ISSUE No. 36

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Oct. - Nov. - Dec. 2017

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

NURAY CHEMICALS PVT. LTD.	Sai Mirra Innopharm Pvt. Ltd.	Delvin Formulations	Numen Healthcare Pvt. Ltd. (Singapore)	Delvin Klarvoyant Biogenics Pvt. Ltd.	Delvin Surgicals
R & D and Manufacturing of API	R & D and Manufacturing of Formulations	Domestic Marketing	International Marketing	Medical Devices	Surgicals

info@delvin.in | www.delvin.in

Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 36 Oct. - Nov. - Dec. 2017

CONTENTS **Page No.**

TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
No. 608A, 6th Floor, Phase I, Spencer Plaza,
768 / 769, Anna Salai, Chennai – 600002
Ph: 044 - 28491232
e-mail : pictrust@hotmail.com Website : www.pictrust.com

EDITORIAL

Dear Readers,

We wish all our readers a very **HAPPY NEW YEAR 2018.**

We are happy to publish the 36th issue of Pharma Web Newsletter for Oct – Dec 2017.

We are happy to inform our readers, the Indian Pharmaceutical Association, Tamilnadu Branch will be conducting IPA Convention 2018 in the month of February 2018 and look forward for this convention as lot of eminent speakers are expected.

In this newsletter the following articles are also published

- Perspective on Indian Pharmaceutical Market by **Dr. Jasdeep Singh, IQVIA Consulting Group - Head, Management Consulting, South Asia**
- Workshop on Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries by **Mr. Rishi Kumar, Senior Pharmacovigilance Associate, IPC, Gazhiabad, NCC, PvPI**

All of you are aware -- Pharmacovigilance has become mandatory requirement from 1st January 2018, as per the Drugs & Cosmetics Act.

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

The PKTI also conducted 5th Industrial Orientation Training Programme for fresh Pharmacy graduates during the month of September 2017. The highlights of this programme are published in this issue and also contain event like Pharmacy Week Celebration – key note address by Dr. Surinder Singh, 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., 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.

We also thank M/ Pharm Products Pvt Ltd., Thanjavur for the support.

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

With Best Regards,

N. SREENIVASEN
Hon. Gen. Secretary

ARTICLES

PERSPECTIVE ON INDIAN PHARMACEUTICAL MARKET

by

Dr. Jasdeep Singh,
IQVIA Consulting Group - Head, Management Consulting, South Asia

Agenda

- Introduction to IQVIA
- Indian Pharmaceuticals Market: Key trends
- Regulatory Scenario and Draft Pharma Policy
- GST Impact
- Winning strategies for Pharma players

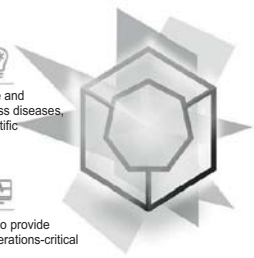
Perspective on IPM I IDMA, Nov, 2017

IMS Health & Quintiles are now IQVIA™

Perspective on IPM I IDMA, Nov, 2017

IQVIA mobilizes unparalleled data, analytic, technology, & expertise through solution connecting stakeholders to improve health

IQVIA CORE™



Domain Expertise
Institutional knowledge and domain expertise across diseases, geographics and scientific methods

Transformative Technology
Leading technologies to provide real-time access to operations-critical information

Unparalleled Data
One of the world's latest curated healthcare data sources with innovative privacy protections

Advanced Analytics
Faster, more precise decision-making generated by advanced analytics designed for healthcare

Perspective on IPM I IDMA, Nov, 2017

Agenda

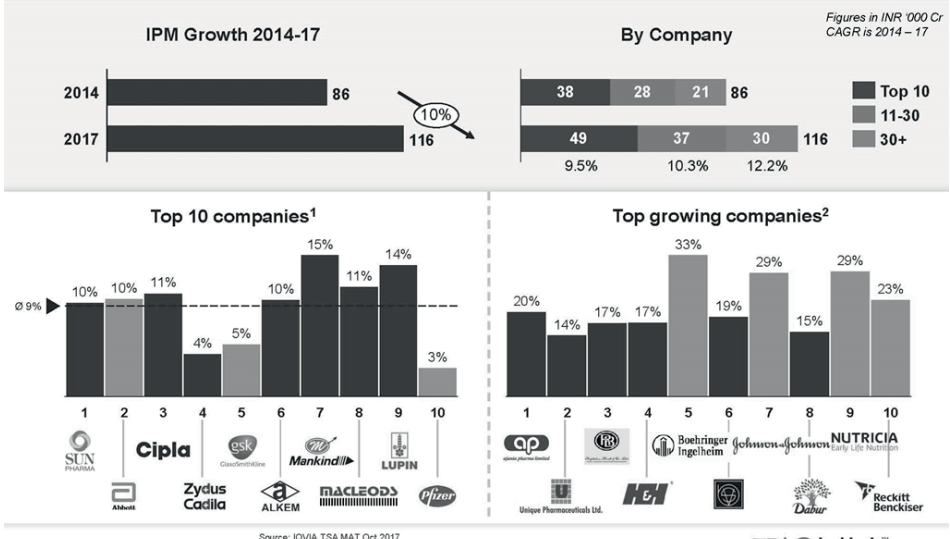
- Introduction to IQVIA
- **Indian Pharmaceuticals Market: Key trends**
- Regulatory Scenario and Draft Pharma Policy
- GST Impact
- Winning strategies for Pharma players

Perspective on IPM I IDMA, Nov, 2017

Opening thought:
Regulated industries tend to be more consolidated

- *Indian Pharma is moving towards a stricter regulatory environment*

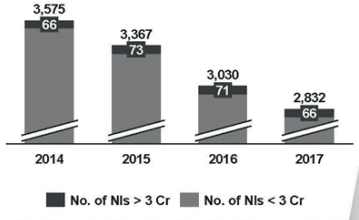
IPM has grown at ~10%, with domestic companies outperforming in Top 10, and portfolio focused companies beyond Top 30



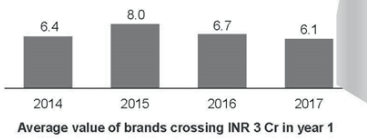
Source: IQVIA TSA MAT Oct 2017
Notes: 1) **Top 10 companies as ranked for revenue in MAT Oct'14**
2) Top growing companies selected based on CAGR 2014-17 (annual revenue > 100 Cr.)
3) Orange color indicates MNCs

NIs in the market have significantly reduced; yield is under pressure; selection and investment behind NI is critical more than ever

1 NIs in the market have reduced over the years…

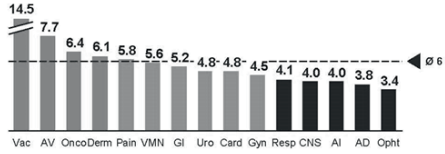


2 … and the yield (revenue/ NI) for successful NI is under pressure



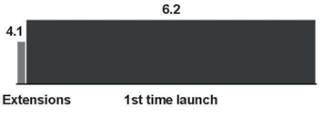
Average value of brands crossing INR 3 Cr in year 1

3 NIs are gaining more value in TAs like Onco, Derma…



Average value of brands crossing 3 Cr in year 1 (2017)

4 ..with 1st time launches being more successful than line extensions NIs



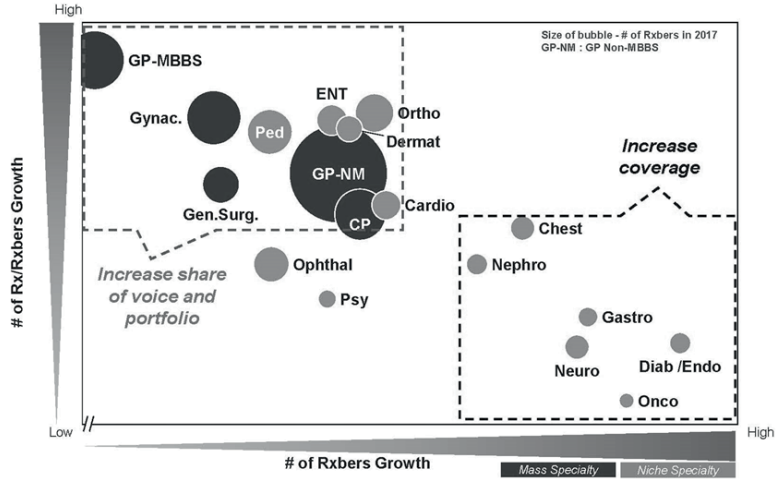
Average value of brands crossing INR 3 Cr in year 1 (2017)

Source: IQVIA TSA MAT Oct 2017, IQVIA Analysis

Perspective on IPM | IDMA, Nov. 2017

IQVIA 7

Specialists have contributed significantly to growth, however primarily through increase in number of prescribers

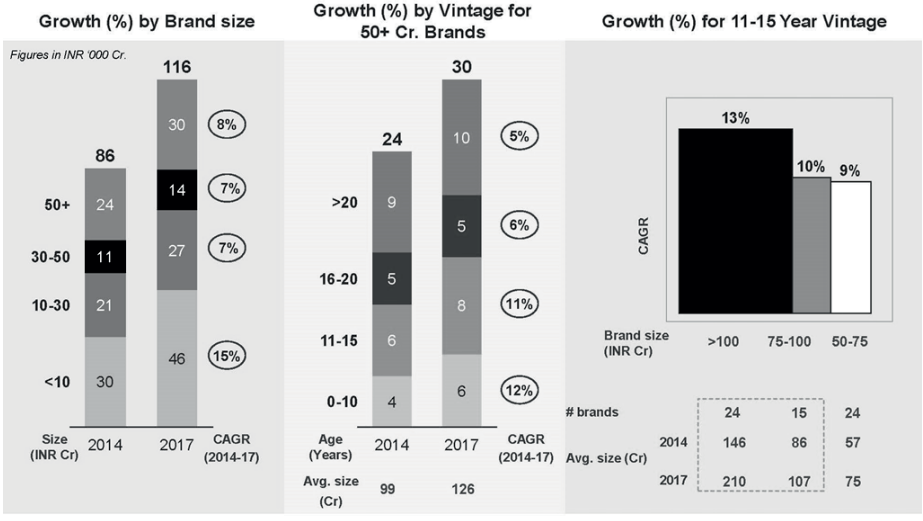


Source: IQVIA TSA MAT May 2017, IQVIA Medical Audit MAT May 2017, IQVIA Analysis

Perspective on IPM | IDMA, Nov. 2017

IQVIA 8

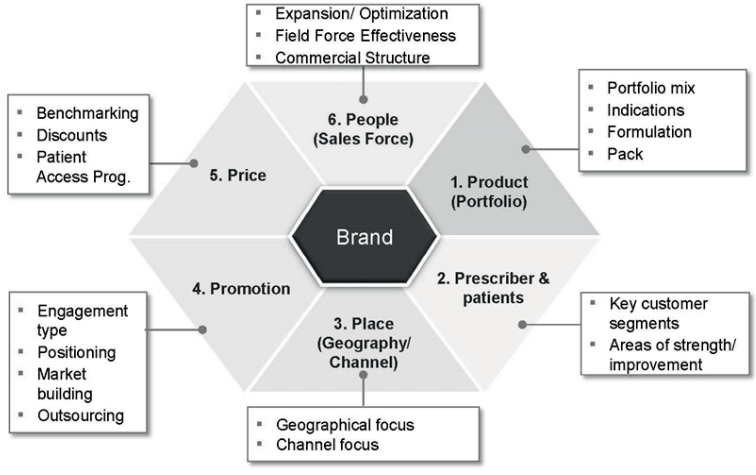
Big brands that have been recently built are driving the market; a strong launch leads to continuous acceleration



Source: IQVIA TSA MAT Oct 2017, IQVIA Analysis
Note: Brands have been classified basis MAT Oct in 2014
Perspective on IPM | IDMA, Nov. 2017

IQVIA 9

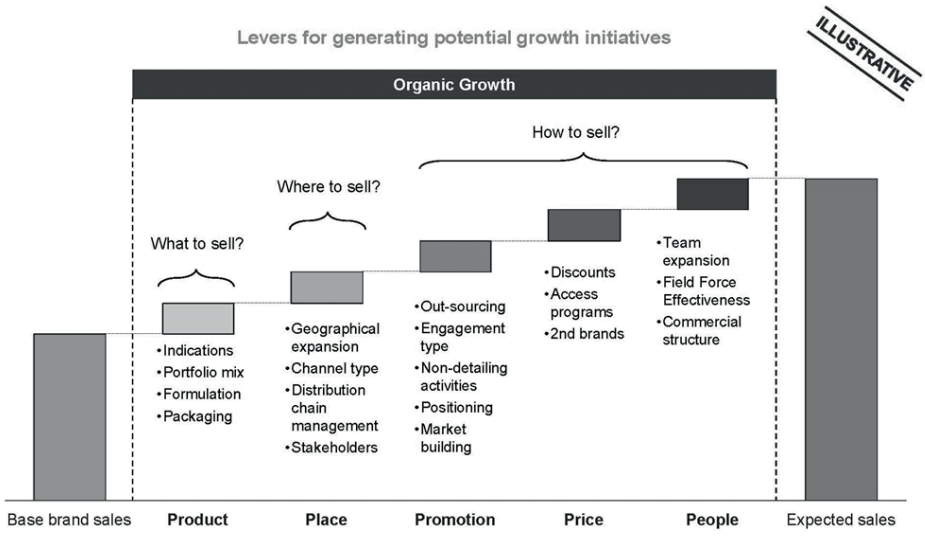
Brand building is likely to be key lever of growth; companies may leverage six P framework



Perspective on IPM | IDMA, Nov. 2017

IQVIA 10

Identifying the potential opportunity across the growth levers will lead to accelerated organic growth



Perspective on IPM | IDMA, Nov. 2017

IQVIA 11

Going ahead, IPM is likely to be shaped by following key trends

Shift in disease profile towards **Non-communicable Disease**

- ~57% of disease burden is estimated to be of non communicable type by 2020 from ~30% in 1990

Health Consumerism on the rise with increased role of **Technology**

- Increasing awareness and trend of self medication for common disease areas especially for acute ailments

Government focus on healthcare is unparallel

- Better health public infrastructure in extra-urban market, increased market access and increased drug consumption

Increasing **Partnerships and enhanced payer roles**

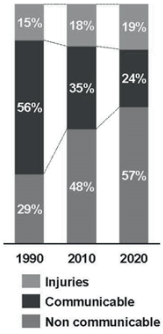
- Leveraging partnerships across the value chain and payers exercising more control

Perspective on IPM | IDMA, Nov. 2017

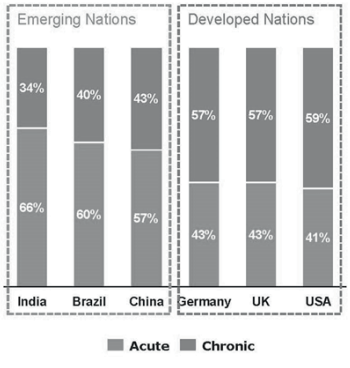
IQVIA 12

Indian pharma is expected to shift to chronic segment in-line with other emerging nations as the market gets matured

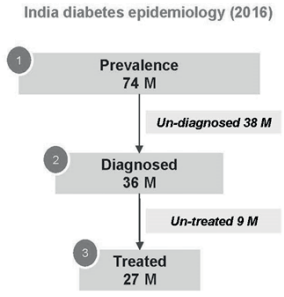
Disease burden[1] estimates in India…



..expected to move towards chronic therapy in line with global markets…



..with present situation too offering significant headroom for growth



Emerging nations are shifting towards chronic segment characterized by lifestyle related diseases like diabetes, hypertension etc.

Source: 1: WHOs global status report on NCDs , IDF Diabetes Atlas, Seventh edition, 2015
IQVIA data assets; IQVIA Analysis
Perspective on IPM | IDMA, Nov. 2017

IQVIA 13

Patients are becoming more aware of diseases enabled by rising medical information portals and healthcare startups…

Health Consumerism on the rise…

52% Indians indulge in self-medication: Study
Wednesday, April 8, 2015
Tweet Share 1
.. survey by Lybrate in top 10 cities

1mg — **20 Mn+** searches/ month

nawa medianCels — **10k+** second opinions/ year/ portal

20+ patient groups for cancer in Mumbai alone

WebMD, Medscape — multiple online medical information portals

… enabled by **Technology**

PATIENT

netmeds.com India Ki Pharmacy
medlife
lybrate
CallHealth Everything about health
practo
PORTEA HEAL AT HOME
CUROFY

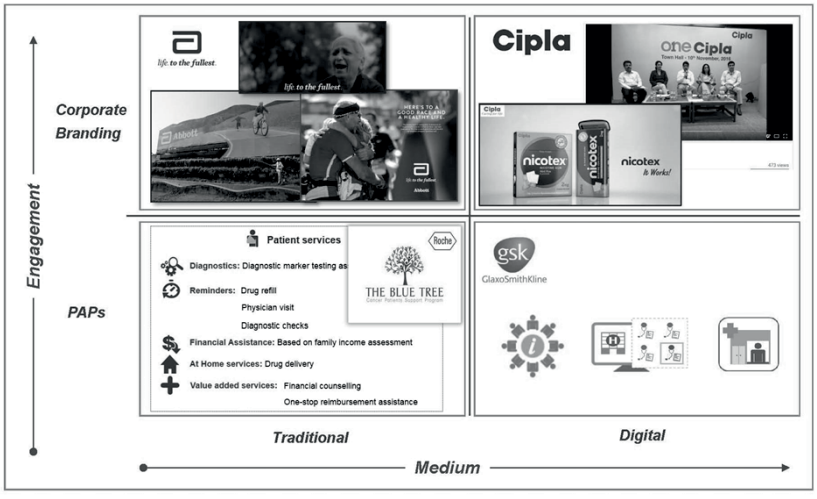
PHYSICIAN

~$500 Mn invested by VCs and PEs

Source: IQVIA Analysis
Perspective on IPM | IDMA, Nov. 2017

IQVIA 14

.. leading to companies engaging with patients across traditional and emerging medium



Perspective on IPM | IDMA, Nov. 2017

IQVIA 15

The government has plans of increasing focus to healthcare, doubling its share of expenditure as % of GDP

Government Run Pharmacies

- Expanding **Jan Aushadhi** initiative, **3,000** new outlets
- Expanding **AMRIT** scheme to all state **government hospitals**

Better Public Healthcare Infrastructure

- Set up **ten new tertiary care facilities (16,000 bed)**
- Super-specialty blocks in **70 medical colleges**
- Establish **72 new cancer centers**
- Expansion of **inpatient provision** at district level

Greater Access to Insurance Coverage

- Long-term vision of **Universal health coverage**
- Expansion of RSBY, providing coverage for **1/3rd of population**

Source: IQVIA data assets; IQVIA Analysis
Notes: AMRIT - Affordable Medicines and Reliable Implants for Treatment

Perspective on IPM | IDMA, Nov. 2017

IQVIA 16

Indian Pharma market is at a critical inflection point in terms of stakeholder partnerships and an enhanced payer role

Partnerships across ecosystem

Pharma – Pharma	Roche	Emcure
Pharma – Hospital	SANOFI	Apollo HOSPITALS
Pharma – Consumer Health	TEVA	P&G
One-Pharma	Abbott	J&J
Hospital – OP Care	Fortis MALAR HOSPITAL	PORTEA

Enhanced payer role

Exercising control on Cost

BusinessLine

Insurers negotiate with hospitals to bring down rates

THE TIMES OF INDIA

Insurers to bat for cutting cost of stent ops

Disease-specific health insurances

HDFC Life *Sar'utha ke jiyo!*

Apollo Munich HEALTH INSURANCE

STAR Personal & Caring Health Insurance

The Health Insurance Specialist

EGON RELIGARE LIFE INSURANCE

Cancer Hypertension Diabetes HIV

Perspective on IPM | IDMA, Nov. 2017

IQVIA 17

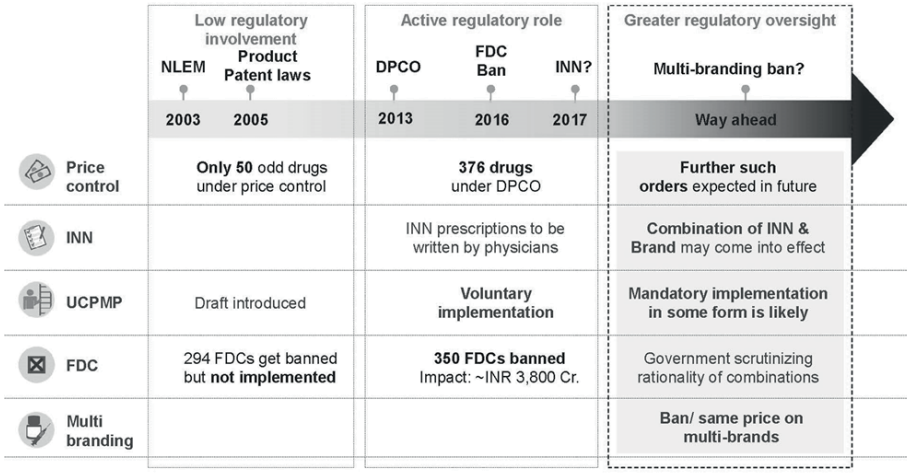
Agenda

- Introduction to IQVIA
- Indian Pharmaceuticals Market: Key trends
- **Regulatory scenario and Draft Pharma Policy**
- GST Impact
- Winning strategies for Pharma players

Perspective on IPM | IDMA, Nov. 2017

IQVIA 18

Regulatory scenario in Pharma is expected to evolve towards greater scrutiny



Draft Pharma policy has put an ambitious framework around Quality, Affordability, Manufacturing and Innovation

Multi-stakeholder discussions will lead to incorporation of Industry view and implementation over a period of time

Affordability – Mandatory INN Generics prescription

We have analyzed INN Rx policy across multiple implementation levers and have a hypothesis built through expert interactions

Levers	Options		Rationale
Sector	Public only	Private + Public	• *Regulation in private likely, which is **90% of the market*** • *Short term, enforcement in **public sector only***
Rx type	INN + Brand/ Company	INN only	• *To ensure adoption from doctors, **Brand** will be allowed to be prescribed*
Molecule	Plain only, FDC excluded	All	• *High resistance from doctors and chemist dispensing challenges to lead to scope for Plain only* • *INN + Brand for FDC also in worst case scenario*
Timelines	5 years	Before 2019	• ***5 years needed** for BA/BE & WHO GMP manufacturing* • *In worst case allow **3 years for BA/BE implementation****
	Best case	Worst Case	

Perspective on IPM | IDMA, Nov. 2017

IQVIA 21

Affordability – Mandatory INN Generics prescription

Vertical integration and consolidation is expected across the value chain with the implementation of INN generics prescription

Changes anticipated in eco-system

1. Retailers are expected to increase their influence in demand generation (through substitution)
2. Consolidation of distribution and chemist channel
3. Large retailers, hospitals and e-pharmacies – are expected launch their own white label brands to maximize profits
4. Large retailers and chains may also have attached physicians writing prescriptions to promote white label sales
5. Corporate branding is expected to gain importance as patients are expected to play key role in brand choice

Perspective on IPM | IDMA, Nov. 2017

IQVIA 22

Affordability – Mandatory INN Generics prescription

Incorrect dispensing, poor quality drugs, trade margins and investment curtailment are expected to be the major challenges

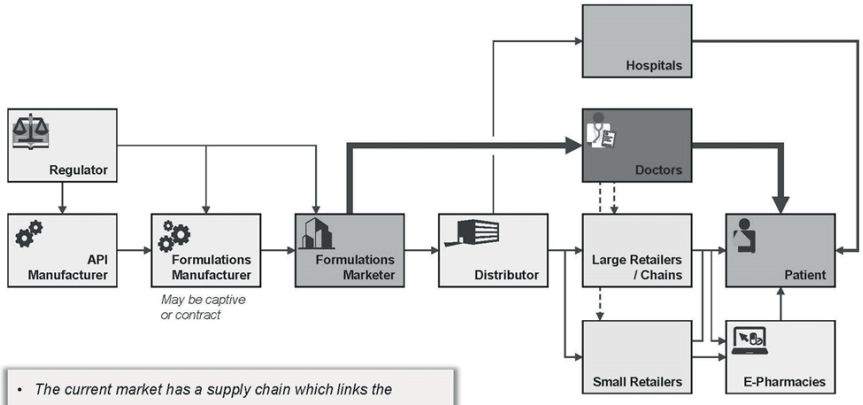
Potential Challenges	Draft Policy Measures
Generic names are complex and drug dispensers may not be adept enough to dispense correctly	Skill development programme for pharmacists
Chemist empowerment may increase prices as they may sell brands with higher absolute margins	Trade margin reforms (capping)
Poor quality drugs may be dispensed due to imperfect quality controls	Mandatory BA/BE studies WHO GMP certification of plants
Financial viability of firms may be impacted affecting investment and decreasing patient access	Shorter approval timelines Incentives for developing new drugs

Perspective on IPM | IDMA, Nov. 2017

IQVIA 23

Affordability – Mandatory INN Generics prescription

Current universe is dominated by brands, where doctors drive demand generation while distributors and retailers fulfil demand



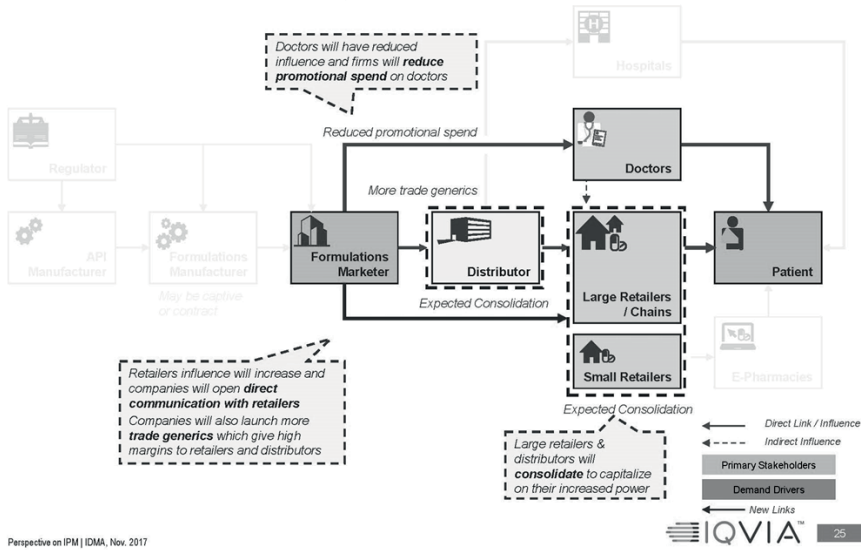
- *The current market has a supply chain which links the marketer to the patient through a distributor and retailer*
- ***Doctors are the key influencers** and remain the key focus for marketers for promotions*
- *Hospitals are key for institutional business*

Perspective on IPM | IDMA, Nov. 2017

IQVIA 24

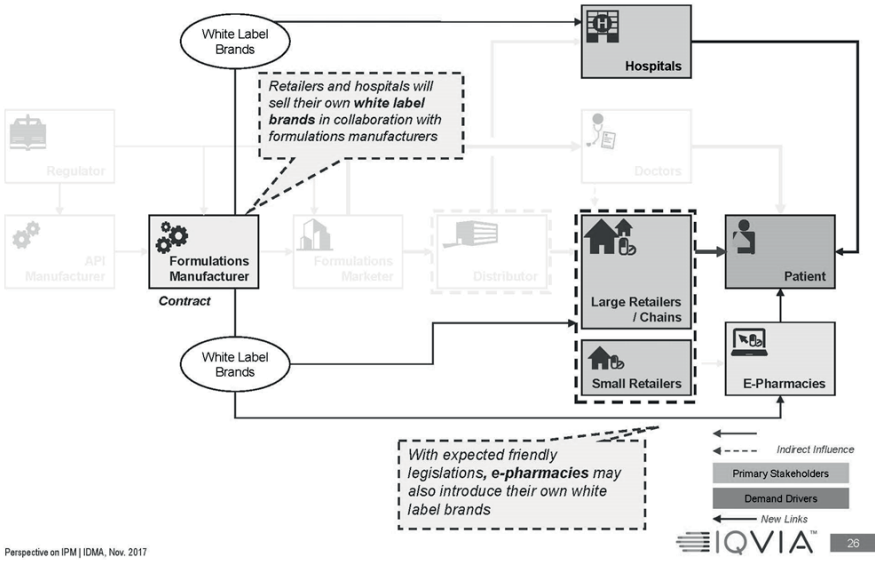
Affordability – Mandatory INN Generics prescription

With the possible new mandate, influence shifts are expected towards retailers; consolidation is expected in distribution & chemist channel



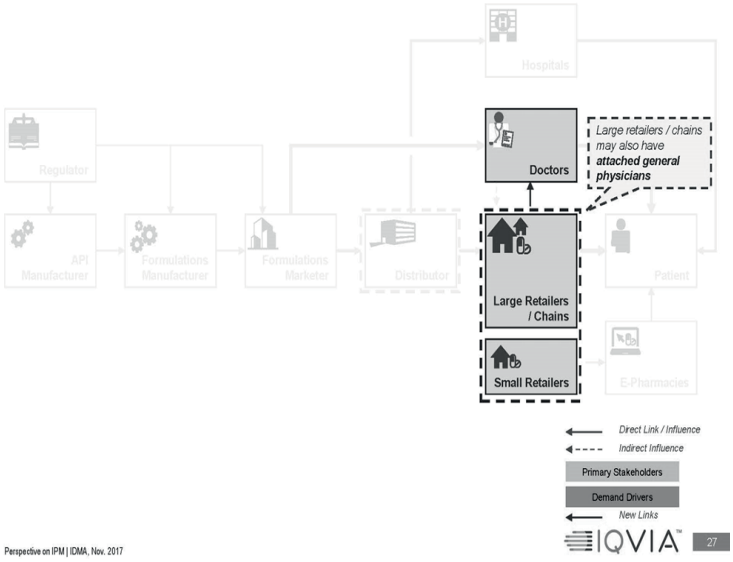
Affordability – Mandatory INN Generics prescription

Large retailers, hospitals and e-pharmacies are likely to launch their own white label brands to maximize profits



Affordability – Mandatory INN Generics prescription

Large retailers and chains may also have attached physicians writing prescriptions to promote white label sales

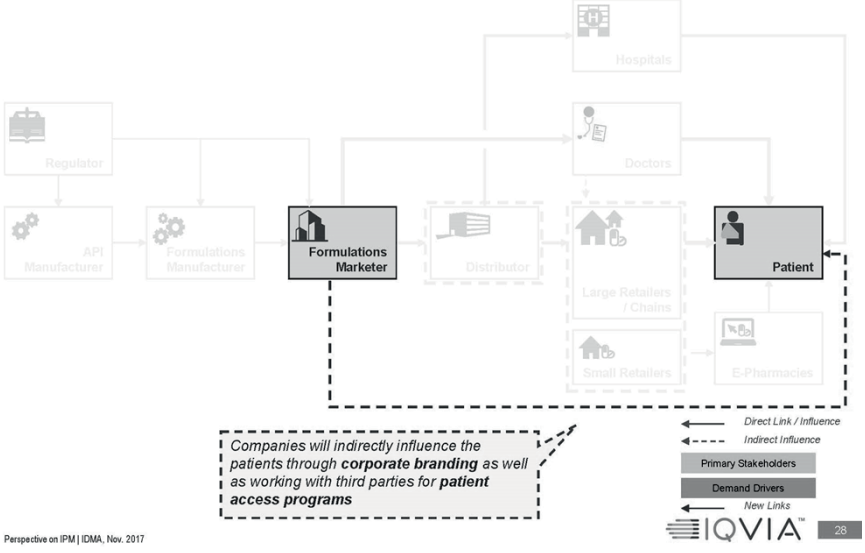


Perspective on IPM | IDMA, Nov. 2017

IQVIA™ 27

Affordability – Mandatory INN Generics prescription

The patients will have the power to choose and corporates would need to create a positive brand image to influence their choice

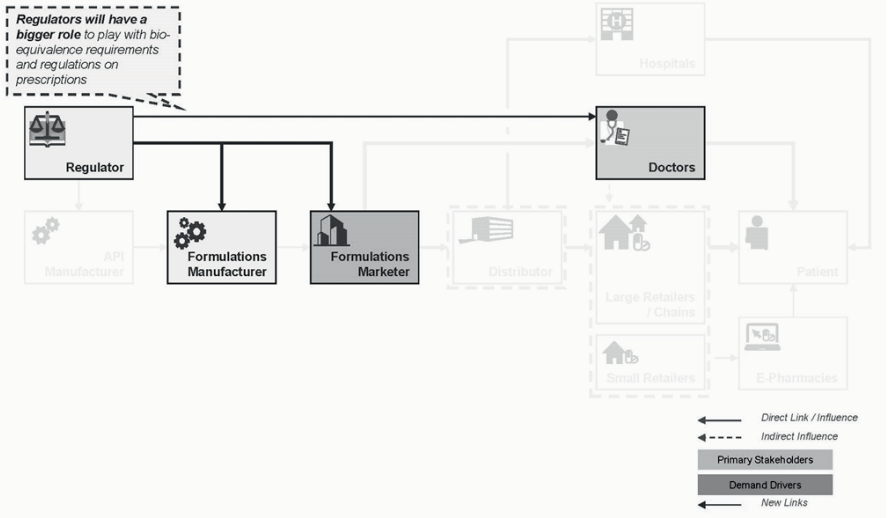


Perspective on IPM | IDMA, Nov. 2017

IQVIA™ 28

Affordability – Mandatory INN Generics prescription

Regulators will be empowered and will play a bigger role in oversight of manufacturers and doctors



Perspective on IPM | IDMA, Nov. 2017

IQVIA 29

Affordability – Multi Branding and Cap on Trade Margins

Multi-branding may continue with same price across the brands; Government expected to follow graded trade margin capping

	Highlights	Potential Challenges	IQVIA View
2	**Multiple brands** of the same molecule manufactured by the same company is marketed **at different prices** • "***One Manufacturer - One Molecule – One Brand – One Price***" principle will be followed discontinuing the multiple brands	• **Many molecules are suitable in more than one TA** • **Different divisions would use different brand names of the same molecule for optimizing their marketing activity**	• Indian pharma companies function in division structure in order to **focus on particular therapy segments** • Players use different brands across the divisions for the molecules with multi therapy benefits for **fixing the accountability of sales** • This helps in realizing the full potential of the molecule by improving the **market reach across TA** • **Multiple brands may continue with same price across the brands** - Price may be determined based on the current lowest price/average price across the brands
3	• Adverse impact of unreasonable **trade margins and/or bonus offers on drugs prices**	• **May impact the availability of the drug in rural India - Daily sales in rural area is low but has comparable overheads as that of cities (due to regulatory requirements)**	• Government is expected to follow Pant committee recommendation of graded margins: MRP (in INR) / Trade margin 50 / 35% 2-20 / 50% <2 / No cap • Rural area operations expected to have higher trade margin considering their lower MRP

Perspective on IPM | IDMA, Nov. 2017

IQVIA 30

Quality – Mandatory BA/BE studies

1 BA/BE studies are expected to become mandatory for BCS class II and IV products with provision of technology transfer

Highlights	Potential Challenges	IQVIA View
• **Mandatory** for all the **manufacturing permissions** accorded by State or Central drug regulator • **Compulsory** for the **renewal of manufacturing** licenses • **Phase wise implementation** to protect the small scale Industries • **Self certification** of BA/BE compliance and manufacturing units • **Annual inspection/audit** of manufacturing plants and BA/BE centers by central drug regulator	**Limited availability of BE centers and volunteers**	• BA/BE study will be mandated for **BCS Class II and IV products** (due to their low solubility) - observed in other ASEAN countries (Philippines) • BA/BE study will be implemented **in phased manner over next 5 years**
	• **Challenge in identification of reference innovator drugs** • **Changes in reference drugs owing to changes in operational techniques, pharmacopeia standards and site**	• Allowing players to refer use **reference products registered in US and Brazil** (implemented in BA/BE requirement in 2013) • **Bio-waiver for few class products** (old molecules) – as per international standards (WHO) • Introduction of **SUPAC (Scale up and Post approval changes) guidelines** so that reference drugs remain "reference" without changes
	Impact on small scale industries	• **Allow technology transfer** reducing the duplication of BE studies – **Inline with the clone generics** in Brazil
	Negative impact on exports	• Waiver for export products and left to the requirements of importing countries
	Dual inspection of state and central authority	• State authorities are expected to continue with inspection responsibility

Companies with products > INR 5 Cr. are expected to conduct independent BA/BE studies while rest of the players are expected to take technology transfer route

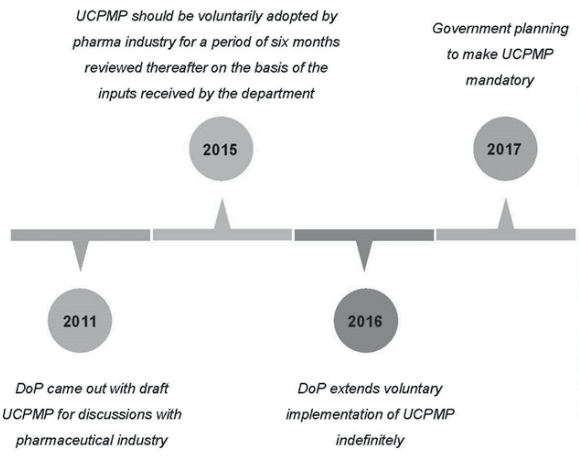
Quality – Other factors

L/L is expected to continue with WHO GMP facilities; Static bar coding is expected to be implemented with financial support

Highlights	Potential Challenges	IQVIA View
2 **Discontinuation of Loan licensing** - since it raises many maintenance and quality issues due to large number of manufacturers Options: • Phasing out over 3 years • Allowed only for WHO GMP plants • Allowed upto 10% of total production of the company	• **Prominent business model for many pharma SMEs – with good manufacturing capability and less marketing ability**	• L/L plants are **also subjected to regulatory approvals** and hence quality issues may not be significant • **Helps in optimizing the plant capacity** – No one can setup its own plant unless plant can be fully utilized • Toll manufacturing is also a prevalent in developed markets • **L/L may continue; but allowed only for WHO GMP plants to control the quality**

3 Compulsory provision of **static bar code** with price information
• **Introduction of bar code reading and computerized billing in distribution and retailing**
	Impact on SME due to required investments in:
	• Changing the packaging to accommodate the serial number
	• Infrastructure to establish the "Parent-Child relation"
	• Handheld scanner across the value chain
		• Many manufacturers already have this system in place
		  • Due to Govt. notification on bar coding of export drugs to control spurious drug with "Made in India" tag
		  • Mar 31, 2017 was the deadline to implement the bar coding
		• For supporting SSI, government is expected to come up with financial aid to implement barcoding

UCPMP code for ethical marketing is likely to be made mandatory by the government



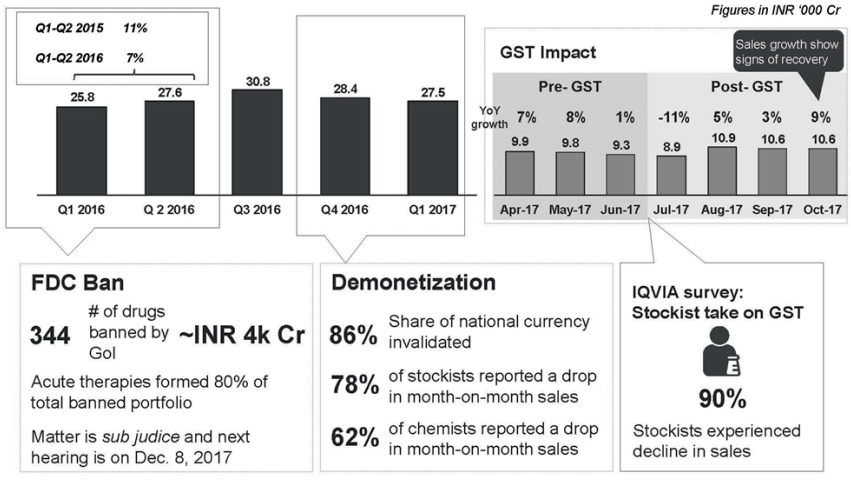
Potential impact of UCPMP

- Gift and trips offered to doctors to the tune of Rs 1,000 only
- Restrictions on marketing promotions around curative abilities and drug efficacy
- Limitations on number of trial samples
- Strict penalties including marketing ban for a year / cash fine of Rs. 10 Cr.

Agenda

- Introduction to IQVIA
- Indian Pharmaceuticals Market: Key trends
- Regulatory scenario and Draft Pharma Policy
- **GST Impact**
- Winning strategies for Pharma players

In addition to regulatory overhang, IPM went through a FDC, Demonetization and GST impact over the last year



FDC Ban

344 # of drugs banned by GoI **~INR 4k Cr**

Acute therapies formed 80% of total banned portfolio

Matter is *sub judice* and next hearing is on Dec. 8, 2017

Demonetization

86% Share of national currency invalidated

78% of stockists reported a drop in month-on-month sales

62% of chemists reported a drop in month-on-month sales

IQVIA survey: Stockist take on GST

90%

Stockists experienced decline in sales

Source: IQVIA data assets; IQVIA Analysis

Perspective on IPM | IDMA, Nov. 2017

IQVIA 35

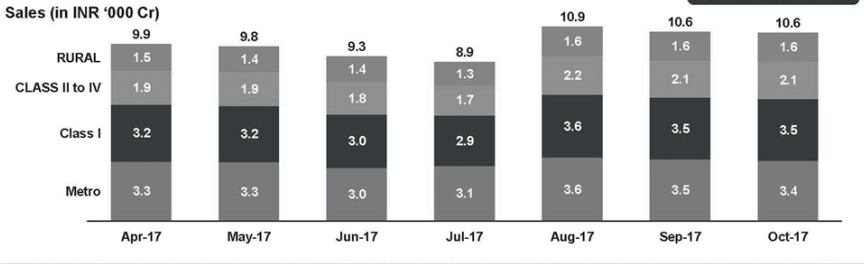
Rural towns were most and Metro the least impacted; the impact was pretty uniform for big and small players

YoY Sales Growth

Figures in INR '000 Cr

Metro	6%	7%	-4%	-6%	5%	4%	6%
Class I	7%	8%	2%	-11%	7%	3%	9%
Class II to IV	8%	10%	5%	-13%	5%	5%	12%
Rural	6%	8%	5%	**-20%**	0%	1%	10%

YoY Sales growth showed signs of recovery

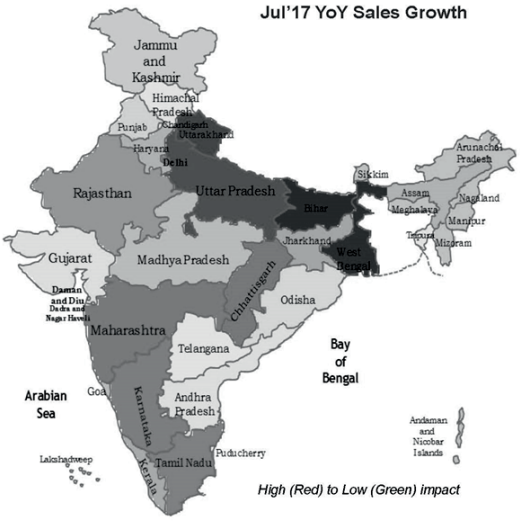


Source: IQVIA TSA MAT Oct 2017, IMSCG Analysis

Perspective on IPM | IDMA, Nov. 2017

IQVIA 36

Impact of GST implementation was more pronounced in Eastern and North Eastern states



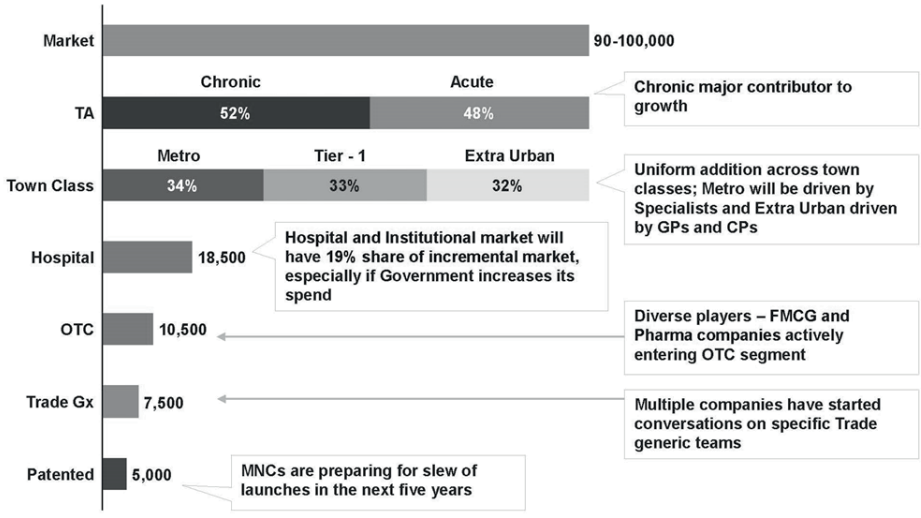
Highlights:

- In July'17, East zone suffered the most with YoY sales decline of 24% compared to national decline of 11%
- Sales decline was worst in UP, Bihar and West Bengal
- Maharashtra, Delhi and Tamil Nadu didn't get impacted by GST and registered positive YoY sales growth
- Among Metros, Kochi, Ahmedabad and Kanpur were among the biggest losers

Agenda

- Introduction to IQVIA
- Indian Pharmaceuticals Market: Key trends
- Regulatory scenario and Draft Pharma Policy
- GST Impact
- **Winning strategies for Pharma players**

Overall, there is significant head room for growth; IPM is likely to add ~90-100,000 Cr. in the next five years



Source: IQVIA data assets; IQVIA Analysis
Perspective on IPM | IDMA, Nov. 2017

IQVIA 39

We have identified few areas where SMEs should actively look for opportunities

- Diversify to include high quality CMO business
- OTx / OTC play
- Trade Gx opportunity
- Institutional opportunity
- Engage beyond physician
- Go Deep Vs Wide
- Managing regulatory risk

Perspective on IPM | IDMA, Nov. 2017

IQVIA 40

ESTABLISHMENT OF PHARMACOVIGILANCE SYSTEM IN PHARMACEUTICAL INDUSTRIES

by

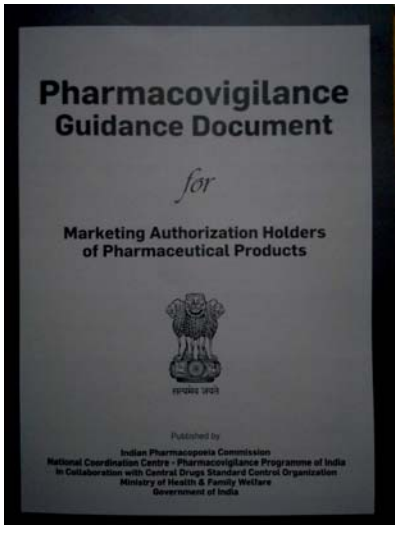
Mr. Rishi Kumar,
Senior Pharmacovigilance Associate, IPC, Gazhiabad, NCC, PvPI

(Lecture delivered during Pharmacovigilance workshop conducted by IPA TN 10th November 2017)

Outline

- Introduction
- Roles and Responsibilities of Authorities
- **Modules**

-Module 1 : Pv System Master File
-Module 2 : Collection, Processing & reporting of ICSRs
-Module 3 : Preparation & Submission of PSURs
-Module 4 : QMS at MAH organization
-Module 5 : Audit and Inspection of Pharmacovigilance System at MAH Organization
-Module 6 : Submission of Risk Management Plan



Reporting Adverse Drug Reactions under D & C Act and Rules 1945

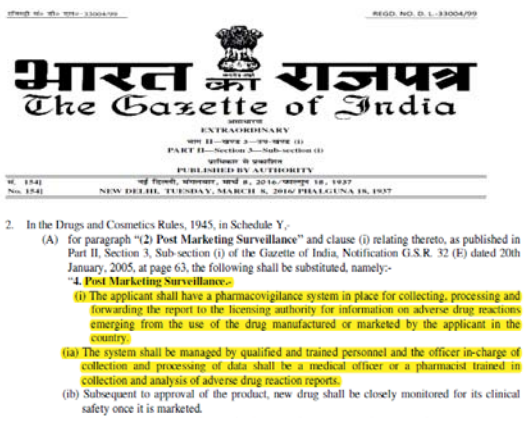
As per the Requirement under sub para (2) of Para 28 of schedule M of Drugs and Cosmetics Act and Rules-

"Reports of serious adverse drug reactions resulting from the use of a drug along with comments and documents shall be forthwith reported to concern licensing authority"

Therefore, It is required under rule to report ADR to licensing authority/NCC-PvPI.

Pharmacovigilance in Drugs & Cosmetics Rules 1945

MoHFW, GoI has amended Drugs & Cosmetics Rules 1945, Schedule Y in which Pharmacovigilance is one of the legal obligations for the Marketing Authorization Holders.



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

भारत का राजपत्र
The Gazette of India

EXTRAORDINARY
PART II—Section 3—Sub-section (i)
PUBLISHED BY AUTHORITY

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.

Post Marketing Surveillance

Post Marketing Surveillance of a Pharmaceutical Product entails:

- Post Licensure Safety Evaluation by Marketing Authorisation holder through
  - Submission of Periodic Safety Update Reports
  - Active/Passive Surveillance
  - Structured Phase IV trial
  - Observational Study

- Pharmacovigilance Programme of India through approx. 250 ADR monitoring Centres located in medical colleges and hospitals

- Quality Monitoring of the marketed product by MA holder and Regulatory system

Pharmacovigilance System

A system used by an organisation to fulfil its legal tasks and responsibilities in relation to pharmacovigilance and designed to monitor the safety of authorised medicinal products and detect any change to their risk-benefit balance .

Quality Objectives of PV System:

- Complying with the legal requirements for pharmacovigilance tasks and responsibilities;
- Preventing harm from adverse reactions in humans arising from the use of authorised medicinal products
- Promoting the safe and effective use of medicinal products,
- Contributing to the protection of patients' and public health

Pharmacovigilance Guidance Document for Marketing Authorization Holders of Pharmaceutical Products

Prepared under the aegis of CDSCO by NCC-PvPI provides guidance to all MAHs of pharmaceutical products (Importers and manufacturers) to establish a Pv system with qualified, trained and experienced manpower to collect and collate AEs/ADRs.

Should conduct decisive causality analysis of the collated AEs/ADRs cases after due investigation, submit to regulatory authority.

Broadly based on Good Pharmacovigilance Practices (GVP) document of EMA and has six modules as guidance for establishing PV system at MAH organization.

Process for Development of Pharmacovigilance Guidelines :

Debated and Suggested to develop a Pv Guidelines on "2nd Interactive Session on Challenges & Issues in ADRs reporting by Pharmaceuticals Industries to PvPI". held on 29th April 2015 at IPC, Ghaziabad .

⇩

NCC-PvPI drafted Pv Guidelines in association with Pharma Industry experts.

⇩

Experts Opinion on Pv Guidelines are obtained from Pharmaceutical Industry and other regulatory authorities.

⇩

Circulated the drafted Pv Guidelines to state licensing members.

⇩

Available in Public Domain for comments.

⇩

Pharmacovigilance Guidance Document for Marketing Authorization Holders of Pharmaceutical Products was launched on 29th September 2017.

Module 01: Pharmacovigilance System Master File (PvMF)

- Pharmacovigilance Officer In-charge
- Pharmacovigilance Organization Structure
- Sources of Safety Data
- Pharmacovigilance Processes
- Pharmacovigilance System Performance

Module 01: Pharmacovigilance System Master File (PvMF)

Pv System Master File (PvMF) includes maintenance, content and associated submissions regarding Pv to competent authorities at organization of MAH.

PvMF shall encompass the list of all approved pharmaceutical products along with the marketing status, approval date and date of pharmaceutical product launched in India.

PvMF shall contain all the information related to MAH's PV system and shall cover the following sections:' and public health

Module 01: Pharmacovigilance System Master File (PvMF)

1. Pharmacovigilance Officer In-Charge (PvOI):

In compliance with Schedule –Y of Drugs and Cosmetics Act, 1940 and Rules 1945, one qualified and trained personnel should be authorized by the company managements as PvOI with responsibilities for collection and processing of AEs/ADRs data following administration of drugs.

PvOI should be a medical officer or a pharmacist trained in the collection and analysis of ADR reports.

Module 01: Pharmacovigilance System Master File (PvMF)

Responsibilities of PvOI:

- Development of training modules & organizing training of staff of Pv system.
- Identification of PV activities and framing of SOPs, revisions of SOPs.
- Establishment & maintenance of QMS of Pv development.
- PvOI should reside in India and respond to queries of regulatory authority whenever required.
- PvMF should contain contact details, CV and description of responsibilities of PvOI.

Module 01: Pharmacovigilance System Master File (PvMF)

2. Pharmacovigilance Organization Structure:

Pv organizational structure of the MAH/ CRO's showing the hierarchy of the Pv department, Name and address of Pv site, and delegated activities.

3. Source of Safety Data:

PvOI shall be responsible to collect data, reports, publications related safety of all pharmaceutical products marketed by the MAH.

Module 01: Pharmacovigilance System Master File (PvMF)

4. Pharmacovigilance Processes

- Description and flow diagram of the entire Pv process.
- Data handling, records and archives of Pv performance and SOPs for all the processes.
- Location, functionality and operational responsibility for computerized systems and databases for receiving, collating and reporting safety information should be described in PvMF.
- Description of quality management system including document and record control, training and auditing should be documented in PvMF.

Module 01: Pharmacovigilance System Master File (PvMF)

5. Pharmacovigilance System Performance:

Key indicators for the performance of Pv system e.g. number and quality of ICSRs, CAPA needs to be identified and measured for annual trend analysis.

PvMF should contain evidence of the ongoing monitoring of the Pv system performance, including compliance of the main Pv output.

Module 01: Pharmacovigilance System Master File (PvMF)

Annexures to the PvMF:

- A list of pharmaceutical products covered by the PvMF, including the name of the pharmaceutical product and active substances.
- A list of all contract agreements covering delegated activities, including the pharmaceutical products and territory concerned.
- A list of tasks delegated by the PvOI for Pv.
- A list of all completed audits and list of audit schedules.

Module 2: Collection, Processing & Reporting of ICSRs

Under reporting of AEs/ADRs is well known problem associated with spontaneous reporting.
Different methods/sources required to be established by MAHs to strengthen spontaneous reporting of AEs/ADRs

1. Collection of ICSRs

Medical inquiries
"Contact us", emails and website enquiries forms
MAH employees
Contractual Partners
Information on AEs/ADRs from the internet or digital media
Solicited reports
Miscellaneous sources for reporting

Module 2: Collection, Processing & Reporting of ICSRs

2. Literature Monitoring

Scientific and medical Literature

3. Follow up of ICSRs

Suspected medications:

- Details of suspected medications such as brand name, manufacturer batch number, expiry date, authorization holder, dose route, frequency etc.
- De-Challenge details
- Action Taken
- Re-challenge details
- Concomitant drugs
- Relevant laboratory data
- Other relevant history

Module 2: Collection, Processing & Reporting of ICSRs

Seriousness of the reaction :

Death, Life threatening, Hospitalization/prolonged, Disabling, Congenital anomaly, Other medically important conditions

Outcomes :

Recovered/Resolved, Not Recovered/Not Resolved, Fatal, Recovering, Recovered with sequele.

Module 2: Collection, Processing & Reporting of ICSRs

Reporter:

Name and professional address, Date of report, Reporter qualification

Coding:

For the purposes of ICSRs reporting (expedited and periodic) to regulatory authority, MAHs are required to code ADRs using the ADRs' coding dictionary and indication of suspected & concomitant drug using the latest version of ICD.

Reporting Time Frames:

- All serious Unexpected Adverse Reactions must be reported to Licensing Authority within 15 days of initial receipt of the information by the applicant.

Module 2: Collection, Processing & Reporting of ICSRs

- All serious AEs/ADRs (like lack of efficacy, medication error etc.) must be reported to the NCC-PvPI, IPC and CDSCO within 15 days of initial receipt of the information by the MAHs.
- Non-serious AEs/ADRs must be reported to the NCC-PvPI, IPC and CDSCO within 30 days of initial receipt of the information by the MAHs.

Causality Assessment

Special Population

Module 3: Preparation & submission of PSUR

Periodic Safety Update Report is document for evaluation of the benefit –risk profile of a pharmaceutical product submitted by the MAH at defined time points as per D & C Act and Rules during post marketing phase.

Structure & Content:

The recommended content of the PSUR should have data as per Schedule Y of D & C Act and Rules , section (4) Post-marketing Surveillance and ICH-E2C (R2) guideline.

Module 3: Preparation & submission of PSUR

1. Title Page
2. Introduction
3. Current worldwide marketing authorization status
4. Update of actions taken for safety reasons
5. Changes to Reference safety Like PIL, CCDS & SmPCs
6. Estimated Patient Exposure
   - 6.1 Cumulative subject exposure in clinical trials
   - 6.2 Cumulative & interval patient exposure from marketing experience in India
   - 6.3 Cumulative & Interval patient exposure from marketing experience from rest of the world

Module 3: Preparation & submission of PSUR

7. Presentation of Individual Case Histories

7.1 Line listing of individual cases received from India

7.2 Line listing of individual cases received from rest of the world.

7.3 Cumulative summary tabulations of SAEs from clinical trials.

7.4 Cumulative & interval summary tabulations from Post marketing data sources

Module 3: Preparation & submission of PSUR

8. Studies

8.1 Summaries of significant findings from clinical trials during the reporting period

8.2 Findings from non-interventional studies

8.3 Information from other clinical trial sources

8.4 Findings from non-clinical studies

8.5 Findings from literature

Module 3: Preparation & submission of PSUR

9. Other Information:

9.1 Lack of efficacy in controlled clinical trials

9.2 Late Breaking Information

9.3 Overview of signals: New, Ongoing, or Closed

10. Overall Safety Evaluation:

10.1 Signal & Risk Evaluation

10.2 Benefit Evaluation

10.3 Benefit –Risk Analysis Evaluation

11. Conclusions

12. Appendix to the PSUR

Based on the evaluation of cumulative safety data and the benefit risk analysis, the MAH should assess the need for further change to reference information and propose changes as appropriate.

Module 3: Preparation & submission of PSUR

1. Title Page
2. Introduction
3. Current worldwide marketing authorization status
4. Update of actions taken for safety reasons
5. Changes to Reference safety Like PIL, CCDS & SmPCs
6. Estimated Patient Exposure

6.1 Cumulative subject exposure in clinical trials

6.2 Cumulative & interval patient exposure from marketing experience in India

6.3 Cumulative & Interval patient exposure from marketing experience from rest of the world

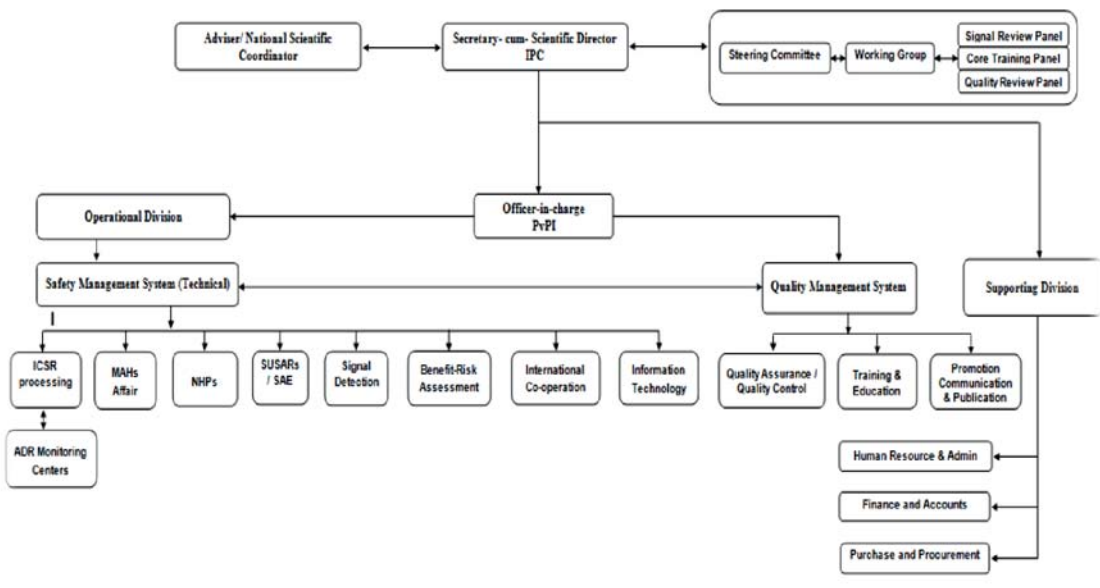
Module 4: Quality Management System at MAH's Organization

MAHs organizational structure - organogram describing Pv system as well as appropriate resource management, compliance management and record management.

Salient Features of QMS:

- MAH shall have a sufficient number of competent and appropriately qualified and trained personnel for the performance of Pv activities.
- All personnel involved in the performance of Pv activities shall receive initial and continued training.
- Facilities and equipment which are critical for the conduct of Pv should be subject to appropriate checks, qualification and/or validation activities to prove their suitability for the intended purpose.

Organogram



Module 4: Quality Management System at MAH's Organization

- Continuous monitoring of Pv data, the examination of options for risk minimization and prevention, appropriate measures are taken by the MAH
- Effective communication with regulatory authority, including communication on new or changed risks, the PvMF, risk management systems, PSURs and CAPAs
- Recording of all Pv information and ensure that it is handled and stored so as to allow accurate reporting, interpretation and verification of that information

Module 4: Quality Management System at MAH's Organization

- Hard copies should be retained for a minimum of 10 years and soft copies to be stored indefinitely.
- All elements requirements and provisions adopted for the quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures.
- Performance indicators to be used continuously for monitoring and effective performance of Pv activities.

Module 5: Audit & Inspection of Pv Systems at MAH's Organization

- Planning, conducting, reporting and follow up of Pv inspections by officials responsible for inspection
- Pv inspections programmes will be implemented, which will include

Routine inspections (risk based approach)

"For Cause" inspections, (triggered, suspected non-compliance or potential risk, impact on specific products)

Module 5: Audit & Inspection of Pv Systems at MAH's Organization

- Inspections report and findings with classification of report as critical, major and minor.
- Regulatory action will be taken depending on the potential negative public health impact of non compliances..

Module 6: Submission of Risk Management Plan

Overall aim of risk management is to ensure that the benefits of a particular pharmaceutical product exceed the risks by greatest achievable margin for the individual patient and for the target population as a whole.

Objectives of RMP:

- Identify or characterize the safety profile of the pharmaceutical (s) concerned.
- Indicate how to characterize further the safety profile of the pharmaceutical product concerned.

Module 6: Submission of Risk Management Plan

- Document measures to prevent or minimize the risks associated with the pharmaceutical product including assessment of the effectiveness of those interventions.
- Document post-marketing obligations that have been imposed as a condition of the marketing authorization.

RMP is a dynamic, stand alone document which should be updated throughout the life cycle of the pharmaceutical products.

RMP of every product should be approved by the regulatory authority and should be updated as and when required.

MAHs-Orders & Circulars

Gazette Notification for MAHs:**Pharmacovigilane: A Legal obligation.**
MoHFW, GoI has amended Drugs & Cosmetics Rules 1945, Schedule Y in which Pharmacovigilance is one of the legal obligations for the Marketing Authorization Holders (MAHs).

Orders & Circulars:

- Office order dated 18th May, 2015 issued by NCC-PvPI, IPC, for The Pharmaceutical Industries are hereby informed to submit Adverse Drug Reactions (ADRs) due to their respective pharmaceutical product to NCC-PvPI, IPC, in E2B-xml format to hasten the process of uploading Individual Case Safety Reports (ICSRs) in VigiFlow, a WHO-UMC, Web database.
- A letter dated 26th October, 2016 issued by MoHFW, GoI to all state Principal Secretaries of (Public Health and Family Welfare), regarding the strengthening of Pharmacovigilance by sensitizing and advising all clinicians and other HCP under their jurisdiction to mandatorily adopt reporting of ADRs to NCC-PvPI, IPC.
- Office Memorandum dated 22nd November, 2016 issued by Drug Controller General (India) for Periodic Safety Update Report regarding its review and evaluation to be done jointly by CDSCO and NCC-PvPI,IPC.

PSURs Office Memorandum

File. No 12-01/16-DC (Pt-151)
Central drugs standard control organization
Directorate General of Health Services
FDA Bhavan, New delhi
(New Drugs Division)

Date: 22.11.2016

Office Memorandum

Subject: Review/ Evaluation of PSURs data-reg.

As per requirements of Schedule Y of Drugs and Cosmetics Rules, subsequent to approval of the product, new drugs should be closely monitored for their clinical safety once they are marketed. The applicants are required to furnish Periodic Safety Update Reports (PSURs), every six months for the first two years after approval of drug is granted to the applicant, and annually for subsequent two years.

Evaluation of PSURs is a part of post marketing surveillance and overall pharmacovigilance activity and PvPI in IPC, the National Coordination Centre (NCC) is responsible for collection of spontaneous Adverse Drug Reactions (ADRs) from the ADR monitoring centres across the country and to collect, collate, analyse and identify new signals of any, for regulatory interventions by CDSCO, whenever necessary.

In view of above, it has been decided in consultation with the ministry that PSURs submitted by the marketing authorisation holders may be jointly evaluated by officials from CDSCO and PvPI at regular intervals and whenever required expert opinion may be taken from the subject experts. Finally, the divisional head of the said new drug (which is under evaluation with respect to PSUR) shall be responsible and may lead the collection, collation, analysis and final regulatory intervention/disposal of PSURs.

(Dr. G.N.Singh)
Drugs Controller General (I)

To

Pharmacovigilance Programme of India, IPC, Ghaziabad.

Copy to: PPS.
AS (F&D)
JS (R)

Reporting of ICSRs & PSURs

MAHs sent ICSRs in E2B, XML format to our Official Mail ID:pvpi@ipcindia.net, pvpi.ipc@gov.in

MAHs sent PSURs in PDF format to our Official Mail ID:pvpi@ipcindia.net, pvpi.ipc@gov.in

Future Plan

- Reporting of ICSRs to PvPI by MAHs should be mandatory & harmonized (i.e E2B, xml format).
- Updated SmPC/PIL for domestic marketed pharmaceutical products should be submitted to PvPI & also uploaded on their web portal of MAHs.

Future Plan

- Benefit-risk analysis.
- MAHs Interactive sessions&Regional Workshop Meetings.
- Implementation of Pharmacovigilance system at applicant site as per recent Gazette notification from MoHFW.
- Regular audit /inspection of MAHs to assure good pharmacovigilance system.
- Review & Evaluation of PSURs.

WHY A COMMUNITY PHARMACIST IS AN IMPORTANT PART OF HEALTH CARE TEAM

by
Mr. K. Arulraj
Sri Ram Nallamani Yadava College of Pharmacy, Tenkasi

Note: This article was awarded 1st prize in the Essay Competition conducted by our Trust

INTRODUCTION: A retail pharmacy practice that deals with service of dispensing prescription directly to the public. Sell over the counter (OTC) product more technicians and pharmacist are employed in community pharmacist are than any other area .The role of community pharmacist and in counselling and education patient is steadily increasing. Add more responsibility to dispense by community pharmacist.

COMMUNITY PHARMACIST ROLE: Aid the pharmacist in the filling, labelling, and recording of prescription .operate and responsible for the pharmacy cash register. Stock and inventory prescription and over the counter (OTC) medication. Maintain computerized patient record prepare insurance claim forms. Order and maintain party of the front end stock.

IN PROCESSING PRESCRIPTIONS: The pharmacist verifies the legality safety and appropriateness of the prescription order ,checks the patient medication record before dispensing the prescription (when such records are kept in pharmacy),ensures that the quantities of medication are dispensed accurately ,and decides whether the medication should be handed to the patient ,with appropriate counselling ,by a pharmacist.

CLINICAL PHARMACY& PATIENT CARE: The pharmacist seeks to collect and integrate information about the patient's drug history, dosage regimen .Patient drug history, mode of administration, precaution, adverse drug reaction, food interaction, advices.

DRUG MONITORING: As practise research project and schemes to analyse prescriptions, for the monitoring of adverse drug reaction.

EXTEMPORANEOUS PREPARATION: Pharmacist engages in the small scale of medicine, which must accord with good manufacture and distribution practice guidelines.

ALTERNATIVE MEDICINES: In some countries pharmacist supply traditional medicines and dispense homoeopathic prescription.

CHECKING SYMPTOMS OF MINOR ALIMENTS: Pharmacist can supply a non-prescription, medicine with advice to consult a medical practitioner if the symptoms persist for more than a few days .Alternatively, the pharmacist is may give advice without supplying medicine.

COUNSELOR: The pharmacist provides an advisory as well as a supply service to residential homes for the elderly, and other long term patients. In some countries policies are being developed under which pharmacists will visit certain categories of house bound patient the counselling service that the patient would have received had they been able to visit the pharmacy.

RESPONSIBILITY OF COMMUNITY PHARMACIST: Dispensing prescription /appropriate filling of prescription by patient drug history. Revisiting the prescription for correctly spell, label, interaction right drugs etc.

CHRONIC DISEASE MANAGEMENT AND PREVENTION: Community pharmacy interactions can improve. Respiratory function and use of medicines in patient with asthma. Improve the management of other chronic disease such as diabetes.

PATIENT CONFIDENTIALITY, RESPECT THE CUSTOMER PRIVACY: A pharmacist technician must be sensitive to maintain patient privacy confidentiality of medical information, and compliance with all state and federal HIPAA regulation.

HEALTH CARE PROFESSIONALS: Provide the information as necessary to other health care professionally and to patients, and use in promoting the rational use of drugs, by providing advice and explanation to physician and to member of the public.

HEALTH PROMOTION: The pharmacist can take part in health promotion campaigns, locally and nationally on a wide range of health related topics (e.g. rational) use of drugs ,alcohol abuse, tobacco use ,discouragement of drug use during pregnancy, organic solvent abuse position prevention) or topics concerned with other health problems (diarrhoea disease, tuberculosis, leprosy, HIV infection /AIDS) and family planning.

HEALTHY EATING AND LIFE STYLE ADVICE: Needs to target patient with chronic disease as part of the national strategy, weight reduction programmes, detect and manage obesity, advice on diet and physical activity.

In commissioning public health service from community pharmacies, some of the service will be associated with the supply of a medicine.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY: All health facilities that access store, maintain or transmit patient identifiable medical information must comply with these regulation.

SENSITIZING AND CREATING AWARENESS AMONG THE PUBLIC: Carrying out seminars, exhibition consumer awareness programme etc., Publishing books, pamphlets, patient information leaflets etc., Patient information and counselling.

DEADDICTION SERVICES BY PHARMACIST: Alcohol DE addiction, Tobacco DE addiction, counselling patient on DE addiction.

NATIONAL PROGAMME FOR CONTROL OF VECTOR BORNE: Ensuring rational use of prescribed medicines. Counselling on malaria/transude malaria. Providing consumer health information& other IEC material. Pharmacist can act as medicine provide for malaria and dengue.

ROLE OF PHARMACIST: Early detection & prompt referral for treatment by, identifying symptomatic cases. Referring to diagnostic center, drug distribution center (DDC)fever treatment depots (FTDS)etc.

INFORMING HEALTH CARE PROFESSIONALS AND THE PUBLIC: The pharmacist can compile and maintain information an all medicines, and particular on newly introduced medicines, provides this information as necessary to other health care professionals and to patient, and used it in promoting the rational use of drugs, by providing advice and explanation to physicians and members of the public.

AGRICULTURAL AND VETERINARY PRACTICE: Pharmacist supply animal medicines and medicated animal feeds.

CONCLUSIONS: In the health care system, pharmacist is underutilized because community pharmacy and pharmacy practice are yet to be established strongly and pharmacist working in community pharmacies do not provide patient counselling in the usual situation. We need to work closely with the pharmacist associations and share our common experiences and frame appropriate guideline for India so that community pharmacist who plays a major role providing better health care can be recognized. Every community pharmacist should always remember, the following lines:

"Do all the good you can, In all the ways you can;
In all the places you can, At all the times you can;
To all the people you can, As long as ever you can".

EVENTS

Pharma Knowledge and Training Institute (Finishing School)
5th Training on
Industrial Orientation Training for Production and Quality Management Personnel

The 5th Training programme for the fresh Pharmacy graduates by Pharma Knowledge and Training Institute (Finishing School) under the aegis of Tamilnadu Pharmaceutical Sciences Welfare Trust was held at Trust premises in Spencer Plaza, Anna Salai, Chennai from **6th September 2017 to 26th September 2017.** The total 26 trainees from, Madras Medical College, Chennai, Jaya College of Pharmacy, Chennai, PSG College of Pharmacy, Coimbatore, SRIPMS, Coimbatore, Karpagam College of Pharmacy, Coimbatore, E.G.S. Pillay College of Pharmacy, Nagapattinam, M.S.A.J. College of Pharmacy, Chennai students were trained in this training programme. The students were given training both theoretically and practical on the subject of **"Industrial Orientation Training on Production and Quality management Personnel"**. The following subjects were taught as theory and practical during this training programme.

Theoretical Training Programme

- Overview of the Pharmaceutical Industry and Job opportunities for the Pharmacy graduates.
- Regulatory Requirements of Production and QC under Drugs & Cosmetics Act and Rules, Role of Govt. Drug Testing laboratories.
- Good Manufacturing Practices under Schedule "M" of Drugs & Cosmetics Act in respect of Production, Quality Control, and Maintenance of record of Drugs & Pharmaceuticals.
- What is Pharmacopoeia, various Pharmacopoeias used world over, how to use pharmacopoeia, monographs, their explanation & general notices in Pharmacopeia and Reference Standards.
- What is quality and why it is essential for manufacture of products. Quality Control and its Relationship, with Quality Assurance, Production, R&D and regulatory divisions of Pharma Industry, what are the various divisions of Quality Control.
- cGMP's for manufacturing including entry & exit procedures.
- Plant Design & Site Master File.
- ICH guidelines for production & Quality Control of Pharmaceuticals.

- Documentation and records in Production and QC
- Standard Operating Procedures
- Sampling of Raw Materials, Packing materials, In- process Materials and Finished products.
- Ointments, Creams, Emulsions, Gargle solutions, Sanitizers, etc Different types of equipment used for their manufacture, Ingredients used and in-process tests to be carried during their production. Packing of the above products.
- Calibration of QC equipments, Reference Standards and Working Standards, Reference / retention samples storage.
- Good Laboratory Practices - Schedule L1
- IQ, OQ, PQ and DQ of equipments of Production & QC, Validation, Qualification and calibration
- Market complaints, CAPA, OOS and OOT etc., what is containment? Essential steps to control contamination, handling of deviation, Risk Assessment.
- Change control, Deviation control and their importance.
- Data Integrity of documents in the Pharmaceutical Industry.
- Selection of Packing Materials like Bottle packing, Strip Packing, Blister Packing etc and selection of different materials according to stability of products Viz: tablets & Capsules, Powders etc.
- Basic Calculations in Quality Control, Dilutions and Statistical Analysis, Qualitative Analysis, Quantitative Analysis & Elemental Analysis.
- Procedure and Validation of environmental monitoring, Plate exposures, Air sampling, etc., in manufacturing of Sterile Pharmaceutical products.
- Introduction to Theory of Chromatography & Spectrophotometry.
- TLC Gas Chromatography (GC), High Performance Liquid Chromatography (HPLC) a brief introduction.
- Air Systems, Water Systems, their sampling and testing.
- Microbiology - An Introduction, Microbiology for non-sterile preparations.
- Dissolution & its Importance, Methods used in Dissolution Testing.

- Different types of Oral Liquid Dosage Forms such as Liquids, Syrups, Suspensions & Emulsions etc. Facilities required and their methods of manufacture, in process tests to be carried out during their manufacture.
- Batch Manufacturing Records, Batch Packing Records and importance of online recording Basics of production planning & Inventory Control.
- General requirements for Tablets, Capsule, Oral liquids & external preparations.
- Stability Testing, Accelerated and Real Time Studies, Packaging Material Stability, Their Testing, Their Importance with Respect to the Product Stability.
- Quality by Desigh (QbD)
- Powders for Dry Syrups: Main ingredients with examples of various materials used, equipment used for their manufacture, In process tests to be done, and their packaging Effervesant Powders their main ingredients their manufacture and packing
- Oral Rehydration Powders(ORS), Equipment used for their manufacture, WHO approved formula, Materials used for formulation of ORS, in process tests to be done and packing of ORS powders-
- Preparation and Standardization of Herbal Formulations.
- Capsules - Processes involved in the production of Capsules such as size reduction, sieving, granulation, Filling, Cleaning & Polishing etc., Various components of Capsules with examples of different materials used. Different sizes of Capsules available in the market,Filling of Capsules: hand filling, Machine Filling High speed filling Machines, In process tests to be carried during production of Capsules, How to control and rectify (in case of failure) weight variation, Disintegration time, Dissolution etc during production of Capsules.
- Analytical method validation
- Tablets - Processes involved in the production of Tablets such as size reduction, sieving, granulation, compression, coating etc., Various components of a Tablet with examples of different materials used &, In process tests to be carried during production of Tablets.
- Types of tablets such as Plain Tablets, Press Coated Tablets, Tablet in Tablet, Film Coated Tablets, Enteric Coated tablets, Delayed Release tablets etc, their advantages , How to control and rectify (in case of failure) weight variation, Disintegration time, Hardness, Friability, Dissolution etc during production , Different types of Coating of Tablets, Materials used for coating & coating process.

- Preventive maintenance, Predictive maintenance & Break down maintenance.
- Soft Skill

The above subjects were taught by well experienced senior level pharma industry manufacturing and quality assurance technical personnel through power point presentation. The faculties who had taken theory classes on the above subjects are as follows.

Mr. J. Jayaseelan, Managing Director M/s. Sai Mirra Innopharm Pvt Ltd.

Dr. G. Selvaraj, Director of Drugs Control (Retd), Tamilnadu.

Dr. N. Murugesan, Director, CDTL, Chennai.

Mr. P.R. Abdul Hameed, Executive Director - Technical, M/s. Medopharm

Mr. Sanjay Kumar Dasmohapatra, Vice President – Technical & Operations, M/s. Medopharm

Mr. K. Saravana Kumar, Corporate – QA Head, M/s. Fourrts (India) Labs Pvt. Ltd.

Mr. D. Srinivasa Rao, GM – Plant Operations, M/s. Apex Laboratories P Ltd.

Mr. N. Chandar, Pharma Consultant,

Dr. D. Natarajan, Pharma Consultant

Mr. V. Arul Selvan - Manager – QC, M/s. Apex Laboratories P Ltd .

Dr. Ramesh Viswanathan – GM & Head – QA & QC, M/s. Allianz Biosciences Pvt Ltd.

Mr. S. Saravanan, IICMS (Indian Institute of Chromatography and Mass Spectrometry)

Mr. V. Saravanan, IICMS, Chennai

Dr. Devasena Kannan, IICMS, Chennai

Mr. S. Jaya Kumar, Head – Quality, M/s. Apex Laboratories Pvt Ltd.

Mr. Mujibur Rahman, Asst Manager – Microbiology, M/s. Fourrts (India) Labs Pvt. Ltd.

Mr. K. M. Sridhar, Head – Quality Control (Plant I), M/s. Fourrts (India) Labs Pvt. Ltd.

Mr. M. Radhakrishnan, Senior Manager – Production, M/s. Fourrts (India) Labs Pvt. Ltd.

Mr. D. Satish Kumar – Senior Manager – Production, M/s. Fourrts (India) Labs Pvt. Ltd.

Mr. S. Murali - GM – Plant Operations, M/s. Apex Laboratories P Ltd.

Mr. M. Ramalingam, Head (Plant II), M/s. Fourrts (India) Labs Pvt. Ltd.

Dr. R. Venkidesh, GM – Quality Control, M/s. Saimirrah Innopharm Pvt. Ltd.,

Mr. S. Ganesan, GM – Works, M/s. Tablets (India) Ltd.

Dr. R. Ilavarasan, Dr. R. Ilavarasan, Assistant Director (S-3) Institute In-charge,
Captain Srinivasa Murthy Regional Ayurveda Drug Development Institute, Chennai.

Mr. M. Sridhar, Head – Production, M/s. Fourrts (India) Labs Pvt. Ltd.

Mr. G.T. Arularasu, Head – Quality Control (Plant II), M/s. Fourrts (India) Labs Pvt. Ltd.

Mr. S. Sridhar, Vice President – Woks, M/s. Medopharm (Malur Plant).

Mrs. Swetha, Manager, L & D, Ripe Consulting Services Pvt. Ltd., Chennai

Practical Training

M/s. Fourrts (India) Laboratories Pvt. Ltd., Plant 1 & Plant 2, Chennai, M/s. Apex Laboratories Pvt. Ltd.,Alathur, Chennai, M/s. Medopharm, Guduvanchery, Chennai, M/s. Tablets (India) Ltd., T H Road, Chennai, M/s. Sai MirraInnopharm Pvt. Ltd., Ambattur, Chennai and M/s. The Madras Pharmaceuticals, OMR, Chennai, offered their facilities for practical training to the trainees for 10 days.

Evaluation

All the trainees were evaluated after each of the lecture programme as well as on the final date of completion of the programme on the basis of the evaluation these students were given 4 merit awards given during the valedictory function.

Valedictory Function

The Valedictory function was held on **26th September 2017.** The Chief guest of the function was Mr. R. Srinivasen, Trustee, Vice-Chairman, C.L. Baid Metha College of Pharmacy, Chennai and the guest of honour Prof. K. Elango, MMC, Chennai. Mr. R. Narayanaswamy, Director, PKTI Welcomed the gathering and explained about the 5thtraining programme. Certificates were distributed all the trainees. Mr. N. Sreenivasen, Secretary, TNPSWT proposed vote of thanks.

Placement Interview

Placement interview conducted for the trainees on 27th September 2017 and the participants companies were M/s. Fourrts (India) Laboratories Pvt. Ltd., Chennai, M/s. Apex Laboratories Pvt. Ltd., Alathur, Chennai, M/s. Medopharm, Guduvanchery, Chennai, M/s. Sai MirraInnopharm Pvt. Ltd., Ambattur, Chennai, M/s. The Madras Pharmaceuticals, OMR, Chennai, M/s. Pharm Products Pvt Ltd, Tanjavur.

All the trainees who are interested in job got the placement.

PKTI – 5th Training Programme

Lecture by Mr. J. Jaysseelan

Lecture by Mr. Sanjay Kumar Dasmohapatra

Lecture by Mr. K. Saravanakumar

Lecture by Mr. S. Jayakumar

Felicitation to Mr. S. Sridhar

Group Photo of the Trainees

Prize distribution to the trainees

Prize distribution to the trainees

Workshop on Pharmacovigilance

Address by Mr. S. V. Veeramani

Lecture by Mr. Rishi Kumar

Audience of the PvPI Programme

Address by Mr. J. Jayaseelan

Workshop on Pharmacovigilance

Pharmacovigilance system to become a mandatory for Pharmaceutical manufacturing from January 2018, the Indian Pharmaceutical Association Tamilnadu Branch organised a **"Workshop on Pharmacovigilance and Establishment of Pharmacovigilance System in Pharmaceutical Industries"** jointly with Indian Drug manufacturers Association, Tamilnadu, Puducherry, Kerala State Board on 10th November 2017 at Chennai & 11th November 2017 at Puducherry

10th November 2017(Chennai): The Chief guest of the programme is Mr. S. V. Veerramani, Past President, IDMA, Mumbai, Chairman & Managing Director M/s. Fourrts India Laboratories Pvt Ltd., Chennai. This programme was presided over by Dr. S. Manivannan, President, IPA TN Branch. 90 participants were attended this programme. The function concluded by vote of thanks by Mr. J. Jayaseelan, vice President, IPA TN Branch.

11th November 2017 (Puducherry): This programme was presided over by Dr. S. Manivannan, President, IPA TN Branch. Mr. J. Jayaseelan, Vice president, welcomed the gathering. 70 participants were attended this programme.

Mr. Rishi Kumar, Senior Pharmacovigilance Associates, Indian pharmacopoeia Commission, Gazhiabad gave the lecture in both the places.

In his address, the PV system, which is set up based on sub para (2) of Para 28 of Schedule M of Drugs and Cosmetics Act and Rules, reports of serious adverse drug reactions resulting from the use of a drug, along with comments and documents, should be henceforth reported to the concerned licensing authority or to the National Coordination Centre of the PvPI.

He said the PV system, set up by the industry, should consist of facilities for collection, processing and forwarding the reports to the licensing authority for information on adverse drug reactions emerging from the use of the drug manufactured or marketed by the applicant (industrial unit). Besides, the system should be managed by qualified and trained personnel, and the officer in charge of the collection and processing of data must be a medical officer or a pharmacist trained in ADR reporting.

The PV system will comply with the legal requirements for pharmacovigilance tasks and responsibilities. It will prevent harm from adverse reactions in humans arising out of the use of authorised medicinal products, promote the safe and effective use of medicinal products and contribute to the protection of patients and public health.

In this programme industry personnel were able to clear their doubts on the new ADR reporting mechanism.

National Pharmacy Week Celebration – IPA TN Branch

The 56th National Pharmacy Week (NPW) was celebrated from 19th to 25th November, 2017

The theme selected for this year is: **"Know your Medicines: Ask your Pharmacist"**.

Seminar at Arulmigu Kalasalingam College of Pharmacy

As the initiative of Pharmacy week by IPA TN Branch, one day National seminar was organised on 18th November 2017 jointly with Arulmigu Kalasalingam College of Pharmacy and Indian Pharmaceutical Association, on the subject of "Scope and Perspectives of Pharm Industry Technology Adaptation". Prof. Dr. K. Chinnaswamy, President, Tamilnadu Pharmacy Council delivered key note address. M. M. Yousuf, Secretary TANIPA Trust, was the Chief guest and the guest of honours were Mr. K. Bangarurajan, Joint Drugs Controller (India) and Dr. S. Manivannan, Deputy Drugs Controller (India), President- Indian Pharmaceutical Association, TN Branch.

Mr. S. Sridhar, Vice-President, Medopharm, Malur delivered his address on "New Technologies in Pharmaceutical Processing, Mr. K. Saravanakumar, Senior General Manager – Corporate Quality, Fourrts (India) Labs Pvt Ltd, Chennai, spoke on "Quality in Pharmaceuticals" and Mr. G. Anandaselvam, Director – Icarus Heaclth Care Pvt Ltd, Chennai, Spoke on "Entrepreneurs Opportunities in marketing Pharma Products.

The programme is well attended by more than 700 students from in and around Pharmacy Colleges. This programme was sponsored by TANIPA Trust.

Blood Donation Camp at Madras Medical College

Blood Donation Camp was organised by College of Pharmacy, Madras Medical College on 25th November 2017. The Camp was initiated by Dr. Narayana Babu, Dean, MMC, Chennai, Dr. S. Manivannan, President, IPA TN Branch and Dr. Jaishree, Principal i/c, College of Pharmacy, MMC. This program was co-ordinated by Dr. N. Deattu, Asst Prof. Department of Pharmaceutics, MMC. More than 50 Pharmacy students donated the blood.

Seminar – Arulmigu Kalasalingam College of Pharmacy

Dignitaries of the programme

Audience of the programme

Blood donation Camp at MMC, Chennai

Dignitaries of the programme

Organizers and Blood donors of the camp

National Pharmacy Week Celebration

Address by Mr. J. Jayaseelan

Address by Dr. Surinder Singh

Pharmacist of the year award to Mr. K. Sivablan

Audience of the programme

Prize distribution to the students

Prize distribution to the students

Prize distribution to the students

Dignitaries and Council members of IPA TN

National Pharmacy Week Celebration - Valedictory

56th National Pharmacy Week Celebration valedictory function was organised on 25th November 2017 at 4.00 PM at R. R. Sabha, Chennai. Dr. Surinder Singh, Chief guest of the function. The Guest of Honours were Mr. K. Sivabalan, Director of Drugs Control, Tamilnadu, Prof. Dr. K. Chinnaswamy, President, Tamilnadu Pharmacy Council. Mr. J. Jayaseelan, vice President, addressed the gathering on the theme "Know your Medicines: Ask your Pharmacist". Dr. Surinder Singh gave the key note address on the subject of spurious drugs in India.

Mr. K. Sivabalan, Director of Drugs Control, Tamilnadu, was awarded as Pharmacist of the year sponsored by M/s. Lalchand Bhimraj, Chennai.

Tamilnadu Pharmaceutical Sciences Welfare Trust, institutes various awards to the Pharmacy graduates as well to students and the same were distributed during the function. The awards were - M. Pharm / Pharm D Scholarship, B. Pharm Essay Competition, sponsored by M/s. Pharm Prdoucts Tanjavur and University Merit award to B. Pharm students sponsored by M/s. Fourrts India Labs Pvt Ltd, Chennai. The function concluded by vote of thanks by Mr. T. Sathish, Secretary, IPA TN Branch

Editorial Policy and Disclaimer

The objective of this newsletter is to impact news to the readers and the newsletter is circulated free of cost. Description or reference to any information or publication does not implement endorsement by us.

Ever 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 publications. Users are advised to recheck the information with original resource material before applying to patient care or other purpose.

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

INFORMATION

M. PHARM & PHARM D SCHOLARSHIP 2017 - 2018

In order to motivate the student community, every year the Tamilnadu Pharmaceutical Sciences Welfare Trust, Chennai awarded scholarship to selected M. Pharm & Pharm D final year students from various colleges in Tamilnadu & Puduchery for their on-going project work. The scholarship scheme was imitated in the year 1998 for M. Pharm and 2013 for Pharm D. The received applications are codified, so that the identity of the student is not disclosed to the evaluator and sent to institutions outside the state of Tamilnadu for evaluation.

This is 20th year of this project, we have received 170 applications from 7 different branches, from 15 institutions. All synopses were sent to Dr. L. Sathiyanarayanan, Associate Professor, Poona College of Pharmacy, Bharathi Vidyapeeth University, Pune & his team for evaluation. Based on the ranking, 22 students have been selected for awards as per the following details

Applications Break up

S. No	Name of the College	M. Pharm						Pharm D		
		PH	PC	PA	PG	PY	PP	CP	PP	Total
1.	Madras Medical College, Chennai		7	1	8	9				25
2.	Madurai Medical College, Madurai	9	3	1		8				21
3.	JSS College of Pharmacy, Ooty	9	2	9	9	2	3	7	1	42
4.	SRIPMS, Coimbatore	4			3		9	8		24
5.	PSG College of Pharmacy	1			1			4	2	8
6.	Sri Ramachandra University				1		2	7		10
7.	SRM University	1			1			5	3	10
8.	Vels University							8	1	9
9.	Swamy Vivekananda College							8		8
10.	Mother Theresa PG Research Institute, Pondy					3				3
11.	Arulmigu Kalasalalingam College	3	1	1						5
12.	Annamalai University							1	1	1
13.	KK College of Pharmacy, Chennai.				1					1
14.	JKKMMRF College of Pharmacy	1								1
15.	JKK Nataraja College of Pharmacy								1	1
	Total	**28**	**13**	**12**	**24**	**22**	**14**	**48**	**9**	**170**

PH- Pharmaceutics
PC – Pharmaceutical Chemistry
PA – Pharmaceutical Analysis
PG – Pharmacology
PY – Pharmacognosy
PP – Pharmacy Practice
CP – Clinical Pharmacy

M. PHARM / PHARM D. SCHOLARSHIPS 2017 - 2018 - RESULT

PHARMACEUTICS

Rank	Name	College	Amount
I	Ms. Chenmala Karthika	JSS College of Pharmacy, Ooty	12,000/-
II	Mr. Sourodip Saha	JSS College of Pharmacy, Ooty	10,000/-
III	Ms. R. Nivetha	Arulmigu Kalasalingam College of Pharmacy, Krishnan Koil	8,000/-

PHARMACEUTICAL CHEMISTRY

Rank	Name	College	Amount
I	Mr. D. Anand	Madras Medical College	12,000/-
II	Mr. Rakesh Kumar Paul	JSS College of Pharmacy, Ooty	10,000/-
III	Mr. Katike Basheer Ahmed	JSS College of Pharmacy, Ooty	8,000/-

PHARMACEUTICAL ANALYSIS

Rank	Name	College	Amount
I	Ms. Gullapalli Kowmudi	JSS College of Pharmacy, Ooty	12,000/-
II	Ms. Charu Baruah	JSS College of Pharmacy, Ooty	10,000/-
III	Ms. Tshamata Shakya	JSS College of Pharmacy, Ooty	8,000/-

PHARMACOLOGY

Rank	Name	College	Amount
I	Ms. Chennu Manisha	JSS College of Pharmacy, Ooty	12,000/-
II	Mr. T. Sandeep	PSG College of Pharmacy, Coimbatore	10,000/-
III	Mr. Navaf MT	JSS College of Pharmacy, Ooty	8,000/-

PHARMACOGNOSY

Rank	Name	College	Amount
I	Ms. G. Hemalatha	College of Pharmacy, Madurai Medical College, Madurai	12,000/-
II	Mr. K. Anandhan	Madras Medical College, Chennai	10,000/-
III	Mr. K. Rajkumar	Madras Medical College, Chennai	8,000/-
III	Ms. R. Suganya	College of Pharmacy, Madurai Medical College, Madurai	8,000/-

PHARMACY PRACTICE

Rank	Name	College	Amount
I	Ms. Aswathy VS	JSS College of Pharmacy, Ooty	12,000/-
II	Ms. Joffy Alex	SRIPMS ,Coimbatore	10,000/-
III	Ms. Rittumol Varghese	SRIPMS ,Coimbatore	8,000/-

PHARM D - CLINICAL PHARMACY

Rank	Name	College	Amount
I	Ms. Kezia Sam; Mr. Prince Wilfred; Mr. Regil C Varghese; Mr. Thomas Eipe	JSS College of Pharmacy, Ooty	15,000/-
II	Ms. M. Bakiya lakshmi ; Ms. P. Neela ; Ms. K. Shri Latha ; Ms. S. Revathy	SRM College of Pharmacy, SRM University, Kattankulathur	12,000/-
III	Ms. Kolli Sowjanya; Mr. Rawa Nawzad Najm; Mr. M. Tulasi Raja	SRM College of Pharmacy ,SRM University Kattankulathur	10,000/-

ESSAY COMPETITION 2017 – FINAL YEAR B. PHARM STUDENTS

TNPSWT imitated a new activity from 2011 for Essay competition and this years subject being **"Why a Community Pharmacist is an important part of health care team"**. This awarded is in the name of **"Shri G. Swaminthan Memorial Award"** -- Sponsored by M/s. Pharm Product Pvt Ltd. Thanjavur.

This year we have received 108 applications from 17 colleges and this was evaluated by **Dr. V. Prabhakarn**, Krishna Teja Colleges of Pharmacy Tirupathi. Based on the marks -- 5 students have been awarded as below

Rank	Name	College	Amount
I	Mr. K. Arulraj	Sri Ram Nallamani Yadava College of Pharmacy, Tenkasi	10,000/-
II	Ms. R. Veerajothi	Annai J.K.K. Sampoorani Ammal College of Pharmacy, Namakkal Dt	8,000/-
II	Ms. S. Shermila	Jaya College of Pharmacy, Chennai	8,000/-
III	Ms. M. Murugeshwari	Arulmigu Kalasalingam College of Pharmacy, Krishnan Koil	6,000/-
III	Ms. K. Krishnaveni	Mother Therasa Post Graduate & Research Institute of health Sciences, Pudhucherry	6,000/-

Applications Break up

S.No	Name of College	No of Applications	Awardees
1	C.L. Baid Metha College of Pharmacy, Chennai	13	
2	Surya School of Pharmacy , Viluppuram	2	
3	College of Pharmacy, SRIPMS, Coimbatore	7	
4	Sri Ramachandra University, Chennai	1	
5	JKK Nataraja College of Pharmacy, Namakkal	1	
6	Periyar College of Pharmaceutical Sciences, Trichy	4	

Applications Break up

S.No	Name of College	No of Applications	Awardees
7	Jaya College of Pharmacy, Thiruninravur	10	1
8	Sri Ram Nallamani Yadava College of Pharmacy,Tenkasi	2	1
9	K K College of pharmacy, Chennai	1	
10	Swami Vivekananda College of Pharmacy, Thiruchengode	6	
11	Arulmigu Kalasalingam College of Pharmacy, Krishankoil	32	1
12	Mother Theresa PG Research Insitutue, Puducheery	9	1
13	S.S.M. College of Pharmacy, Erode	6	
14	Annai J.K.K. Sampoorani Ammal College of Pharmacy, Namakkal	4	1
15	Vinayaka mission's college of Pharmacy,Salem	1	
16	Karpagam College of Pharmacy, Coimbatore	1	
17	R.V.S. College of Pharmaceutical Sciences, Coimbatore	8	
	TOTAL	**108**	**5**

UNIVERSITY MERIT AWARD

From year 2015 M/s. Fourrts India ltd sponsored university merit award for topper candidates, who have secured high marks in B.Pharm examinations passed during August 2017 of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai

Rank	Name	College	Amount
I	Ms. Nandhini. V	Jaya College of Pharmacy, Chennai	10,000/-
II	Ms. Akila. K	Periyar College of Pharmacy, Trichy	8,000/-
II	Ms. Sandhiyadevi. S	Aadhibhagavan College of Pharmacy, Thiruvannamali Dt	8,000/-

We thank Mr. S. V. Veerramnai, Chairman & Managing Director, M/s. Fourrts (india) Laboratories Pvt Ltd, Chennai, for the above awards

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 27th October, 2017

G.S.R. 1337(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required under sub-section (1) of 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. 319(E), dated the 31st March, 2017, in the Gazette of India,Extraordinary, Part II, section 3, sub-section (I), dated the 31st March, 2017, 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 containing the said notification were made available to the public on 31st March, 2017;

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 by section 12 read with 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 further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (Tenth Amendment) Rules, 2017.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 59,-
(a) in sub-rule (2), the words "or renewal" shall be omitted;
(b) sub-rule (4) and the proviso thereto shall be omitted.

3. In the said rules, in rule 62B, in sub-rule (2), in the proviso, the words "or renew" shall be omitted.

4. In the said rules, in rule 62C, in sub-rule (1),-
(a) the words "or renewal", shall be omitted;
(b) the proviso thereto shall be omitted.

5. In the said rules, for rule 63, the following rule shall be substituted, namely:-
"63. Duration of licence.- (1) A licence issued in Forms 20, 20A, 20B, 20BB, 20F, 20G, 21, 21A, 21B or Form 21BB shall remain valid, if licencee deposits a licence retention fee referred to in sub-rule (2) before the expiry of a period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

(2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee required for the grant of such licence.

(3) If the licencee fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent. of the licence fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.".

6. In the said rules, rules 63A and 63B shall be omitted.

7. In the said rules, in rule 64,-
(a) the words “or renewed” wherever they occur shall be omitted;
(b) in sub-rule (2),-
(i) the words “or renewing” shall be omitted;
(ii) in first proviso, the words “or renew” shall be omitted.

8. In the said rules, in rule 65, the words “or renewal” at both the places where they occur shall be omitted.

9. In the said rules, after rule 65A, the following new rule shall be inserted, namely:-
“65B. Inspection for verification of compliance.- The licensing authority shall cause inspection, by the Inspector appointed under the Act, of each premises licensed under this Part, to verify the compliance with the conditions of licence and the provisions of the Act and these rules, not less than once in three years or as needed as per risk based approach.”.

10. In the said rules, in rule 68A,-
(a) in the marginal heading, the words “or Renewal” shall be omitted;
(b) in sub-rule (1), the words “or renewed, as the case may be,” shall be omitted;
(c) the words “or renewal” where they occur shall be omitted;
(d) in sub-rule (2), clause (iii) shall be omitted;
(e) in sub-rule (3), the words “or renewed” shall be omitted;
(f) the words “or renew” at both places where they occur shall be omitted.

11. In the said rules, in rule 69,-
(a) in sub-rule (1), the words “or renewal” shall be omitted;
(b) in sub-rule (2), the words “or for the purpose of renewal of the licence” wherever they occur shall be omitted;
(c) sub-rule (3) shall be omitted.

12. In the said rules, in rule 69A, in sub-rule (1),-
(a) the words “or renewal” shall be omitted;
(b) the proviso thereto shall be omitted.

13. In the said rules, in rule 71,-
(a) in the marginal heading, the words “or renewal” shall be omitted;
(b) the words “or renewed” shall be omitted.

14. In the said rules, in rule 71A,-
(a) in the marginal heading, the words “or renewal” shall be omitted;
(b) the words “or renewed” shall be omitted.

15. In the said rules, in rule 71B,-
(a) in the marginal heading, the words “or renewal” shall be omitted;
(b) the words “or renewed” shall be omitted.

16. In the said rules, for rule 72, the following rule shall be substituted, namely:-
“72. Duration of licence.- (1) A licence issued in Form 25, Form 25B and Form 25F shall remain valid if the licencee deposits a licence retention fee referred to in sub-rule (2) before the expiry of a period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

(2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee required for thegrant of such licence excluding inspection fee paid for grant of licence.

(3) If the licencee fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent. of the licence fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.".

17. In the said rules, the rules 73 and 73A shall be omitted.

18. In the said rules, for rule 73AA, the following rule shall be substituted, namely:-

"73AA. Duration of loan licence.- (1) A licence issued in Form 25A shall remain valid if licencee deposits a licence retention fee referred to in sub-rule (2) before the expiry of a period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

(2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee required for the grant of such licence excluding inspection fee paid for grant of licence.

(3) If the licencee fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent. of the licence fee for every month or part there of up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.".

19. In the said rules, after rule 73AA, the following new rule shall be inserted, namely:-

"73AB. Inspection for grant of licence and verification of compliance.-

(1) Before a licence in Form 25 or Form 25A or Form 25B or Form 25F is granted, the licensing authority shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected jointly by the Drugs Inspectors appointed by the Central Government and the State Government under this Act who shall examine the establishment intended to be used or being used for the manufacture of drugs.

(2) The premises licensed under sub-rule (1) shall be inspected jointly by Inspector appointed by the Central Government and State Government to verify the compliance with the conditions of licence and the provisions of the Act and these rules not less than once in three years or as needed as per risk based approach.".

20. In the said rules, rule 73B shall be omitted.

21. In the said rules, in rule 75,-

(a) in sub-rule (1),-

(i) the words "or renewal" and "or for the purpose of renewal of licences" shall be omitted;

(ii) the proviso thereto shall be omitted;

(b) in sub-rule (2),-

(i) the words "or renewal" and "or for the purpose of renewal of licences" shall be omitted;

(ii) the second proviso thereto shall be omitted;

(c) in sub-rule (3),-

(i) the words "or renewal" and "or for the purpose of renewal of licences" shall be omitted;

(ii) the proviso thereto shall be omitted.

22. In the said rules, in rule 75A,-

(a) in sub-rule (1),-

(i) the words "or renewal" and "or for the purpose of renewal of licences" shall be omitted;

(ii) the proviso thereto shall be omitted;

(b) in sub-rule (1A),-

(i) the words "or renewal" and "or for the purpose of renewal of licences" shall be omitted;

(ii) the proviso thereto shall be omitted;

23. In the said rules, in rule 76,-

(a) in the marginal heading, the words "or renewal" shall be omitted;

(b) in the opening portion, the words "or renewed" shall be omitted.

24. In the said rules, in rule 76A, in the marginal heading, the words "or renewal" shall be omitted.

25. In the said rules, rule 77 shall be omitted.

26. In the said rules, in rule 79,-

(a) in the marginal heading, the words "or renewal" shall be omitted;

(b) the words "or renewed" shall be omitted.

27. In the said rules, rules 83, 83A and 83AA shall be omitted.

28. In the said rules, in rule 84A,-

(a) in the marginal heading, the words "or renewed" shall be omitted;

(b) the words "or renew" shall be omitted.

29. In the said rules, after rule 84B, the following new rule shall be inserted, namely:-

"84C. Inspection for verification of compliance.- (1) Before a licence in Form 28 or Form 28A or Form 28B or Form 28D or Form 28DA, is granted the licensing authority or Central Licence Approving Authority, as the case may be, shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected jointly by the Drugs Inspectors appointed by the Central Government and the State Government under this Act, who shall examine the establishment intended to be used or being used for the manufacture of drugs.

(2) The premises licensed under sub-rule (1) shall be inspected jointly by Inspector appointed by the Central Government and State Government to verify the compliance, with the conditions of licence and the provisions of the Act and these rules, not less than once in three years or as needed as per risk based approach.".

30. In the said rules, in rule 85, in sub-rule (2), the words "or renewed" shall be omitted.

31. In the said rules, in rule 138,-

(a) in sub-rule (1), the words "or renewal" and "or for the purpose of renewal of licence" shall be omitted;

(b) sub-rule (2) shall be omitted.

32. In the said rules, in rule 138A,-

(a) in sub-rule (1), the words "or renewal" shall be omitted;

(b) sub-rule (2) shall be omitted.

33. In the said rules, in rule 139,-

(a) in the marginal heading, the words "or renewal" shall be omitted;

(b) in the opening portion, the words "or renewed" shall be omitted.

34. In the said rules, in rule 139AA,-

(a) in the marginal heading, the words "or renewal" shall be omitted;

(b) the words "or renewed" shall be omitted.

35. In the said rules, in rule 139AC,-

(a) in sub-rule (1), the words "or renew" shall be omitted;

(b) in sub-rule (2), the words "or renewed" shall be omitted.

36. In the said rules, in rule 139AE, the words "or renew" shall be omitted.

37. In the said rules, for rule 140, the following rule shall be substituted, namely:-

"140.Duration of licence.- (1) A licence issued under Form 32, Form 32A and Form 33 shall remain valid if the licencee deposits a licence retention fee referred to in sub-rule (2) before the expiry of period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

(2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee required for the grant of such licence excluding inspection fee paid for grant of licence.

(3) If the licence holder fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent. of the licence fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.".

38. In the said rules, rules 141, 141A and 141AA shall be omitted.

39. In the said rules, after rule 143, the following new rule shall be inserted, namely:-

"143A. Inspection for grant of licence and verification of compliance.-

(1) Before a licence in Form 32 or Form 32A or Form 33 is granted, the licensing authority shall cause the establishment in which the manufacture of cosmetics is proposed to be conducted or being conducted to be inspected jointly by the Drugs Inspectors appointed by the Central Government and the State Government under this Act, who shall examine the establishment intended to be used or being used for the manufacture of cosmetics.

(2) The premises licensed under sub-rule (1) shall be inspected jointly by Inspector appointed by the Central Government and the State Government to verify the compliance, with the conditions of licence and the provisions of the Act and these rules, not less than once in three years or as needed as per risk based approach.".

40. In the said rules, in rule 150B,-

(a) in the sub-rule (1), the words "or renewal" shall be omitted;

(b) in second proviso threto shall be omitted.

41. In the said rules, in rule 150C,-

(a) in the marginal heading, the words "or renewal" shall be omitted;

(b) in sub-rule (2), the words "or renewed" shall be omitted.

42. In the said rules, for rule 150D, the following rule shall be substituted, namely:-

"150D.Duration of approval.- (1) A licence issued under Form 37shall remain valid if the licencee deposits a licence retention fee referred to in sub-rule (2) before the expiry of period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

(2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee required for the grant of such licence.

(3) If the licence holder fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent. of the licence fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.".

43. In the said rules, in Schedule A,-

(a) in Form 20, Form 20A, Form 20B, Form 20BB, Form 21, Form 21A, Form 21B, Form 21BB, Form 25B and Form 32, for paragraph 2, the following paragraph shall respectively be substituted, namely:-

"2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.";

(b) in Form 20F, Form 20G, Form 25, Form 28DA and Form 32A, for paragraph 3, the following paragraph shall respectively be substituted, namely:-

"3. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.";

(c) in Form 25A, Form 28 and Form 28B, for paragraph 4, the following paragraph shall respectively be substituted, namely:-

"4. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.";

(d) in Form 25F and Form 28D, for paragraph 5, the following paragraph shall respectively be substituted, namely:-

"5. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliancewith the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and theDrugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.";

(e) in Form 28A, for paragraph 3A, the following paragraph shall be substituted, namely:-

"3A. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.";

(f) in Form 37, for paragraph 3, the following paragraph shall be substituted, namely:-

"3. The approval, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of approval and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.";

(g) in Form 19, Form 19A, Form 19AA and Form 19C, in the heading, the words "OR RENEWAL" shall respectively be omitted;

(h) Form 21C, Form 21CC, Form 26, Form 26A, Form 26B, Form 26F, Form 26H, Form 33, Form 33A and Form 38 shall be omitted;

(i) in Form 24, Form 24A, Form 24B, Form 24C, Form 24F, Form 27, Form 27A, Form 27B, Form 27D, Form 27DA, Form 31 and Form 31A,-

(a) In the heading, the words "OR RENEWAL" shall respectively be omitted;
(b) in paragraph 1, for the words "grant/renewal", the words "grant" shall respectively be substituted;

(j) in Form 25, Form 25A, Form 25B, Form 25F, Form 28, Form 28A, Form 28B, Form 28D, Form 28DA, Form 32 and Form 32A, in condition 1, the words, "and any certificate of renewal in force" shall be omitted;

(k) In Form 36,-
(a) In the heading, the words "or renewal" shall be omitted;
(b) In paragraph (1), the words "or renewal" shall be omitted.

[F.No.X.11014/6/2017-DRS]
SUDHIR KUMAR, Jt. Secy.

Note: The principal rules were published in the Official Gazette vide notification No. F. 28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R. 327(E), dated 3rd April, 2017.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 1st November, 2017

G.S.R.1357(E).—The following draft of certain rules, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby, and notice is hereby given that said draft rules will be taken into consideration on or after the expiry of a period of forty-five days from the date on which copies of the Gazette of India containing these draft rules are made available to the public.

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D Wing, Nirman Bhavan, New Delhi – 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (.....Amendment) Rules, 2017.
   (2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in Schedule H, after serial number 537 and entries relating thereto, the following serial numbers and entries shall be inserted, namely,-

"538. Alclometasone
539. Beclomethasone
540. Betamethasone
541. Desonide
542. Desoximetasone
543. Dexamethasone
544. Diflorasone diacetate
545. Fluocinonide
546. Fluocinolone acetonide
547. Halobetasol propionate
548. Halometasone
549. Methylprednisone
550. Prednicarbate
551. Triamcinolone acetonide"

[F. No. X-11014/14/2017-DRS]
SUDHIR KUMAR, Jt. Secy.

Foot note: The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R. .....(E) dated.....

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 3rd November, 2017

G.S.R.1367(E).—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by sections 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published as required by sub-section (1) of the section 33 of the said Act for information of all persons likely to be affected thereby; and notice is hereby given that said draft rules will be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing these draft rules are made available to the public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (.....Amendment) Rules, 2017.
(2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in Schedule A, in Form 12B, for clause 3, the following clause shall be substituted, namely

"3. The permit shall, unless previously suspended or revoked, be in force during the period till the patient requires the drug as per the prescription of Registered Medical Practitioner and permit holder shall submit the details of drugs imported, utilised to the licensing authorities on yearly basis from the date specified below."

[F. No. X-11014/13/2017-DRS]
SUDHIR KUMAR, Jt. Secy.

Foot note: The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (1) dated 21st December 1945 and last amended vide notification number GSR .....(E) dated.....

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 3rd November, 2017

G.S.R. 1368(E).—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by sections 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published as required by sub-section (1) of the section 33 of the said Act for information of all persons likely to be affected thereby; and notice is hereby given that said draft rules will be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing these draft rules are made available to the public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D Wing, Nirman Bhavan, New Delhi - 110011 or emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (.....Amendment) Rules, 2017.
   (2) They shall come into force on the date of their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945, in Schedule K, for Serial Number 34 and the entries relating thereto, the following shall be substituted namely,—

Class of Drugs	Extent and Conditions of the exemption
"34. Production of Oxygen 93 per cent USP or Oxygen 93 per cent IP, produced from air by the molecular sieve process or Oxygen 93 per cent supplied from liquid Oxygen, by a hospital or Medical Institute for their captive consumptions	The Provision of the Chapter IV of the Act and the rule made thereunder which require them to be covered by manufacturing licence under the rules, provided that the production facilities shall be open to inspections by an inspector appointed under the Act, who can, if necessary, take samples for test"

[F. No. X-11014/17/2017-DRS]
SUDHIR KUMAR, Jt Secy.

Foot note: The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (1) dated 21st December 1945 and last amended vide notification number G.S.R. .....(E) dated.....

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 3rd November, 2017

S.O. 1369(E).—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by sections 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published as required by subsection (1) of the section 33 of the said Act for information of all persons likely to be affected thereby; and notice is hereby given that said draft rules will be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Official Gazette containing these draft rules are made available to the public;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D Wing, NirmanBhavan, New Delhi - 110011 or e-mailed at drugsdiv-mohfw@nic.in;

Objections and suggestions which may be received from any person within the aforesaid period will be considered by the Central Government.

DRAFT RULES

1. (1) These rules may be called the Drugs and Cosmetics (_____Amendment) Rules, 2017.
(2) They shall come into force after their final publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 96, in sub-rule (1), in clause (xi), for the portion beginning with the words "In addition to the'' and ending with the words "in the above list:", the following shall be substituted, namely:-

"In addition to the other particulars which are required to be printed or written under these rules, the label of inner most container of the following categories of drugs and every other covering in which the container is packed shall bear caution/ warning in legible black coloured font size in completely red rectangular box without disturbing other conditions printed on the label under these rules, namely:-

Narcotic analgesics, hypnotics, sedatives, tranquillisers, corticosteroids, hormones, hypoglycemic, antimicrobials, antiepileptics, antidepressants, anticoagulants, anti-cancer drugs and all other drugs falling under Schedules G, H, H1 and Schedule X whether covered or not in the above list:".

3. In the said rules, in rule 97, in sub-rule (1),

(i) for clause (a), the following shall be substituted, namely:—
"(a) if it contains a drug substance specified in Schedule G, be labeled with following words in legible black coloured font size in completely red rectangular box:

SCHEDULE G PRESCRIPTION DRUG – CAUTION It is dangerous to take this preparation except under medical supervision.

(ii) for clause (b), the following shall be substituted, namely:—

"(b) if it contains a drug substance specified in Schedule H, be labeled with symbol Rx and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H PRESCRIPTION DRUG – CAUTION Not to be sold by retail without the prescription of a Registered Medical Practitioner..

(iii) for clause ©, the following shall be substituted, namely:—

"© if it contains a drug substance specified in Schedule H and comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) be labeled with symbol NRx which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H PRESCRIPTION DRUG – WARNING To be sold by retail on the prescription of a Registered Medical Practitioner only.

(iv) for clause (d), the following shall be substituted, namely:—

"(d) if it contains a drug substance specified in Schedule X, be labeled with symbol Xrx which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE X PRESCRIPTION DRUG – WARNING To be sold by retail on the prescription of a Registered Medical Practitioner only.

(v) for clause (e), the following shall be substituted, namely:—

"(e) if it contains a drug substance specified in Schedule H1, be labeled with symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION − It is dangerous to take this preparation except in accordance with the medical advice. − Not to be sold by retail without the prescription of a Registered Medical Practitioner.

(vi) after clause (e), the following clause shall be inserted, namely:—

"(f) if it contains a drug substance specified in Schedule H1 and comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) be labeled with symbol NRx which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION − It is dangerous to take this preparation except in accordance with the medical advice. − Not to be sold by retail without the prescription of a Registered Medical Practitioner.

4. In the said rules, in Schedule H, after Note 3 appended to the said Schedule, the following Note shall be inserted, namely:-

"4. The salts, esters, derivatives and preparations containing steroids for topical or external use are also covered by this Schedule."

5. In the said rules, in Schedule K, against serial number 27, for the entries under the column 'class of drugs' the following shall be substituted, namely:—

"Oral Rehydration Salts (Manufactured as per the following formula):-Composition of the formulation in terms of the amount in g, to be dissolved in sufficient water to produce 1000 ml.

- Sodium Chloride 2.6
- Dextrose (anhydrous) or 13.5
- Dextrose mono-hydrate 14.85
- Potassium chloride 1.5
- Sodium Citrate 2.9."

[F. No. X. 11014/06/2016-DFQC]
SUDHIR KUMAR, Jt. Secy.

Note : The principal rules were published in the Gazette of India vide notification No. F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R. (E) dated

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 10th November, 2017

G.S.R. 1380(E)..— Whereas the draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required under section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), dated the 1st February, 2017 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. 80(E), dated the 1st February, 2017 for inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And, whereas, the copies of the said Official Gazette were made available to the public on 1st February, 2017;

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 by section 12 and section 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (11th Amendment) Rules, 2017.
(2) They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 67C, the followingproviso shall be inserted, namely:-

"Provided that no licence shall be required for exhibiting the drugs for promotional activities in any fair.";

3. In the said rules, in rule 67F, in sub-rule (1),
(i) for the words "who is in the opinion of the Licensing Authority competent to deal in Homeopathic medicines:" the following shall be substituted, namely:-

"who is having,–
(a) degree in Homoeopathy from a recognised University; or
(b) degree in Pharmacy from a recognised University; or
(c) Bachelor's degree from a recognised University with one year experience of dealing in Homoeopathic medicines in the clinic of a registered Homoeopathic Medical Practitioner or with the holder of licence in Form 20C or Form 20D; or
(d) diploma in Homeopathic Pharmacy; or
(e) diploma in Homeopathy Medicine and Surgery:";

(ii) as so amended, for the Proviso, the following Provisos shall be substituted, namely:-

"Provided that the person already registered with the State Licensing Authority as competent person for the purposes of grant of license in Form 20C or Form 20 D or both prior to the coming into force of the Drugs and Cosmetics (11th Amendment) Rules, 2017, shall continue to be considered as a competent person for the said purposes:

Provided further that no registered Homeopathic medical practitioner who is practising Homeopathy in the premises where Homeopathic medicines are sold shall deal in Homeopathic medicines.";

4. In the said rules, in rule 67G, for clause (2), the following clause shall be substituted, namely:-

"(2) In the case of licence in Form 20C the Homeopathic medicines shall be sold,-

(i) under the supervision of a person having qualifications referred to in sub-rule (1) of rule 67F; and

(ii) in manufacturer's sealed packing only except dispensing of medicines in globules, water or milk sugar or as per prescription of a Homoeopathic Medical Practitioner.";

5. In the said rules, in rule 85E, after sub-rule (2), following sub-rule shall be inserted, namely:-

"(2A) Certificate of Good Manufacturing Practice.- The certificate of Good Manufacturing Practice to manufacturers, who comply with the requirements of Good Manufacturing Practices of Homeopathy drugs, as specified in Schedule M-I, shall be issued up to the date of validity of licence.";

6. In the said rules, in Schedule K, for serial number 31 and the entries relating thereto, the following shall be substituted, namely:-

Class of Drugs	Extent and Conditions of Exemptions
"31. Homoeopathic medicines	The provisions of Chapter IV of the Act and the rules made thereunder which relates to sale licence in Form 20-C, subject to the following conditions: - (i) These medicines shall be sold in the original sealed small quantity packings of the licensed manufacturers; (ii) Medicines shall be stocked and sold by retail dealers of medicines licensed under rule 61; (iii) Medicines shall be stored separately from other allopathic drugs; (iv) Medicines shall be purchased from a manufacturer or a dealer licensed under these rules; and (v) Purchase and sale records of medicines shall be maintained by the dealer for a minimum period of three years.";

7. In the said rules, in Schedule M-I,-

(i) in paragraph 1 relating to 'General requirements', in sub-paragraph 1.1, the words "or outside" shall be omitted;

(ii) in paragraph 2 relating to 'Plant and Equipment', in sub-paragraph 2.1, for the word "origins", the word "types" shall be substituted;

(iii) in paragraph 3 relating to 'Requirement of Equipment and Facilities',-

(A) in sub-paragraph 3.1,-

(a) in items (v), (vi) and (ix), for the words and figures "stainless steel of grade 304", the words and figures "stainless steel of grade not below 304" shall respectively be substituted;

(b) for the words and figures "shall be separate and shall be 55 square meters for each for basic installations", the words and figures "shall not be less than 55 square metres for basic installations" shall be substituted;

(B) in sub-paragraph 3.3, in the Notes, in Note (b), for the words, "neutral glass", the words "neutral glass or stainless steel" shall be substituted;

(C) in sub-paragraph 3.4, after the words, "shall be provided", the words "as per the requirements of manufacturing process" shall be inserted;

(D) in sub-paragraph 3.6, after the words "shall be provided", the words "as per the requirements of manufacturing process" shall be inserted;

(iv) in paragraph 4 relating to 'Quality Control Division', in sub-paragraph 4.3, for item "(ii) Dissecting microscope", the item "(ii) Compound microscope" shall be substituted;

(v) in paragraph 5 relating to 'Raw Materials', in sub-paragraph 5.1,

(A) in clause (a),-

(I) for item "(iv) the materials shall be free of inorganic or organic foreign matter;", the item "(iv) the materials shall conform to the pharmacopoeial standards;" shall be substituted;

(II) in item (v), the words "and should not be more than six months old" shall be omitted;

(B) in clause (b),-

(I) for item "(i) a small twig of the plant with leaves shall be available if the part used is bark of the plant;", the item "(i) the raw materials of plant origin shall be as per pharmacopoeia;" shall be substituted;

(II) for item "(vi) the materials shall be in open mesh bags or in suitable material which permits the passage of air inside;", the item "(vi) fresh herbs shall be stored in open mesh bags and materials in closed containers;" shall be substituted;

(III) for item (vii), the following item shall be substituted, namely:-

"(vii) each consignment of the material shall be accompanied by a statement of the supplier's name; name of the plant with description of the part supplied; the Pharmacopoeial reference, place of collection, date of packaging and weight";

(vi) in paragraph 6 relating to procedures, sub-paragraph 6.4 shall be omitted;

(vii) in paragraph 9, relating to 'Expiry Date', for the words "date of manufacture", the words "date of manufacture except Homoeopathic dilutions and back potencies, if preserved under hygienic conditions." shall be substituted.

[F. No. X.-11014/1/2017-DRS]
SUDHIR KUMAR, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification No. F. 28-10/45-H (1), dated the 21st December, 1945 and last amended vide notification number G.S.R. 1337(E), dated the 27th October, 2017.

NEWS

Sun Pharma Gets USFDA Nod For Generic Cardiac Drug

Sun Pharmaceutical Industries today said its subsidiary has received approval from the US health regulator to market generic verision of GSK's Coreg CR, extended release capsules in the American market.

One of the company's wholly-owned subsidiaries has received final approval from US Food and Drug Administration (USFDA) for the generic product in strengths of 10mg, 20mg. 40mg and 80mg, Sun Pharma said in a statement.

Coreg CR extended release capsules are indicated for treating various heart conditions, including heart failure and high blood pressure.

As per IMS, Coreg CR had annual sales of around USD 208 million in the US for the 12 months ended August 2017.

Source: *ET Healthworld, 26th October 2017*

Unichem Recalls 96.8 K Bottles of Hypertension Tablets in US

Unichem Laboratoriesis recalling around 96.8 thousand bottles of Bisoprolol Fumarate tablets used for treatment of hypertension, from the US market, latest Enforcement Report of the US health regulator has said.

Unichem Pharmaceuticals USA Inc is recalling 96,876 bottles of Bisoprolol Fumarate tablets in the strength of 5 mg manufactured by Unichem Laboratories at its Goa plant, USFDA said in its Enforcement Report.

The reason for the recall is "Failed Impurities/ Degradation specifications: out of specification for an unknown impurity was observed during the 18-month stability testing," it added.

The voluntary ongoing nationwide recall is a class II recall, the report said.

As per the USFDA, a class II recall is initiated in a "situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote".

Unichem Pharmaceuticals USA, Inc is a wholly-owned subsidiary of Unichem Laboratories.

Source: *ET Healthworld, 27th October 2017*

Merck Swings to 3Q Loss on Big Charge but Raises Forecast

Lower sales for multiple medicines and a whopping charge for a big collaboration in cancer drugs drove Merck & Co. to a third-quarter loss of $56 million.

But the Kenilworth, New Jersey, company beat Wall Street's muted expectations and it also narrowed, and raised, its outlook for the year.

Merck on Friday reported a loss of 2 cents per share, after posting a profit of $2.18 billion, or 78 cents per share, in 2016's third quarter.

Adjusted for non-recurring costs, earnings amounted to $1.11 per share. That's 8 cents better than industry analysts had forecast, according to a survey by Zacks Investment Research.

Merck reported revenue of $10.33 billion in the quarter, down 2 percent from $10.54 a year earlier.

Keytruda sales nearly tripled in the quarter versus a year earlier, hitting $1.05 billion, and sales of hepatitis C-curing Zepatier jumped 185 percent to $468 million. But for Merck's top-selling portfolio, Type 2 diabetes drugs Januvia and Janumet, sales declined 2 percent to $1.53 billion due to pricing pressure, and the Gardasil vaccine against cancer-causing human papilloma virus had a sales drop of 22 percent, to $675 million. Recent generic competition to former blockbuster cholesterol drugs Zetia and Vytorin halved their sales, to a combined $462 million.

Veterinary medicines brought in $1 billion, up 15 percent.

The latest results included a one-time charge of $2.35 billion for a new partnership with Britain's AstraZeneca PLC to market their existing cancer drugs and develop new ones.

Merck's key medicine portfolio revolves around Keytruda, an immuno-oncology drug approved for treating several cancer types that works by enabling the immune system to better spot and kill cancer cells. Merck will now help sell AstraZeneca's Lynparza, a cancer drug from the new class called PARP inhibitors that's approved for treating ovarian and fallopian tube cancer. The companies will test those drugs and an unapproved one from AstraZeneca called selumetinib against various cancer types, separately and in combination.

Merck said it now expects full-year earnings in the range of $1.78 to $1.84 including one-time items, up from its prior forecast of $1.60 to $1.72 per share. It expects revenue in the range of $40 billion to $40.5 billion, up from $39.4 billion to $40.4 billion.

Source: *ET Healthworld, 27th October 2017*

Natco Pharma Raises Rs 915 Crore Via QIP

Natco Pharma has raised Rs 915 crore through issue of securities to qualified institutional investors, according to a regulatory filing.

During its meeting today, the company's committee of directors decided to allocate 1 crore shares at issue price of Rs 915 apiece, Natco Pharma said.

The shares were allotted to eligible qualified institutional buyers pursuant to the QIP amounting to an issue size of Rs 915 crore, it added.

Specific details about utilisation of the proceeds were not disclosed.

Source: *ET Healthworld, 15th December 2017*

Govt Plans to Allow Chemists to Suggest Generic Substitutes

In a move that will further push PM Narendra Modi's agenda on affordable healthcare, the government plans to allow pharmacists to substitute a cheaper (generic) drug against the brand prescribed by the doctor, provided the patient wants the change. This is being proposed to serve the twin objective of "empowering the patient", and promoting affordable generic options.

The existing guidelines do not allow any change, with the pharmacist bound to dispense the same product as specified in the prescription. This is in line with the government's plan to bring healthcare costs down, with the PM having earlier announced that laws will be enacted to ensure doctors prescribe medicines with their generic names, instead of brands. While this has not taken off in totality due to complexities in implementation, the government has been successful in capping prices of cardiac stents and orthopaedic implants earlier. The proposal, once finalised, will provide an option to a patient to pick up a generic drug or even a brand manufactured by a domestic firm, which are usually cheaper than the prescribed one (for example by an MNC), sources told TOI.

According to Section 65 (11) of the Drugs and Cosmetics Act, "no person dispensing a prescription containing substances specified in Schedule H or X may supply any other preparation, if containing the same substances or not, in lieu thereof". "Discussions are on at present, the government will invite comments from stakeholders before amending the laws," a health ministry official said.

Source: *ET Healthworld, 13th December 2017*

Cadila Gets USFDA Nod for Generic Drug to Treat Parkinson's

Cadila Healthcare today said it has received approval from the US health regulator to market Pramipexole Dihydrochlorideextended-release tablets, used for treating Parkinson's disease, in the American market.

The company's subsidiary, Zydus Pharmaceuticals (USA) Inc, has received the final approval from the USFDA to market Pramipexole Dihydrochloride extended-release tablets in strengths of 0.375 mg, 0.75 mg, 1.5 mg, 2.25 mg, 3 mg, 3.75 mg and 4.5 mg, Cadila Healthcare said in a statement.

The drug is indicated to treat signs and symptoms of Parkinson's disease (PD).

The Ahmedabad-based firm also received final approval from the USFDA to market Nitrofurantoin Capsules USP, used for treating acute uncomplicated urinary tract infections, in the US market.

Both the drugs will be manufactured at Zydus group's formulations manufacturing facility at Moraiya, Ahmedabad.

Source: *ET Healthworld, 14th December 2017*

Alembic Pharma Gets USFDA Go-Ahead for Bladder Drug

Alembic Pharmaceuticals has received US health regulator's nod for a drug used to treat overactive bladder with symptoms of urinary incontinence, urgency and frequency.

"The company has received approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Darifenacin extended release tablets, 7.5mg and 15mg," Alembic Pharmaceuticals said in a BSE filing today.

The approved product is equivalent to Enablex of Allergan Pharmaceuticals.

According to IMS December 2016 data, Darifenacin extended release tablets had an estimated market size of USD 64 million.

The company now has a total of 70 ANDA approvals from the USFDA.

Source: *ET Healthworld, 12th December 2017*

Lupin Gets USFDA Nod for Generic Contraceptive Tablets

Drug major Lupin today said it has received approval from the US health regulator to market its Tydemy tablets, used to prevent pregnancy, in the American market.

The company has received final approval from the US Food and Drug Administration (USFDA) to market Tydemy, which is a generic version of Bayer HealthCare Pharmaceuticals' Safyral Tablets, Lupin said in a statement.

Tydemy is indicated for use by women to prevent pregnancy and to raise folate levels in women who choose to use an oral contraceptive for contraception.

As per IMS MAT data, the product had annual sales of around USD 22.9 million in the US.

Source: *ET Healthworld, 14th December 2017*

NPPA Notifies Prices of 65 Essential Formulations

National drug pricing regulator NPPA today said it has notified prices of 65 essential formulations, including those used for the treatment of diabetes, infections, pain and high blood pressure.

"NPPA has fixed/revised ceiling prices/Retail Prices of 65 scheduled formulations under Drugs (Prices Control) Order, 2013," it said in a statement.

NPPA fixes ceiling price of essential medicines of Schedule I under the Drugs (Prices Control) Order (DPCO) 2013.

In respect of medicines that are not under price control, manufacturers are allowed to increase the maximum retail price by 10 per cent annually.

The calculation for essential drugs is based on the simple average of all medicines in a particular therapeutic segment with sales of more than 1 per cent.

Set up in 1997, NPPA has been entrusted with the task of fixation/revision of prices of pharma products, enforcement of provisions of DPCO and monitoring of prices of controlled and decontrolled drugs.

Source: *ET Healthworld, 19th December 2017*

CCI Starts Probe on Alleged Price Fixing of Key Anti Diabetic Drugs

Competition Commission of India has initiated an investigation on drug makers Abbott, Novartis, Emcure Pharma and USV Pvt Ltd over alleged price fixing of the blockbuster anti-diabetic drug Vildagliptin, people aware of the development said.

The fair play regulator has sent notices to the four drug makers, asking them for trade details of this drug in an attempt to find out if the companies colluded with each other to keep the price of the drug at certain levels, they said. Competition Commission of India (CCI) is also looking at the involvement of senior executives from these companies over price fixing, sources said.

Swiss drug maker Novartis confirmed it has received a notice from CCI and has responded to it. “Given that the matter is sub-judice, you will appreciate that we are unable to comment any further,” a company spokesperson said in an email response to ET.

Abbott did not respond to repeated phone calls and an email sent by ET as of press time Wednesday. Emcure also did not respond to an email query as of press time while USV remained unreachable for a comment.

CCI's notice comes 10 months after ET had reported that a whistle-blower had reached out to various Indian regulators over details of cartel allegedly formed by these drug companies for this specific drug.

Vildagliptin, sold under the brand name Galvus, is a proprietary drug of Novartis that comes under the new class of antidiabetic drugs known as DPP 4 inhibitors. These drugs are prescribed for patients with Type 2 diabetes and are considered to be far more effective in controlling blood glucose level compared to the older class of drugs.

Novartis, which reported revenues worth Rs 397 crore this year for this drug, has licensed the marketing rights to Abbott, Emcure and USV. This year, the combined brand of Vildagliptin recorded a sales worth Rs 790 crore, in the Rs 2,600-crore gliptin market.

The whistle-blower had reached out to several Indian regulators in February alleging that Novartis controls the pricing structure for Vildagliptin and that is followed by the other license holders, where the drug prices are matched to the lowest decimal. Though there is no written communication between partners, these companies also synchronise every price change, the person alleged. To back these claims, the whistle-blower had sent a chart that listed the various dosage size of these brands, and all of them were priced in the same range.

Price cartelisation is prohibited under the Competition Act, 2002.

Antitrust lawyers that ET spoke to said that though cartel enforcement has been a focus of CCI since the beginning, it has taken time to gain traction.

Estimates suggest that CCI has investigated several cases of cartels (including in pharmaceuticals sector), imposing a fine of more than Rs 7,500 crore on various companies and their officers.

Source: *ET Healthworld, 14th December 2017*

Torrent Pharma Completes Acquisition of Unichem Laboratories Ltd

Torrent Pharmaceuticals Limited on Thursday announced that it has completed acquisition of branded business of Unichem Laboratories Limited for India and Nepal, including its Sikkim manufacturing facility, on a going concern basis by way of slump sale. This transaction was in pursuance of the definitive binding agreement entered into between Torrent and Unichem on November 3, 2017.

"From today, Torrent begins the integration of the Unichem business following the successful closure of its acquisition. The integration will aim to fuel and support strong growth of the acquired Unichem brands, consolidating speciality reach with a relentless focus on enhancing productivity. The acquisition will accelerate Torrent's presence in the chronic space especially in the high growth segments of Indian Pharma market like Cardiology, Diabetology and Gastroenterology. Moreover, Unichem brings in an important new platform in Torrent's sustainable growth strategy by expanding the Company's presence in the OTC segment," Torrent said in a statement.

Samir Mehta, Chairman -Torrent Pharma said: "The acquisition of Unichem's domestic branded business by Torrent Pharma is a major step forward in the company's growth strategy in consolidating its India business. Both companies Unichem and Torrent share a long and proud history in the Indian pharma market with a common business culture, a factor which I believe will immensely aid in the successful integration of the combined business"

Source: *ET Healthworld, 14th December 2017*

Sanofi India Appoints N Rajaram As Managing Director

Pharma company Sanofi India today said it has elevated N Rajaram as the Managing Director of the company with effect from January 1, 2018.

Rajaram will succeed Shailesh Ayyangar, who served as MD for 12 years and will now take up a new role in the Sanofi Asia region effective January 1, the company said in a statement.

Ayyangar will continue as the non-executive director on the board of Sanofi India Ltd (SIL).

Rajaram was appointed whole-time director of the company in October 2015. He had joined in February 2014.

He brings with him nearly two decades of experience and has worked with Hindustan Unilever and Airtel earlier.

"This transition has been planned well in advance and I am very confident that under his (N Rajaram) leadership, SIL will scale greater heights of performance and continue to serve the patients of our country," Ayyangar said. PRJ MKJ

Source: *ET Healthworld, 16th December 2017*

SC Asks Drugs Advisory Body to Decide Fate of 349 Banned Combination Medicines

In a potential relief to several drug makers, the Supreme Courthas asked the country's technical advisory body on drugs to decide on the fate of more than 300 combination medicines banned by the government between March 2016 and June 2017.

Companies can make and sell the 349 contested fixed dose combination drugs(FDCs) while Drugs Technical Advisory Board (DTAB) deliberates on the issue.

In an order dictated in open court on two government notifications banning these FDCs, aSupreme Court bench of Justices Rohinton Fali Nariman and Sanjay Kishan Kaul on Thursday said it was setting aside the ban on 15 such drugs which were manufactured in India before 1988. The bench will pronounce its official judgement on Friday.

For the remaining 334 FDCs, the court suggested that DTAB should decide whether the manufacture and sale of these drugs should be regulated, restricted or outright banned, and submit a report with its recommendations to the government within six months.

FDCs are cocktail drugs that contain two or more therapeutic ingredients packed in a single dose. While 344 of the contested drugs are currently available in the market as the Delhi High Court in December last quashed the ban on them imposed in March last year, the other five FDCs banned in June, too, can now return to the market.

The Supreme Court bench said DTAB, or a sub-committee it sets up, should hear arguments by the drug industry as well as patients group All India Drug Action Network (AIDAN), which is in favour of the ban notifications, before preparing its report. The government is expected to carefully consider this report, “apply its mind” and accordingly either maintain or modify its ban notifications, according to it.

The court also clarified that this verdict is specific to the two ban notifications due to “peculiar facts” of the cases. The Kokate committee — the government's expert committee that had studied the FDCs and declared them “irrational” — was not clear as to the reasoning behind its decision, it observed.

However, if it chooses to, the government can carry out further inquiry on whether such drugs should continue to be marketed in the country, the court suggested.

“The judgment means that the government need not mandatorily consult DTAB to prohibit the manufacture and sale of FDCs it finds irrational and can use expert committees like the Kokate committee,” said S Srinivasan, a member of AIDAN.

“Earlier, the Delhi High Court had quashed the ban only on the reasoning that DTAB was not consulted, but now the government has been empowered to act fast,” he said.

Source: *ET Healthworld, 15th December 2017*

Drug Makers Can Now Expect More Regular Checkups From USFDA

Audits of Indian drug manufacturing facilities by the Food and Drug Administration are set to rise sharply after October's Mutual Recognition Agreement between the US regulator and eight European Union member states.

The pact, seen as an unprecedented move, includes Sweden, Austria, Croatia, France, Italy, Malta and Spain. It allows for recognition of each other's inspection outcomes and better use of expertise and resources by eliminating duplication. Relying on inspections by EU regulators will allow USFDA to shift resources to other locations, the latter told ETin a statement.

"This will allow USFDA to better identify drug quality problems earlier and prevent poor quality drugs from entering the US market," it said.

While that may lead to increased scrutiny for Indian drug companies — a significant number are already grappling with regulatory compliance — the decision may benefit units with a consistently better track record with EU.

Indian Pharmaceutical Alliance secretary general DG Shah agreed that inspections could be stepped up but termed it a long-term benefit, underscoring the positive outcome of a few recent inspections.

Clearing a growing backlog of pending approvals is also seen as a favorable effect of increased inspections.

A comparative analysis of FDA inspections in EU, China and India shows higher inspection coverage leads to lower rates of manufacturing violations. During 2010-15, the number of FDA inspections of Indian companies more than doubled to 270 from 108, indicating tighter regulatory oversight. Almost a third of facilities in India have never been inspected by the agency, a senior industry official said.

Barring a few exceptions such as Aurobindo, Zydus Cadila and Divis Labs that have seen comparatively better inspection outcomes, the likes of Sun Pharma, Dr Reddy's Laboratories (DRL), Lupin and Wockhardt are in longwinded remediation processes following warning letters and import restrictions.

Smaller peers are in a similar state. IPCA Labs, Emcure and USV, having exposure to the US markets, have also been slapped with a steady stream of adverse observations.

Effects are noticeable. In one of its worst showings, Sun slipped into losses in the first quarter, ending a 12-year dream run of profits, while others like Lupin and DRL showed a wobbly trend, their market value nearly bottoming out in the medium term. Indian companies account for around 30% (by volume) and about 10% (by value) of the $70-80 billion US generics market, according to a November note the India Brand Equity Foundation (IBEF).

Serious challenges lurk. A report released in July by CARE Ratings shows in FY16, pharmaceutical exports to the US rose 27.8% to $5.5 billion but weakened dramatically the next year to 1.3%.

Crimped supplies from Indian sites due to repeat failures on several counts are cited as a key reason for the sudden nosedive, apart from a shrunken launch pipeline, pricing pressures and a wave of consolidation in US distribution channels. However, compliance records may improve with USFDA routinely stepping in with training workshops in key industry hubs like Goa, Ahmedabad, Chandigarh and Hyderabad. Commitment of leadership teams and investment toward upgrade and automation is also expected to reap benefits, experts said.

Arista to be India Dy Director

USFDA said Thomas Arista will assume the role of deputy director of India office, pending clearances. Arista is regarded as a specialist in auditing units that make injectable drugs. Associated with several India inspections, he's reputed to be tough but hands-on. USFDA also confirmed Letitia Robinson will be director of the India office (as had been previously reported) and will assume the role once clearances are completed, the agency spokesperson said.

Source: *ET Healthworld, 18th December 2017*

Glenmark Completes Phase 3 Study for Nasal Spray

Glenmark Pharmaceuticals today said it has completed phase 3 study of its investigational fixed-dose combination nasal spray and plans to submit a new drug application with the US health regulator.

In a BSE filing, Glenmark said it met its primary clinical endpoint in a phase 3 study evaluating the safety of Ryaltris, an investigational fixed-dose combination nasal spray, used to treat seasonal allergic rhinitis.

Glenmark plans to "submit the company's first new drug application (NDA) to the USFDA for Ryaltris for the treatment of patients with seasonal allergic rhinitis (SAR) in the first quarter of calender year 2018," it added.

The company said Ryaltris has been conditionally accepted as the brand name for GSP 301 Nasal Spray by the US Food and Drug Administration (USFDA).

"We have worked closely with the USFDA on the clinical development programme for Ryaltris, and look forward to providing robust data to support its potential approval," Glenmark Pharmaceuticals President and Chief Medical Officer Fred Grossman said.

This Phase 3, US-based trial was a study that enrolled 601 adults and adolescents, 12 years of age and older, with at least a two-year history of perennial allergic rhinitis.

Patients were randomised to 52 weeks of twice-daily treatment with Ryaltris, or two different formulations of a placebo nasal spray, the filing said.

Source: *ET Healthworld, 14th December 2017*

Aurobindo, Dr Reddy's Laboratories Frontrunners to Buy out Bankrupt Orchid Pharma

Indian drug companies Aurobindo Pharma Ltd. and Dr Reddy's Laboratories Ltd. are emerging as the frontrunners to buy out bankrupt Orchid Pharma Ltd. as they seek to expand their capacities.

A key player in injectables and active pharmaceutical ingredients (API) in its heyday, Orchid has received interest from 7-8 companies including international private equity funds and stressed asset buyout firms, people familiar with the development said. Aurobindo Pharma and Dr Reddy's, both based in Hyderabad, did not respond to emails seeking responses on the matter.

"Several parties have submitted their interest. We have received bids from a few local pharma companies as well, who we believe could be a right fit for the company," said a person involved with the matter who did not wish to be identified. "Things will become clearer when we receive binding bids and hopefully at good valuations."

Lakshmi Vilas Bank referred Chennai-based Orchid Pharma to the National Company Law Tribunal for defaulting on repayments to the tune of Rs 50 crore. The company owes more than Rs 3,500 crore to a group of lenders led by the State Bank of India. It was on the Reserve Bank of India's second list of 28 defaulters that had to be referred to the NCLT before December 31 if no resolution was found by December 13.

The resolution professional appointed for Orchid Pharma, Sripatham Ramkumar, called for expressions of interest last month from potential investors after the NCLT Chennai bench ordered initiation of the insolvency process against the debt-laden firm in August. The last date for submitting expressions of interest was set as December 1, after which the process of submitting non-binding and binding agreements would start.

ET reported in October that Orchid had attracted interest from both private equity funds and strategic domestic companies and the likes of KKR, the distressed asset platform of Piramal Enterprises & Bain Capital and pharma giant Lupin.

"The assets are good. Orchid Pharma has two API manufacturing facilities in India and three formulation manufacturing sites in India. These are all approved by the US Food & Drug Administration, the UK's Medicines and Healthcare Products Regulatory Agency and other regulators and agencies. All these demonstrate the potential of these plants," said another person familiar with the transaction.

Orchid Pharma, once a leader in injectables and manufacturing of some APIs, has been facing a financial crisis with lenders and investors approaching legal fora for a remedy. It was brought under the corporate debt restructuring scheme, initiated during 2013, for the revival of its operations.

Source: *ET Healthworld, 17th December 2017*

Online Pharmacy Huge Health Risk

Indian pharmacists fear rise in self-medication and abuse unless online drug sales are checked.

In the run up to the 69th Indian Pharmaceutical Congress to be held from December 22-24 in Chandigarh, the hosts of the event Indian Pharmaceutical Congress Association (IPCA) and Association of Pharmaceutical Teachers of India (APTI) have asked government to regulate online pharmacy in the interest of common man.

"A statutory provision needs to be made," said Dr. Shailendra Saraf, Chairman Organising Committee, IPC 2017, and added, "insisting that e-pharmacies need proper checks and balances fearing the huge potential of exploitation and health risk".

The Drugs Controller General of India is considering tracking online sale of medicines to ensure patient safety. In December 2015, the drug regulator- Drugs Controller General of India had issued a circular stating that sale of drugs over the internet is in contravention of the Drugs and Cosmetic Act, a legislation which governs the sale of drugs in India. The Act says that all medicines have to be dispensed under the supervision of a registered pharmacist after declaring e-pharmacies illegal. But there is no legal framework in site yet.

Online pharmacies have been increasingly popular in India because they offer discounts and the convenience of getting a doorstep delivery of medicines. But pharmacy experts are worried about the absence of a pharmacist in dispensing medicines.

Pharmacist as gatekeeper

A pharmacist is responsible for dispensing the right medicines and even counseling a patient about side-effects and dosage. In the online space, where the medicines are delivered at the patient's home, there is no possibility of an interaction between a patient and a pharmacist.

The Drugs and Cosmetic Act requires that a pharmacy should run under the continuous personal supervision of a registered pharmacist whose name should be displayed conspicuously on the premises.

The pharmacy profession comprising the industrial and practice sectors is undergoing a rapid change. Indian Pharma industry, which has registered a spectacular progress today, ranks 4th in volume and 13th in value in the global pharmaceutical market with exports worth US Dollars 2.6 billion besides domestic sales amounting to over US Dollars 4 million.

Dr. Shailendra Saraf, Vice President, Pharmacy Council of India, says, "The ever expanding Pharma's industrial and practice sectors need clinically and technologically trained pharmacy professionals who can face global challenges and compete with the multinationals. The pharmacist is no longer a mere dispenser of drugs but has assumed a more crucial role in medicine management and as overall health care programmer."

69th Indian Pharmaceutical Congress 2017

The Indian Pharmaceutical Congress is a national annual event of pharmacist from all walks of pharmacy profession to deliberate various issues relating to industry, regulatory,

academia, hospital and community pharmacy and to evolve collective wisdom for formulating newer policies for the country in the relevant fields and for the betterment of mankind.

IPCA organizes the IPC every year with an objective to "advance and promote the cause of Pharmaceuticals Sciences and Profession of pharmacy in all their aspects so as to ensure that Indian Pharmacy Products and profession are the best in the world and to help the public to get the best benefit out of the same."

The theme of the 69th IPC, "Skill And Will To Make And Serve Quality Pill" envisages how a pharmacist can play a leading role in the country to promote and realize the vision of healthy India as well as stimulate discussions and thought process centered around how the country and the pharmacy profession respond to realize the vision.

Source: *ET Healthworld, 18th December 2017*

Nod to Indian Firm to Conduct Phase-I Clinical Trial on Zika Vaccine: Govt

The Drugs Controller General (India) has granted permission to an Indian firm to conduct Phase-I clinical trial, in pursuance to its application to the DCG (I) on a Zika virus vaccine, the government has said.

Union Minister of State for Health and Family Welfare Ashwini Kumar Choubey in the Lok Sabha had said that an Indian firm had submitted an application to the drugs controller.

"The application was on the Zika virus vaccine, along with non-clinical (Animal) Toxicity data, claiming 100 per cent efficacy in animals for grant of permission to conduct the Phase-I clinical trial," he said in a written reply to a question.

"Based on the evaluation of application, in consultation with the Experts Committee, the DCG (I) has granted permission to conduct the Phase-I clinical trial," Choubey said.

On the same day, Anupriya Patel, also Union Minister of State for Health and Family Welfare, said in a written reply that the World Health Organisation (WHO) had declared the Zika virus disease to be a Public Health Emergency of International Concern (PHEIC) on February 1, 2016, following the Zika outbreak in Brazil and other Latin countries and its association with birth defects (microcephaly) in new borns.

"Further, the WHO declared that it ceased to be a Public Health Emergency on November 18, 2016," she said.

She added that the ministry has a three-pronged action plan on combating the disease, and there are 27 laboratories in the government sector that can test the Zika virus disease.

Source: *ET Healthworld, 19th December 2017*

Fourrts

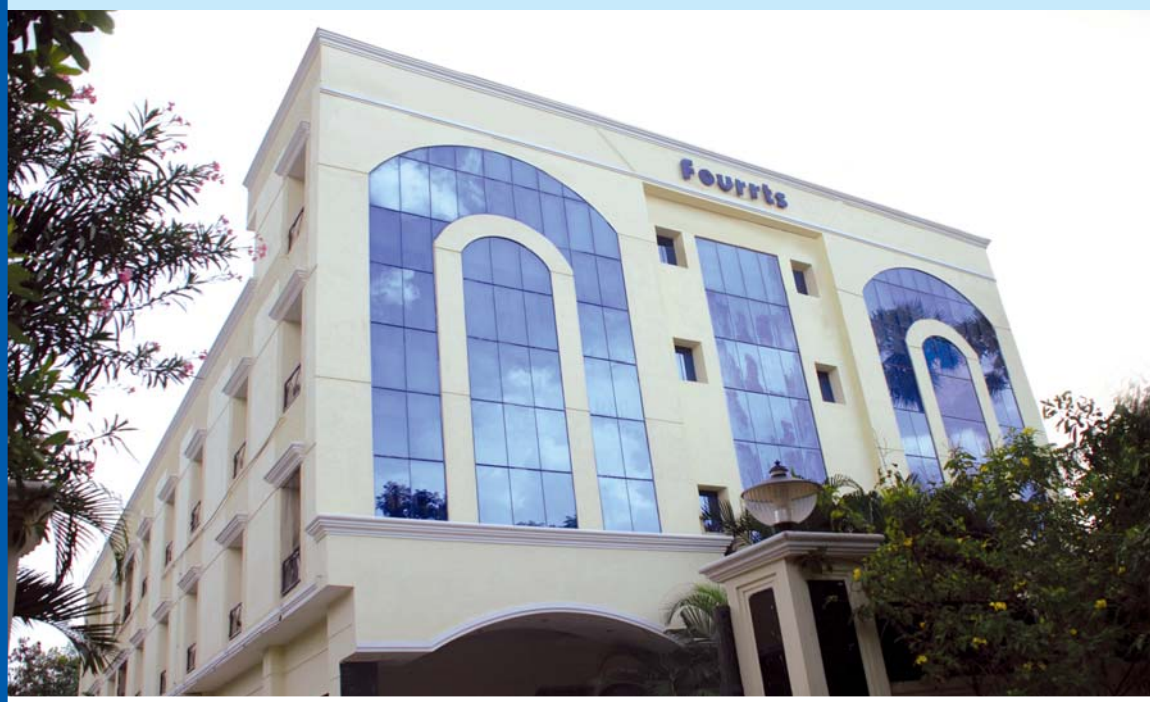
(India) Laboratories Pvt. Limited

Manufacturers and Exporters of
Quality Pharmaceutical Formulations
as per cGMP Standards

'7' Time Quality Excellence Award Winner

ISO 9001
BUREAU VERITAS
Certification

UKAS
QUALITY MANAGEMENT
008



AN ISO 9001:2008 CERTIFIED COMPANY

Fourrts

Innovating for good health...

Corporate Office : No. 1, Fourrts Avenue, Annai Indra Nagar, Okkiyam Thoraipakkam, Chennai - 600 097, India.
Phone : 91-44-4344 1880 Fax : 91-44-2458 1199 E-mail : admin@fourrts.com www.fourrts.com

Works : Vandalur Road, Kelambakkam, Tamil Nadu - 603 103, India.
Phone : 91-44-47404310 Fax. 91-44-27475083 E Mail : fourrts@plant.fourrts.com