA), New Delhi to work on seven collaborative projects that focus on the uses and efficacy of Ayurvedic formulations and drugs.

The projects are a result of an MoU signed by both the parties last year to promote interdisciplinary research in Ayurveda and applying engineering science principles to it.

The projects include studying the effect of the six Ayurvedic rasas (tastes) on gastrointestinal secretions, developing herbal formulations that would reduce the harmful effects of reusing cooking oil, developing a biodegradable, herbal wound dressing, study the effects of the 'Brahmari pranayama' on the nervous system, analyzing the impacts of bhasmas (ashes) on proteins implicated in neurodegenerative diseases, developing 'dhoopan-yantra' - a fumigation device for aiding wound healing and early cancer detection and assessment of breast cancer response to Ayurvedic drugs.

The projects will be carried out for two years. V. Ramgopal Rao, Director, IIT Delhi, while speaking of the collaborative projects between IIT Delhi and AIIA, said, “The amalgamation of traditional knowledge with technology is expected to benefit the society at large by offering better health care options. Validation of the traditional knowledge systems is the key, in order to make these forms of medicine more widely acceptable worldwide. IIT Delhi researchers will be focussing on the validation aspects by working closely with the AIIA faculty.”

Tanuja Nesari, Director, AIIA, New Delhi, said, “Both the institutions aim to develop a deeper understanding of the fundamental principles of Ayurvedic diagnosis and treatment of diseases, to develop innovative diagnostic tools and equipment for various Ayurvedic procedures.”

Ayurveda is a branch of alternative medicine with roots in the Indian subcontinent. It focuses on holistic health, and makes use of several herbs and naturally occurring substances. Over the last few decades, there has been renewed interest in Ayurveda across the world.

Source: *ET Healthworld,* 5th January 2021

Imbalances in Gut Bacteria Can Increase the Severity of Covid, Hurt Immune System

Imbalances in the type and volume of bacteria found in the gut may be associated with the risk of 'long Covid', the symptoms of which last for weeks or months beyond the initial illness, according to an observational study. The research, published in the journal Gut, found that the variety of bacteria in the gut, known as the microbiome, may influence the severity of Covid-19 as well as the level of the immune system response to the infection.
The researchers from the Chinese University of Hong Kong also found that imbalances in the make-up of this microbiome may be implicated in persisting inflammatory symptoms, known as 'long Covid'.

They noted that Covid-19 is primarily a respiratory illness, but the evidence suggests that the gut may also play a role.

"In light of reports that a subset of recovered patients with Covid-19 experience persistent symptoms such as fatigue, breathlessness and joint pains, some over 80 days after onset of symptoms, we posit that the dysbiotic gut microbiome could contribute to immune-related health problems post-Covid-19," the researchers said.

"Bolstering of beneficial gut species depleted in Covid-19 could serve as a novel avenue to mitigate severe disease, underscoring the importance of managing patients' gut microbiota during and after Covid-19," they noted.

The researchers noted that the gut is the largest immunological organ in the body and its resident microbes are known to influence immune responses.

The team, therefore, wanted to find out if the bacteria might also affect the immune system response to Covid-19 infection.

They obtained blood and stool samples and medical records from 100 hospital inpatients with laboratory-confirmed Covid-19 infection between February and May 2020, and from 78 people without Covid-19 who were taking part in a microbiome study before the pandemic.

The severity of Covid-19 was classified as mild in the absence of x-ray evidence of pneumonia and moderate if pneumonia with fever and respiratory tract symptoms were detected.

The disease was considered severe if patients found it difficult to breathe normally, and critical if they needed mechanical ventilation or experienced organ failure requiring intensive care.

To characterise the gut microbiome, 41 of the Covid patients provided multiple stool samples while in hospital, 27 of whom provided serial stool samples up to 30 days after clearance of SARS-CoV-2, the virus responsible for Covid-19.

Analysis of all 274 stool samples showed that the make-up of the gut microbiome differed significantly between patients with and without Covid-19, irrespective of whether they had been treated with drugs, including antibiotics.

The researchers found that Covid patients had higher numbers of Ruminococcus gnavus, Ruminococcus torques and Bacteroides dorei species than people without the infection.

They also had far less microbiome species that can influence immune system response, such as Bifidobacterium adolescentis, Faecalibacterium prausnitzii and Eubacterium rectale.

Fewer numbers of F. prausnitzii and Bifidobacterium bifidum were particularly linked with infection severity after taking into account the antibiotic use and patient age, according to the researchers.

The numbers of these bacteria remained low in the samples collected up to 30 days after infected patients had cleared the virus from their bodies, they said.

Covid-19 infection prompts the immune system to produce inflammatory cytokines in response.

In some cases, this response can be excessive and lead to a 'cytokine storm' which causes widespread tissue damage, and multiorgan failure.

Analysis of the blood samples showed that the microbial imbalance found in the Covid patients was also associated with increased levels of inflammatory cytokines and blood markers of tissue damage.

This suggests that the gut microbiome might influence the immune system response to Covid-19 infection and potentially affect disease severity and outcome, the researchers said.

The team noted that the study is observational, and as such, cannot establish cause, adding the gut microbiome varies widely among different populations.

Therefore, the changes observed in the research may not be applicable to other Covid patients elsewhere, they said.

Source: *ET Healthworld,* 12th January 2021

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