ISSUE No. 31

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Jul. - Aug. - Sep. 2016

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

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 31 Jul. - Aug. - Sep. 2016

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

Pharma Web wishes you all a "Happy Dashera and a very Happy Deepawali".

The 31st issue of Pharma Web News letter for the months of Jul-Sep 2016 is being released for your reading. We had a very grand Silver Jubilee Celebration on 16th July 2016, which was attended by 200 and more Pharma Professionals. Our Congratulations to Shri. J. Jayaseelan and his team for the way in which they have conducted the function making it a grand success. Our sincere thanks to Our Chairman Shri. S.V. Veerramani and all the other dignitaries who have graced the Occasion. Our sincere thanks to Hotel Le Royal Meridien for the great ambience and the excellent food provided by them.

We are Happy to announce that The Tamilnadu Pharmaceutical Sciences Welfare Trust has moved in to their more spacious fully air conditioned premises at Spencer Plaza, Anna Salai from 1st of Sept 2016.

We reproduce in this issue the two guest lecturers delivered during the Silver Jubilee function viz **"Roadmap for marketing to Small and Medium Pharma companies in the current scenario"** by Dr. Shailesh Ayyangar and **"Intellectual Strategies to Indian Pharma Companies"** by M/s. Swapna Sundar. The third article **"Pharmacist Role: safety First with medicines"** is by Mr. T. Senthamil Selvan, J K K Nattaraja College of Pharmacy, Kumarapalayam. In addition we have the highlights of Silver Jubilee function, Notifications, Events and the Pharma News.

The Chairman and trustees of Tamilnadu Pharmaceutical Science Welfare trust Congratulate Prof. Chinna Swamy for being conferred the prestigious IRF **'Life Time Achievement Award- 2015'** by **THE INDIAN PHARMACEUTICAL ASSOCIATION** at the IPA CONVENTION held at Raipur, Chhattisgarh on 22nd. Jul 2016.

I am very happy to be amongst you once again through this editorial. Your views, comments and suggestions about this news letter will help us to further improvement of Pharma Web.

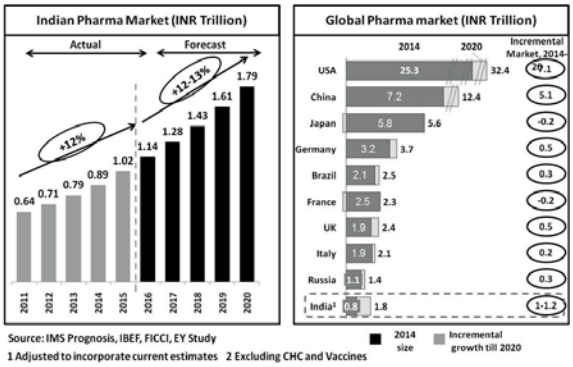
With Best regards
K. Prafulla Chandra
Associste Editor.

ARTICLES

ROAD MAP FOR MARKETING TO SMALL & MEDIUM PHARMA COMPANIES IN THE CURRENT SCENARIO

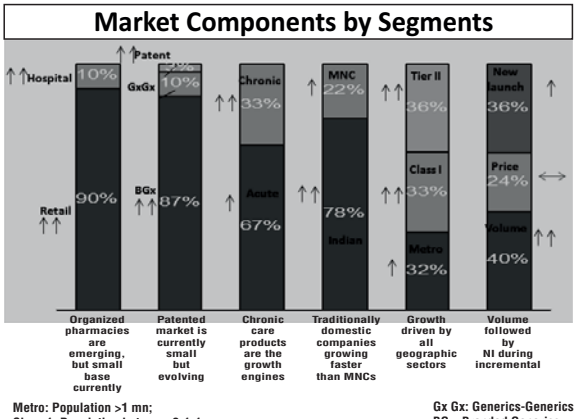
By
Dr. Shailesh Ayyangar,
Managing Director - Sanofi India Limited, Vice President - South Asia, Global Operations - Sanofi Group
President - Organisation of Pharmaceutical Producers of India (OPPI)
(Lecture Delivered on 16th July, 2016 during the TNPSWT Silver Jubilee Celebration)

India -a volume driven market has had a dream run in the last decade and would continue to grow double digit



Source: IMS Prognosis, IBEF, FICCI, EY Study
1 Adjusted to incorporate current estimates 2 Excluding CHC and Vaccines

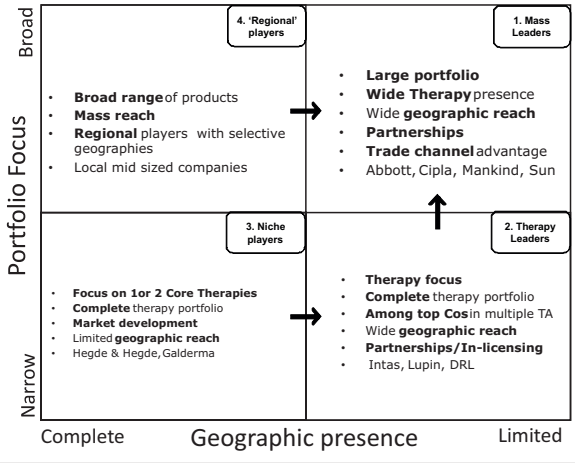
Primarily a retail market dominated by branded generics; growth largely from chronic segment and domestic companies



Metro: Population >1 mn;
Class 1: Population between 0.1-1 mn

Gx Gx: Generics-Generics
BGx: Branded Generics

How have companies positioned themselves in the industry….



What are the imperatives for each cluster…….

	1. Mass Leaders	2. Therapy Leaders
Key characteristics	✓ Portfolio : Large ✓ Coverage : Mass and specialists. Multiple lines of FF in same therapy areas ✓ Geographic reach : Urban and Rural ✓ Range of 'me-too' as well as differentiated products with competitive pricing	✓ Portfolio : Leadership in multiple therapy areas ✓ Quick to launch new products and LCM ✓ Marketing tie-ups to ensure complete therapy presence ✓ Coverage : Multiple lines of FF in key therapy areas ✓ Price : Competitive to premium
What you need	✓ **Cost** leadership ✓ **Channel** engagement ✓ Ability to invest in **large FF** ✓ Portfolio to **reach rural**	✓ **Quick to innovate and launch** ✓ **High partnership zeal** ✓ Ability to invest in **large FF** ✓ **Building big brands** ✓ **Market development** ✓ **KOL** management

What are the imperatives for each cluster…….

	3. Niche players	4. 'Regional' players
Key characteristics	✓ Portfolio : Differentiated offering ✓ Coverage : Dedicated FF and/or task force for specialists ✓ Geography : More urban than rural focus ✓ Price : Potential for premium products	✓ Portfolio : Large but not complete ✓ Presence in multiple therapy areas ✓ Coverage : Mass but limited to regions ✓ Price : Low
What you need	✓ Focused **innovation** and pipeline in niche area ✓ Equity in area of **expertise** ✓ **Skilled FF** to establish equity with specialists ✓ **Building big brands** ✓ **Market development** and **KOL** engagement	✓ **Cost** advantage ✓ **Regional** focus / limited focus ✓ **Channel** engagement

We have to make choices….

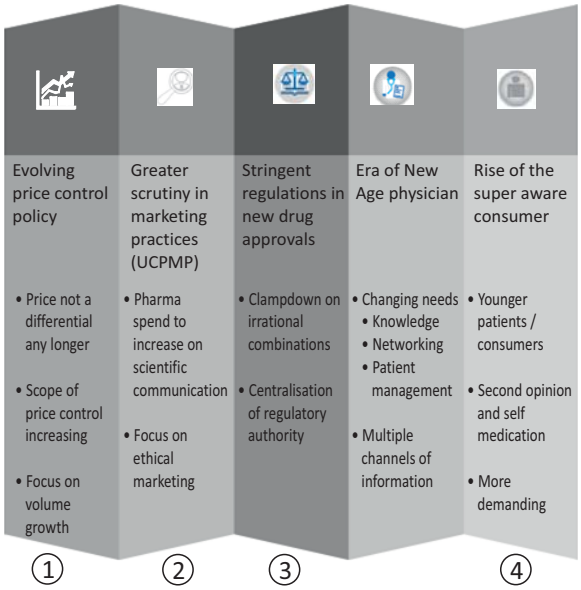
Organisation Vision

- Where do we want to reach
- Do we have a path
- What options do we have

Core Competencies

- What do we have and what do we need
- How do we bridge the gap

Adapt to changing environment



1 Build Big Brands

Develop brand building excellence

- Research and insight driven marketing
- Strong brand planning process
- Active life cycle management
- Strong KPI focus and tracking

- Sales Force Effectiveness Monitoring
- Robust sizing and deployment methodologies
- Focus on SF skill and knowledge upgradation

- Building stronger customer relationships
- Emphasis on customer segmentation rather than just customer value
- Customer delight or Customer Experience

② Value Added Services

Market development programs to improve patient adherence and access

Key programs

Disease management / Treatment protocols

- Focus on disease management by improving diagnosis and treatment / compliance levels
- Touches both HCPs & patients through online and offline medium

Disease awareness

- Improve quality of care and awareness by patient education
- Focus on detection and screening
- Presence in chronic TA such as Diabetes, CKD, Osteoporosis

Patient assistance

- MNCs more active in patient support programs in prohibitive and high priced treatments in Oncology, Vaccines, CNS
- Indian co's also become active in PAP especially in Biosimilars

Benefits

- Patient support program (PSP) help companies to expand the markets by enhancing diagnosis rates and treatment protocols
- Enables differentiation in the minds of doctors and patients, and build therapy leadership

② Value Added Services

Engagement models with stakeholders and channel partners

−Companies are partnering with hospitals for operational improvement and knowledge sharing

AstraZeneca — Helps in formulating antibiotic policy for hospitals

Cipla — Conducts inventory management workshop for pharmacists in key hospitals

- A blanket approach for retail and hospital channel may not yield optimal results
- Engagement models with hospital stakeholders need to be defined, which will provide a distinct competitive edge

RANBAXY — Companies are extending 50-80% margins to distributors for generics

Cipla — Distributors, in turn, are pushing the products in retail channels, especially in lower tier towns

- Generics can provide an opportunity for penetration in lower tier towns
- At the same time, generic generics can also pose a threat to branded generics, if promoted in similar markets

③ Launch Excellence

Focus on long term launch value rather than number of launches

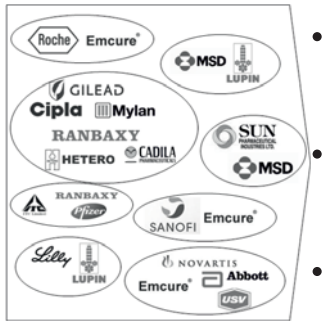
15% — Decrease in the rate of new launches in last 2 years

< 1 cr — Value of majority of new products in 1st year of launch

2% — Success rate of new launches in the Indian Pharma Industry

③ Partnerships

Partnerships drive "whole greater than simple sum of parts"



Benefits:

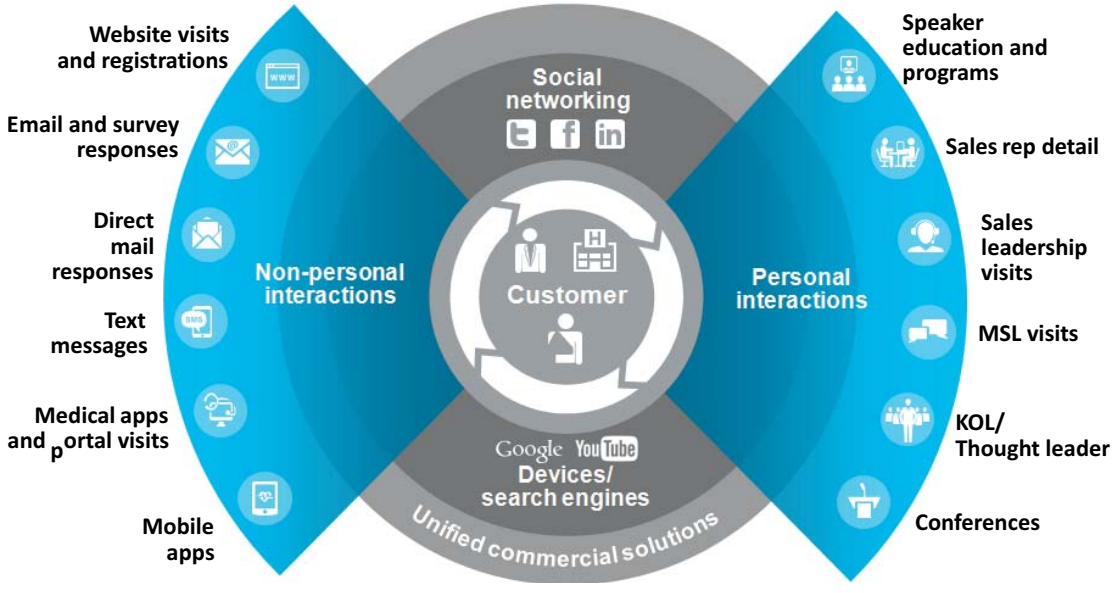
- Partnerships bring in portfolio differentiation to the partner
- Together partners gain considerable share of voice
- Partnerships enable greater reach beyond Metro and Class I cities
- Together partners are able to manage pricing and competitive threats (esp. in bio-similars)

Key learning:

- Co-marketing is the way forward and not co-promotion
- Technology transfers enable capability development on manufacturing and R&D

④ Multichannel Marketing

Multichannel marketing- one size does not fit all



Above all- build an organisation culture that fosters innovation and challenges the norm

- **Tremendous opportunities – but also challenging environment**
- **Quality will remain a key differentiator**
- **People centric organization will retain an edge**
- **Partnerships and collaborations – a new norm**
- **Focus and make choices**

Editorial Policy and Disclaimer

The objective of this newsletter is to impart current 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.

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

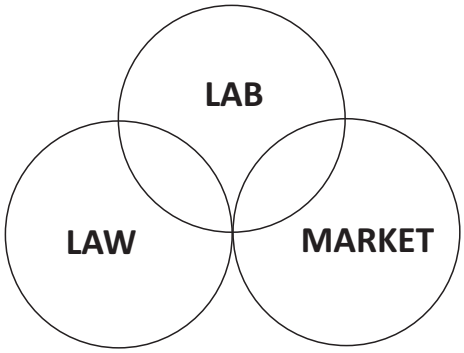
This issue of Pharma Web is also available online at the Trust website www.pictrust.com

INTELLECTUAL STRATEGIES TO INDIAN PHARMA COMPANIES

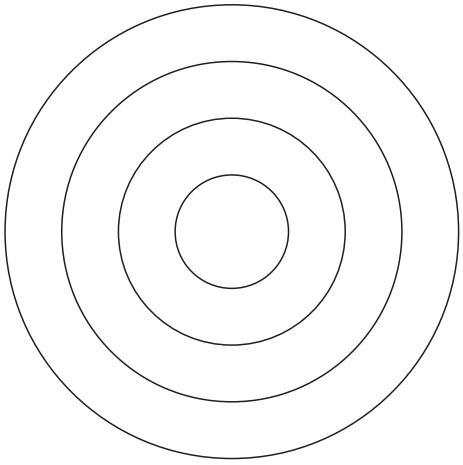
By

Mrs. Swapna Sundar,
CEO, IP DOME Strategy Advisors Pvt. Ltd. Chennai
(Lecture Delivered on 16th July, 2016 during TNPSWT Silver Jubilee Celebration)

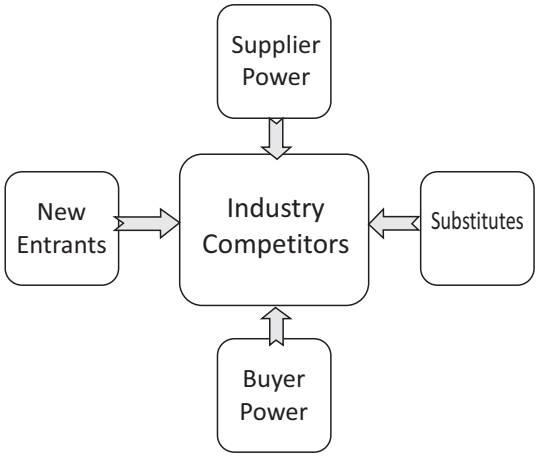
At the intersection of the Lab, the Law and the Market ™



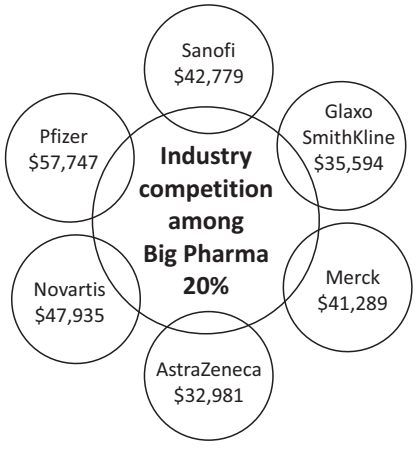
IP Strategy "at the intersection of the lab, the law and the market" ™



Porter's five forces

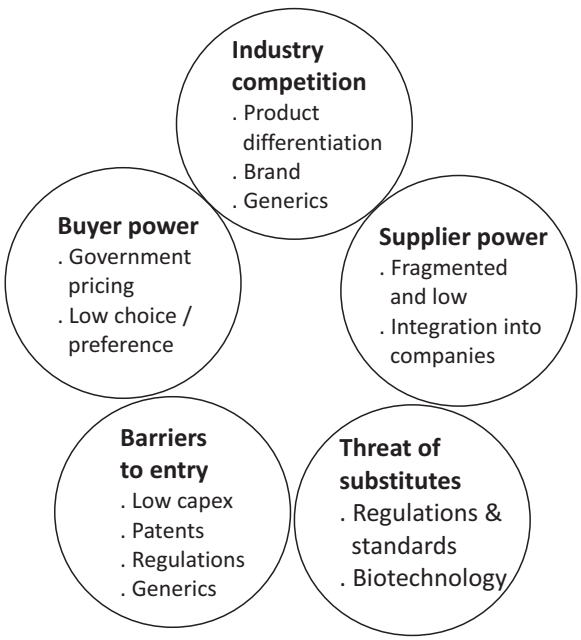


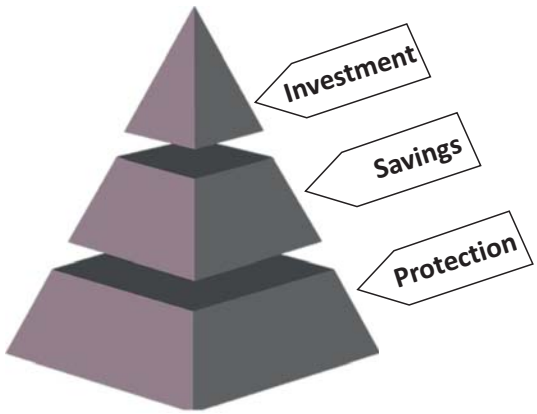
Porter's five forces



Business Strategists at MNCs depend on

Two types of markets

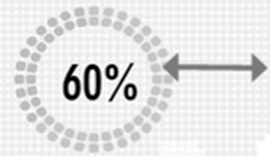


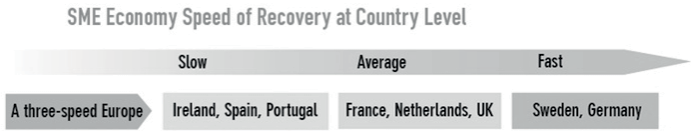


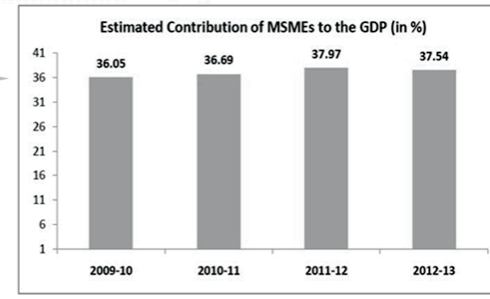
MSME In Europe…

…are the engine of the European economy. They are essential source of jobs, create entrepreneurial spirit and innovation in the EU and are thus crucial for fostering competitiveness and employment.

-Gunter Verheugen,
Member of European Commission,
Responsible for Enterprise and Industry







At the intersection of the Lab, the Law and the Market

Mikael Dolsten, President – Worldwide Research and Development of Pfizer says, "We have also learned that it takes more than just great science to deliver meaningful new therapies… We have better integrated science and business, which meant transforming our approach to be more collaborative, more focused, and, we believe, more powerful for patients. Ultimately, we've worked to design an engine that can deliver patients a sustainable flow of important new medicines and vaccines, year after year."

Protection

- Policy on IP Acquisition: consider the best protection package and make sure that all the formal rights are acquired as early as possible.
- Policy on IP Exploitation: Protect IP which may not require formal registration. Exploit IP assets through commercialization; entering into licensing or franchising agreements; assignment; the creation of JV; cross-licensing; or the use of IP to obtain business finance.
- A Policy on IP Monitoring: Consulting patent and trademark databases regularly to find out about recent technical developments and new technologies, identify new licensing partners or suppliers, new market opportunities, monitor activities of competitors, identify possible infringers, and avoid infringing competitors' rights.
- A Policy on IP Enforcement: Determine the steps you would take against infringement and ensure a 'dispute' budget. Create barriers to entry.

Savings

Jugaad is a Hindi word meaning an innovative fix. It's an improvised solution using ingenuity and resourcefulness, often due to very limited resources.

When we talk about jugaad innovation, we are referring to the mindset and principles that are used to make this happen. Jugaad innovation is frugal, flexible and inclusive. It's also called a 'hack' in the US.

INVISIBLE INNOVATION
FRUGALITY, FLEXIBILITY, INCLUSIVENESS

- Innovation is a company priority affecting every aspect of the organisation.
- Integrated at every level, and aligned with strategy and objectives of the company.
- Innovation should not be restricted to products, but encompass business processes and business models as well.
- Novelty in technology, organisational structure, products and services.
- Business model innovation and Business Process Management to generate cost savings and improve customer satisfaction by increasing efficiency and reducing cycle-time.
- Climbing up the skill-ladder, forward integration

Simplicity, deep understanding of customers – their needs and habits; 'Good enough' delivers higher value, with 'functional specialisation.'

SME or Start-up?

A start-up is a “temporary organization designed to search for a repeatable and scalable business model.”

A start-up owner's intent is to scale and to grow into a large, disruptive company that has a significant impact on the existing market and may even be intent on creating new markets.

Start-ups are focused on top-end revenue volume and growth potential. They are agile, innovative, rapidly changing.

A start-up will either "exit" the startup phase and become a real business or it might fail.

SME or Start-up?

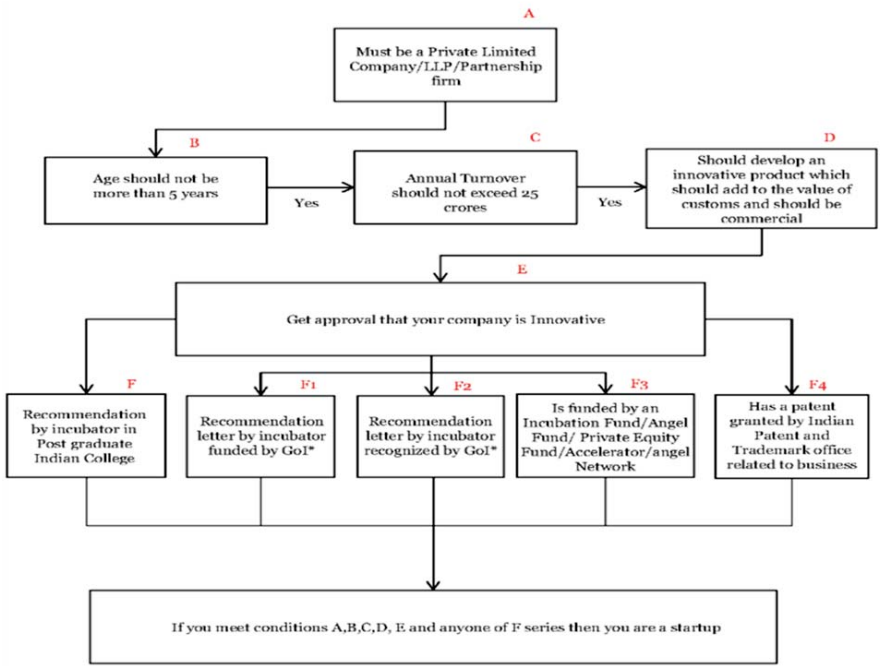
An SME is an "independently owned and operated, organized for profit, and not dominant in its field.”

The SME owner's intent is to be their own boss and secure a financially sustainable place in a local market.

SMEs are driven by making a profit and creating a business offering stable long-term value.

An SME starts out in a structured organisation that is focused on the delivering value to known customers. An SME does not need to change nor is it structured to change rapidly.

START-UP in India

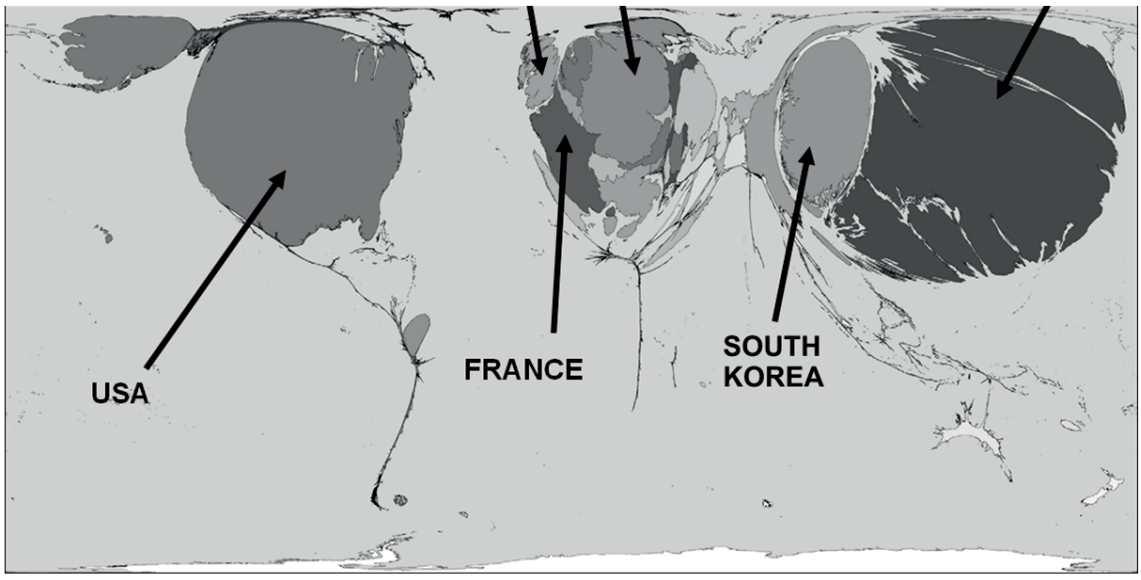


Investment

- Disruptive innovation to capture a small part of the incumbent's business, overcoming his sustainable innovations.
  a. New product
  b. New process
  c. New distribution or service
- Move upstream to the next higher value business.
- Agile, social and inclusive -
- Remember this when you are on top!
- Accelerate innovation and encourage intrapreneurs.
- Collaborate with outside 'thought leaders'.
- Co-innovate with customers.
- License the best, invent the rest!

Co-opetition

As P. Drucker (1996): "The greatest change in corporate culture, and the way business is being conducted, may be accelerating growth of relationships based not on ownership, but on partnership."



In which countries should SMEs file patents?

Window of opportunity

- Brand
- Create independent research units
- Collaborative product development
- Cluster development
- Shared goals
- Publications

TARIFF FOR ADVERTISEMENTS

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

Back Cover	**Rs. 6,000/-**
2nd and 3rd Cover	**Rs. 4,000/-**
Full Page	**Rs. 3,000/-**
Half Page	**Rs. 2,000/-**

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Page size : 24 cm x 18.5 cm

Print area : 20 cm x 16 cm

Advertisers may send the cheque in favour of **'Tamilnadu Pharmaceuticals Sciences Welfare Trust"** to the address of the Trust along with the advertisemen matter is soft copy.

Note: 20% discount on the above rates for four consecutive issues.

PHARMACIST ROLE : SAFETY FIRST WITH MEDICINES

By

Ms. Monisha Harini,
Periyar College of Pharmaceutical Sciences, Trichy

Note: This article was awarded Second Prize in the Essay Competition conducted by our trust.

Introduction:

Pharmacy is a noble and sacred profession committed to the cause of health care of human beings. The pharmacist is charged with the responsibility of providing professional services of high order to the community at large by ensuring production of quality medicine and their scale and distribution to the consumers. The pharmacist is the link between physician and patient.

The pharmacist of today is – Drug Maker, Drug Dispenser, Drug Custodian, Patient Counsellor, Drug Researcher, Drug Educator and above all an Honest & patriotic Citizen. The pharmacist should ensure the patient safety while dispensing the drugs. He/she should provide information to the patients and educate them about the usage of drugs before dispensing it. The roles of the pharmacist are as follow;

Patient Details:

Before dispensing the medicines to the patient, the pharmacist should collect the details of the patient such as: Family history, any hereditary disorder, profession, past accidents, immunodeficiency, allergic reaction if any, etc. This helps the pharmacist to dispense the correct medicine to the patient or change any prescribed medicine if there is a problem with it. It helps to prevent the patient taking medicine that causes allergic reaction.

Information about the medicine to patient:

While dispensing the medicines/drugs to the patient, pharmacist should inform the patient about the medicine like

- What the medicine do,
- Why more than 1 medicine,
- When and How the medicines should be taken,
- How long should tale the medicines,
- What are the side effects,
- What precaution needs to be taken?
- At the time of dispensing the pharmacist should check the medicine for any drug interaction and if found ask the physician to change the prescription.

Shelf life of medicines:

While dispensing the medicines to the patient, pharmacist must check and ensure the expiry date of the medicines. Because the expired medicine not only have less efficacy but also might

develop toxic effects. Pharmacist must also check the expiry date of cosmetics, medical devices and nutraceuticals also. If the medicine is prescribed to a patient for a long time use in chronic conditions, the pharmacist must inform the patient to watch for its expiry date.

Storage of the medicines:

Storage of the medicines is very important. It should be properly stored in pharmacy as well as at home after dispensing the medicines. The pharmacist should properly store the medicines and also should instruct the patients about the storage. Some medicines are hygroscopic, such medicines are to be stored in dark places and should avoid in contact with light and atmosphere. Some drugs are needed to be stored in cool places. Safety & quality of medicine entirely depends on the storage conditions.

Dose:

Dose of the medicine is also important. The low dose causes inadequate effect whereas the high dose might cause toxicity. Hence, the adequate and proper dose is necessary for optimum therapeutic effect. Also the timing of dose is essential. Each dose should be taken at proper intervals. If a dose is left, two doses should not be taken at a time. Pharmacist should educate the patient about the dose.

OTC drugs:

Over the counter (OTC)drugs abuse are increasing now a days and it also causes dangerous effect. Pharmacist should develop the awareness about using the OTC drugs among the patients. While dispensing the OTC drugs, pharmacist should provide the information about the drugs and its side effects. He/she should advice the patients not to take self medication.

Medicines according to patient:

In pregnancy women, the pharmacist should check the medicines that prescribed should be safe to mother and foetus and the medicines dispensed should be non-teratogenic.

For geriatrics patients, the pharmacist should pack each dose individually and should give training to use calendar since they used to forget the dose andmay take two doses at a time.

In paediatric medication, the dose for infants are calculated and dispensed by the pharmacist. For the comfortable administration of medicines to infants special devices like dropper should be dispensed. The vaccine schedule of the infants should be checked by the pharmacist.

Usage of Sterile Equipments:

The pharmacist should give advice about the usage of syringes since it comes in contact with the blood. Pharmacist should give consultation in following regards:

- Needle, syringe, vials and ampoules containing drug should be sterile.
- Disposable syringes should be used.
- It should not be reused.

- Vials, Ampoules & syringes are tested for leakage, microbial growth.
- Eye drops should also be sterile.

Vaccines:

Pharmacist should provide the detailed leaflet about the vaccines to the patient. After vaccination, pharmacist should get receipt from the physician as well as the patients as the proof of vaccination. And also examine the patient for any allergic reaction.

Conclusion:

Preparing & dispensing the medicine are not alone the role of pharmacist. It is the profession of community services that Pharmacist is responsible for the welfare & management of the health of people in the society. Pharmacist's role starts from preparation of medicines, dispensing, andto the regular monitoring of the patient health even after the treatment. Pharmacist should do the patient medication counselling. And should educate the people about the safe handling, storage and usage of medicine. It is very important because any mistake in this regard leads to serious problem.

Thus safety first with medicine is the primary role of the pharmacist!

INFORMATION

M. PHARM & PHARM D SCHOLARSHIPS 2015-16 AWARDED BY TNPSWT

Profile of 3rd Rank Projects

PHARMACEUTICS

Name: Mr. Deepak Upadhyay

Project Title: Formulation development and in vitro and in vivo characterization of curcumin loaded nanodroplets: an attempt to target colon for the treatment of adenocarcinoma

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. R. Suresh Kumar

PHARMACEUTICAL CHEMISTRY

Name: Ms. S. Mala

Project Title: Design, synthesis, characterization and biological evaluation of some novel hetrocyclic compounds using as anti-tubercular agents targeting l,d-transpepdidase-2"

College: Madras Medical College, Chennai

Guide's Name: Dr. A. Jerlad Suresh

PHARMACEUTICAL ANALYSIS

Name: Mr. Shaik Nowshad

Project Title: Isolation and Characterization of some degradation products during stability indicating assay of Tadalafil

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. N. Krishnaveni

PHARMACOLOGY

Name: Mr. V. Rajendran

Project Title: Docking, in vitro acetylcholinesterase inhibitory activity and in vivo memory enhancing activity of certain synthesized flavonoids

College: Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Dr. K. Asok Kumar

PHARMACOGNOSY

Name: Ms. T. Uma Poorani

Project Title: Studies on the edible marine sea weed ulvalactuca linn—a pharmacological promise towards cell cycle target inhibition in anticancer drug discovery

College: Madurai Medical College, Madurai

Guide's Name: Dr. K. Periyanayagam

PHARMACY PRACTICE

Name: Mr. Alfatih Khalil

Project Title: Study on Appropriate and Rational Drug Use In Hypertensive Patients With Other Comorobid Diseases

College: Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Mr. Shiva shanker

PHARM D- PHARMACY PRACTICE

Name: Ms. Gangula Jaswanthi, Ms. K. Manobala,
Mr. R. Nandha Kumar, Ms. S. Neha

Project Title: Assessment of 10-year risk of developing cardiovascular disease in cancer patients and healthy individuals - A case control study

College: Sri Ramachandra University, Chennai

Guide's Name: Dr M.G. Rajanandh

PHARM D- CLINICAL PHARMACY

Name: Ms. Esther K Thomas, Ms. Gayathiri G.R.,
Ms. Georgeena George, Ms. Ginsy Thankachan

Project Title: A Prospective Observational study on Intravenous Heparin Dosing and Therapeutic activated Partial Thromboplastin Time (aPTT) in Patients with Cardiovascular Diseases

College: Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore

Guide's Name: Dr. Manjula Devi A.S

EVENTS

SILVER JUBILEE CELEBRATIONS - TAMILANDU PHARMACEUTICAL SCIENCES WELFARE TRUST

Silver Jubilee Celebrations of Tamilnadu Pharmaceutical Sciences Welfare Trust was celebrated on 16th July 2016 at Hotel Le Royal Meridien, Guindy Chennai – 600032. Mr. J. Jayaseelan, Chairman, Silver Jubilee Celebrations committee, welcomed all the members and this was followed by honoring of the dignitaries on the dias. Mr. S. V. Veerramini, Chairman of our Trust, delivered the ongoing and future developments of the trust.

25 years journey of the trust was explained by a slide show by past secretary Mr. K. Prafulla Chandra & present secretary Mr. N. Sreenivasen. Dr. V. K. Subburaj, former Secretary, Department of Pharmaceuticals , Ministry of chemicals & fertilizers Govt of India, and Dr. J. Radhakrishnan, Secretary, Health and Family Welfare, Govt of Tamilnadu were the chief guests for the function.

Felicitations were offered by Dr. S. Manivannan, Deputy Drugs Controller (India), CDSCO, South Zone, Mr. S. Abdul Khader, Director of Drugs Control, Tamilnadu , Dr. B. Suresh, President Pharmacy council of India and vice chancellor, JSS University, Mysuru, and The President Indian Pharmaceutical Association, Dr. Rao V S V Vadlamudi .

The Silver jubilee Special issue of Pharma Web was released by Dr. J. Radhakrishnan and received by Mr. K. Prafulla Chandra, Associated Editor Pharma Web. This was followed by the address by the chief guest. Dr. V. K. Subburaj inaugurated the new office of the Trust at Spencer Plaza in Anna Salai through video followed by his address. He also distributed Mementoes to all the Trustee members

A special address on the topic " Roadmap for Marketing to small & medium Pharma companies in the current scenario" was delivered by Dr. Shailesh Ayyangar, Managing Director, Sanofi India Ltd & VP- South Asia, Global operations- Sanofi group. This was followed by Lunch. After Lunch Mrs. Swapna Sundar, CEO, IP DOME Strategy advisors Pvt. Ltd. Chennai delivered a talk on the topic of " IP Strategies for SME Pharma Companies".

The concluding part of the celebrations was a lively Pattimandram on "ONLINE PHARMACY-REQUIRED/NOT REQUIRED". The celebrations ended with the vote of thanks by Mr. Krishna Dev, Vice Chairman of the trust.

.About 200 guests from all facets of Pharma Profession attended the gala function.

SILVER JUBILEE CELEBRATIONS - TAMILANDU PHARMACEUTICAL SCIENCES WELFARE TRUST

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Prof. K. CHINNASWAMY
Receives IRF 'Life Time Achievement Award- 2015'

The Tamilnadu Pharmaceutical Sciences Welfare Trust, Governing Body Meeting held on 3rd September 2016 extended its felicitations and Congratulations to Prof. K. Chinnaswamy for receiving the Prestigious IRF 'Life Time Achievement Award - 2015' from THE INDIAN PHARMACEUTICAL ASSOCIATION.

The award was presented to him by Dr. Rao V S V Vadlamudi, President, IPA at the IPA CONVENTION held at Raipur, Chhattisgarh on 22nd July 2016.

The TNPSW Trust members wish him long life to enable him to continue his selfless services in the field of pharmacy at both National and International level and continue to receive many more laurels.

NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 29th June, 2016

G.S.R. 640 (E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by section 12 read with 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. 357(E), dated the 29th March, 2016, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), dated the 29th March, 2016, inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on 29.03.2016;

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

Now, therefore, in exercise of the powers conferred under section 12 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 (Fourth Amendment) Rules, 2016.

(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 (hereinafter referred to as the said rules), in rule 69,-

(a) in sub-rule (2), in clause (c), for the words, letters and figures "categorized in Schedule M and Schedule M-III", the words, letters and figures "referred to in Schedule M relating to pharmaceuticals products and Schedule M-III relating to medical devices and *in-vitro* diagnostics", shall be substituted;

(b) in sub-rule (5), for words, letters and figures "categorized in Schedule M and Schedule M-III", the words, letters and figures "referred to in Schedule M relating to pharmaceuticals products and Schedule M-III relating to medical devices and *in-vitro* diagnostics", shall be substituted;

3. In the said rules, in rule 69A,

(a) in sub-rule (1), for the words, letters and figures "categorized in Schedule M and Schedule M-III", the words, letters and figures "referred to in Schedule M relating to pharmaceuticals products and Schedule M-III relating to medical devices and *in-vitro* diagnostics", shall be substituted;

(b) in sub-rule (3), for the words, letters and figures "specified in Schedule M and Schedule M-III", the words, letters and figures "referred to in Schedule M relating to pharmaceuticals products and Schedule M-III relating to medical devices and *in-vitro* diagnostics", shall be substituted;

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

(a) in sub-rule (1), for the words, letters and figures "categorized in Schedule M and Schedule M-III", the words, letters and figures "referred to in Schedule M relating to pharmaceuticals products and Schedule M-III relating to medical devices and *in-vitro* diagnostics", shall be substituted;

(b) in sub-rule (2), for the words, letters and figures "categorized in Schedule M and Schedule M-III", the words, letters and figures "referred to in Schedule M relating to pharmaceuticals products and Schedule M-III relating to medical devices and *in-vitro* diagnostics", shall be substituted;

(c) in sub-rule (5), for the words, letters and figures, "categorized in Schedule M and Schedule M-III", the words, letters and figures "referred to in Schedule M relating to pharmaceuticals products and Schedule M-III relating to medical devices and *in-vitro* diagnostics", shall be substituted;

5. In the said rules, in rule 75A, in sub-rule (1), for the words, letter and figures, "categorized in Schedule M and Schedule M-III", the words, letters and figures "referred to in Schedule M relating to pharmaceuticals products and Schedule M-III relating to medical devices and *in-vitro* diagnostics", shall be substituted;

6. In the said rules, in rule 76,

(i) for conditions (2) and (3), the following conditions shall respectively be substituted, namely:-

"(2) The applicant proposing to manufacture pharmaceutical products shall comply with the provisions referred to in Schedule M.

(2A) The applicant proposing to manufacture medical devices and *in-vitro* diagnostics shall comply with the quality management system as referred to in Schedule M-III.

(3) The applicant shall provide adequate space, plant and equipment for pharmaceutical products as referred to in Schedule M and for Medical devices and *in-vitro* diagnostics as referred to in Schedule M-III.".

(ii) for condition (8), the following condition shall be substituted, namely:-

"(8) The licensee of pharmaceutical products shall comply with the requirements of 'Good Manufacturing Practices' as laid down in Schedule M and the licensee of Medical Devices and *in-vitro* diagnostics shall comply with the requirements of "Quality Management System" as laid down in Schedule M-III.".

7. In the said rules, for Schedule M-III, the following Schedule shall be substituted, namely:-

"SCHEDULE M-III

[See rules 69, 69A, 75, 75A and 76]

QUALITY MANAGEMENT SYSTEM –FOR NOTIFIED MEDICAL DEVICES AND IN-VITRO DIAGNOSTICS

1. General Requirements:

1.1. This schedule specifies requirements for a quality management system that shall be used by the manufacturer for the design and development, manufacture, packaging, labeling, testing, installation and servicing of medical devices and *in-vitro* diagnostics. If the manufacturer does not carry out design and development activity, the same shall be recorded in the quality management system. The manufacturer shall maintain conformity with this Schedule to reflect the exclusions.

1.2. If any requirement in clause 7(product realisation) of this Schedule is not applicable due to the nature of the medical device and *in-vitro* diagnostics for which the quality management system is applied, the manufacturer does not need to include such a requirement in its quality management system.

1.3. The processes required by this Schedule, which are applicable to the medical device and *in-vitro* diagnostic devices, but which are not performed by the manufacturer are the responsibility of the manufacturer and are accounted for in the manufacturer's quality management system.

1.4. If a manufacturer engages in only some operations subject to the requirements of this part, and not in others, that manufacturer need only to comply with those requirements which are applicable to the operations in which it is engaged.

1.5. It is emphasised that the quality management system requirements specified in this Schedule are in addition to complementary to technical requirements for products.

1.6. Manufacturers of components or parts of finished devices and *in-vitro* diagnostics are encouraged to use appropriate provisions of this regulation as guidance.

2. Applicability:

The provisions of this Schedule shall be applicable to manufacturers of finished devices, In-Vitro Diagnostics, mechanical contraceptives (condoms, intrauterine devices, tubal rings), surgical dressings, surgical bandages, surgical staplers, surgical sutures and ligatures, blood and blood components collection bags with or without anticoagulants intended for human or animal use.

3. Terms and definitions:

3.1 Active implantable medical device.- Active medical device which is intended to be totally or partially introduced, surgically or medically, into the human or animal body or by medical intervention into a natural orifice and which is intended to remain after the procedure.

3.2 Active medical device.- Medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human or animal body or gravity.

3.3 Advisory notice.- Notice issued by the manufacturer, subsequent to delivery of the medical device and *in-vitro* diagnostic devices, to provide supplementary information or to advise what action should be taken in or both in:-

a. the use of a medical device and *in-vitro* diagnostic devices;

b. the modification of a medical device and *in-vitro* diagnostic devices;

c. the return of the medical device and *in-vitro* diagnostic devices to the organization that supplied it; or

d. the destruction of a medical device and *in-vitro* diagnostic devices.

3.4 Customer complaint.- Written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a medical device and *in-vitro* diagnostic devices that has been placed on the market.

3.5 Implantable medical device.- Medical device intended:-

a. to be totally or partially introduced into the human or animal body or a natural orifice; or

b. to replace an epithelial surface or the surface of the eye;

by surgical intervention, and which is intended to remain after the procedure for at least thirty days, and which can only be removed by medical or surgical intervention.

3.6 Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.

3.7 Design input means the physical and performance requirements of a device that are used as a basis for device design.

3.8 Design output means the results of a design effort at each design phase and at the end of the total design effort. The finished design output is the basis for the device master record. The total finished design output consists of the device, its packaging and labeling, and the device master record.

3.9 Design review means a documented, comprehensive, systematic examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems.

3.10 Finished device means any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled or sterilized.

3.11 *In-vitro* Diagnostic means *in-vitro* diagnostics referred in this Schedule including diagnostics kits and reagents that fall under sub-clause (i) of clause (b) of section 3 of Drugs and Cosmetics Act, 1940.

3.12 Management with executive responsibility means those senior employees of a manufacturer who have the authority to establish or make changes to the manufacturer's quality policy and quality system.

3.13 Medical device referred in this Schedule means devices that are notified under clause (iv) of sub-section (b) of section 3 of Drugs and Cosmetics Act, 1940.

3.14 Quality audit means a systematic, independent examination of a manufacturer's quality system that is performed at defined intervals and at sufficient frequency to determine whether both quality system activities and the results of such activities comply with quality system procedures, that these procedures are implemented effectively, and that these procedures are suitable to achieve quality system objectives.

3.15 Quality policy means the overall intention and direction of an organization with respect to quality, as established by management with executive responsibility.

3.16 Quality system means the organisational structure, responsibilities, procedures, processes, and resources for implementing quality management.

3.17 Rework means action taken on a nonconforming product that will fulfill the specified Device Master File requirements before it is released for distribution.

3.18 Specification means any requirement with which a product, process, service, or other activity must conform.

3.19 Validation means confirmation by examination and provision of objective evidence that the particular requirement for a specific intended use can be consistently fulfilled;

3.19.1 Process validation means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications.

3.19.2 Design validation means establishing by objective evidence that device specifications conform with user needs and intended use(s).

3.20 Verification means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

4 Quality management system.-

4.1 General:

The manufacturer shall establish, document, implement and maintain a quality management system and maintain its effectiveness in accordance with the requirements of this schedule.

The manufacturer shall;-

(a) identify the processes needed for the quality management system and their application throughout the organization;

(b) determine the sequence and interaction of these processes;

(c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective;

(d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes;

(e) monitor, measure and analyse these processes; and

(f) implement actions necessary to achieve planned results and maintain the effectiveness of these processes.

These processes shall be managed by the manufacturer in accordance with the requirements of this Schedule. Where a manufacturer chooses to outsource any process that affects product conformity with requirements, the manufacturer shall ensure control over such processes. Control of such outsourced processes shall be identified within the quality management system.

NOTE: Processes needed for the quality management system referred to above shall include processes for management activities, provision of resources, product realization and measurement.

4.2 Documentation requirements.-

4.2.1 General

The quality management system documentation shall include;-

(a) documented statements of a quality policy and quality objectives;

(b) a quality manual;

(c) documented procedures required by this schedule;

(d) documents needed by the manufacturer to ensure the effective planning, operation and control of its processes;

(e) records required by this schedule, and

where this schedule specifies that a requirement, procedure, activity or special arrangement be "documented", it shall, in addition, be implemented and maintained.

For each type or model of medical device or *In-vitro* Diagnostics, the manufacturer shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements. These documents shall define the complete manufacturing process and, if applicable, installation.

The manufacture shall prepare documentation for device or *in-vitro* diagnostics in a form of a Device Master File containing specific information as referred to in Annexure-A appended to this Schedule.

Data may be recorded by electronic data processing systems or other reliable means, but documents and record relating to the system in use shall also be available in a hard copy to facilitate checking of the accuracy of the records. Wherever documentation is handled by electronic data processing methods, authorized persons shall enter or modify data in the computer. There shall be record of changes and deletions. Access shall be restricted by 'passwords' or other means and the result of entry of critical data shall be independently checked. Batch records electronically stored shall be protected by a suitable back-up. During the period of retention, all relevant data shall be readily available.

4.2.2 Quality manual.-

The manufacturer shall establish and maintain a quality manual that includes:-

(a) the scope of the quality management system, including details of and justification for any exclusion or non-application or both;

(b) the documented procedures established for the quality management system, or reference to them; and

(c) a description of the interaction between the processes of the quality management system.

The quality manual shall outline the structure of the documentation used in the quality management system.

The manufacturer shall prepare documentation in a form of a Plant Master File containing specific information about the facilities, personnel and other details as prescribed in Annexure B appended to this Schedule.

4.2.3 Control of documents.-

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in the control of records. Documents shall be approved, signed and dated by the appropriate and the authorised person.

A documented procedure shall be established to define the controls needed.-

(a) to review and approve documents for adequacy prior to issue;

(b) to review and update as necessary and re-approve documents;

(c) to ensure that changes and the current revision status of documents are identified;

(d) to ensure that relevant versions of applicable documents are available at points of use;

(e) to ensure that documents remain legible and readily identifiable;

(f) to ensure that documents of external origin are identified and their distribution controlled; and

(g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

Changes to document shall be reviewed and approved. Change records shall be maintained which will include a description of the change, identification of the affected documents, the signature of the approving individual, the approval date, and when the change becomes effective.

The manufacturer shall ensure that changes to documents are reviewed and approved either by the original approving functionary or another designated functionary which has access to pertinent background information upon which to base its decisions.

The manufacturer shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that documents to which medical devices or *in-vitro* diagnostics have been manufactured and tested are retained for at least one year after the date of expiry of the medical device or *in-vitro* diagnostic as defined by the manufacturer.

4.2.4 Control of records.-

Records shall be established and maintained to provide evidence of conformity to the requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable. A documented procedure shall be established to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

The manufacturer shall retain the records for a period of time at least one year after the date of expiry of the medical device or *in-vitro* diagnostics as defined by the manufacturer, but not less than two years from the date of product release by the manufacturer.

5 Management responsibility.-

5.1 Management commitment:

Top management of the manufacturer shall provide evidence of its commitment to the development and implementation of the quality management system and maintaining its effectiveness by:-

(a) communicating to the employees the importance of meeting customer as well as statutory and regulatory requirements;

(b) establishing the quality policy;

(c) ensuring that quality objectives are established;

(d) conducting management reviews; and

(e) ensuring the availability of resources.

5.2 Customer focus:

Top management of the manufacturer shall ensure that customer requirements are determined and are met.

5.3 Quality policy:

Top management of the manufacturer shall ensure that the quality policy:-

(a) is appropriate to the purpose of the manufacturing facility;

(b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system;

(c) provides a framework for establishing and reviewing quality objectives;

(d) is communicated and understood within the manufacturer's organization; and

(e) is reviewed for continuing suitability.

5.4 Planning.-

5.4.1 Quality objectives:

Top management of the manufacturer shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the manufacturing organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning:

Top management of the manufacturer shall ensure that.-

(a) the planning of the quality management system is carried out in order to meet the specified requirements, as well as the quality objectives; and

(b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication.-

5.5.1 Responsibility and authority:

Top management of the manufacturer shall ensure that responsibilities and authorities are defined, documented and communicated within the manufacturing organisation.

Top management of the manufacturer shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.

5.5.2 Management representative:

Top management shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority that includes:-

(a) ensuring that processes needed for the quality management system are established, implemented and maintained;

(b) reporting to top management on the performance of the quality management system and any need for improvement; and

(c) ensuring the promotion of awareness of regulatory and customer requirements throughout the manufacturing organization.

5.5.3 Internal communication:

Top management shall ensure that appropriate communication processes are established within the Manufacturing organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review.-

5.6.1 General:

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained.

5.6.2 Review input:

The input to management review shall include information on:-

(a) results of audits,

(b) customer feedback,

(c) process performance and product conformity,

(d) status of preventive and corrective actions,

(e) follow-up actions from previous management reviews,

(f) changes that could affect the quality management system,

(g) recommendations for improvement, and

(h) new or revised regulatory requirements as and when issued.

5.6.3 Review output:

The output from the management review shall include any decisions and actions related to:-

(a) improvements needed to maintain the effectiveness of the quality management system and its processes,

(b) improvement of product related to customer requirements, and

(c) resource needs.

6 Resource management.-

6.1 Provision of resources:

The manufacturing organization shall determine and provide the resources needed

(a) to implement the quality management system and to maintain its effectiveness, and

(b) to meet regulatory and customer requirements.

6.2 Human resources.-

6.2.1 General:

Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. Number of personnel employed shall be adequate and in direct proportion to the workload. Prior to employment, all personnel, shall undergo medical examination including eye examination, and shall be free from communicable or contagious diseases. Thereafter, they should be medically examined periodically, at least once a year. Records shall be maintained thereof.

6.2.2 Competence, awareness and training:

The manufacturer shall:-

(a) determine the necessary competence for personnel performing work affecting product quality,

(b) provide training or take other actions to satisfy these needs,

(c) evaluate the effectiveness of the actions taken,

(d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives,

(e) maintain appropriate records of education, training, skills and experience, and

(f) establish documented procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities.

6.3 Infrastructure:

The organisation shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable:-

(a) buildings, workspace and associated utilities.

(b) process equipment (both hardware and software), and

(c) supporting services (such as transport or communication).

The manufacturer shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality. Records of such maintenance shall be maintained.

6.4 Work environment:

The organisation shall determine and manage the work environment needed to achieve conformity to product requirements. The following requirements shall apply, namely:-

(a) the manufacturer shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product;

(b) if work environment conditions can have an adverse effect on product quality, the manufacturer shall establish documented requirements as per **Annexure-C** of this schedule for the work environment conditions and documented procedures or work instructions to monitor and control these work environment condition;

(c) the manufacturer shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained and supervised by a trained person;

(d) if appropriate, special arrangements shall be established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel.

(e) all personnel shall bear clean body covering appropriate to their duties. Smoking, eating, drinking, chewing or keeping food and drink shall not be permitted in production, laboratory and storage areas.

7 Product realisation.-

7.1 Planning of product realization:

The manufacturer shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

In planning product realisation, the manufacturer shall determine the following, as appropriate:-

(a) quality objectives and requirements for the product;

(b) the need to establish processes, documents, and provide resources specific to the product;

(c) required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;

(d) records needed to provide evidence that the realisation processes and resulting product meet requirements.

The output of this planning shall be in a form suitable for the manufacturer's method of operations.

The manufacturer organisation shall establish documented requirements for risk management (as per the IS or ISO 14971) throughout product realisation. Records arising from risk management shall be maintained.

7.2 Customer-related processes.-

7.2.1 Determination of requirements related to the product:

The manufacturer shall determine:-

(a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

(b) requirements not stated by the customer but necessary for specified or intended use, where known;

(c) statutory requirements related to the product, and

(d) any additional requirements determined by the manufacturer.

7.2.2 Review of requirements related to the product:

The manufacturer shall review the requirements related to the product. This review shall be conducted prior to the manufacturer's commitment to supply a product to the customer and shall ensure that:-

(a) product requirements are defined and documented;

(b) contract or order requirements differing from those previously expressed are resolved; and

(c) the manufacturer has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained.

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the manufacturer before acceptance.

Where product requirements are changed, the manufacturer shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

7.2.3 Customer communication:

The manufacturer shall determine and implement effective arrangements for communicating with customers in relation to:-

(a) product information;

(b) enquiries, contracts or order handling, including amendments;

(c) customer feedback, including customer complaints; and

(d) advisory notices.

7.3 Design and development.-

7.3.1 Design and development planning:

The manufacturer shall establish documented procedures for design and development. The manufacturer shall plan and control the design and development of product. During the design and development planning, the manufacturer shall determine :-

(a) the design and development stages;

(b) the review, verification, validation and design transfer activities that are appropriate at each design and development stage; and

(c) the responsibilities and authorities for design and development.

The manufacturer shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be documented, and updated as appropriate, as the design and development progresses.

NOTE: Design transfer activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications.

7.3.2 Design and development inputs:

Inputs relating to product requirements shall be determined and records maintained. The design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patients.

These inputs shall include:-

(a) functional, performance and safety requirements, according to the intended use;

(b) applicable statutory and regulatory requirements;

(c) where applicable, information derived from previous similar designs;

(d) other requirements essential for design and development; and

(e) output(s) of risk management.

These inputs shall be reviewed for adequacy and approved by designated individual.

Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs:

The outputs of design and development shall be provided in a form that enables verification against the design and development input and shall be documented, reviewed, and approved prior to release.

Design and development outputs shall:-

(a) meet the input requirements for design and development;

(b) provide appropriate information for purchasing, production and for service provision;

(c) contain or reference product acceptance criteria; and

(d) specify the characteristics of the product that are essential for its safe and proper use.

Records of the design and development outputs shall be maintained.

Records of design and development outputs can include specifications, manufacturing procedures, engineering drawings, and engineering or research logbooks.

7.3.4 Design and development review:

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements:-

(a) to evaluate the ability of the results of design and development to meet requirements; and

(b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel.

Records of the results of the reviews and any necessary actions shall be maintained

7.3.5 Design and development verification:

Verification shall be performed in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained.

7.3.6 Design and development validation:

Design and development validation shall be performed in accordance with planned arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.

Design validation shall be performed under defined operating conditions on initial production units, lots, or batches or their equivalence. Design validation shall include software validation and risk analysis, where appropriate validation shall be completed prior to the delivery or implementation of the product.

Records of the results of validation and any necessary actions shall be maintained.

As part of design and development validation, the manufacturer shall perform clinical evaluations and/or evaluation of performance of the medical device or *In-vitro* Diagnostics.

NOTE 1.- If a medical device or *In-vitro* Diagnostic can only be validated following assembly and installation at point of use, delivery is not considered to be complete until the product has been formally transferred to the customer.

NOTE 2.- Provision of the medical device for purposes of clinical evaluations and/or evaluation of performance is not considered to be delivery.

7.3.7 Control of design and development changes:

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained.

Note.-Each manufacturer shall establish and maintain a Design History File for each type of device. The Design History File shall contain or reference the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of design and development.

7.4 Purchasing.-

7.4.1 Purchasing process:

The manufacturer organisation shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realisation or the final product.

The manufacturer shall evaluate and select suppliers based on their ability to supply product in accordance with the manufacturer's requirements. Criteria for selection, evaluation and re-evaluation shall be established.

Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

7.4.2 Purchasing information:

Purchasing information shall describe the product to be purchased, including where appropriate:-

(a) requirements for approval of product, procedures, processes and equipment;

(b) requirements for qualification of personnel; and

(c) quality management system requirements.

The manufacturer shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

To the extent required for traceability, the manufacturer shall maintain documents and records of relevant purchasing information.

7.4.3 Verification of purchased product:

The manufacturer shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements. Where the manufacturer intends to perform verification at the supplier's premises, the manufacturer shall state the intended verification arrangements and method of product release in the purchasing information. Records of the verification shall be maintained.

7.5 Production and service provision.-

7.5.1 Control of production and service provision:

7.5.1.1 General requirements:

The manufacturer shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable:-

(a) the availability of information that describes the characteristics of the product,

(b) the availability of documented procedures, documented requirements, work instructions; and reference materials and reference measurement procedures as necessary;

(c) the use of suitable equipment;

(d) the availability and use of monitoring and measuring devices;

(e) the implementation of monitoring and measurement;

(f) the implementation of release, delivery and post-delivery activities; and

(g) the implementation of defined operations for labeling and packaging.

The manufacturer shall establish and maintain a record for each batch of medical device or *In-vitro* Diagnostic devices that provides traceability and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved.

7.5.1.2 Control of production and service provision — Specific requirements

7.5.1.2.1 Cleanliness of product and contamination control:

The manufacturer shall establish documented requirements for cleanliness of product if:-

(a) product is cleaned by the manufacturer prior to sterilisation or its use; or

(b) product is supplied non-sterile to be subjected to a cleaning process prior to sterilisation or its use; or

(c) product is supplied to be used non-sterile and its cleanliness is of significance in use; or

(d) process agents are to be removed from product during manufacture.

If the product is cleaned in accordance with (a) or (b) above, the requirements content in clause 6.4 (a) and (b) do not apply prior to the cleaning process

7.5.1.2.2 Installation activities:

If appropriate, the manufacturer shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device or *In-vitro* Diagnostic device.

If the agreed customer requirements allow installation to be performed other than by manufacturer or its authorised agent, the manufacturer shall provide documented requirements for installation and verification. Records of installation and verification performed by the manufacturer or its authorized agent shall be maintained.

7.5.1.3 Particular requirements for sterile medical devices:

The manufacturer shall maintain records of the process parameters for the sterilisation process which was used for each sterilisation batch. Sterilisation records shall be traceable to each production batch of medical device.

7.5.2 Validation of processes for production and service provision.-

7.5.2.1 General:

The manufacturer shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement. This includes any processes where deficiencies become apparent only after the product is in use. Validation shall demonstrate the ability of these processes to achieve planned results.

The manufacturer shall establish arrangements for these processes including, as applicable:-

(a) defined criteria for review and approval of the processes;

(b) approval of equipment and qualification of personnel

(c) use of specific methods and procedures,;

(d) requirements for records; and

(e) revalidation.

The manufacturer shall establish documented procedures for the validation of the application of computer software (and its changes to such software or its application) for production and service provision that affect the ability of the product conform to specified requirements. Such software applications shall be validated prior to initial use.

Records of validation shall be maintained.

7.5.2.2 Particular requirements for sterile medical devices:

The manufacturer shall establish documented procedures for the validation of sterilization processes. Sterilisation processes shall be validated prior to initial use. The records of validation of each sterilisation process shall be maintained.

7.5.3 Identification and traceability.-

7.5.3.1 Identification:

The manufacturer shall identify the product by suitable means throughout product realization, and shall establish documented procedures for such product identification. The manufacturer shall establish documented procedures to ensure that medical devices and *In-vitro* Diagnostics returned to the manufacturer are identified and distinguished from conforming product.

7.5.3.2 Traceability.-

7.5.3.2.1 General:

The manufacturer shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required.

Where traceability is a requirement, the manufacturer shall control and record the unique identification of the product.

NOTE.- Configuration management is a means by which identification and traceability can be maintained.

7.5.3.2.2 Particular requirements for active implantable medical devices and implantable medical devices:

In defining the records required for traceability, the manufacturer shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements.

The manufacturer shall require that its agents or distributors maintain records of the distribution of active implantable medical devices and implantable medical devices to allow traceability and that such records are available for inspection. Records of the name and address of the shipping package consignee shall be maintained.

7.5.3.3 Status identification:

The manufacturer shall identify the product status with respect to monitoring and measurement requirements. The identification of product status shall be maintained throughout production, storage, implant, usage and installation of the product to ensure that only product that has passed the required inspections and tests (or released under an authorized concession) is dispatched, used or installed.

7.5.4 Customer property:

The manufacturer shall exercise care with customer property while it is under the manufacturer's control or being used by the manufacturer. The manufacturer shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained.

NOTE.- Customer property can include intellectual property or confidential health information.

7.5.5 Preservation of product:

The manufacturer shall establish documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination. This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

The manufacturer shall establish documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded.

7.6 Control of monitoring and measuring devices:

The manufacturer shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.

The manufacturer shall establish documented procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall be:-

(a) calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to Bureau of Indian Standards wherever available ; where no such standards exist, the basis used for calibration or verification shall be recorded;

(b) adjusted or re-adjusted as necessary;

(c) identified to enable the calibration status to be determined;

(d) safeguarded from adjustments that would invalidate the measurement result;

(e) protected from damage and deterioration during handling, maintenance and storage.

In addition, the manufacturer shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The manufacturer shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

8 Measurement, analysis and improvement.-

8.1 General:

The manufacturer shall plan and implement the monitoring, measurement, analysis and improvement processes needed:-

(a) to demonstrate conformity of the product;

(b) to ensure conformity of the quality management system; and

(c) to maintain the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

Note.- If relevant Indian standards are not available, International standards are applicable. In case no Indian or International standards are available, validated testing process of the manufacturer is applicable.

8.2 Monitoring and measurement.-

8.2.1 Feedback:

As one of the measurements of the performance of the quality management system, the manufacturer shall monitor information relating to whether the manufacturer has met customer or regulatory requirements. The methods for obtaining and using this information shall be determined.

The manufacturer shall establish a documented procedure for a feedback system to provide early warning of quality problems and for input into the corrective and preventive action processes.

8.2.2 Internal audit:

The manufacturer shall conduct internal audits at planned intervals to determine whether the quality management system:-

a) conforms to the planned arrangements, to the requirements of this schedule and to the quality management system requirements established by the manufacturer, and

b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records shall be defined in a documented procedure. The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

8.2.3 Monitoring and measurement of processes:

The manufacturer shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

8.2.4 Monitoring and measurement of product.-

8.2.4.1 General requirements:

The manufacturer shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realisation process in accordance with the planned arrangements and documented procedures.

Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product. Product release shall not proceed until the planned arrangements have been satisfactorily completed.

8.2.4.2 Particular requirement for active implantable medical devices and implantable medical Devices wherever applicable:

The manufacturer shall record the identity of personnel performing any inspection or testing.

8.3 Control of nonconforming product

The manufacturer shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

The manufacturer shall deal with nonconforming product by one or more of the following ways:

(a) by taking action to eliminate the detected nonconformity;

(b) by authorizing its use, release or acceptance under concession;

(c) by taking action to preclude its original intended use or application.

The manufacturer shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met. Records of the identity of the person authorisng the concession shall be maintained.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. When nonconforming product is detected after delivery or use has started, the manufacturer shall take action appropriate to the effects, or potential effects, of the non-conformity.

If product needs to be reworked (one or more times), the manufacturer shall document the rework process in a work instruction that has undergone the same authorisation and approval procedure as the original work instruction. Prior to authorisation and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented.

8.4 Analysis of data:

The manufacturer shall establish documented procedures to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate whether improvement of the effectiveness of the quality management system can be made.

This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to:-

(a) feedback

(b) conformity to product requirements;

(c) characteristics and trends of processes and products including opportunities for preventive action; and

(d) suppliers.

Records of the results of the analysis of data shall be maintained.

8.5 Improvement.-

8.5.1 General:

The manufacturer shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

The manufacturer shall establish documented procedures for the issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time. Records of all customer complaint investigations shall be maintained. If investigation determine that the activities outside the manufacturer's organisation contributed to the customer complaint, relevant information shall be exchanged between the organisations involved.

If any customer complaint is not followed by corrective or preventive action, the reason shall be recorded and approved. Manufacturer shall notify the adverse event to the regulatory authority and establish documented procedures for the same.

8.5.2 Corrective action:

The manufacturer shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for:-

(a) reviewing nonconformities (including customer complaints);

(b) determining the causes of nonconformities;

(c) evaluating the need for action to ensure that nonconformities do not recur

(d) determining and implementing action needed, including, if appropriate, updating documentation;

(e) recording of the results of any investigation and of action taken; and

(f) reviewing the corrective action taken and its effectiveness.

8.5.3 Preventive action:

The manufacturer shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems. A documented procedure shall be established to define requirements for

(a) determining potential nonconformities and their causes,

(b) evaluating the need for action to prevent occurrence of nonconformities,

(c) determining and implementing action needed,

(d) recording of the results of any investigations and of action taken, and

(e) reviewing preventive action taken and its effectiveness.

Annexure 'A'

(refer para 4.2.1)

The manufacturer shall prepare a succinct document in the form of Device Master File containing specific information about the device manufacturing in the premises.

1.0 Executive Summary:

An executive summary shall be provided by the manufacturer and shall contain:

Introductory descriptive information on the medical device or *In-vitro* Diagnostics, the intended use and indication for use, Class of Device, novel features of the device (if any), shelf life of the device and a synopsis on the content of the dossier information regarding sterilisation of the device (whether it is sterile or non-sterile; if sterile, mode of sterilisation)

2.0 Device Description And Product Specification, Including Variants And Accessories:

2.1 Device Description

2.2 Product Specification

2.3 Reference to predicate and/or previous generations of the device

3.0 Labelling

4.0 Design And Manufacturing Information:

4.1 Device Design

4.2 Manufacturing Processes

5.0 Essential Principles (Ep) Checklist

6.0 Risk Analysis And Control Summary

7.0 Product Verification And Validation:

7.1 Biocompatibility

7.2 Medicinal Substances

7.3 Biological Safety

7.4 Sterilisation

7.5 Software Verification and Validation

7.6 Animal Studies

7.7 Shelf Life/Stability Data

7.8 Clinical Evidence

7.9 Post Marketing Surveillance Data (Vigilance Reporting)

8. Additional information in case of the diagnostic kits:

Product dossier showing the:

8.1 The details of source antigen or antibody as the case may be and characterization of the same.

Process control of coating of antigen or antibody on the base material like Nitrocellulose paper, strips or cards or enzyme-linked immunosorbent assay (ELISA) wells etc.

Detailed composition of the kit and manufacturing flow chart process of the kit showing the specific flow diagram of individual components or source of the individual components.

8.2 Test protocol of the kit showing the specifications and method of testing. In house evaluation report of sensitivity, specificity and stability studies.

8.3 The detailed test report of all the components used/packed in the finished kit.

8.4 Pack size and labelling.

8.5 Product inserts.

Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the kit.

Specific processing like safe handling, material control, area control, process control, and stability studies, storage at quarantine stage and finished stage, packaging should be highlighted in the product dossier.

Annexure `B`

(refer para 4.2.2)

The manufacturer shall prepare a succinct document in the form of Plant Master File containing specific information about the production and/or control of device manufacturing carried out at the premises. It shall contain the following information:

1. General Information:

(i) brief information on the site (including name and address), relation to other sites;
(ii) manufacturing activities;
(iii) any other operations carried out on the site
(iv) name and exact address of the site, including telephone, fax numbers, web site URL and e-mail address;
(v) type of medical devices handled on the site and information about specifically toxic or hazardous substances handled, mentioning the way they are handled and precautions taken;
(vi) short description of the site (size, location and immediate environment and other activities on the site);
(vii) number of employees engaged in Production, Quality Control, warehousing, and distribution;
(viii) use of outside scientific, analytical or other technical assistance in relation to the design, manufacture and testing;
(ix) short description of the quality management system of the company;
(x) devices details registered with foreign countries;

2. Personnel:

(i) organisation chart showing the arrangements for key personne;l
(ii) qualifications, experience and responsibilities of key personnel;
(iii) outline of arrangements for basic and in-service training and how records are maintained;
(iv) health requirements for personnel engaged in production
(v) personnel hygiene requirements, including clothing.

3. Premises and Facilities:

(i) layout of premises with indication of scale;
(ii) nature of construction, finishes/fixtures and fittings;
(iii) brief description of ventilation systems. More details should be given for critical areas with potential risks of airborne contamination (including schematic drawings of the systems). Classification of the rooms used for the manufacture of sterile products should be mentioned;
(iv)special areas for the handling of highly toxic, hazardous and sensitizing materials;
(v) brief description of water systems (schematic drawings of the systems are desirable) including sanitation;
(vi)maintenance (description of planned preventive maintenance programmes for premises and recording system);

4. Equipment:

(i) Brief description of major production and quality control laboratories equipment (a list of the equipment is required);
(ii) maintenance (description of planned preventive maintenance programmes and recording system);
(iii) qualification and calibration, including the recording system. Arrangements for computerized systems validation.

5. Sanitation:

Availability of written specifications and procedures for cleaning the manufacturing areas and equipments.

6. Production:

(i) Brief description of production operations using, wherever possible, flow sheets and charts specifying important parameters ;
(ii) arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage;
(iii) arrangements for reprocessing or rework;
(iv)arrangements for the handling of rejected materials and products;
(v) brief description of general policy for process validation.

7. Quality Assurance:

Description of the Quality Assurance system and of the activities of the Quality Assurance

Department. Procedures for the release of finished products.

8. Storage:

Policy on the storage of medical device.

9. Documentation:

Arrangements for the preparation, revision and distribution of necessary documentation, including storage of master documents.

10. Medical Device Complaints and Field Safety Corrective Action:

(i) Arrangements for the handling of complaints ;
(ii) Arrangements for the handling of field safety corrective action

11. Internal Audit:

Short Description of the internal audit system.

12. Contract Activities:

Description of the way in which the compliance of the contract acceptor is assessed.

Annexure 'C'

Environmental requirement for Notified medical devices and *in-vitro* diagnostics

Name of Device	Type of Operation	ISO Class (At rest)
Cardiac stent/Drug Eluting Stent	Primary Packing and Crimping	5
	Washing, Ultrasonic cleaning &Drug coating	7
	Assembly, Wrapping & Packaging	8
	Laser cutting, Descaling, Annealing & Electro polishing	9
Heart Valves	Valve Packing	5
	Ultrasonic Cleaning & Visual Inspection	7
	Frame & Disc Assembly	7
Intra Ocular Lenses	Packing & Sealing	5
	Final Inspection	7
	Power Checking& Final Cleaning	8
	Tumble Polishing & Lathe Cutting	9
Bone Cements	Final Product Filling	5
	Sieving & Calcinations	7
	Powder Preparation, Granulation &Drying	8
Internal Prosthetic Replacement	Packing	5
	Product Preparation	7
	Component Preparation	8
Orthopedic Implants	Polishing &Cleaning & packaging (to be sterilized in factory premises)	7
	Polishing , cleaning & packaging (Non Sterile- to be sterilized in Hospital)	8
	Cutting, lathing	9
Catheters /Ablation Device / I V Cannulae / Scalp Vein Set/ Hypodermic Syringes/ Hypodermic Needles / Perfusion Sets	Assembly, Coating, Wrapping & Packing	7
	Component Preparation & Cleaning	8
	Moulding	9
Condom	Compounding	Well ventilated area with minimum 5 micron filter
	Moulding	Well ventilated area with minimum 5 micron filter
	Vulcanising	Normal air
	Packing	Air conditioned
Intra Uterine Devices	Moulding	Well ventilated area with minimum 5 micron filter
	Assembling	7
	Packaging	7
Tubal ring	Extrusion	7
	Cutting and Assembly	7
	Packaging	7
Blood bags	Moulding/Extrusion of components	8
	Assembly	7
	Filing	5
Suture	Extrusion	9
	Assembly	8
	Packing	8
Staplers	Staple formation	9
	Staple assembly	8
	Staple final pack	8
Ligatures	Extrusion	9
	Cutting and assembly	8
	Final Pack	8

Surgical dressings	Weaving	9
	Assembly and Gauzing	9
	Final pack	9
In-vitro diagnostics Kit/Reagents	Dry, Liquid Reagent Preparation	Well Lighted and Ventilated controlled temperature & humidity as per process or product requirement
	Coating of sheets etc.	
	Assembly and primary packing	
	Filling	Well Lighted and Ventilated controlled temperature and humidity as per process or product requirement. Provision of Laminar hood if required, Clean Room class 8 or class 9 as per product/process requirement
	Secondary Packing	Well Lighted and Ventilated controlled temperature if required
	Storage	As per recommended storage condition of the product

[F. No. X. 11014/8/2015-DFQC]

K. L. SHARMA, Jt. Secy.

Note. - The principal rules were published in the Gazette of India *vide* No. F.28-10/45-H (1) dated the 21st December, 1945 and lastly amended by notification *vide* G.S.R. 532(E) dated the 18th May, 2016.

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Ministry of Health and Family Welfare
(Department of Health and Family Welfare)

NOTIFICATION
New Delhi, the 23rd August, 2016

G.S.R. 812(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 section 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 for information of all persons likely to be affected thereby, and notice is hereby given that the 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 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' Nirman Bhawan, New Delhi- 110011 or emailed at rg.singh72@nic.in;

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

Draft Rules

1. (1) These rules may be called the Drugs and Cosmetics (9th Amendment) Rules, 2016.
(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 Y, in Appendix III relating to Animal Toxicology (Non-clinical Toxicity Studies), in paragraph 1, in sub-paragraph 1.4 relating to Local toxicity,-
(A) In Note (i) relating to Dermal toxicity study, for the words and brackets "Daily topical (dermal) application of test substance in its clinical dosage form should be done", the words and brackets "The initial toxicity study may be carried out by validated non-animal alternative tests, where such alternatives are available. In rabbit and rat studies, daily topical (dermal) application of test substance in its clinical dosage form should be done." shall be substituted;
(B) in Note (vi) relating to Ocular toxicity studies (for products meant for ocular instillation), after the words "need to include a recovery group." The words "Such initial studies may be carried out by validated nonanimal alternative tests, where such alternatives are available." shall be inserted.

[No. X 11014/07/2016-DFQC]
K. L. SHARMA, 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 GSR 789(E), dated 12.08.2016.

DCG(I) / Misc. / 2016 – (56)
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organisation

FDA Bhawan, New Delhi
Dated: 26-05-16

Office Order

In order to streamline the processing of applications for grant of license, approval, permission etc., in partial modification of earlier office order no. DCG(I)/Misc./15/2013-DC dated 10.04.2015 and other related orders, it has been decided that the applications relating to following categories of functions shall be processed and disposed of at the level as under:

Category of Function	**Matter to be processed and submitted by the concerned ADC(I) / DDC(I) as per existing channel of submission directly to DCG(I) for disposal.**	**Matter to be processed and submitted by the concerned ADC(I) / DDC(I) as per existing channel of submission to JDC(I) for disposal.**
Import of drugs	Applications for grant of Registration Certificate.	Applications for Import License, amendment, post registration approval, and other related activities.
Medical devices	Applications for grant of permission for clinical trial, Manufacturing / import permission in Form 46 / Form 45, Import Registration and License under CLAA.	Applications for Import License, Test License, amendments, post registration/permission approval, and other related activities.
New Drugs & Clinical Trials	Applications for grant of permission for clinical trial & BA/BE study, Ethics Committee Registration, Manufacturing / Import permission in Form 46 / Form 46A / Form 45 / Form 45A, SAEs and compensation matters.	Applications for Test License, protocol amendments, post registration approval changes and other related activities.
Biological products including Vaccines and r-DNA products	Applications for grant of permission for clinical Trial, Manufacturing / Import permission in Form 46 / Form 46A / Form 45 / Form 45A, Import Registration and Licence under CLAA.	Applications for Import License, Test License, protocol amendments, post registration approval changes, and other related activities.
Blood Banks	Applications for grant of licence to operate Blood bank, Blood products and Blood components.	Post approval changes and other related activities.

The DDC(I) will be supported by concerned ADC(I)s / DIs / ADIs as per the existing arrangement. This shall come in force with immediate effect.

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

To

All JDC(I)s/DDC(I)s/ADC(I)s of CDSCO(HQ)

Copy for information:-

1. PPS to Secretary / PPS to DGHS / PPS to AS(F&D) / PS to JS(R)
2. Director (Admin), CDSCO(HQ)
3. Guard File

No. DCGI/MISC/2016 (92)
Central Drugs Standards Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare

FDA Bhavan, Kotla Road,
New Delhi-110002.
Dated: 4th August, 2016

NOTICE

The Government of India, Ministry of Health and Family Welfare has taken various steps to streamline conductance of Clinical Trials in India by creating strong regulatory platform for ensuring safety, rights and well beings of the subject trials.

Based on field experience, it has become imperative to bring clarity on certain scientific issues which have become bottlenecks in the area of clinical trials in the country. This issues were under deliberations/consultations with national/international; associations/institutions/subject experts for couple of months.

In order to utilize full potential of talented human resource and infrastructural facilities available in this area, it has been decided to consolidate functions in such a way that India may become a favourable destination for doing clinical trials and create conducive environment for pharma sector to enter swiftly into Drug Discovery and Research phase to address issues of emerging diseases for its people and assist the patients of the continent to get safe, efficacious and high quality medical products at affordable prices mainly related to neglected diseases.

The some of the initiatives taken in recent days are as follows:

1. Number of trials to be taken by an investigator
2. Requirement of beds in a hospital
3. Addition of new clinical site or investigator
4. Parallel submission of applications in RCGM and CDSCO for their approval

Stakeholders are requested to give their feedback on further improving the regulatory pathways to provide high quality medical products to the patients.

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

No. DCGI/MISC/2016 (97)
Central Drugs Standards Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare

FDA Bhavan, Kotla Road,
New Delhi-110002.

Dated: 18th August, 2016

NOTICE

The Central Drugs Standard Control organization (CDSCO) in pursuance of implementation of e-governance has launched various services for Import of Drugs, Medical Devices, Drugs for Personal use, Drugs for Test & Analysis and Import of Cosmetics in first and second phase.

Now in third phase, the online service for grant of NOC for conducting Clinical Trials have to be launched. In this regard, a hands-on workshop on "Online Process for Grant of NOC for Clinical Trials" has been organised on 24th August, 2016 between 11 A.M. - 4 P.M. at CDAC NOIDA premises (Centre for Development of Advanced Computing- Academic Block, B 30, Sector-62, Institutional Area, Noida 201307).

The On-Spot registration to the workshop will be done on 24th Aug 2016 itself on first-come first serve basis. Only first 30-participants (one or maximum two person from each Applicant firm/Institution) be accommodated in hands-on training.

Participants need to bring their own laptops compulsorily and bring their data cards optionally. Participants also need to bring soft copy of their documents for a particular application of CT that they would be filing online during the workshop. Those without these prerequisites may not be useful in the training and may be denied access

The link for test application seen is as following:
online portal 220.156.189.68/CDSCO_FORM44/homepage for which User ID is testuser@gmail.com and Password is Test@123.
With this notice a copy of Form 44, the field of checklist, Proforma of executive summary, Proforma of Investigational Medicinal Product Dossier and Proforma of general information to be filled are attached, which you will need to fill step wise during hands on training.
It is desired that, the stakeholders may conduct a test run on their own before coming for workshop, which will help (you and us) to understand the process of on-Line application in better manner.
Your active involvement and participation in doing prior exercise and the workshop exercise is highly solicited
Wishing you all the success,

(Dr. V.G SOMANI)
JOINT DRUGS CONTROLLER (INDIA)

Attachments:
1. GUIDANCE
2. GCT Online Steps
3. Checklist for Form 44
4. Executive Summary
5. IMPD Format

No. DCG (I)/MISC/2016 (100)
Central Drugs Standards Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare

FDA Bhavan, Kotla Road,
New Delhi-110002.

26 August, 2016

NOTICE

Subject: Upgradation of skill sets of persons employed in pharma manufacturing units

The Government of India had entrusted the work relating to development of qualification packs (National Occupational Standards) to the Life Sciences Sector Skill Development Council with the objective of upgrading the skills of persons employed in the Life Sciences sector in the country. Accordingly, the Life Science Skill Sector Development Council has, after an elaborate exercise and extensive consultations with industry, evolved the following modes for certification:

(i) Post fresh skilling and assessment of eligible youth; and
(ii) Post assessment under 'Recognition of Prior Learning (RPL)' for existing workforce in industry.

2. The objective of the certification is to enhance the skills of the workforce engaged in pharmaceutical and Bio technology industry and enable organisations to effectively meet quality standards.

3. Keeping in view the objective of bringing substantial improvement in the quality of pharmaceutical products, it has become imperative that all personnel employed in pharmaceutical manufacturing units shall undergo the certification programmes developed by Life Science Skill Sector Development Council and with effect from 01.0.12018, no person shall be employed in any pharmaceuticals/bio pharmaceutical manufacturing units unless he has obtained a formal diploma or degree in the relevant area, or has been certified by the Life Sciences Sector Skill Development Council or equivalent organisation in the area in which he has been deployed.

4. All pharma manufacturing units in the country, are accordingly requested to take steps for ensuring that persons employed by them are duly trained and certified. In case of any assistance, the following can be contacted:

1. Shri Ranjit Madan
Chief execute Officer
Life Sciences Skill Development Council
14, Palam Marg, Rear 2nd Floor,
Vasant Vihar, Delhi 110057
Tel. 011-41042408/407 Mobile 09818932470
E-mail: ranjit.madan@issdc.in

2. Dr. D Sengupta
Life Sciences Skill Development Council
14, Palam Marg, Rear 2nd Floor,
Vasant Vihar, Delhi 110057
Tel: 011-41042408/407
e-mail: d.sengupta@cii.in

(Dr. G. N. Singh)
Drug Controller General of India

NEWS

New Drug Vaccines to get Booster Dose from Government

The biotechnology sector is set to get a booster dose to expand work in drug discovery, vaccines and antimicrobial resistance. The Department of Biotechnology (DBT) is in the midst of finalising several programmes and global partnerships to give a thrust to these areas, Secretary K Vijay Raghavan said.

DBT is looking to invest in a programme to expand the existing centres for drug discovery and vaccine research. The department will take up the possibility of investing "a few thousand crores" over the next few years with the finance ministry and hopes the proposal will be approved, he said.

"We're going to see a multiple hub model where there will be many more top quality centres for drug discovery and vaccines," Raghavan told ET on the sidelines of a Science & Technology in Society Forum work shop. The programme is expected to be announced in August or early September, he said. In addition to national investment programmes, DBT is in the process of finalising international collaborations in vaccines and to combat the growing problem of anti-microbial resistance, he said. "We are likely to see big announcements over the next few months".

Source: *The Economic Times, 7th June 2016*

Biocon, Quark Get DCGI Nod for Trials of New Eye Disease Drug

Bio-pharmaceutical firm Biocon said the Drug Controller General of India (DCGI) has given nod to it and partner Quark Pharmaceuticals to proceed with clinical trials on human subjects for a new drug candidate, 'QPI 1007' aimed for ocular neuro-protection. Biocon and Quark Pharmaceuticals also announced the randomisation of the first patient in India in the global Phase II/III study of the new drug candidate, the company said in a statement.

Randomisation is the allocation of subjects to treatment groups to prevent selection and accidental bias. The company further said, “Biocon and its partner, Quark Pharmaceuticals, have received approval from the Drug Controller General of India (DCGI) to proceed with the study, the first ever clinical trial of a siRNA (small interfering RNA) therapy in India.

” The study will determine the effect of QPI-1007 on visual function in subjects with acute non-arteritic ischemic optic neuropathy (NAION), which is a rare ocular disorder with an unmet need globally, it added. “This is part of a global Phase II/III study run by Quark in collaboration with 'Neuro-Ophthalmology Research Disease Investigator Consortium' (NORDIC) and is already enrolling in the US and a number of other countries,” the statement said

Biocon Chairperson and Managing Director Kiran Mazumdar Shaw said, “India has a significant NAION patient population and we are pleased to be the first bio-pharma company in the country to provide an siRNA-based therapy that is likely to benefit thousands of patients who either have no access to treatment or cannot afford it.” Quark Chairman and CEO Daniel Zurr said the study in India is

part of a multi-national study to seek a treatment for NAION, a debilitating condition. “QPI-1007 represents a novel therapeutic strategy for treating NAION and future plans are to develop it for additional optic neuropathies, including glaucoma, which, similar to NAION, are characterized by the death of retinal ganglion cells,” Zurr. said.

Biocon and Quark Pharma had entered into a licensing and collaboration agreement in 2013 to co-develop, manufacture and commercialize QPI-1007 in India and other key markets.

Source: *The Economic Times, 24th June 2016*

RNA Molecule that Fuel Cancer Growth Identified

Researchers have identified an RNA molecule that helps cancer cells in growing opportunistically, offering scientists a new target for drug development. The study showed that NEAT1, a non-coding RNA, plays an important role in the survival of highly dividing cells — and in particular of cancer cells. These findings can help develop new drugs that target NEAT1, in order to kill cancer cells more effectively.

As a non-coding RNA, NEAT1 is not translated into a protein. It does, however, contribute to the formation of so-called 'paraspeckles', subnuclear particles that can be found in the cell nuclei of cancer cells. The function of these particles has remained obscure. Although highly conserved through evolution, NEAT1 appears to be dispensable for normal embryonic development and adult life as mice lacking the non-coding RNA are viable and healthy.

“In our study, we have found that the expression of NEAT1 in the cell nucleus is regulated by p53. This protein plays an important role in protecting people against cancer and is known as 'the guardian of the genome',” Carmen Adriaens, PhD student at Flanders Institute for Biotechnology (VIB), KU Leuven, Leuven, Belgium. The researchers also found that NEAT1/paraspeckles are required for the survival of highly dividing cancer initiating cells and that mice lacking NEAT1 are protected from developing skin cancer. This means that cancer cells can 'hijack' the survival principle of NEAT1 for their own good.“We expected NEAT1 to be a tumor suppressor, since it is regulated by p53. Instead, it turned out that NEAT1 helps cancer cells in growing opportunistically,” Professor Jean-Christophe Marine from VIB-KU Leuven said.

“They use the survival mechanisms put in place by NEAT1 to survive standard chemotherapeutics. Our research shows that cancer cells die more effectively after removing NEAT1/paraspeckles from the cell nucleus. In other words: the loss of NEAT1 leads to increased chemo sensitivity and cell death,” Marine explained. The findings appeared in the journal Nature Medicine.“Therefore, our findings can help develop new drugs targeting NEAT1 in order to kill cancer cells more effectively,” Marine said.

Source: *The Economic Times, 5th July 2016*

Customizable RNA Vaccine Successful in Mice

MIT scientists have devised a customizable RNA vaccine, which could lead to a faster response during infectious disease outbreaks.

Messenger RNA, or mRNA, can be made to code for any pathogenic protein. In a vaccine, they are administered in another molecule, which then delivers the RNA into host cells where it translates into proteins that cause an immune response. The MIT team created mRNA candidates against Ebola, H1N1 and Toxoplasma gondii, all of which proved 100% successful in mice, according to a statement. They hope that the approach will also be applicable to cancer vaccines.

Instead of simply delivering proteins to induce an immune reaction like traditional vaccines, RNA vaccines make the host cell produce numerous copies of the proteins they code for, thus provoking a stronger immune response. And while the concept of using mRNA in vaccines has persisted for 30 years, a significant hurdle has been finding a way to deliver them safely and effectively.

Omar Khan of MIT's Koch Institute for Integrative Cancer Research encased the RNA molecules in nanoparticles made from a branched molecule, dendrimer. He designed the nanoparticle to fold over itself several times, resulting in a spherical vaccine particle about the same size as many viruses. This particle uses the same surface proteins on host cells as to enter them as viruses do, the statement said.

The vaccine is injected and takes 7 days to make, a far cry from the years or even decades that the traditional vaccine development model takes. “Typically a vaccine becomes available long after the outbreak is over,” said Jasdave Chahal, who led the project, in the statement. “We think we can become interventional over the course of a real outbreak.”

“The option of rapidly creating a completely synthetic formulation that can be effective as a vaccine is an important addition to currently available vaccine strategies,” said Hidde Ploegh, an MIT professor of biology and an author of the paper, in the statement.

Chahal and Khan are also working on cancer vaccines to teach the immune system to identify and attack tumors. They also plan to create a company to license and commercialize the RNA vaccine. Their next targets include Lyme disease and Zika virus, for which a slew of biotechs and pharmas are already racing to develop vaccines..

Source: *Fierce Biotech, 6th July 2016*

In a Big Clean-up Drive, Government Plans to Scan 500 Indian Drug Facilities

In perhaps the biggest move of its kind so far, the Indian drug regulator has flagged about 500 manufacturing plants for quality-related issues. The government plans to inspect these facilities for compliance with good manufacturing practices and take action where they don't meet the standards. The move is part of a drive to weed out supplies of substandard drugs in the market, a senior official in the health ministry told ET.

The government has begun inspection

of 200-250 facilities in the first leg on a risk priority-basis, the official said, requesting not to be named. The official declined to divulge the names of the companies involved. Under the Central Drugs Standard Control Organisation's (CDSCO) newly introduced "risk-based" inspection system, manufacturing sites found to pose maximum risk due to non-compliance issues would be inspected on priority.

"This kind of inspection had never been taken up in India before. We are planning to cleanse the system completely," the official said. "We are checking for practices like hygiene and qualification of the personnel (at the plant) and whether they (the drug makers) are adopting shortcuts in procedures they have to follow when internally testing their products," the official said, adding that the government will analyse and take action on lapses found only after it completes inspections at all the manufacturing sites.

The government expects the latest action and punitive follow up measures to cut the deficiencies associated with the quality of drugs in India by 80-90%. While the ministry's main aim is to point out problems that companies should fix in their manufacturing processes, government representatives had also earlier told ET of actions like suspension of manufacturing licences where major faults were detected.

The regulator will prioritise the sites for inspections based on the number of products that failed quality tests over the past seven years. Another criterion will be the complaints it received from state and foreign drug regulators.

These facilities have made at least five medicinal products that failed quality tests, with one even having made as many as 70, said another senior health ministry official who also didn't wish to be named.

State authorities will investigate and take the required action against companies flagged with substandard drugs, while the Centre's inspection team will check whether the facilities comply with the country's good manufacturing practices.

CDSCO has currently sent out seven teams to check compliance of facilities in Andhra Pradesh, Telangana, Uttar Pradesh, Punjab, Gujarat and Assam. The teams, which include a lab expert to check the drug testing equipment at these sites, are inspecting facilities of 20 companies, sources said.
"The objective of this inspection is to see whether the companies have a system in place that meets all the technical requirements to ensure the consistency and quality of the product," the health ministry official said So far, 19 teams have been trained to conduct these risk-based inspections, the official said, adding that more teams were being trained for the same. In perhaps the biggest move of its kind so far, the Indian drug regulator has flagged about 500 manufacturing plants for quality-related issues. The government plans to inspect these facilities for compliance with good manufacturing practices and take action where they don't meet the standards.

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Source: *The Economic Times, 11th July 2016*

Medical Devices Act to be Tabled in Winter Session of Parliament

The ministry of health has announced that the Medical Device Act would be tabled in the forthcoming winter session of the Parliament. The announcement came from minister of health while taking part in a consultation convened by the Prime Minister's Office (PMO) on promoting Make in India in the medical devices sector in India on Monday here.

Associations of medical device industry including FICCI, Association of Indian Medical Device Manufacturers, CII and Medical Technology Association of India presented to the PMO a series of issues relating to ease of doing business, regulation, fiscal imperatives, scaling up manufacturing, promoting exports and encouraging innovations, to make India an attractive destination for investment in medical

devices sector. A detailed discussion on streamlining regulatory issues was held on which the government assured an early action. The uniqueness of medical devices, as different from pharmaceuticals was acknowledged

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A detailed discussion on streamlining regulatory issues was held on which the government assured an early action. The uniqueness of medical devices, as different from pharmaceuticals was acknowledged and the participating associations were informed that the new Medical Device Rules would be notified at the earliest. Industry has appreciated the proactive, progressive approach of the government and welcomed the engagement of consultation with the industry. Probir Das, chairman, FICCI Medical Device Forum said "An attractive fiscal package coupled with the streamlining of regulation will help attract global investment and greenfield & brownfield expansion in India".

"We thank the government for this opportunity to engage and enable quick resolution of regulatory issues. This will certainly help the industry", added Pavan Choudary, Medical Technology Association of India. “An added focus on promoting exports will add value. On the other hand, continued investment in healthcare will help expand the market of medical devices increasing India's attractiveness as a manufacturing destination", said Himanshu Baid, chairman - CII Medical Technology Division.

The meeting was chaired by principal secretary to the Prime Minister and held in presence of senior officials from PMO, NITI Ayog, ministry of health & family welfare, and department of pharmaceuticals, department of revenue. Medical devices sector has emerged as a focus sector in Make in India aspirations of the country. It has a tremendous potential to grow with a huge demographic dividend on demand side and India's R&D innovation capabilities on the supply side. Despite the immense opportunity it remains shackled in an unpredictable regulatory environment, which is expected to change very soon and is also impeded by concerns around Pharma style price control and an abysmally low market penetration, which shall need a gradual increase in public spend and awareness campaigns.

Source: *Pharma biz, 13th July 2016*

Granules to Acquire 12.5% Stake in US Pharma

Granules India Ltd today said its wholly-owned subsidiary Granules Pharmaceuticals Inc will acquire a 12.5 per cent stake in US-based US Pharma for an undisclosed sum.

According to a statement by Granules, the acquisition of the stake will enable it to participate in product selection and gain right of first refusal to market select products which are under development by US Pharma.

US Pharma is a development-stage pharmaceutical company specialising in research, development and manufacture of high entry-barrier generic pharmaceuticals, including controlled release, controlled substance and patent-challenge products.

US Pharma, in collaboration with manufacturing partners, had submitted five ANDAs with Paragraph IV certifications, out of which four ANDAs have already been licensed to Granules exclusively, it said.

US Pharma has formulation development and manufacturing facilities in Philadelphia and Pennsylvania in the US and a centre in Mumbai. It also has a cGMP (Current Good Manufacturing Practice) analytical laboratory in Kansas City, US.

Krishna Prasad Chigurupati, Chairman and Managing Director, Granules India said, "This agreement with USpharma complements our internal product development programme, and expands our product portfolio by leveraging external product development capabilities."

"The successful development of limited competition products by USpharma provides further long-term growth for the company. "We are impressed with USpharma's product development capabilities with niche pipeline, and firmly believe that these products represent a substantial commercial opportunity," he added.

Source: *The Economic Times, 14th July 2016*

New Oral Nanomed could Deliver Insulin, Cancer Drugs via Non Competitive Drug

Researchers at Texas A&M University have developed a nano-sized delivery system that could help bring injected treatments such as insulin into the oral realm, making the regimen easier on the patient and clinician.

According to the university, normal injected meds, from insulin to cancer drugs, make use of ligands that compete with the body's own ligands. But the new vehicles achieved a noncompetitive transport by using gamboric acid, prompting a patient's cells to still take up the particle even if it already has enough of its own ligands and would normally reject more.

With this stealthier mode of transport, the nanoparticles can cross the intestinal barrier, making them ideal for oral treatments. When packed with insulin--a peptide that would break down quickly in the gut and rendered ineffective--the nanoparticle acts as a protective barrier to ferry the treatment past the intestinal wall. And because the method is

noncompetitive with the body's own cells, the same can be done with cancer treatments or meds that need to cross the blood-brain barrier.

"The way we put these things together is completely novel," lead researcher Ravikumar Majeti said. "This approach enables the development of carrier systems that have no equivalent in the world of competitive ligands."

Source: *Fierce Pharma, 19th July 2016*

Five Diabetes Drugs in Top-10 Selling List

In perhaps a grim reminder of the growing incidence of lifestyle diseases, five out of the top 10 largest-selling drugs in the country are now anti-diabetes, with the therapy registering a robust double-digit clip year-on-year.

The control of non-communicable diseases like diabetes poses one of the biggest challenges for the country's healthcare practitioners, even as the World Health Organisation for the first time highlighted recently the need to step up prevention and treatment of the disease. A couple of years ago, only two-three diabetes drugs featured in the top-10 list of medicines (see chart). Also, top-selling drugs in the organised Pharma retail market had largely been dominated by anti-infectives and antibiotics in the past.

Insulin brand Human Mixtard, oral formulation Glycomet GP, insulin Lantus, oral formulations Galvus Met and Janumet are now in the top-selling list of drugs in the country. Overall, the anti-diabetic therapy - estimated at nearly Rs 8,500 crore (moving annual total, or MAT for June 2016) - is the fifth-largest in the organised Pharma retail market, growing at a strong double-digit rate of 12%, data culled from market research firm AIOCD Awacs said.

Human Mixtard, an insulin brand of Novo Nordisk, continues to occupy the top slot in the organised pharmaceutical market, with sales of nearly Rs 500 crore for the 12-month period ended June.

Industry experts and doctors say that the huge sales uptick in diabetes medicines is due to multiple reasons. "The diabetes market has witnessed an upward trend based on new launches and detection cases, leading to a larger number of brands in the top 10 of the Indian pharmaceutical market," Hari Natarajan, vice-president of AIOCD Pharma softtech Awacs, said.

While the entry of a newer class of diabetes medicines (like gliptins) has contributed to the rise, there are certain external environmental factors which have also played a hand. Anti-infective therapy Augmentin, which was at one time the largest-selling drug, has slipped due to supply constraints faced by manufacturer Glaxo SmithKline Pharmaceuticals.

Dr Anoop Misra, chairman, Fortis Centre of Excellence for Diabetes, Metabolic Diseases and Endocrinology, says medicines for treatment of diabetes have increasingly become largest selling drugs because of multiple factors. These include an increasing number of patients with diabetes, earlier diagnosis, people surviving longer with better treatment, better drugs currently available, and patients becoming more compliant with

treatment. "Moreover, some of these drugs are being used for various other indications as well metformin for treatment of polycystic ovaries,obesity and insulin resistance, liraglutide for obesity, pioglitazone for fatty liver, etc."

Newer brands within the recent class Teneligliptin have entered the market too, including Tenglyn M (Zydus) and Tenepan (Panacea), while the category itself has registered massive growth due to its affordability.Says Glenn Saldanha, CMD, Glenmark Pharma - a frontrunner in launching the third-generation oral diabetic drug Teneligliptin, "The anti-diabetic therapy is growing on account of movement from plains (single molecule) to combinations (increase in consumption of 2-3 drug combinations). Also, the emergence of DPP4 segment in the last few years has accelerated the growth momentum. Currently, the company's diabetes franchise is growing at over 30% every year and, with the introduction of Teneligliptin, it's been a game changer for diabetes patients in the country".

Source: *The Times of India, 21st July 2016*

Government may Regulate e-Pharmacies Soon

The government may back e-pharmacies amidst the long-drawn battle between chemists and online medicine retailers in the country. A health ministry sub-committee tasked with deciding the online model's viability has spoken in its favour, according to the country's apex drug regulator.

The sub-committee, which deliberated over the issue for almost a year, is also set to release a report of recommendations to regulate e-pharmacies here, said Central Drugs Standard Control Organisation (CDSCO) joint drugs controller S Eswara Reddy, who was speaking at an event organised by FICCI on Monday.

"This report will mainly accept online pharmacies only with respect to e-prescriptions," said Reddy. The committee has also recommended a standardised format for these prescriptions, he said.

The sub-committee has defined terms related to online medicine retail, including e-prescriptions, online pharmacies, over-the-counter (OTC) drugs, according to Reddy. It has suggested amendments to the country's drug rules and a "negative list" specifying the drugs that online pharmacies are not allowed to sell to "ensure the safe running of online pharmacies", he added.

Stakeholders also discussed the prospect of integrating AADHAAR into the overall e-pharmacy framework to make the retail process more transparent. Nearly 80% of the Indian population has an AADHAAR number, said health ministry additional secretary KB Aggarwal, who was also at the event.

Regulation of e-pharmacies is expected to improve the patient's access to quality medicines, according to Aggarwal. "(e-Pharmacy) has the potential to provide proper digital tracking of medicine sales, prescriptions, prescriber's information...thereby reducing the problems of counterfeit medicines and their abuse," he said.

At the same time, measures such as mandating e-prescriptions would not be effective to check the abuse of medicines through e-pharmacies, according to legal experts like Luthra & Luthra partner Vaibhav Kakkar. Pharmacy regulations issued in 2015 under the Pharmacies Act already provide for e-prescriptions, he said.

"This new technology is going to bring about disruption, (which) can only be utilised if you don't put limitations of this nature. How many doctors do we know who actually these days will continue to issue e-prescriptions?" said Kakkar.

At present, there is little clarity on provisions to regulate online pharmacies in India, according to the industry. India's Drugs and Cosmetics Act does not differentiate between drugs sold online or through brick-and-mortar retail stores. This has led to several conflicts between chemists and online drug sellers, with the chemist lobby group All India Organisation of Chemists and Druggists (AIOCD) approaching 10 high courts over the continued operation of e-pharmacies earlier this month.

Clear laws to regulate e-pharmacies will enable a friendly environment for existing online retailers and may also encourage more entrepreneurs to enter the space, according to Prashant Tandon, CEO of online pharmacy 1mg.

Chemists maintained that they would continue to oppose the government's latest move, as the current drug laws do not permit e-pharmacies. It is not in the interest of consumers and over eight lakh brick-and-mortar pharmacies, according to AIOCD general secretary Suresh Gupta.

Source: *The Economic Times, 26th July 2016*

Pharma Sector Receives Rs 4,975-Crore FDI in FY16: Government

The drugs and pharmaceuticals sector has received foreign direct investment (FDI) of Rs 4,975 crore in 2015-16, parliament was informed today.

"In the year 2014-15, FDI equity inflow of Rs 9,052 crore and in the year 2015-16, inflow of Rs 4,975 crore have been received in the drugs and pharmaceutical sector," Minister of State for Chemicals and Fertilizers Mansukh L Mandaviya said in a reply to Lok Sabha. FDI policy provides for 100 per cent FDI under automatic route in greenfield Pharma and upto 100 per cent under government route in brown field Pharma, he added.

"Up to 74 per cent FDI under automatic route in brownfield pharmaceuticals and government approval route beyond 74 per cent has been permitted," Mandaviya said.The government on June 20 had relaxed FDI norms in various sectors including civil aviation, single-brand retail, defence and Pharma by permitting more investments under automatic route.

The decision was taken at a meeting chaired by Prime Minister Narendra Modi.

Source: *The Economic Times, 26th July 2016*

More Cancer, HIV Drugs to Cost Less Post Price Cap

The National Pharmaceutical Pricing Authority (NPPA) has slashed by up to 35% prices of several essential medicines, including those to treat cancers and HIV infections. In its latest notification, the drug pricing watchdog has capped price of antibiotic doxycycline (100mg) and revised ceiling prices of 23 medicines already included in the National List of Essential Medicines (NLEM). Patients should see a drop between 10% and 35% in the prices of these medicines, NPPA told ET.

The list includes drugs like Melphalan (2mg) and Melphalan (5mg), which are indicated for the treatment of multiple myeloma (a type of blood cancer), cancer of the ovaries and breast cancer. Chlorambucil (2mg), another tablet used to slow the growth of certain cancer cells in the body, also figures in the list.

NPPA has also revised the ceiling prices of antiretroviral drugs Zidovudine (300mg) and the Lamivudine (150mg) + Zidovudine (300mg) combination, which are used in the treatment of HIV infections.

"Manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955," NPPA said in its notification dated July 30.

By March end, pharmaceutical companies owed NPPA dues that exceeded Rs 4,551 crore for overcharging patients. This amount had piled up over the past two decades.

Source: *The Economic Times, 2nd August 2016*

NPPA to Launch App with Key Drug Prices

India's drug pricing watchdog is planning to introduce an app that will enable patients to check prices of essential medicines on-the-go.

The National Pharmaceutical Pricing Authority (NPPA) will do this by extending its "Pharma Jan Samadhan" web-portal facility to smartphones to slash instances of drug makers and retailers overcharging consumers for life-saving, often expensive, medicines.

Developed by the National Informatics Centre, the app —"Search Medicine Price"— is slated for an android phone launch on August 29 by the minister of chemicals and fertilisers Anant Kumar. iPhone users can also expect to have this information at their fingertips within another two months, according to NPPA. A test version has already been made available for public feedback.

In this version, patients can search for the ceiling price of all medicines under the National List of Essential Medicines (NLEM) on the basis of its generic name and the state they're buying it from.

They can then enter the number of units (tablets or millilitres) of the medicine sold in one

pack to see the maximum retail price (MRP) including taxes. Consumers will have up-to-date MRPs for all the medicines capped under NLEM 2011 and 2015, as NPPA intends on simultaneous incorporation of any ceiling price fixes and revisions on the app.

The drug pricing body seeks to hold drug companies and medicine retail outlets more accountable to patients through its new app, according to NPPA chairman, Bhupendra Singh.

"Retailers and manufacturers will come to know that they cannot take consumers for granted," he told ET. "Consumers can use the app before paying for a medicine to ensure that they get the right price. At present, whatever action we take against the companies, including recoveries, the consumer does not get back the overcharged amount he or she has paid."

Source: *The Economic Times, 4th August 2016*

Directorate General of Foreign Trade Unveils Norms for Human Bio Samples Trade

Import and export of human biological samples by domestic diagnostic labs or clinical research centres should be permitted by customs authorities without prior approvals, subject to certain conditions, the Directorate General of Foreign Trade said.

Laying down the policy condition for import/export of human biological samples for commercial purposes, the DGFT said that "the central government hereby inserts import policy...and export policy for human biological samples for commercial purposes".

It said the export and import should be permitted by "customs authorities at the port of entry/exit without prior approvals (import licence/export permit) from any other government agency, provided the concerned Indian company/ agency submits an undertaking that they are following and will follow all the applicable rules, regulations and procedures for safe transfer and disposal of the samples".

In a separate trade notice, DGFT said that grapes packed in imported packing material do not fall under ineligible category under a norm of the foreign trade policy.

Source: *The Economic Times, 5th August 2016*

Antimicrobial Resistance: Clear and Present Danger

After years of doing little to tackle the silent but potentially deadly proliferation of antibiotic-resistant bacteria in India, all hell broke loose in 2008, when New Delhi was tacked onto the name of a one such bug. The New Delhi Metallo-beta-lactamase-1 was an enzyme that rendered bacteria resistant to a broad spectrum of antibiotics. A strain of the NDM1 had crossed the shores and spread resistance in the U.K. as well.

Despite its outrage over being associated with a resistant bug the nation sat up to the danger of anti-microbial resistance within its boundaries, and is beginning to understand the disastrous societal consequences of rendering

certain life-saving drugs impotent. Prior to the detection of the NDM, isolated calls for regulating antibiotics use were being made by doctors in surgeries and those manning Intensive Care Units.

It was in 2011 that the Union government came up with a National Policy for Containment of Antimicrobial Resistance in India, seeking to reverse what seemed to be spiralling healthcare concern.

The policy makes no bones about recognising the real threat: "Antimicrobial resistance in pathogens causing important communicable diseases has become a matter of great public health concern globally including our country. Resistance has emerged even to newer, more potent antimicrobial agents like carbapenems."

A March 2016 paper on 'Antibiotic Resistance in India: Drivers and Opportunities for Action' in PLOS Medicine makes a convincing case for action against resistance: "Antibiotic resistance is a global public health threat, but nowhere is it as stark as in India. The crude infectious disease mortality rate in India today is 416.75 per 100,000 persons… twice the rate in the U.S. (200) when antibiotics were introduced." Among the key factors responsible are the widespread use and availability of practically all the antimicrobials across the counter, increasing and wanton use of antibiotics in livestock production, inappropriate doses, and irrational use of antibiotics in hospitals.

Attempts have begun to regulate at least the human consumption of antibiotics: there are now guidelines for appropriate antibiotics usage which have revised Schedule H drugs to make over-the-counter availability of certain antibiotics nearly impossible. Stringent enforcement of drugs control, making the dispensing of some antibiotics over the counter punishable, is the need of the hour.

Source: *The Hindu, 10th August 2016*

With Price Cap 22 Drugs Get Cheaper

In a move that would make some commonly used cancer drugs, anti-retrovirals and medicines to treat malaria cheaper by up to 45%, the central drug regulator has capped prices of 22 essential medicines with immediate effect.

The price cap announced by National Pharmaceutical Pricing Authority (NPPA) would bring down maximum retail price or MRP of these medicines down by 10-45%. It is likely to impact prices of nearly 220 medicine brands containing 22 formulations.

For instance, the price of 1ml Doxorubicin HCl Pegylated Liposomal Injection -used in the treatment of different types of cancer including blood, breast, stomach, lungs, ovaries and kidneys -has been fixed at Rs 723.93, whereas a pack of Zoledronic Acid infusion - used with cancer chemotherapy to treat bone problems - will now cost Rs 3,609.13. "The average price reduction on these drugs would be at least 25% after the latest order," an official told TOI.

Source: *The Economic Times, 20th August 2016*

Cadila Torrent Pharma GSK in Race for Top Selling Multivitamin

Leading Pharma players Cadila Healthcare, Torrent Pharma & GSK Pharma are in a three-way race to acquire top-selling zinc-based multi-vitamin brand owned by Chennai based Apex Labs, multiple sources familiar with ongoing negotiations told ET NOW on the condition of anonymity.

"Zincovit, India's largest-selling zinc based multi-vitamin and Zincofer, also a zinc based multi vitamin are two brands that have been put on the block by Apex Labs. All three suitors are keen on entering this niche segment. Apex Labs has an upcoming dermatology business and a contract manufacturing business and the deal proceeds will be used to drive the growth of these two verticals, which are the focus segments for the company, going ahead. It's a strategic shift by the company and the deal proceeds will be used to drive the growth of these two verticals, which are the focus segments for the company, going ahead. It's a strategic shift by the company and the deal value is expected to be in the range of Rs 1,100-Rs 1,200 crore," sources added.

Apex Labs pioneered the introduction of zinc-based formulations in the Indian market and the company's flagship brand Zincovit is the brand leader in its segment with a 19% market share, according to the company website.

"Due diligence has been completed on the deal and binding offers are expected shortly. The sales force connected to these brands may also move as part of the deal and Apex Labs will continue to supply the products via a contract manufacturing agreement post the deal. EY is advising Apex Labs on the sale process," added one of the sources cited above. The products of Apex Labs are available in oral solids, oral liquids and topical dosage forms and are marketed in more than 20 countries, mainly in Asia & Africa. The company's plant is UK-MHRA approved and is engaged for contract manufacturing for Pharma majors in UK, Europe and Canada.

In response to an email query from ET NOW, a GSK India spokesperson said, "We constantly look for growth opportunities. As regards your query, we don't comment on speculation." ET NOW is awaiting official responses from Torrent Pharma, Cadila Healthcare and EY.

Source: *The Economic Times, 29th August 2016.*

Pharma cos Offer Freebies to Doctors, Violate Code: MP

A Rajya Sabha Member of Parliament has alleged that four drug companies have bribed doctors across India to push their products, violating the Medical Council of India's code of conduct.

USV Ltd., Abbott Laboratories, Macleods Pharmaceuticals and Sun Pharmaceuticals allegedly sponsored "pleasure trips" for doctors or, in some cases, doled out cash in violation of the code of conduct, Tapan Sen, a Communist Party of India (M) MP, wrote in a letter to Minister of Chemicals & Fertilisers Ananth Kumar. The letter dated 18th August was reviewed by ET.

The Department of Pharmaceuticals said in a report in July that there was a need to

take up the issue in the interest of consumers and patients as such promotional expenses that were being extended to doctors had a direct implication on the pricing of drugs and affordability. In addition, the Comptroller & Auditor General, in a report in 2015, criticised the Central Board of Direct Taxes for allowing promotional expenses by pharma companies as deductible expenses while calculating tax.

"I am waiting for the minister's response on this issue. Nothing has come so far. We also have the names of the doctors who have taken bribes, which we will release eventually," Sen told ET. Two of the companies denied any wrongdoing, one could not be reached and the fourth did not immediately respond to queries.

Sen lists allegations such as Sun Pharma paying for tickets for a pleasure trip to Srinagar for nine doctors and its Stancare Division picking up the hotel bill for a doctor; money paid by USV to 13 doctors for a trip to Vancouver and an amount of Rs 163,8200 directly paid to 149 doctors in Madhya Pradesh; Abbott India paying money to 300 doctors and Macleods Pharma paying money to about 40 doctors in Karnataka and Uttar Pradesh.

The names are based on an investigation by People's Health Movement, an NGO that presented its report to the ministry last year. All these acts are a gross violation of the code of conduct formulated by the Medical Council of India, Sen wrote. "So far, MCI had not taken any action when complaints were filed to them. But this code is only applicable to doctors," he said in the letter.

US drug maker Abbott said its interaction with doctors is guided by the company's code of conduct and policies, laws and industry codes.

"Our policies don't allow any activity with doctors as an incentive to recommend or prescribe Abbott products. We also have strict policies against providing entertainment, gifts, leisure activities or incurring expense for a doctor's family," an Abbott spokesperson said in response to an email query from ET.

Mumbai-based Macleods Pharma refuted the allegations as wrong and baseless. "It seems to be inspired by some fake and morphed WhatsApp message, which was being circulated some time back. On investigation of the matter, we found that the message was morphed and created by one 'Creativa INDIA,' purported to be an advertising agency based in Delhi. In fact, we had filed an FIR and civil case also against it and obtained an injunction order in our favour," Niteesh Srivastava, vice president at Macleods Pharma, said in an email response to ET.

USV was unreachable for comment on the matter and repeated phone calls to the company's board line went unanswered. Sun Pharma, too, till the time of going to press, did not respond to ET's emailed queries.

Source: *The Economic Times, 30th August 2016*

Anti Obesity Injections Good or Bad

According to a recent survey, 80 per cent of Delhi NCR residents are obese. In the year 2014, there were around 20 million obese women and 9.8 million obese men recorded in India alone. The figures published in the Lancet also stated that worldwide, the number rose from 105 million obese people in 1975 to 641 million in 2014. Two years later, the numbers are still dangerously high. But with more and more people realizing the ill effects of obesity, bariatric surgeries, weight loss diets and anti-obesity medications are finding more takers.

Aiming to do the same, an injection named Victoza was launched in India a few years ago. The weight loss potential of injection Victoza, which was originally used for the management of Diabetes mellitus, was recognized early in the course of drug usage. Subsequently US FDA accepted it as a weight loss therapy in non-diabetics too. And people wanting to lose weight obviously got lured - after all who wouldn't want to opt for an anti-obesity injection over spending hours at the gym. But it isn't as simple as it sounds. Dr Ashish Ahuja, Senior Consultant Laproscopic Bariatric Surgeon and Associate Professor in Department of Surgery, Dayanand Medical College and Hospital, Ludhiana, warns, "Victoza is primarily an anti-diabetes injection and is not meant to treat obesity. It may cause weight loss but poses high risk of thyroid and pancreatic cancer. Moreover, Victoza-led weight loss is temporary, unlike weight loss surgeries that keep away lost weight for a longer time. Also, if the injection is self administered, it can even lead to hypo or hyperglycemia."

Diabetes and obesity, though considered to be two different diseases, are closely linked with each other. Dr Sanjay Kalra, Consultant Endocrinologist, Bharti Hospital Karnal & Vice President, South Asian Federation of Endocrine Societies elaborates, "Both diabetes and obesity share so many causes, clinical features and complications that the term 'diabesity' is often used to describe them in combination. Liraglutide is an effective medication, which is used to manage both diabetes and obesity. A once daily injection, it is used in differing doses (up to 1.8 mg daily for diabetes, and 3.0 mg for obesity)."

A large multinational trial, the LEADER trial, conducted in over 10000 participants, demonstrated not only safety, but benefits of liraglutide or victoza. "This drug reduces the risk of death, the risk of death due to cardiovascular cause, and the risk of worsening of kidney disease. This represents a major advance in diabetes care, as we can prevent progression of diabetes and postpone its complications with liraglutide," Dr Kalra adds.

So how exactly does Victoza function? Dr Ambrish Mithal, Chairman-Endocrinology & Diabetes, Medanta elaborates, "The dose of this daily injection recommended for weight loss is 1.5 to 2 times higher than what is used for diabetes. It functions by controlling our intake. The dose alerts our brain centers to reduce appetite, simultaneously slowing down emptying of our stomach to produce a sensation of fullness."

Having said that, it doesn't work for everyone. Dr Manoj Chadha, Consultant Endocrinologist, P D Hinduja Hospital & MRC, Mumbai says, "Patients may lose between 5-10 per cent of their body weight within 3-4 months. However, a small but significant proportion of patients are categorized as non-responders as these patients do not lose weight.

"Dr.S.K. Wangnoo, Endocrinologist, Indraprastha Apollo Hospitals adds, "The possible side effects of Victoza are pancreatitis and thyroid tumors, both of which can be fatal. The Institute for Safe Medication Practices (ISMP) reported that the FDA's clinical safety reviewer originally voted against approving the drug because of its link to thyroid tumors, insufficient study to rule out increased heart attack and stroke risk, as well as an increased risk for pancreatitis. FDA published a warning that doctors weren't fully aware of thyroid risks associated with Victoza. That notice also mentioned that clinical trials suggested an increased risk of pancreatitis in Victoza patients."

Comparing it to weight loss surgeries, Dr Chadha adds, "Bariatric surgery works through multiple mechanisms to reduce weight. Patients end up losing up to 30-40 per cent of their original body weight. However, the earliest weight loss noticed in patients after surgery is through an increase in a hormone called GLP1. Injection Victoza stays in blood circulation for nearly 24 hours. The weight loss following Victoza is a modest 5-10 per cent. However, it could be used pre-operatively to prepare the patient for surgery and judge the possible response of the patient to surgery."

Dr Anup Dhir, MD cosmetic surgery A +Mediart warns against the ill effects of the injection, "I would any day recommend bariatric weight loss over Victoza injection as these injections are mainly meant for Type -2 diabetics. It can cause cancer, thyroid and pancreatic diseases and are also second line medicine. On the other hand, bariatric surgeries aid weight loss by restricting the amount of food the stomach can hold."

With a huge number of people struggling to shed weight, a fat-fighting injection surely seems irresistible. But remember the popular adage - 'all that glitters is not gold'. While more studies will be conducted over a period of time to prove its efficacy and safety, it's always advisable to try the natural way - Eat well and burn calories.

Source: *The Times of India, 5th September 2016*

Govt Plans to Cap Prices of More Drug NPPA to Meet Next Week

More essential drugs are likely to come under price control with the government expected to decide on the matter in a meeting scheduled for next week. Out of a total of around 900 drugs in the National List of Essential Medicines (NLEM) 2015, around 450 drugs are already under price control.

Out of a total of around 900 drugs in the National List of Essential Medicines (NLEM) 2015, around 450 drugs are already under price control. "Some of the drugs which are not under the price control yet will be considered for price cap," NPPA Chairman Bhupendra Singh told PTI.

He, however, declined to share details of the drugs that are likely to come under price control. In a tweet, the National Pharmaceutical Pricing Authority (NPPA) said: "NPPA's next meeting scheduled for September 14, 2016. Some more drugs are likely to come under price control."

The government currently fixes the prices of essential drugs based on the simple average of all medicines in a particular therapeutic segment, having sales of more than 1 per cent. It also monitors the maximum retail prices (MRP) of all the drugs and

companies are allowed to hike prices of non-scheduled drugs by up to 10 per cent in a year.

The government had notified DPCO, 2013, which covers 680 formulations, with effect from 15 May 2014, replacing the 1995 order that regulated prices of only 74 bulk drugs. Last month, Union Minister of Chemicals and Fertilisers Ananth Kumar said the government is mulling providing more than 50 essential drugs, including those used in treatment of cancer and AIDS, at cheaper rates to a large section of the population.

Set up in 1997, NPPA has been entrusted with the task of fixation/revision of prices of pharma products, enforcement of provisions of the Drugs (Prices Control) Order and monitoring prices of controlled and decontrolled drugs.

Source: *The Economic times, 9th September 2016*

Genrics Are a Lifeline

Médecins Sans Frontières (MSF) or Doctors without Borders, the international humanitarian medical aid organisation that is active in 69 countries, serves populations affected by epidemics, armed conflicts, natural calamities and manmade disasters. MSF has relied heavily on generic drugs, much of which has been sourced from India, to deliver health care to some of the most deprived peoples on the planet. Addressing healthcare exclusion has been a major part of its work, and this has often meant locking horns with big pharmaceutical companies. MSF was in the news recently for its decision not to take any more funds from the European Union and member countries in protest against their tough refugee policies. Jerome Oberreit, Secretary General of MSF, tells A. Rangarajan why the organisation is the doughty fighter it is. Excerpts:

Tell us a bit about the role that generic drugs — which MSF sources from India — play in your work globally.

Generic drugs play a vital part in our programmes. These generics that we source from India are used by us in 60 countries and constitute nearly two-thirds of the drugs we use for HIV, TB and malaria. We have limited resources and we are committed to delivering health care to as many as possible. It is imperative that we keep costs low. Take the case of AIDS treatment; it is on account of the competition largely from Indian generic drugs that the annual cost of the HIV cocktail needed has been brought down 99 per cent from about $10,000 in 2000 to about $100 today. This has made another 16 million people possible to have the treatment. These statistics speak for themselves. The role generics play in affordable health care hardly needs emphasis. In many cases they are lifeline.

MSF has expressed concern over the ongoing Regional Comprehensive Economic Partnership (RCEP) talks. Are you apprehensive that these could impact the generic drugs production in India?

India has always maintained the right balance between awarding patents to drugs and its commitment to the interests of public health. Since 2005 India has been obligated to issue patents under the WTO but it has wisely used the provisions of TRIPS flexibilities to maintain this fine balance and the poor of the world have benefitted from that. It is not just MSF alone but several ministries of health and other aid organisations have been able to deliver affordable health care to the needy, relying on generics. We are particularly

concerned about two provisions that are being discussed in RCEP, Data Exclusivity and Patent term extensions. Data exclusivity is a backdoor route to awarding monopoly status to drugs. And Patent term extension will extend the monopoly hold of a pharmaceutical company on a drug beyond the current 20 years. Both these provisions go beyond the mandates of International Law. We gather that Japan and South Korea are brining pressure on India on both these counts. We feel it is imperative that the current status quo is preserved in the interests of the public health needs of some of the most marginaliaed and vulnerable peoples. And to that extent we would appeal to the Indian IP negotiators.

You have been campaigning against TPP — the U.S.-led Trans Pacific Partnership as well. MSF has made an oral testimony to the U.S. House of Representatives Committee and has written to President Barack Obama. What are your concerns there?

TPP introduces far-reaching monopoly protection for pharmaceutical companies that would unnecessarily strengthen, lengthen and broaden patents much to the detriment of public health safeguards, enshrined in international law. This will push drug prices up and make access to affordable drugs difficult. It will seek to impose the same conditions on all signatory countries regardless of their public health needs or affordability of governments and patients. We have also pointed out the flaws in the current bio-medical innovation paradigm that seeks to reward R&D through monopolies and high drug prices. That this is affecting the richer countries as well is demonstrated in the case of antibiotic resistance. Cash-rich pharmaceutical companies have not taken up R&D in antibiotic development because they must be affordable and should be used sparingly. Instead they focus on drugs that are necessitated by life-long treatments like cancer cure and other conditions. They spend more on sales and marketing than R&D. Bio medical innovation should be responsive to needs.

Seeking to demonstrate an alternative approach is feasible and viable, MSF has been a part of the Drugs for Neglected Diseases Initiative (DNDi) programme. How does it counter the ills of the current paradigm you point put?

The Drugs for Neglected Diseases Initiative (DNDi) was actually started in 2003 with the Nobel Prize money providing the seed funding. In 10 years we have developed six new therapies. Based on DNDi's estimates we reckon that the cost to develop a new chemical entity to be between €100 to €150 million. Whereas estimating costs involved in developing a drug by the industry is a difficult exercise as there is hardly any transparency. Current studies however place that cost anywhere between $802 million to $2.6 billion. That is the staggering difference we are talking about. Pharmaceutical industry has been afflicted by excessive financialisition. Shareholder accountability becomes paramount, over and above public health needs. DNDi is about supporting both innovation and access.

It is a momentous decision indeed that MSF will be no longer taking funds from EU or member countries, foregoing nearly €68 million. Why did you decide to shame the EU?

The EU has been pursuing policies of damaging deterrence that are aimed at pushing people and suffering away from the shores of Europe. These refugees are fleeing some of the most dangerous and violent war-torn regions like Syria, Iraq and Afghanistan. The EU-Turkey deal goes even beyond deterrence and it places the very concept of a “refugee” and the entitled protection in danger. In Azaz,

where 100,000 people are stuck between closed borders and frontlines, the situation is dangerously precarious. Further, to be talking about safe zones with in Syria is misleading and irresponsible. No security can be ensured in these so called safe zones. When Lebanon can take refugees almost equalling half its population and when Turkey can accommodate nearly three million refugees, indeed it is shameful that Europe with about a 400-500 thousand people should be turning its back on a proportionally much smaller number. These closure of borders is leading to more disasters at sea. Europe is abrogating its responsibilities towards refugees under agreed international conventions and this cannot become the norm and has to be challenged.

Has MSF started assuming a larger political profile?

MSF was founded by both doctors and journalists. Much of our work happens in places farthest from the presence of media. We also speak out publicly on what we see. We are impartial and neutral when it comes to conflicts. Bearing witness to acts of violence and suffering does not mean we remain silent. Taking a position on these vital issues does not make us political.

Source: *The Hindu, 11th September 2016*

Novo Nordisk Searches for Tablet to Replace Insulin Shots

For decades, a substitute for invasive insulin needles — tablets or insulin delivered via inhalable pumps — is seen as a holy grail but scientific endeavours have so far achieved limited success. But good news for millions of diabetes patients may be in sight.

Danish drug maker Novo Nordisk, a dominant player in the global insulin market, is raving up for at least two oral products that it believes could give the company a clear breakthrough lead and potentially alter the treatment paradigm.

The company that reaped nearly 80% of its $16 billion sales from insulin products last year is hopeful for a regulatory approval for its first time oral therapies, a GLP-1 receptor agonist for type-2 diabetes and an insulin packed in a tablet form in three to four years. Once commercially launched the company said it could see steady growth and visible switch from the currently used needles.

GLP-1 is a potent hormone that induces beta cells of the pancreas to release insulin in response to rising glucose and controls glucagons secretion.

Speaking to ET, Mads Krogsgaard Thomsen, chief science officer at Novo Nordisk, said the company is on track for an oral long-acting diabetes therapy, semaglutide, and hoped to see it in reality around 2020. Novo Nordisk commenced phasethree global clinical studies for the drug last year. In contrast to the existing similar products under development that are likely to be short-acting and need more than a single dose in a day, the oral semaglutide may have an edge with a longer effect accompanied with a superior cardiovascular safety profile.

The injectable form of semaglutide, being developed for once-a-week dose, is expected to be ready for a review by the US FDA later this year, Krogsgaard, who is known among the best in the world for cutting-edge research, told ET at the company's headquarters at Copenhagen earlier this month.

"We have come a long way in terms of developing insulins. We can actually show that semaglutide is better than the currently developed oral (insulin) drugs and also matches the (benefits) of injectable GLP-1. That means the patients can get the convenience of the tablet and still have the power of a biologic," Krogsgaard said.

Source: *The Economic Times, 13th September 2016*

Pharma Cos Cipla and Wockhardt in Global Alliance to Fight Drug Resistance

Major Indian drug makers CiplaBSE -0.65 % and WockhardtBSE -1.35 % are among a group of 13 global pharmaceutical firms which have joined hands in laying out a roadmap to combat antimicrobial resistance (AMR) by 2020.

The roadmap by these 13 drug firms follows the Industry Declaration signed in January 2016 at the World Economic Forum by more than 100 companies and trade associations, the companies said in a joint statement.

The other companies in the alliance include global majors such as Johnson & Johnson, NovartisBSE 0.42 %, PfizerBSE -0.21 %, Sanofi and AstraZeneca.

The four key commitments on reducing antimicrobial resistance are: reducing the environmental impact from the production of antibiotics; ensuring antibiotics are used only by patients who need them; improving access to current and future antibiotics, vaccines and diagnostics and exploring new opportunities for open collaborations between industry and the public sector, the statement said.

Welcoming the initiative, WHO Antimicrobial Resistance Secretariat Director Marc Sprenger said: "In particular, the measures to reduce the environmental impact of the production of antibiotics, advance stewardship and minimise over-the- counter and non-prescription internet sales of antibiotics will be of great benefit.

"I strongly encourage the collaboration between industry and governments, as it is only together that we can tackle antimicrobial resistance." Chairman of the Review on Antimicrobial Resistance Jim O'Neill hailed the latest commitments from major pharma firms to do their bit in the world's response to drug-resistant infections.

"We will only overcome this challenge through effective collaboration between governments, NGOs and the private sector," he added.

The companies support the establishment of a high-level coordinating mechanism to provide global leadership, mobilize resources, set goals, and measure progress towards them, the statement said.

Antimicrobial resistance (AMR) is the natural process by which bacteria and other microbes develop resistance to the drugs commonly used to treat infections. Antimicrobials include antibiotics (which act only on bacteria), antivirals, antiparasitics and antifungals.

Source : *The Economic Times, 20th September 2016*

Debate on e-pharmacy by Leaders of Pharma Trade and Civic Associations Evokes Mixed Responses

Mixed responses have come up in a deliberation held on the scope of online trade of medicines (e-pharmacy) in the Indian scenario by the pharma captains and representatives of civic associations in Chennai last week.

The deliberation was in the form of a debate between two panels of supporters of online pharmacy and off-line pharmacy, and the subject was, 'Online Pharmacy – Needed or Not-needed'.

The panel who supported online sale of drugs represented pharmacy academia, clinical research association and media. Those opposed were from wholesale trade, pharmacy council and consumer awareness group. There was no representation from the retail sector, regulatory side and manufacturing industry.

Though divergent views have come up in the arguments, speakers from both the sides were focusing on the patients' safety and guarantee for quality medicines. The panel which supported e-pharmacy said that the web-based platform for medicine sale would definitely benefit the consumers for availing quality drugs and it was advantageous for them. One panelist pointed out that drugs through e-pharmacy would be delivered only on online production of prescription by doctors. The pharma trade leader and managing director of Essen Associates, R. Sreenivasan, has argued in favour of conventional system of medicine trade under the supervision of a pharmacist. He said the existing mode of medicine business should be continued as the system supports drug dispensing by a pharmacist. According to him, e-pharmacy was started not in public interest. There is no source to control e-pharmacy, he said.

Countering his point, T S Jayashankar, managing director of the clinical research organisation, Quest Life Sciences Ltd, argued that online sale of drugs is already in practice in all the developed countries, and it helps the masses to access any kind of drugs on reasonable prices everywhere. He said a vast country like India cannot remain unnoticed of the developments happening in foreign countries and it has to go on par with the developed nations. According to him, India has all the facilities to create a very good platform for online trade of medicines.

Another supporter of e-pharmacy in the debate was Dr V Ravichandran, director of NIPER, Kolkata, who said online pharmacy is an off-shoot of modern technology that must be utilized for the masses to satisfy their increasing demands.

T Ilango, Registrar of Tamil Nadu Pharmacy Council, supporting off-line trade said e-pharmacy will not succeed in India and it is utter failure wherever it is in practice. He said the government should immediately stop e-pharmacy for medicine sale and allow the conventional system of medicine trade under the supervision of a qualified pharmacist.

The deputy editor of The Hindu publications, R K Radhakrishnan, highlighting the advantages of e-pharmacy, argued that there was no point in opposing on-line business. He pointed out that to each and every concept there are two sides of opinions. He questioned the rationale behind the demand of stoppage of online sale of drugs when there are web based platforms

for several other things. Online pharmacy is the need of the hour, he stated.

Raising concerns over the sale of prescription medicines illegally online and highlighting the risk of misuse of drugs, M R Krishnan, deputy director of a consumer education research group, said secure purchase of drugs is made only when a consumer buys it directly from the hands of a pharmacist from a medical store. He said online pharmacy has no mechanism to check the medicines.

The debate, which was conducted by the Tamil Nadu Pharmaceutical Welfare Trust in association with Tamil Nadu IPA, has ended in a heated battle of words between the supporting and opposing participants. The chairman of the Tamil Nadu IPA, J Jayaseelan moderated the function, while Prof K Chinnaswami, president of TN Pharmacy Council, presided over.

Since the debate has evoked mixed responses, the president of the forum reserved his judgment in the discussion.

Source: *Pharmabiz, Tuesday, August 02, 2016,*

உலக நாடுகளின் மருந்தகம் இந்தியா!

குறைந்த விலை, நிறைந்த தரம் இதனை தாரக மந்திரமாக கொண்டு இந்திய மருந்து நிறுவனங்கள் செயல்படுவதால் உலக நாடுகளின் மருந்தகமாக இந்தியா மாறியுள்ளது. உலக நாடுகளுக்கு மருந்து பொருள்களை ஏற்றுமதி செய்வதில் இந்தியா, சீனா இடையே கடந்த சில ஆண்டுகளாகவே கடும் போட்டி நிலவுகிறது.

இந்த நிலையில், கடந்த 2015-ஆம் ஆண்டில் உலக நாடுகளுக்கான மருந்து ஏற்றுமதியில் சீனாவை பின்னுக்குத் தள்ளி இந்தியா முதலிடத்தை மீண்டும் தக்க வைத்துக் கொண்டது.

அந்த ஆண்டில் இந்திய மருந்து பொருள்கள் ஏற்றுமதி 7.55 சதவீதம் வளர்ச்சி கண்டு ரூ.82,764 கோடியாக (1,254 கோடி டாலர்) இருந்தது. அதேசமயம், சீன மருந்துகள் ஏற்றுமதி 5.3 சதவீதம் அதிகரித்து ரூ.45,804 கோடியாக (694 கோடி டாலர்) காணப்பட்டது.

அமெரிக்கா, ஆப்பிரிக்கா, ஐரோப்பிய நாடுகளுக்கான மருந்து பொருள்கள் ஏற்றுமதியில் சீனாவுடன் ஒப்பிடுகையில் இந்தியாவே முன்னிலை வகிக்கிறது. இதற்கு இந்திய நிறுவனங்களின் தரம் மற்றும் குறைந்த விலை ஆகியவையே முக்கிய காரணங்களாகும்.

குறிப்பாக, உலக நாடுகளோடு ஒப்பிடுகையில் இந்திய நிறுவனங்கள் எச்.ஐ.வி./எய்ட்ஸ், ஹைபடைட்டிஸ் பி,சி, புற்றுநோய், ஆஸ்துமா மற்றும் காச நோய்க்கான எதிர்ப்பு மருந்துகளை மிக குறைந்த விலையில் தயாரித்து அளிக்கின்றன. இதற்கான பெருமை, இந்தியாவின் காப்புரிமை சட்டத்தையே சாரும்.

இந்த காப்புரிமை சட்டத்தின் பயனால் இந்திய நிறுவனங்கள் மக்களின் நலனை முதன்மையாக கொண்டு ஜெனரிக் மருந்துகளை கட்டுப்படியாகக் கூடிய விலையில் தயாரித்து விற்பனை செய்கின்றன. ஜெனரிக் மருந்துகள் என்பது காப்புரிமை செய்யப்பட்ட மருந்துகளை மாற்று வழிமுறையில் தயாரித்து வழங்குவதாகும்.

அமெரிக்காவுக்கு மருந்து பொருள்களை ஏற்றுமதி செய்வதில் இந்தியா கடந்த 2015-இல் 23.4 சதவீத வளர்ச்சியை (474 கோடி டாலர்) எட்டியது. அதேசமயம், சீனாவின் வளர்ச்சி 15 சதவீதமாக (134 கோடி டாலர்) மட்டுமே இருந்தது.

இந்திய மருந்துகளுக்கு உலக சந்தைகளில் எப்போதுமே தனிப்பட்ட வரவேற்பு உண்டு. அந்த வகையில் ஸன் ஃபார்மா, லூபின், அரவிந்தோ உள்ளிட்ட முன்னணி இந்திய மருந்து நிறுவனங்களின் வளர்ச்சி அமெரிக்க சந்தையை மையமாக கொண்டே உள்ளன.

இதன் தொடர்ச்சியாக, இந்தியாவைச் சேர்ந்த மருந்து நிறுவனங்களும் அமெரிக்காவில் புதிய ஆலைகளை அமைத்து மருந்து உற்பத்தியை தொடங்குவதில் அதிக ஆர்வம் காட்டி வருகின்றன.

இதற்காக, அந்த நாட்டின் உணவு-மருந்து கட்டுப்பாட்டு ஆணையத்தின் அனுமதியைப் பெறுவதிலும், மருந்து தயாரிப்புக்கான ஒப்பந்தங்களைப் பெறுவதிலும் ஸன் ஃபார்மா உள்ளிட்ட நிறுவனங்கள் தீவிரமாக உள்ளன.

குறைந்த வருவாயைக் கொண்டு, வறுமையில் வாடும் ஏழை நாடுகளுக்கு மருந்துகளைத் தயாரித்து அளிக்கவும் உலக சுகாதார அமைப்புடன் அரவிந்தோ, எம்கியூர், ஹெட்டிரோ லேப்ஸ், லாரஸ் லேப்ஸ், லூபின் மற்றும் சைடஸ் உள்ளிட்ட இந்திய நிறுவனங்கள் ஒப்பந்தங்களை மேற்கொண்டுள்ளன.

இதன் மூலம், ஏழை நாடுகளில் எச்.ஐ.வி., ஹெபடைட்டிஸ் சி, காசநோயால் வாடுவோருக்கு குறைந்த செலவில் மருந்துகள் கிடைப்பது உறுதிப்படுத்தப்பட்டுள்ளது உலக சுகாதார அமைப்பு,3 பில்லியன் அளவுள்ள மருந்துகளை 121 நாடுகளுக்கு வழங்கி கடுமையான நோய் பாதிப்புக்குள்ளோரை காப்பாற்றிவருகிறது.

மருந்து துறையின் சீரிய வளர்ச்சியை கருதி மருந்து துறையில் அன்னிய முதலீடுகளை வரவேற்கும் விதமாக மத்திய அரசும், பல முக்கிய கொள்கை முடிவுகளை எடுத்துள்ளது.

இந்தியாவில் புதிய ஆலைகளை தொடங்கும் வகையில் நிறுவனங்கள் 100 % அன்னிய நேரடி முதலீட்டை மேற்கொள்ள கதவுகள் திறந்து விடப்பட்டுள்ளன. ஏற்கெனவே உள்ள திட்டங்களில் விரிவாக்க நடவடிக்கைகளை மேற்கொள்ளும் வகையில் 74 சதவீத அன்னிய முதலீட்டுக்கும், அரசு அனுமதியின் பேரில் 100 சதவீத அன்னிய நேரடி முதலீட்டுக்கும் அனுமதி அளிக்கப்பட்டுள்ளது மருந்து பொருள் ஏற்றுமதியில் இந்தியா முதலிடத்தில் இருந்த போதும், அதற்கான மூலப் பொருள் இறக்குமதிக்கு சீனாவையே சார்ந்திருக்க வேண்டிய நிலை உள்ளது.

மருந்து தயாரிக்கத் தேவைப்படும் முக்கிய மூலப் பொருளான பாராசிட்டமால், அமோக்ஸிஸிலின் உள்ளிட்ட 12 வகையான மூலப் பொருள்களை சீனாவில் இருந்தே இறக்குமதி செய்ய வேண்டிய நிலை உள்ளது.

இதற்கு முக்கிய காரணம் இதர நாடுகளுடன் ஒப்பிடுகையில் இத்தகைய மூலப் பொருள்களின் விலை சீனாவில் மிகவும் குறைவாக இருப்பதே என்று மத்திய வர்த்தக அமைச்சர் நிர்மலா சீதாராமன் ஒப்புக் கொண்டுள்ளார்.

கடந்த 2014-15 முழு நிதி ஆண்டில் 222 கோடி டாலருக்கு மருந்து மூலப் பொருள்கள் சீனாவிலிருந்து இறக்குமதி செய்யப்பட்டன. இந்த நிலையில் 2015-16-இல் ஒன்பது மாத காலத்தில் மட்டும் இதன் இறக்குமதி 174 கோடி டாலராக இருந்தது.

மருந்து பொருள்களின் விற்பனை, ஏற்றுமதி, வருவாய் இதில் முன்னிலை வகித்தாலும் மூலப் பொருள்களுக்கு சீனாவை மட்டுமே நம்பியிருப்பது கவலை அளிப்பதாக உள்ளது. எனவே, உள்நாட்டில் மருந்து மூலப் பொருள்களை தயாரிக்கும் வகையில் ஆலைகளை தொடங்க, முதலீடுகளை அதிகரிக்க மத்திய அரசு நடவடிக்கை எடுக்க வேண்டும் என்பது இத்தொழிலில் ஈடுபட்டுள்ளோரின் கோரிக்கையாக உள்ளது.

Source : *Dinamani, 22nd August 2016*

போலி மருந்துகள் புழக்கத்தை கட்டுப்படுத்த அரசின் அதிரடி: கூடுதல் ஆய்வாளர்களை நியமிக்க திட்டம்

"நாட்டில் போலி மருந்துகளின் புழக்கத்தை கட்டுப்படுத்த, கூடுதலாக மருந்து ஆய்வாளர்-களை நியமிக்க முடிவு செய்யப்பட்டுள்ளது," என, மத்திய மருந்துகள் துறை இணை செயலர் சுதான்ஷ் பந்த் தெரிவித்துள்ளார்.

அவர், டில்லியில் நடைபெற்ற இந்திய – அமெரிக்க வர்த்தக கூட்டமைப்பின் ஆண்டு பொதுக் கூட்டத்தில் மேலும் பேசியதாவது: மத்திய, மாநில அரசுகளின் மருந்து தரக் கட்டுப்பாட்டு அமைப்புகள், நாடு முழுவதும் உள்ள, 10 ஆயிரத்திற்கும் அதிகமான மருந்து தயாரிப்பு தொழிற்சாலைகளின் கண்காணிப்பு பணியை மேற்கொண்டு வருகின்றன. மருந்துகளின் தரம் குறித்து தொழிற்சாலைகளில், ஆய்வாளர்கள் சோதனை மேற்கொள்கின்றனர். அதுபோல, மருந்து கடைகளில் விற்கப்படும் மருந்துகளின் தரம் குறித்தும், சோதனை நடத்தப்படுகிறது. இதன் காரணமாக, நாட்டில், போலி மருந்துகளின் புழக்கம், 2 சதவீதத்திற்கும் குறைவாகவே உள்ளது.

சமரசம் இல்லை :இருந்தபோதிலும், மருந்து துறையின் வளர்ச்சிக்கு ஏற்ப, மருந்துகளின் தரம் மற்றும் போலி மருந்துகளின் கண்காணிப்பு நடவடிக்கைகளை விரிவுபடுத்த வேண்டிய சூழல் உருவாகியுள்ளது. நாட்டில், 6 லட்சத்திற்கும் அதிகமான மருந்து கடைகள் உள்ளன. ஆனால், அவற்றுக்கான ஆய்வதிகாரிகளின் எண்ணிக்கை, 500 – 1,000 கடைகளுக்கு ஒருவர் வீதம் என்ற அளவில் தான் உள்ளது. ஆகவே, ஆய்வு அதிகாரிகளின் எண்ணிக்கையை உயர்த்த அரசு திட்டமிட்டுள்ளது. இதன் மூலம் தரமற்ற மருந்துகள் தயாரிப்பும், போலி மருந்துகள் விற்பனையும், கட்டுக்குள் வரும்.

இந்திய மருந்து தயாரிப்பு தொழிற்சாலைகளில், அமெரிக்க மருந்து கட்டுப்பாட்டு அமைப்பும் ஆய்வு செய்து, மருந்துகளின் தரத்தை பரிசோதிக்கிறது. இதற்கும், மத்திய, மாநில அமைப்புகளின் மருந்து ஆய்வுகளுக்கும் தொடர்பு இல்லை. அமெரிக்க மருந்து கட்டுப்பாட்டு கழகம், கடந்த நான்கு ஆண்டுகளில், இந்திய மருந்துகளின் தரம் குறித்து 26 எச்சரிக்கை அறிக்கைகளை வெளியிட்டுள்ளது. அவை ஒரு பொருட்டல்ல என்ற போதிலும், மருந்துகளின் தரத்தில் எவ்வித சமரசத்திற்கும், அனுமதி கிடையாது என்பதில், மத்திய அரசு உறுதியாக உள்ளது. பிரதமர் மோடி தலைமையிலான அரசு, இந்திய மருந்து நிறுவனங்கள் மீதான, அமெரிக்க மருந்து கட்டுப்பாட்டு அமைப்பின் நடவடிக்கை குறித்து அந்நாட்டின் சுகாதார கட்டுப்பாட்டு அமைப்பின் கவனத்திற்கு கொண்டு சென்றுள்ளது.

கட்டுப்பாடுகள் :மத்திய அரசு, இந்தியாவில் சுலபமாக தொழில் துவங்குவதற்கு வசதியாக, பல்வேறு கட்டுப்பாடுகளை நீக்கியுள்ளது. இது, மருந்து துறையின் வேகமான வளர்ச்சிக்கு வழி கோலியுள்ளது. கடந்த, 4 – 5 ஆண்டுகளில், இந்திய மருந்து துறையில், முதலீடுகள் குறிப்பிடத்தக்க அளவிற்கு அதிகரித்துள்ளன. கடந்த நான்கு ஆண்டுகளில் இந்தியா, 460 கோடி டாலர் மதிப்பிற்கு, மருந்துகளை ஏற்றுமதி செய்துள்ளது. இவ்வாறு அவர் கூறினார்.

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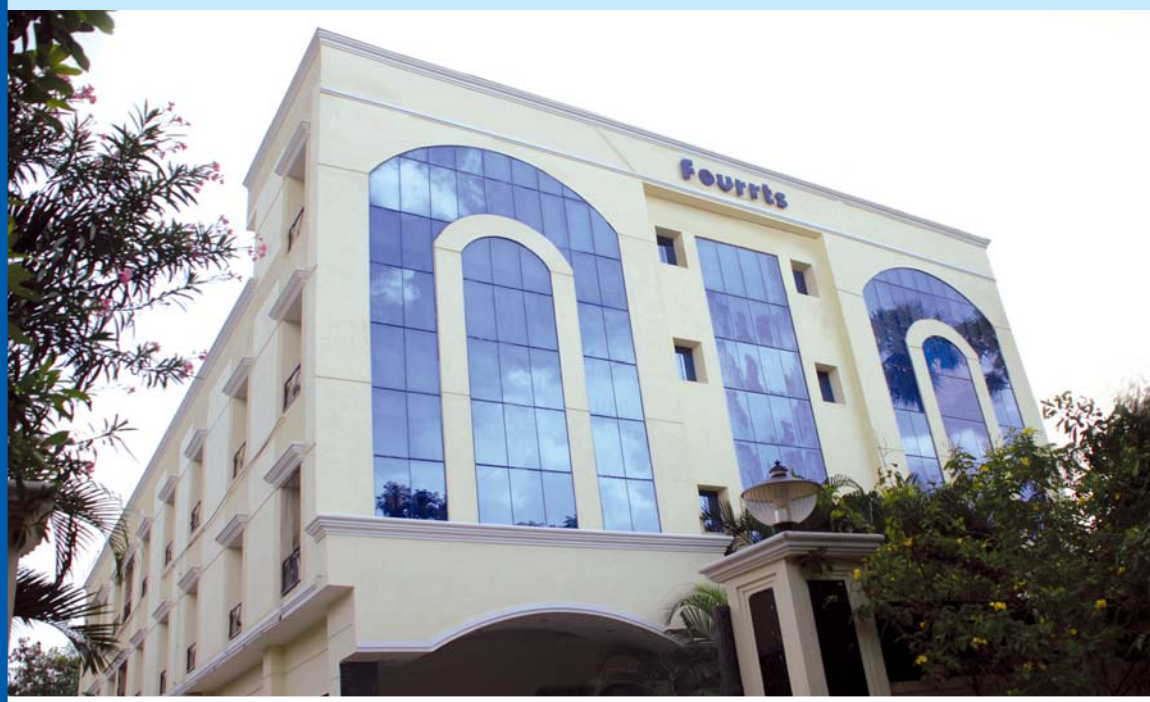

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