



ISSUE No. 47



e-NewsLetter

Pharma Web

Newsletter of
Tamilnadu Pharmaceutical
Sciences Welfare Trust

Jul. - Aug. - Sep. 2020



Destiny for Innovation

Moving Globally

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- R & D and Manufacturing of Formulations
- International Marketing
- Domestic Marketing
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**Tamilnadu Pharmaceutical
Sciences Welfare Trust**

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 47

Jul. - Aug. - Sep. 2020

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST

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EDITORIAL

Dear Readers,

We are happy to publish the 47th issue of Pharma Web Newsletter for Jul – Sep 2020.

We are publishing this issue also e-newsletter, and this issue is delayed, due to non-availability of suitable articles and other information. We are sending this issue to all our Pharma professionals through email and What's app. This news letter will also be available in our website.

This 47th issue contains the following article, which was written by our Trustee, Dr. G. Selvaraj

- Transforming Global Health, by **Dr.G.Selvaraj**. B.Pharm.,M.B.A., B.L.,D.Tax.Law.,M.L., Ph.D. Director of Drugs Control (Retd), Tamilnadu.

The above lecture was delivered as presentation during world Pharmacist Day celebration on 25th sep organised by IPGA, Tamilnadu Branch.

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

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ARTICLES

TRANSFORMING GLOBAL HEALTH

by

Dr.G.Selvaraj. B.Pharm.,M.B.A., B.L.,D.Tax.Law., M.L., Ph.D.

Director of Drugs Control (Retd), Tamil Nadu

Lecture Delivered during Pharmacist Day Celebration by Indian Pharmacy Graduates' Association, Tamilnadu Branch
(Thematic Speech) held on 25th September 2020



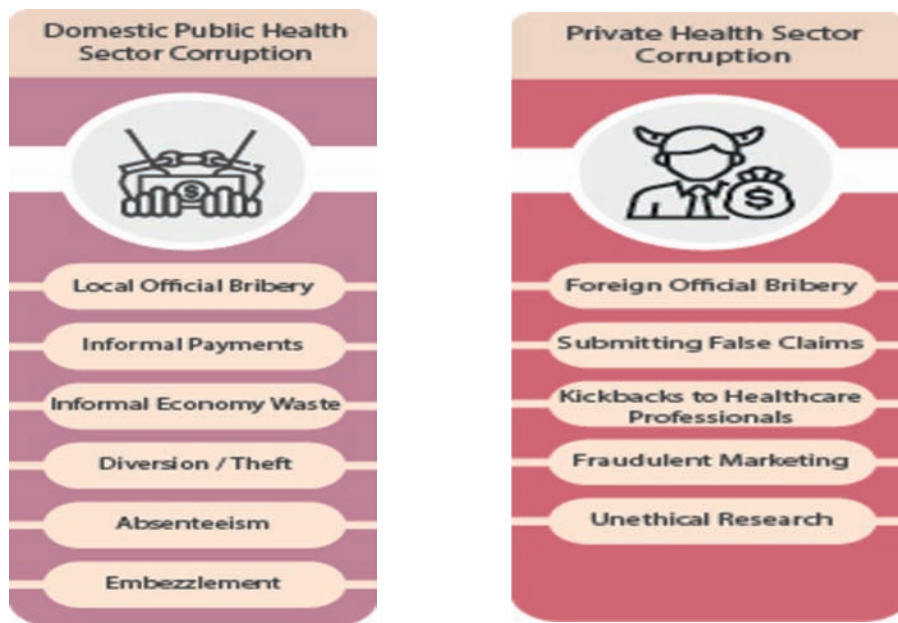
- Medical science has made progress by leaps and bounds
- However, the way we provide healthcare to people across the world needs massive improvement



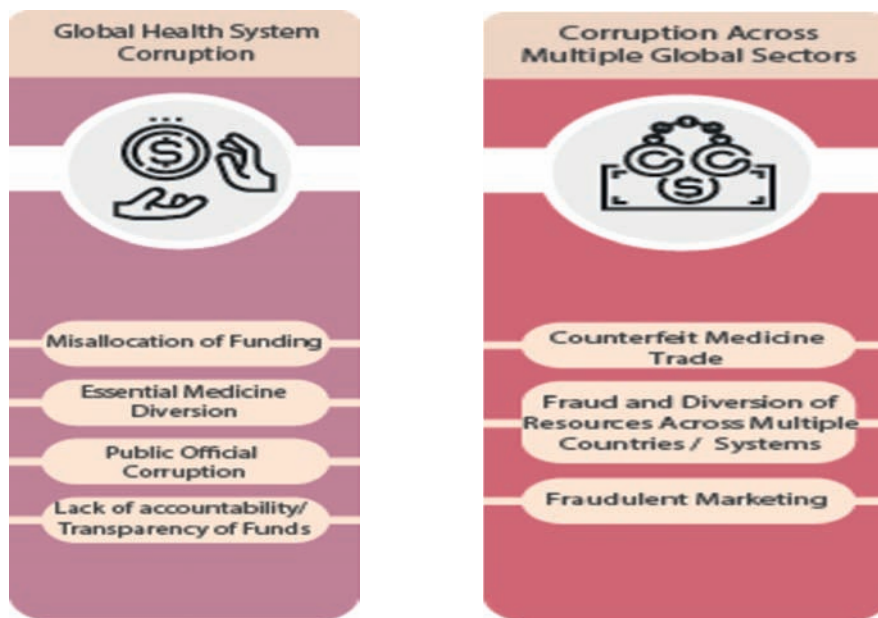
LACKINGS IN HEALTHCARE

- Deficiency of healthcare infrastructure , a lack of physicians & healthcare professionals across world
- At least half of the world's population cannot obtain essential health services (lack access to safe, affordable surgical and anaesthesia care)
- Global spending on health is expected to increase from US\$7.83 trillion in 2013 to \$18.28 trillion in 2040
- Many low-income & lower-middle-income countries will not meet internationally set health spending targets, while developed nations continue to spend too much
- For almost 50 years, spending has grown by 2 % in excess of GDP growth

VARIOUS LEVELS OF CORRUPTIONS IN HEALTHCARE SYSTEM



VARIOUS LEVELS OF CORRUPTIONS IN HEALTHCARE SYSTEM



PHARMA PROFESSIONALS

- Pharmacists - third largest healthcare professional group in the world
- Majority of pharmacists practice in Community Pharmacies, Hospitals & other medical facilities.
- Smaller numbers of pharmacists are employed in the Pharmaceutical Industry.



PHARMACIST PER 10:1000 POPULATION (WHO GUIDELINES)

India	
2018	8.87
2017	6.79
2016	5.6
2013	5.19
2012	4.98
2011	5.26
2010	5.32
2009	5.39
2006	4.96
2004	1.15
2003	5.03
1991	1.99

ROLE OF PHARMACIST IN HEALTH CARE TEAM

- WHO States to have less than 10 pharmaceutical personnel per 10000 population.
- Pharmacists have an important role to play in health care more than just selling medicines at pharmacies.
- Pharmacists play an integral part in the health care team

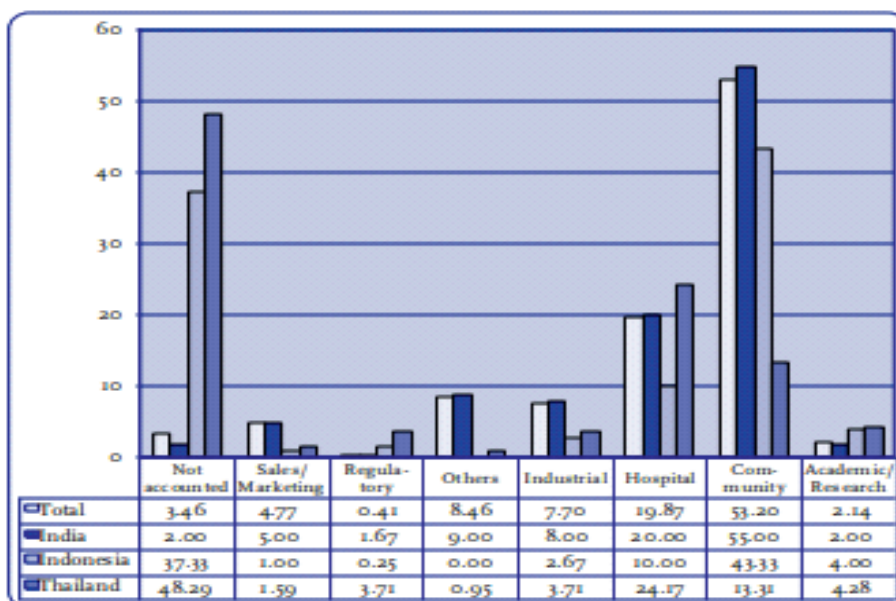
Various Role

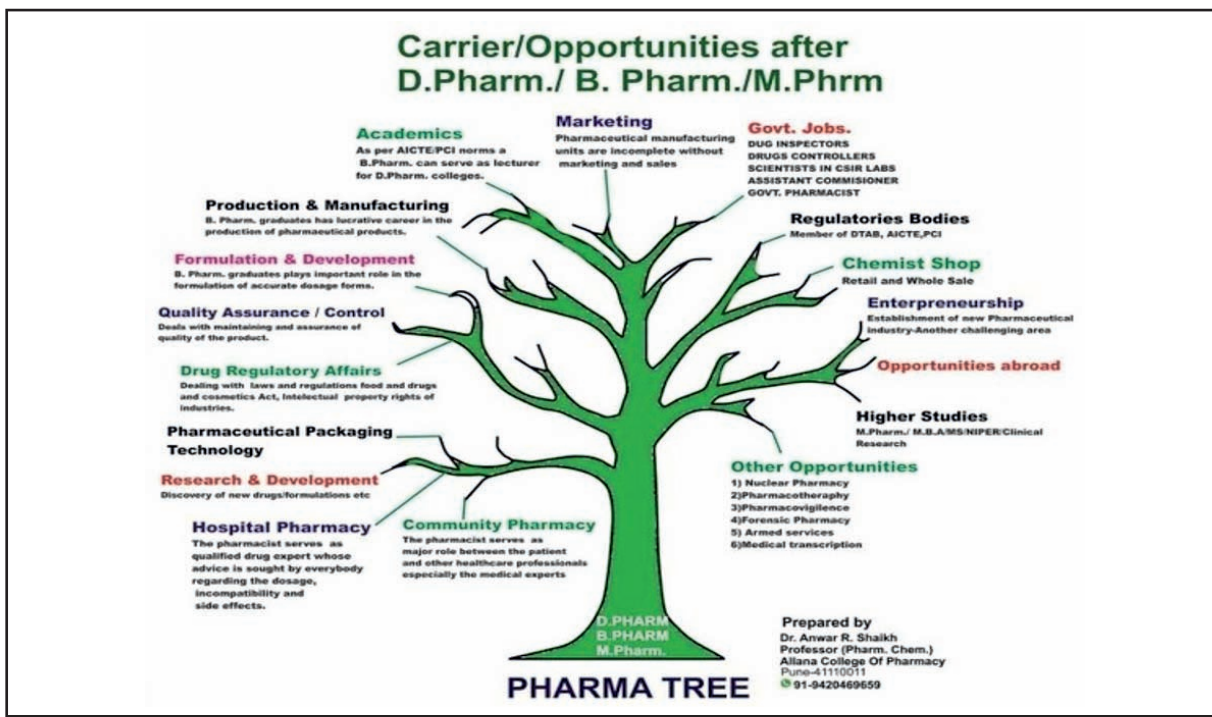
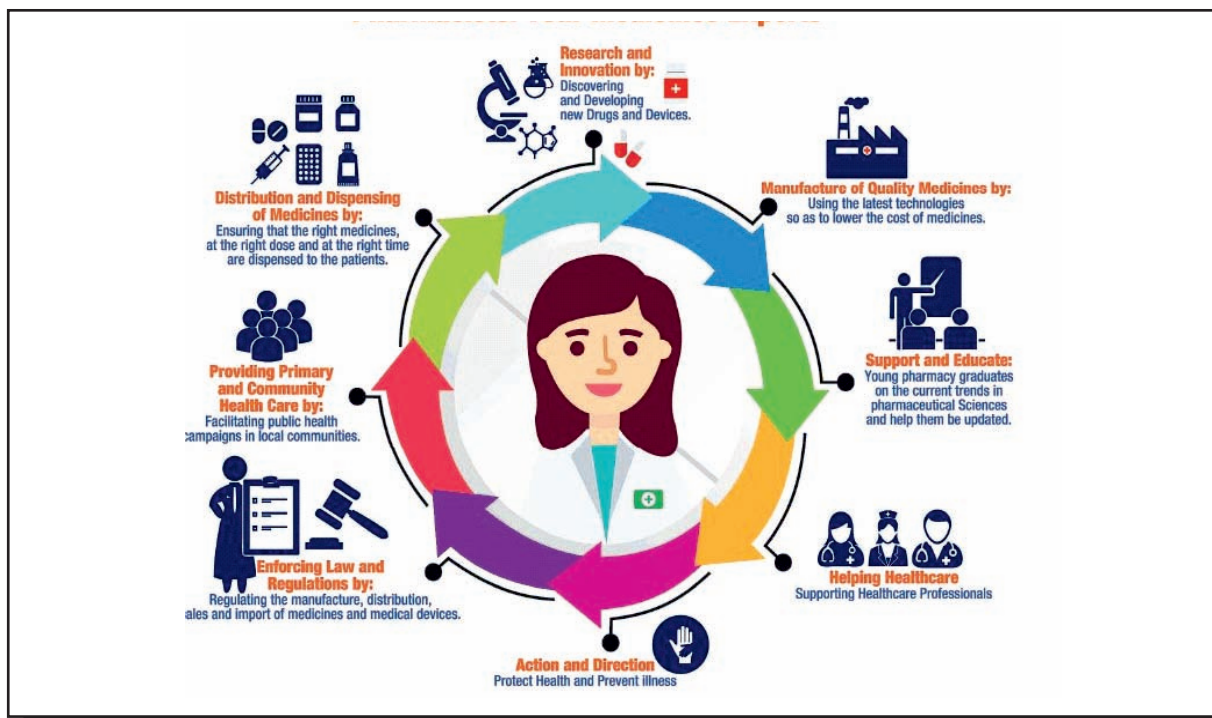
- Procurement & supply of medicines to pharmaceutical care services
- Helping to ensure the best treatment for patients
- Pharmaceutical care process involves establishing a relationship between the patient and the pharmacist
- Developing an evidence-based care plan for medicine therapy
- Follow-up on the patient's expected health outcome

DIMENSIONS OF A PHARMACIST

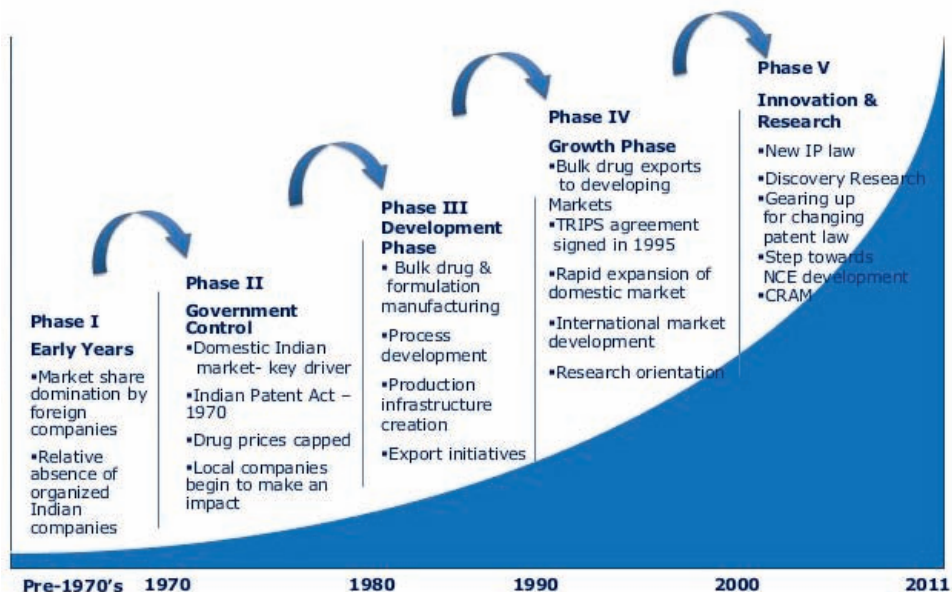


DISTRIBUTION OF PHARMACISTS IN SOUTH ASIA REGION





Indian Pharmaceutical Evolution

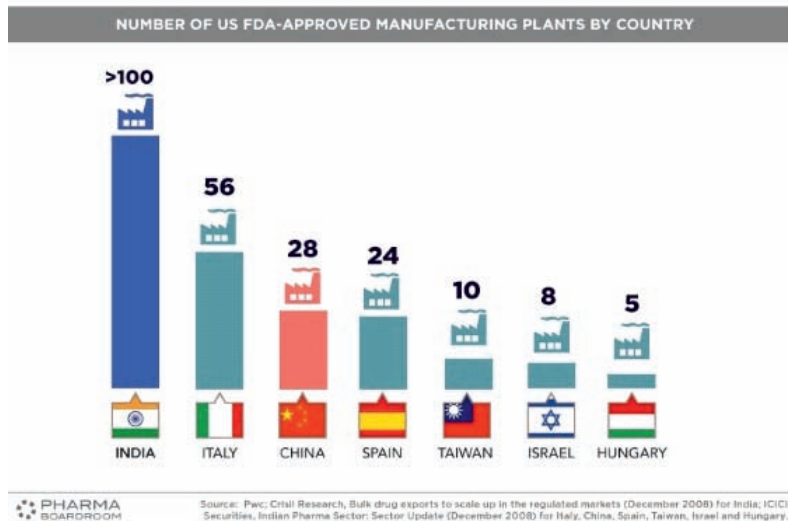


INDIAN PHARMACEUTICAL INDUSTRY IN GLOBAL

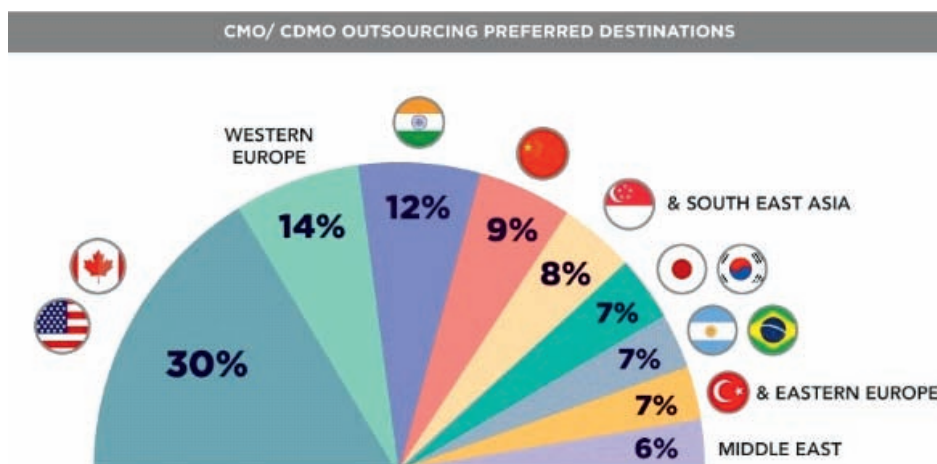
- India has established itself as a leading producer of low cost drugs, vaccines & diagnostics
- India played a crucial role in bringing a range of affordable medicines to developing countries.



- India already manufactures most of the drugs, vaccines, and diagnostic tests it uses and has established itself as an important supplier of affordable drugs and vaccines to other developing countries

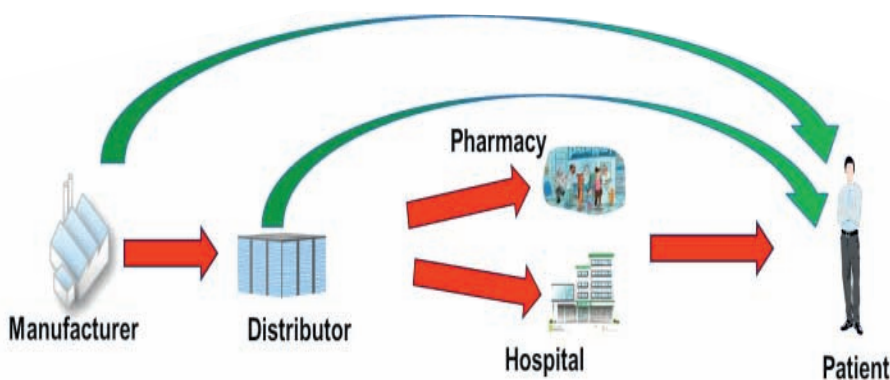


- Indian vaccine industry began as a network of state-owned manufacturers supplying basic childhood vaccines to the national immunization program.
- In recent decades, a number of privately owned firms have grown rapidly, developed the capacity to produce more sophisticated vaccines



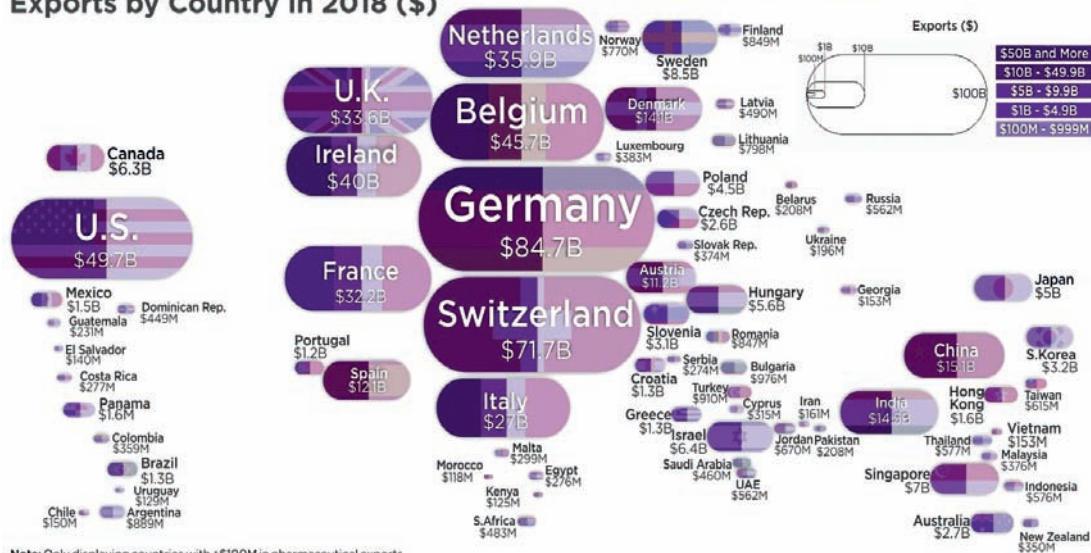
INDIAN PHARMACEUTICAL INDUSTRY IN GLOBAL

- Despite India's rapid economic growth & growing technological, it continues to suffer from widespread poverty & a heavy burden of infectious disease
- To reduce this burden, India have to strengthen its health system, especially for the poor, and increase access to existing medicines



Pharmaceutical Trade Around the World

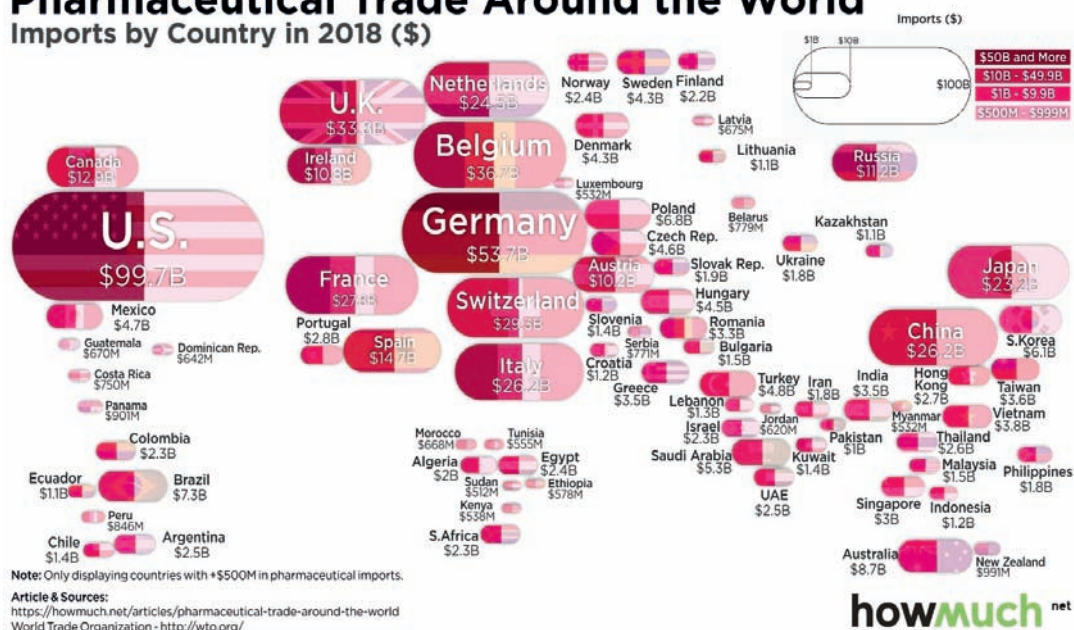
Exports by Country in 2018 (\$)



howmuch.net

Pharmaceutical Trade Around the World

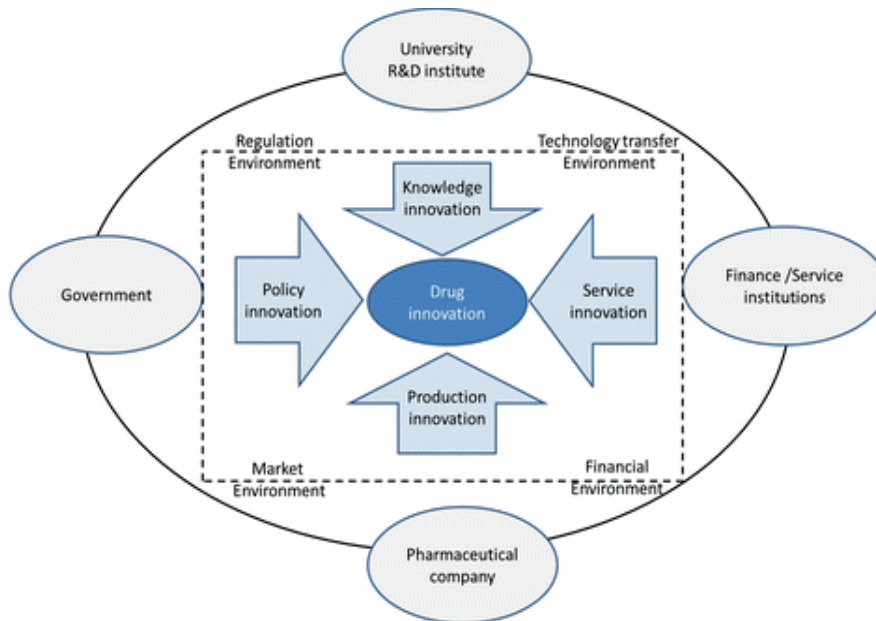
Imports by Country in 2018 (\$)



OBSTACLES IN THE GLOBAL PHARMACEUTICAL SUPPLY

- Currently no new effective drugs or vaccines
- Existing technologies are too expensive
- Require infrastructure that is not broadly available
- Pharmaceutical and biotech industries are thriving but not in full scale
- Recently focused mostly on production of generic drugs or versions of existing vaccines & diagnostics rather than on innovation

OBSTACLES IN THE GLOBAL PHARMACEUTICAL SUPPLY



GAPS TO BE CORRECTED TO ACHIEVE GLOBALIZATION

Elements in India to varying degrees, but important gaps remain

- Biomedical innovation requires scientists, engineers, and managers with the right mix of skills
- Publicly supported research with strong links to industry
- Financing for product development; access to technology
- Vigorous but supportive Regulation
- Functioning infrastructure and markets for products

GAPS TO BE CORRECTED TO ACHIEVE GLOBALIZATION

- New government programs providing grants and soft loans to industry have helped fill this gap
- International funding has been important for late-stage clinical trials of several vaccines.

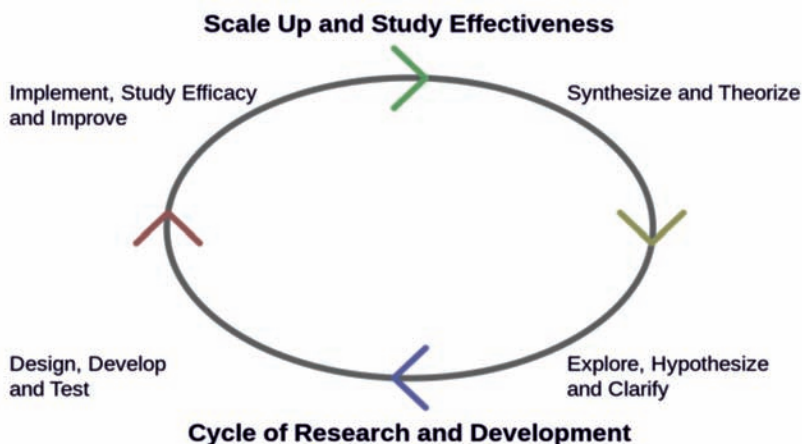


INDUSTRY GLOBALIZATION REQUIREMENTS

- Industry executives is a managerial system that is poorly equipped to oversee the development and approval of new products (favouring to generic)
- Regulatory obstacles are particularly severe for products based on genetic engineering and biotechnology, which require review by several different agencies.
- According to firms, regulators often lack familiarity with the relevant science.
- No Indian firm has ever developed a truly new, first-in-class vaccine
- Industry's current products, as well as most of the vaccines in its R&D portfolios, are based to varying degrees on licensed vaccines.
- Indian industry has little experience with the large-scale community-based clinical trials necessary to prove efficacy of new vaccines, and it remains relatively weak in vaccine discovery.

RESEARCH AND DEVELOPMENT

- In R&D, the leading firms have moved from process development and incremental innovation in combinations and formulations to the development of new vaccines and have developed expertise in recombinant technology

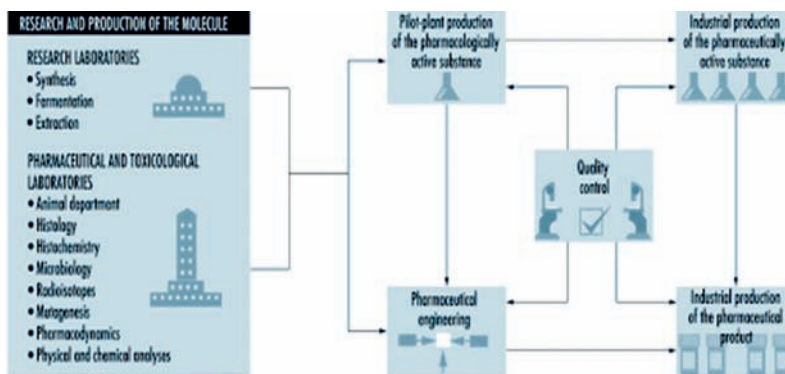


RESEARCH AND DEVELOPMENT

- Indian drug industry would shift toward a more R&D-based model after India changed its patent laws in 2001 has not been fully met, however.
- Leading firms have increased R&D spending in past decade, levels of investment remain relatively low, averaging 8 % of sales compared with 10 to 20 % of much larger sales for the big multinationals
- Most firms have drawn back from new drug development, focusing instead on R&D related to their thriving generic businesses
- At the same time, a contract research industry focused primarily on process and analytical chemistry and on clinical trials had grown rapidly in recent years
- Lucrative international markets for generic drugs promise quick returns for shareholders
- Drug discovery are limited, & the R&D efforts of both large generic producers & contract research organizations are focused primarily on products with global markets
- Lack of clarity about regulatory standards & processes for assessing new diagnostic tests, in India & at the international level

Indian companies are most able to contribute in three ways:

- by developing more affordable or locally adapted versions of existing products
- by bringing to market some new products to which technological barriers are not too high
- Participating in specific aspects of international product development initiatives in areas where they have a cost or other advantage



STRENGTHEN INDIAN R&D CAPACITY

- Indian government & International partners can help strengthen Indian R&D capacity & ensure the capacity is used to meet public health needs in India & other developing countries through action in three areas
- First, both the government & International donors should expand financing for product development projects, including for late-stage clinical trials & for new innovation driven firms
- Second, International partnerships that provide technical assistance & access to technology should also be expanded
- Both the Indian government & International health donors & procurement agencies could give product development a big boost by sending clearer signals about the products they wish to buy, technical standards that will have to be met, approval & procurement procedures
- Thirdly the Indian system for regulating pharmaceutical and biotechnology R&D, needs to be streamlined and systems & capacity for evaluating new technologies to be strengthened

OVERALL OBJECTIVES

- To understand where India & Indian industry, can contribute to the development of needed new drugs, vaccines & diagnostics for the poor
- To understand how Indian industry can best be engaged by the Indian government or International donors to achieve health R&D goals.
- To identify the most important obstacles to health R&D in India and recommend ways that the Indian government or International partners might ease these obstacles.

CONCLUSION

- Unlike the vaccine companies, Indian drug firms show little interest in developing new drugs against many diseases, although they remain crucial suppliers of affordable medicines to India and to other low- and middle-income countries.
- **The Indian drug industry is considered a success story for Indian industrial policy.**



EVENTS

World Pharmacist Day by IPA, Coimbatore Local Branch on 25th September 2020 in Zoom online

The World Pharmacist Day on the theme of “Transforming Global Health” was conducted by the IPA, Coimbatore Local Branch on 25th September 2020. The event was presided over by Prof. (Dr.) K. Chinnaswamy, President IACP. He addressed the gathering on the recognition of Pharmacist in pharmaceutical care and their role during this pandemic situation. The Chief guest for the function Dr. T. V. Narayana, President – IPA, Mumbai shared his thoughts on Global visualization of IPA and the significance of celebrating World Pharmacist Day. He also emphasized the significant role played by the pharmacist from manufacturing of drugs to academics; drug discovery to regulatory aspects. The Guest of honors Dr. S. Ramalingam, Dean, PSG Institute of Medical Sciences & Research, Dr. P. Sukumaran, Medical Director / Dean, Sri Ramakrishna Hospital, also addressed the audience and elaborated on the practicing pharmacy aspect and clinical pharmacist contribution in health care. They also emphasized that more such pharmacy professionals have to contribute to health care to benefit the patient community. To mark this occasion, competitions like Essay writing, Art competition and Power point presentation were conducted for the students. Students from the Western region of Tamil Nadu (Coimbatore) actively participated in all the events. The winners were awarded with cash prize and certificate. As a moment to cherish, the recorded message of the President, Pharmacy Council of India was also broadcasted. Dr. S. Mohan, Treasurer, IPA Coimbatore local branch administrated the Pharmacy oath. President Dr. T.K. Ravi welcomed the gathering and Dr. M. Ramanathan, Secretary delivered the vote of thanks. The event was attended by 200 pharmacist and students.



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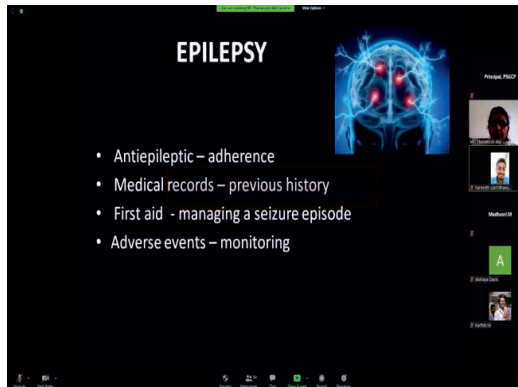
Every effort has been made to ensure the timeliness and accuracy of information presented in this newsletter. The authors, editors and publisher will not in any way be held responsible for the timeliness of information, errors, omissions and inaccuracies in this publication. Users are advised to recheck the information with original resource material before applying to patient care or other purposes.

This issue of Pharma Web is also available online at the Trust website : www.pictrust.com

World Pharmacist day Celebration by PSG College of Pharmacy

World Pharmacist day was celebrated by the PSG College of Pharmacy, Coimbatore on 25th Sep 2020 under the theme “Transforming global health”. The celebration was intended to mark the importance of pharmacist in health care team. The event was conducted through virtual platform. The chief guest for the event was Prof R. Mahesh, Principal, PSG College of Physiotherapy. The programme was started with Tamizh Thaaai Vazhthu followed by welcome address by Mr. D. Sivakumar, Asst Professor, Dept of Pharmaceutical Chemistry. Dr M. Ramanathan, Principal, PSG College of Pharmacy signifies the importance of pharmacist in the society through his presidential address. Mr. Hareenth. S, Community Pharmacist, Kandy, Sri Lanka and Dr Anita Ann Sunny, Clinical Pharmacist, Dept of Neurology, PSG Hospitals the proud alumni of our college were invited as the Guest of honor for this celebration.

Mr. Hareenth. S shared his experience as a community pharmacist and talks about the pharmaceutical regulations in Sri Lanka. Dr Anita Ann Sunny delivered a talk on Transforming global health-Our (Pharmacist) role. She emphasized on the importance of health literacy in the local community to achieve global health transformation. Faculty and pharmacist working in PSG hospitals, took pharmacy oath presided by Dr. V. Sankar, Vice Principal, PSG College of Pharmacy. The event was concluded with vote of thanks by Mrs. S. Vijayalakshmi, Asst. Professor, Dept of pharmaceutics.



Talk by the Guest of Honor –Virtual Platform

Pharmacist Oath

Pharmacist Day Celebration – IPGA, TN Branch

The World Pharmacist Day, was celebrated by Indian Pharmacy Graduates Association, Tamilnadu Branch, by virtual meet under the theme of “Transforming Global Health”. The meeting started with welcome address by Mr. R. Narayanaswamy, President, IPGA-TN. He welcomed all the participants from various places of Tamilnadu and briefed various new activities initiated by the association for the benefit of Pharmacy Profession.

Mr. M. Rajarathinam, Secretary, IPGA, TN was presented the Secretary's report for the year 2019- 2020. He was briefed about the membership and various new activities taken during the above period.

Women's forum of IPGA, was Inaugurated by, Dr. (Ms.) Sanju Dhawan, M.Pharm., Ph.D., Associate Vice President, Head Product Development, Pfizer Healthcare India Pvt. Ltd., Chennai.

Inauguration of Student's Forum of Chennai was done by Dr. A. Jerad Suresh, Principal, College of Pharmacy, Madras Medical College, Chennai

Dr. Abdul Hasan Sathali, M.Pharm., Ph.D, Principal, College of Pharmacy Madurai Medical College, Madurai, was inaugurated the Madurai chapter of IPGA.

Inauguration of Academia-Industry Co-ordination Centre (AICC), was inaugurated by Dr. Prof. V. Ravichandran, M.Pharm., PhD., Director, NIPER, Kolkatta & NIPER Hajipur-Bihar, Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers Govt. of India. He enlightened about the research conducted by the colleges and transforming the same to the industry.

Dr. S. Jayakumari, M.Pharm., Ph.D., Professor and Head, Department of Pharmacognosy, School of Pharmaceutical Sciences, Vels Institute of Science, Technology & Advanced Studies (VISTAS) Old Pallavaram, Chennai, spoke about the availability of facilities in the teaching institutions and advised the industries to utilize the same for development of their new products. Mr. M. Varadharajan, B.Pharm, Vice President, IPGA & Managing Director, M/s. Kniss Laboratories Pvt. Ltd., Chennai, also spoke on the Industry needs from the academia.

During the event, The GroupHealth Insurance for IPGA members was inaugurated by Mr. J. Jayaseelan. B.Pharm. MBA, PGDMM, Managing Director, M/s. Delvin Group of Companies, Chennai. Mr. Baranidharan, Service Provider narrated and explained about the insurance scheme.

Dr. G. Selvaraj, B.Pharm, MBA., BL., D.Tax Law., ML, PhD., Drugs Controller of Tamilnadu (Retd.), gave a keynote address about the theme "Transforming Global Health".

During this event, a blood donation camp was organized by Madurai chapter of IPGA. The event was concluded with a vote of thanks, by Mrs. K. C. Meenakshi. IPGA Committee member. Master of Ceremony by Mr. Lakshmanan, of Pfizer Healthcare India Laboratories, Chennai.



TARIFF FOR ADVERTISEMENTS

The members of the Tamilnadu Pharmaceutical Science Welfare Trust desire to accept and publish important advertisements in Pharma Web, from Pharma and allied industries, Pharmacy colleges, etc. The following are the tariff :

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Advertisers may send the cheque in favour of "Tamilnadu Pharmaceutical sciences welfare trust" to the address of the trust along with the advertisement matter in soft copy

INFORMATION

M. PHARM & PHARM D SCHOLARSHIPS 2019-20 AWARDED BY TNPSWT

Profile of 3rd Rank

PHARMACEUTICS

Name: Mr. S.R. Aravind
Project Title: Bupropion Hydrochloride loaded nanostructured lipid carriers (NLC) for antagonizing the post synaptic Nicotinic acetylcholine receptor (nAChR) through Intra-nasal delivery: A novel approach for smoking cessation.
College: JSS College of Pharmacy, Ooty
Guide's Name: Dr. N. Jawahar

PHARMACEUTICAL CHEMISTRY

Name: Ms. Sowmiya. P
Project Title: In-silico Design, Synthesis and study of novel Isatin derivatives against targeted enzymes for its Antimicrobial and Anticancer activity
College: College of Pharmacy, Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry
Guide's Name: Dr. K. Girija

PHARMACEUTICAL ANALYSIS

Name: Mr. Arup Bhattacharya
Project Title: Identification, Isolation and Characterisation of degradation products for Anti-retrovirals (Efavirenz & Stavudine) by LC-MS-MS
College: JSS College of Pharmacy, Ooty
Guide's Name: Dr. N. Krishnaveni

PHARMACOLOGY

Name: Mr. Vikash. R.S
Project Title: Evaluation of cardioprotective activity of daidzein on isoproterenol induced myocardial damage by alleviating cardiac markers, oxidative stress and inflammation in rats.
College: JSS College of Pharmacy, Ooty
Guide's Name: Dr. R. Vadivelan

PHARMACOGNOSY

Name: Ms. Archana. I
Project Title: Development and Optimisation of Nanoemulsion containing volatile oil from *Cyperus bulbosus* and its Pharmacological evaluation
College: College of Pharmacy, Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry
Guide's Name: Dr. E. Selvakumari

PHARMACY PRACTICE

Name: Mr. Anandu M Das
Project Title: Prevalence and Predictors for Overweight and Obesity in Adolescents students.
College: JSS College of Pharmacy, Ooty
Guide's Name: Mr. Vishwas. H. N

PHARM D – CLINICAL PHARMACY

Name: Mr. Anirudh. M, Ms. Fatema Juser Haji, Ms. Keerthana G.C, Ms. M. Arthi
Project Title: Evaluation of lacosamide over pregabalin in patients newly diagnosed with neuropathic pain: A randomized pilot study.
College: SRM College of Pharmacy, SRMIST, Kattankulathur,
Guide's Name: Dr. Jagadeesan

Name: Mr. Bhaktraj Singh, Mr. Dineshkumar. N, Mr. Manikandan. P, Mr. Vivian D Cruz
Project Title: A study to investigate the relationship of serum iron concentration and platelet count as biomarker among the pregnancy induced hypertensive women.
College: JSS College of Pharmacy, Ooty
Guide's Name: Ms. Roopa. BS.

Name: Mr. U. Sanvas.
Project Title: Effect of Cholecalciferol on the eradication rates of *helicobacter pylori* induced peptic Ulcer disease
College: School of Pharmaceutical Sciences, VISTAS, Chennai
Guide's Name: Dr. Vijey Anandhi. M





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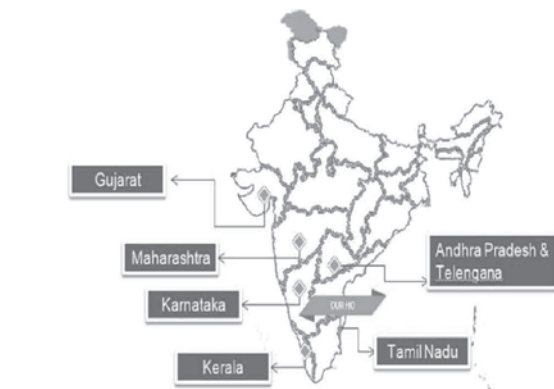
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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 21st October, 2020

S.O. 3722(E).—In pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby amends the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) No. S.O. 3721(E), dated the 16th October, 2019 published in PART II - Section 3 - Sub-section (ii) of the Gazette of India, Extraordinary, namely,—

In the said notification, for the words and figures “the 1st day of November, 2020”, the words and figures “the 1st day of November, 2021” shall be substituted.

[F. No. X.11014/8/2018-DR]
Dr. MANDEEP K BHANDARI, Jt. Secy.

Note : The principal notification was published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (ii) vide number S.O. 3721(E), dated the 16th October, 2019.



Mr. B. Sethuraman

(1950-2020)

Mr. B. Sethuraman - Managing Director, Abhilash Pharma Pvt. Ltd.

Mr. B. Sethuraman was born on 01.08.1950. He passed out B.Pharm from Madurai medical College in the year 1972. From 1973 he started working with Pharmaceutical companies as Manufacturing Chemist in Parenteral, Tablets, liquid Oral sections.

During 1982 he has started his own Company Abhilash Pharma (P) Ltd in Chennai Manufacturing Liquid Orals.

He has held various positions such as:-

- **President** - The Pharmaceutical Manufacturers' Association of Tamilnadu,
- **Trustee** - Tamilnadu Pharmaceutical Sciences Welfare Trust,
- **Trustee** - Tamilnadu Indian Pharmaceutical Association Trust,
- **Spl. Invitee** - Indian Drug Manufacturers' Association (Tamilnadu, Puducherry & Kerala State board),
- **Secretary** - Alathur Pharmaceutical Manufacturers' Association.
- **Ex-Secretary General and founder member** - CIPI
- **Chairman** - FOSIPMA
- **Secretary General** - NAPA

He was instrumental in many legal battles like Schedule M GMP, 294 FDCs to name a few.

He was part of all national and international conferences held in Chennai.

He worked a lot for FDC issue, spurious drugs bill and various issues faced by the pharma industry, he was an asset to SME pharma industry of India.

Friends & Relatives



NEWS

Central Unit to Monitor Security and Affordability of Pharma Drugs in Goa

In an effort to monitor prices of Pharmaceutical drugs and to ensure availability of crucial medicines, the Centre has setup a Price Monitoring and Resource Unit (PMRU) in Goa under the aegis of National Pharmaceutical Pricing Authority (NPPA).

The PMRU will function under the direct supervision of the Goa's drug controller, the Food and Drug Administration.

Since the start of Covid-19 pandemic, NPPA has been working in close coordination with state governments to ensure seamless availability of life saving medicines including HCQ, paracetamol, vaccines, insulin and medicines required for treatment of Covid patients, including medical oxygen. Working together with the Goa government, NPPA has strived to ensure that there is no shortage of drugs throughout the country.

Source: *ET Healthworld*, 25th October 2020



Cipla Launches Generic Idiopathic Pulmonary Fibrosis Drug in India

Pharma major Cipla, it has launched generic Nintedanib used for the treatment of Idiopathic Pulmonary Fibrosis (IPF) under the brand name 'Nintib' in India. Available as 100 mg and 150 mg capsules, the launch marks another milestone in the company's decade-long commitment to treat IPF, a rare lung disease that impacts ten in one lakh people, Cipla said in a statement.

Nintib is priced at Rs 69 (100 mg) and Rs 85 (150 mg) per capsule, it added.

IPF is a chronic progressive form of lung disease with an average survival rate of three to five years if left untreated. It is characterised by scarring in the lungs, wherein the lung tissue becomes stiff and thick, Cipla said.

In line with its endeavour of enabling effective and affordable management of IPF,

Source: *ET Healthworld*, 20th October 2020



E-pharmacies Urge Government to Notify e-pharmacy Rules

Online pharmacies said they have requested the government to notify the final e-pharmacy rules. A vibrant e-pharmacy remains a vital cog in the implementation of the National Digital Health Mission, association of Indian internet pharmacies Digital Health Platforms said in a letter to Prime Minister Narendra Modi.

notify the final e-pharmacy rules," the association added.

Draft e-Pharmacy Rules are in addition to, and not in substitution of, the existing legal framework of the IT act and DC (Drugs and Cosmetics) Act and Rules, which the existing e-pharmacies are fully compliant with, the letter said.

"It is our sincere request that the government

Source: *ET Healthworld*, 2nd October 2020



Pharma Mkt Rebounds in Sept, 1st time since Covid

The domestic Pharma retail market bounced back for the first time during the pandemic, registering a growth of over 4% in September, helped by increased sales of chronic medication and anti-virals being used to treat the coronavirus. This comes on the back of positive trends in macro-economic indicators, raising hopes of a pick-up in the economy.

The market, valued at around Rs 1.5 lakh crore, had been sluggish since March, though the sector itself did not face restrictions during the lockdown since it's categorised as an essential service. In April and May, the Pharma market had dropped into negative territory due to the absence of prescriptions and lower OPD (outpatient department) visits.

During September, cardiac medicines registered a growth of 17% compared to 11.5% in the previous month, while anti-diabetic drugs grew 6.5% (1.6%). The growth in respiratory medicines stood at -10.5% in September, compared to -12.4% in August, according to data culled from Pharma research firm AIOCD Awacs. Sales of vitamins have also bounced back with a 16.3% growth during the month, as against 6.2% in August, while pain and analgesics stood at -4.3% (-9.8%).

The MAT (moving annual total) growth for the 12-month period ended September is

3.5%, while the market is valued at Rs 13,170 crore in the month. Growth over the last few months has been pulled down due to tepid sales of acute therapies, including anti-infectives with lower incidence of fever and normal flu as most people stayed indoors due to the lockdown. Now with the opening up of the economy, and winter round the corner, experts feel this could change over the next few months.

Sales of anti-infectives, which had dipped to -11% in August, showed a slight revival of 1.4% in September, while associated therapy like gastro showed a low growth of 5.5% (-3.1% in August). Though growth is still low in September, there are signs that it could be sustainable in future on the back of higher sales of anti-Covid medicines, fever medication and vitamins, experts added. Sales of anti-infectives and respiratory drugs could also pick up, particularly in the north.

Over the last few months, the Pharma retail market dipped to negative territory in May (-9%), while in June and July it was lacklustre due to lower sales of acute therapies, and slowing down of panic buying in chronic medication. In August, the growth had declined by 2.2%.

Source: *The Times of India*, 14th October 2020



Six Indian Drug Companies to Set up a Large Pharma Cluster in Mexico

Six generic drug makers — Dr Reddy's Laboratories, Zydus Cadila, Glenmark Pharmaceuticals, Torrent Pharmaceuticals, Hetero Drugs and Ackerman Pharma — have signed a deal with Hidalgo state of Mexico to set up a large Pharmaceutical cluster for production and logistics.

The move, facilitated by the Union commerce ministry, is expected to help them penetrate neighbouring Latin American markets. A commerce ministry official said a couple of Indian drug makers have also agreed, in principle, to set up manufacturing facilities in

Hidalgo to make Mexico their production and logistics hub and cater to Latin American regions.

The Mexican Pharmaceutical market, the second largest in Latin America after Brazil, was worth \$10.6 billion last year. The country, considered one of the most developed drugs markets in the region, houses around 200 Pharmaceutical companies, including some large multinationals.

Source: *ET Healthworld*, 13th October 2020



Medical Oxygen Price Capped for 6 Months

Amid rising demand for medical oxygen which is essential in treatment of moderate to severe Covid-19 patients, the Pharmaceutical pricing regulator has capped the price of medical oxygen cylinders and liquid medical oxygen (LMO) for six months to ensure availability of medical oxygen at stable rates.

While issuing the order, the National Pharmaceutical Pricing Authority (NPPA) said

the high price of LMO was impacting operational viability of fillers, creating a supply shortage. The demand for medical oxygen has increased up to almost four times from 750 MT per day to around 2,800 MT per day after the Covid outbreak. Around 6% of around 9.6 lakh currently “active” Covid cases need oxygen support.

Source: *ET Healthworld*, 27th September 2020



Need a Change in Ecosystem to Make our Drug Production Cost Competitive vis-à-vis China: Navdeep Rinwa

The Department of Pharmaceuticals (DoP) has come out with a report on catalyzing the transformation of the R&D and innovation in the Pharma and medical devices sector, announced Joint Secretary Navdeep Rinwa.

Speaking at the 14th edition of FICCI's

annual healthcare conference – FICCI Heal 2020, he said, “We don't want the situation to repeat, where we have to put export restrictions on a sector that is earning so much of foreign exchange for us. This will only happen if we are confident that we are not relying totally on some country.”

Rinwa was chairing the virtual panel discussion on the theme “Changing Landscape of Pharma Industry” which deliberated on turning the Covid crisis into an opportunity for strengthening the domestic Pharma supply chain.

India which is often called as the pharmacy of the world imports more than 70% of the API and intermediates from China. The over-dependence had led to massive disruptions in the Indian Pharma supply chain post implementation of lockdown to contain the spread of coronavirus in China.

With the aim to reduce this dependence on imports and boost domestic manufacturing of critical active pharmaceutical ingredients (APIs), the Ministry of Chemicals and Fertilizers announced a production linked incentive (PLI) scheme for the promotion and manufacturing of pharmaceutical raw materials in India.

Elaborating on the progress made by

the schemes, Rinwa said, “Through bulk drug parks, the states are coming out with their incentive policies to make capital expenditure and operational expenditure lower. We should not restrict make in India for India, but go for Make in India for the world and if we achieve that scale, only then we'll be able to compete with China.”

However, he also added that there should be some change in the ecosystem which should make our cost of production competitive vis-à-vis China.

The Department of Pharmaceuticals (DoP) aims to come up with many more initiatives to strengthen the Indian Pharma ecosystem. According to Rinwa, the Covid pandemic is a blessing in disguise, as it showed that the issues can be solved faster if there is a regular interaction between the Department of Pharmaceuticals and the industry.

Source: *ET Healthworld*, 29th September 2020



'Sunshine' Vitamin D Could Serve as a Shield Against Covid, Limit its Severity

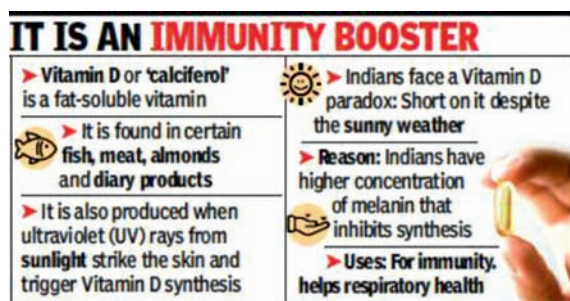
There is growing evidence that Vitamin D could help in the fight against Covid-19. Local doctors-and studies from other countries-say adequate levels of the Sunshine Vitamin, as it is called, could protect one against Covid or reduce its severity among infected patients.

A study published in PLOS ONE medical journal by Boston University School of Medicine showed Covid-19 patients with 25-hydroxyvitamin D level of 30 ng/mL (nanogram

per millilitre) in blood had a lower risk of low oxygen called hypoxia, or death. These patients also had lower inflammation levels and higher lymphocytes (a type of immune cell to fight infection)

Dr Shashank Joshi, a member of the state task force on Covid-19, said most studies in the Covid field are in the research mode. "However, there is indeed evidence from many European studies that Vitamin D helps Covid-19 patients," he said.

Vitamin D is advised for patients with various conditions, ranging from arthritis to tuberculosis. "There is already proof that Vitamin D helps reduce the severity of respiratory infections, including pneumonia," said Dr Joshi. He, though, said before announcing that Vitamin D helps against Covid-19, there is a need for randomized and prospective studies to prove the assumption. "At present, most studies are retrospective studies done among patients admitted in hospitals," he added.



The Boston study looked at 235 patients admitted for care. In patients older than 40 years, doctors found those with sufficient Vitamin D levels were 51.5% less likely to die than those who were deficient with

a blood level of 25-hydroxyvitamin D of less than 30 ng/mL.

"This study provides direct evidence that Vitamin D sufficiency can reduce the complications, including the cytokine storm (release of too many proteins into the blood too quickly) and ultimately death from Covid-19," said the study's main author Michael F Holick in a press release. Recently, Dr Anthony Fauci, head of US's National Institute of Allergy and Infectious Diseases, said, "If you are deficient in Vitamin D, that does have an impact on your susceptibility to infection." He said he takes Vitamin D supplements.

The state's treatment protocol includes Vitamin C and zinc supplements for Covid patients.

Many doctors in the private sector prescribe megadose of Vitamin D for hospitalized patients as well.

Source: *The Times of India*, 26th September 2020

China Tests India's Efforts of Atmanirbhar; Hikes Prices of Key Drug Materials

China has increased prices of key starting materials (KSMs), which are used for making medicines, by 10-20%, leaving those of basic raw materials — or active pharmaceutical ingredients (APIs) — largely unchanged. Both KSMs and APIs are imported in India for making lifesaving antibiotics, steroids and other medicines.

While increased prices will put cost pressure on the domestic industry over the next few months, more importantly it has

sparked speculation that this could be a potential ploy by China to scupper efforts of India's drug industry to be self-reliant, or 'Atmanirbhar'.

Here's how China's action may impact India's Atmanirbhar plans: Any increase in prices of imported KSMs will discourage indigenous API production in the country, making units unviable and APIs less competitive against Chinese products globally. At present, India is dependent on China for

KSMs and APIs, with 70-80% of basic raw materials imported for making medicines.

For certain life-saving antibiotics like cephalosporins, azithromycin and penicillin, the dependence on Chinese imports is as high as 90%.

BUILDING BLOCKS OF MEDICINES

➤ Key starting materials (KSMs), which are the building blocks of active pharmaceutical ingredients (APIs) or **medicine raw materials**, have become costlier recently

➤ KSMs needed for **steroids and antibiotics** have seen an increase in prices, while, **prices of imported APIs have come down** to pre-Covid levels

All major antibiotics are made from two KSMs:

1 Penicillin G is used to manufacture most of Cephalosporins
Its prices have recently risen by about 15% from \$9.5 to \$11

2 Erythromycin Thiocyanate (TIOC) is used in the production of Macrolides
TIOC prices have jumped from RMB 300 to RMB 400 in six months

Source: Industry, RMB: Renminbi

To boost indigenous manufacturing and self-reliance, the government announced an incentive scheme to manufacture 50-odd crucial APIs, where import dependence is high. Plans to spur domestic manufacturing have been there for a while. Now high volatility in prices due to the Covid-19 pandemic, and tensions with the neighbouring country, have highlighted the risk of dependence on a single source.

Typically, a spike in prices of KSMs is cyclical, and is followed by those in APIs too. But this did not happen this year. This has raised eyebrows and triggered apprehension. Experts said, “Coupled with appreciation in the

RMB (Chinese currency renminbi), the move defies economic logic.”

Further, the RMB increased 4% against the dollar over the last 45 days. Chinese companies are believed to be operating through a cartel and manipulating KSM prices for steroids and antibiotics, a Mumbai-based executive who trades in bulk drugs told TOI. Indian Drug Manufacturers' Association president Mahesh Doshi said, “Cost pressure will be there (on API manufacturers) due to the increase in prices of imported KSMs.”

The government's production-linked scheme proposes to provide financial incentives to promote domestic manufacturing, but involves large investments from companies, particularly for the much-needed fermentation-based products. “It is crucial to ensure that investment happens. If we do not draw investment, then it will be impacted,” said PwC India Pharma leader Sujay Shetty.

To be competitive and a volume player in APIs globally, India will need to keep input costs low. Countries' procurement strategies are now gradually being recalibrated and they are looking at diversifying their procurement sources away from China or seeking alternative sources for the same API.

Source: *The Times of India*, 22nd September 2020





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