ISSUE No. 44

SILVER JUBILEE YEAR 2016

TAMILNADU PHARMACEUTICALS SCIENCES WELFARE TRUST

25 Years

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Oct. - Nov. - Dec. 2019

Delvin Formulations

Destiny for Innovation

Moving Globally

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

Our Group of Companies

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

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Tamilnadu Pharmaceutical Sciences Welfare Trust

Pharma Web

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ISSUE : 44 Oct. - Nov. - Dec. 2019

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

We wish all our readers a very HAPPY NEW YEAR 2020.

We are happy to publish the 44th issue of Pharma Web Newsletter for Oct – Dec 2019.

It is great pleasure to intimate all our readers that our IPA (TN) branch again got best branch in the country. Mr. A. Krishnadev, Vice Chairman of our Trust was awarded life time achievement in IPA activities. These awards were given during the recent IPC meeting in Chennai. In the Pharmacy week celebration conducted by our IPA (TN) branch, Hon,ble Health Minister and Health Secretary announced Medical Device and Pharma Pharma park near Chengelput. This is great achievement by IPA TN branch. We congratulate the office bearers of our IPA TN branch.

This 44th issue contains the program highlights as well as the following lectures given by various resource persons.

- Adverse Event/Complaints Handling Specific for In-Vitro Diagnostics Medical Devices (IVDs) - **Mr. Manish Ragtah,** Manager, Regulatory Affairs, Perkin Elmer (India) Pvt Ltd.,
- Overview of Nutraceutical Regulations - **Dr. M. Kannan**, Deputy Director, Southern Region, FSSAI (Central Licensing Authority)
- Regulatory Pathway for Approval of Fixed Dose Combinations (FDCs) - **Dr. K. Bangarurajan,** Joint Drugs Controller (India), CDSCO, FDA Bhawan, New Delhi.

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

The important events like National Pharmacy Week Celebration, IPA Best Branch award, IPA Life time achievement awards are published.

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

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

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

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

With Best Regards,
R. NARAYANASWAMY
Chief Editor

ARTICLES

ADVERSE EVENT / COMPLAINTS HANDLING SPECIFIC FOR *IN-VITRO* DIAGNOSTICS MEDICAL DEVICE (IVDs)

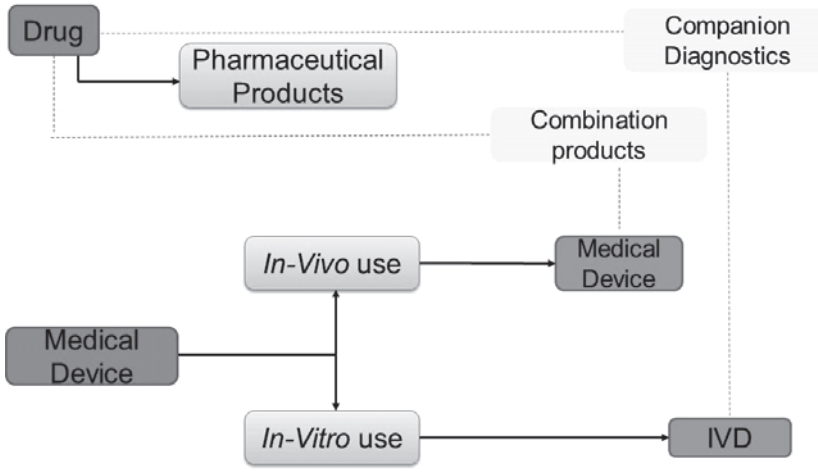
by

Mr. Manish Ragtah,
Manager, Regulatory Affairs, Perkin Elmer (India) Pvt Ltd.,
(Lecture Delivered during the Training Programme on "Management & Ensuring Safety of Medical Devices" held on 2nd & 3rd May 2019, conducted by IPC, NCC-MvPI)

Content

- How Drugs, Medical Devices and IVDs are categorized?
- How IVDs are different from Medical Devices?
- Definitions
- Possible Reasons for occurrence of Adverse Events
- Reportable Incidents?
- Adverse Events examples
- Incidents NOT to be reported
- Examples: IVD specific
- Timelines as per Materiovigilance Programme of India
- QUIZ

How IVDs are different from Drugs and Medical Devices?



How IVDs are different from Medical Devices?

- IVDs are used to conduct tests outside of human body
- IVDs do not comes in direct contact with the patients
- Performance and Risks are different as compared to medical devices
- Tests are done on the specimens derived from human body and these specimens are not re-introduced into the body
- Medical devices are evaluated on humans at final step. However, IVDs are evaluated on human specimens from concept to final device
- Rarely the sole determinant for diagnosis and treatment decisions
- Clinical Evidence for medical devices and IVDs are basically different

Definitions

- **Complaint:** Any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market.
- **Incident:** any malfunction or deterioration in the characterization and/or performance of a device, as well as inadequacy in the labelling or instruction for use, which directly or indirectly, may lead to or might have lead to the death of the patient or user or to a serious deterioration in their state of health.
- **Harm:** Physical injury or damage to the health of people or damage to property or the environment.
- **Adverse Events:** any event or other occurrence, that reveals any defect in a medical device or concerns any adverse effect arising out of the use thereof.
- **Indirect harm:** in majority of cases, IVD medical devices, due to their intended use, do not directly lead to physical injury or damage to the health of people. These devices therefore are more likely to lead to indirect harm rather than direct harm.

Indirect harm examples	Indirect harm caused by
Misdiagnosis, Delayed Diagnosis, Delayed treatment, Inappropriate treatment, Absence of treatment, Transfusion of inappropriate material	Imprecise results, Inadequate quality controls, Inadequate calibrations, False positives, False negatives

Definitions

- **Field Safety Corrective Actions:** A FIELD SAFETY CORRECTIVE ACTION is an action taken by a MANUFACTURER to reduce a risk of death or serious deterioration in the state of health associated with the use of a MEDICAL DEVICE that is already placed on the market.

- **Sensitivity:** Also called as true positive rate, measures the proportion of actual positives that are correctly identified as positives.

$$\text{Sensitivity (\%)} = \frac{\text{True positives} \times 100}{\text{True positives + False Negatives}}$$

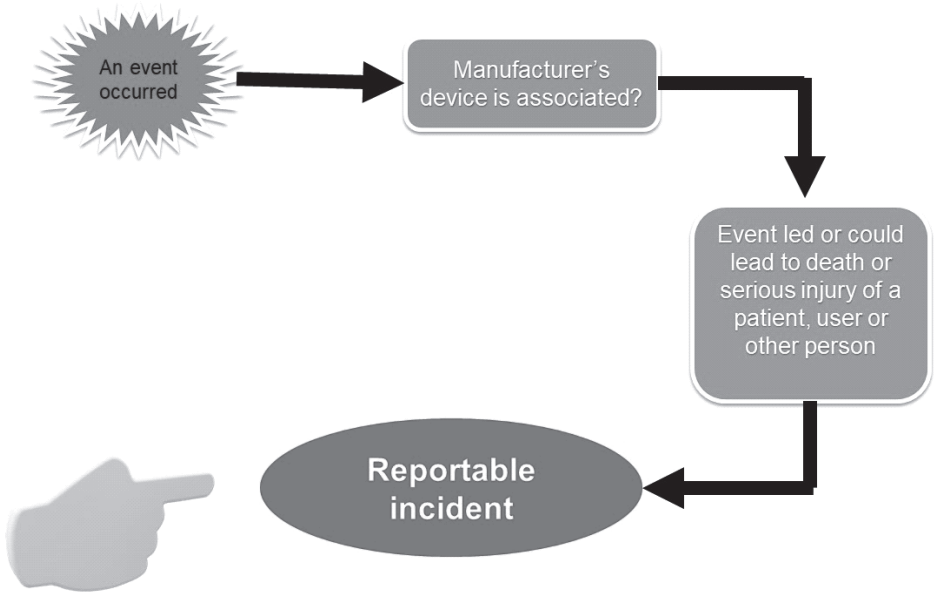
- **Specificity:** Also called as True negative rate, measures the proportion of actual negatives that are correctly identified as negatives.

$$\text{Specificity (\%)} = \frac{\text{True Negatives} \times 100}{\text{True Negatives + False Positives}}$$

Possible reasons for occurrence of Adverse Events

- Shortcomings in the design or manufacture of the IVD medical device
- Inadequate instruction for use
- Inadequate servicing and maintenance.
- Locally initiated modifications or adjustments by the user
- Inappropriate user practice
- Inappropriate management procedures
- Inappropriate environment in which an IVD medical devices is used or stored
- Selection of the incorrect IVD medical device for the purpose

Reportable incident?



Adverse Events examples

- Malfunction or deterioration
- Lead to patient management decision
- Imminent life threatening situation to the patient or to the offspring
- Cause death or severe disability- Individual/ offspring/fetus
- False positive or false negative results

- Death of the patient, user or any other person

Serious deterioration in state of health of patient user or any other person.
- Life-threatening illness
- Permanent impairment of a body function or permanent damage to body structure
- A condition necessitating medical or surgical intervention
- Any indirect harm as consequence if an incorrect diagnosis or IVD test result
- Fetal distress, fetal death or any congenital abnormality or birth defects.

- Degradation/destruction of device
- Unanticipated adverse reactions
- Interaction with other substances or products
- Inappropriate therapy based on the results obtained
- Inaccuracy in the labeling, instruction for use and/or promotional material

Incidents NOT to be reported

Deficiency of IVD medical device found by the user prior to its use

• : in an IVD testing kit a bottle labelled lyophilized is found to be in a fluid state and this is discovered by the user prior to its use.

Event caused by the patient condition

•To justify no report, the manufacturer should have information available to conclude that the device performed as intended and did not cause or contribute to death or serious deterioration in state of health of the patient

Shelf life of the medical device is exceeded

•a patient is admitted to hospital with hypoglycemia on an incorrect insulin dosage following a blood glucose result. The investigation found that the test strip was used beyond the expiry date specified by the manufacturer.

An IVD medical device not stored at the recommended storage conditions/temperature by the manufacturer

•An HIV kit gives a false negative result. The investigation found that the kit was stored at room temperature and not in the refrigerator (between 2-8ºC) as mentioned in instruction for use

Examples of incidents

A Batch of out-of-specifications blood glucose test strips is released by manufacturer. Patient uses strips according to instruction for use, but readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization

An HBV test gives false negative result, may be due to improper storage condition, which means patient will have wrong diagnosis and no treatment will be provided

Control line does not appear.

One or more individuals receive HIV-contaminated blood product that has been produced from one blood donation that was screened as HIV negative by an HIV – 1/2 RDT.

Desiccant has changed color.

An HIV test gives false positive result, which means person is getting treatment of infection which he/she does not have at all. E.g.: An individual presenting for ART initiation has testing repeated to confirm their HIV diagnosis. The re – testing results are negative

A component labelled lyophilized is found to be fluid, this is discovered by the user prior to use

The packaging of a device is labelled with the caution 'do not use if the packaging is opened or damaged'. Prior to use, obvious damage to the packaging was observed, and the device was not used.

Control kit failed for Cholesterol measurement for one day

MvPI-Reporting Timelines

Reporter	What to report	To Whom	When
Manufacturers	Initial reports for an event on MDAE reporting form with remedial action to prevent an unreasonably risk of substantial harm to public health. Adverse events or incident resulting in death or of serious public health treat should submit initial report	MvPI	Within 5 working days of becoming aware of an event
Manufacturers	Medical Device Adverse Events (MDAE) of incident on MDAE-reporting form with causality assessment report and future preventive or corrective steps that would be taken in a defined timeframe	MvPI	Within 30 Calendar days of becoming aware of an event
Healthcare service providers/ clinical establishments	MDAE or incident on MDAE-reporting form with causality assessment report.	MvPI	MDAE reporting form within 5 working days of becoming aware and root cause analysis in next 30 calendar days

QUIZ: Reportable or Not reportable?

A Batch of out-of-specifications blood glucose test strips is released by manufacturer. Patient uses strips according to instruction for use, but readings provide incorrect values leading to incorrect insulin dosage, resulting in hypoglycemic shock and hospitalization

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The packaging of a device is labelled with the caution 'do not use if the packaging is opened or damaged'. Prior to use, obvious damage to the packaging was observed, and the device was not used.

OVERVIEW OF NUTRACEUTICAL REGULATIONS

by

Dr. M. Kannan,
Deputy Director, Southern Region, FSSAI (Central Licensing Authority)
(Lecture Delivered during the Pharmac South Exhibition 2019,
organized by IDMA, TN held on 28th & 29th June 2019 at Chennai Trade Centre, Chennai.)

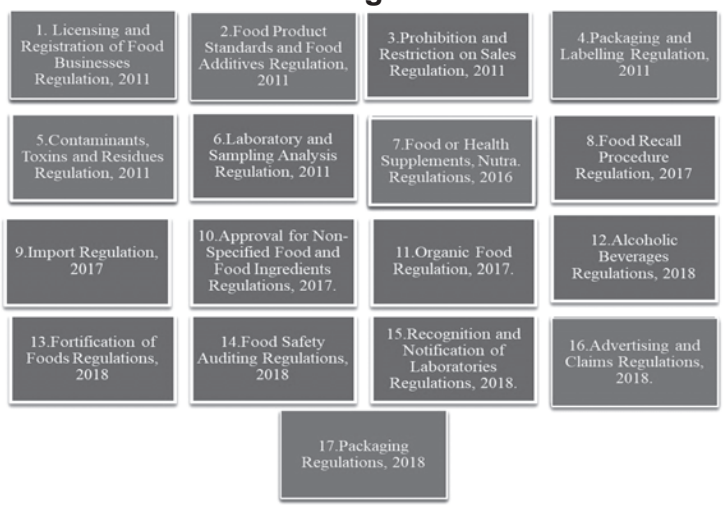
What is FSSAI??

Food Safety and Standards Authority of India (FSSAI)

A Statutory Body governing the Food Safety of the country

- Setting up science based standards for articles of food
- Regulate their manufacture, storage, distribution, sale and import
- Ensure availability of safe and wholesome food for human consumption

FSS Regulations



Nutraceuticals Regulation

- Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016
- Published online 23rd December, 2016 ; in harmony with Section 22 of the FSS Act, 2006.
- Covering a wide inventory of approved functional food ingredients and permissible additives, Labelling requirements and claims
- Various implementation orders dt. 29.12.17, 29.06.18, 24.08.18, 31.12.18, 10.05.19

Categories under the Regulation

- The regulation – 8 categories of foods and VIII Schedules covering the permissible ingredients and additives along with labeling requirements and claims
    - Health Supplements
    - Nutraceuticals
    - Food for special Dietary use
    - Food for special medical purpose
    - Specialty food containing plant or botanicals
    - Foods containing probiotics
    - Foods containing prebiotics
    - Novel Foods

Health Supplements

- Supplement the normal diet of a person above the age of 5 years
- Shall contain concentrated source of one or more nutrients like amino acids, enzymes, minerals, proteins, vitamins as per the prescribed schedules
- **Dosage Forms :** capsules, tablets, pills, sachets; jelly or gel, semi-solids and other similar forms
- Nutrients added shall not exceed ICMR RDA

Nutraceuticals

- Shall provide a physiological benefit and help maintain good health
- Usually a extract/isolate in purified state - Nutraceuticals
- Shall contain at-least one ingredient from Schedule VI with standardisation to marker compounds
- Dosage Forms : granules, powder, tablet, capsule, liquid, jelly or gel, semi-solids and other formats
- Ingredients shall not exceed ICMR RDA

Food for special Dietary use

- Specially processed or formulated to satisfy particular dietary requirements
  - Low weight, obesity, diabetes, high blood pressure;
  - Pregnant and lactating women; and
  - Geriatric population and celiac disease and other health conditions
- To be taken under medical advice
- Dosage Forms : granules, capsules, tablets, pills, jelly, semi-solid and other similar forms
- Nutrients may be added at levels higher than RDA, but shall not exceed as specified in Schedule III (under revision - currently one-RDA shall be applicable)
- Product may be formulated as a meal replacement as well

Food for Special Medical Purpose

- Food for special medical purpose shall include food specially prepared for weight reduction and intended as total replacement of normal diet
- Formula for very low energy diet - energy intake of 450-800 kcal
- Shall have adequate dietary fiber
- Nutrients may be added at levels higher than RDA, but shall not exceed as specified in Schedule III (under revision - currently one-RDA shall be applicable)

Specialty food containing plant or botanicals

- Preparation of specialty food containing plant or botanical ingredients
- To use any other plant or botanical ingredient, which is not specified in Schedule IV - seek prior approval of the Food Authority

Foods containing Probiotics

- Shall contain Probiotic culture of the microorganisms specified in Schedule VII only
- Viable number of organisms in food 108 CFU in recommended serving per day
- Commonly used starter cultures of lactic acid producing bacteria - used in the preparation of fermented milk (dahi) and related products shall not be considered as probiotics

Foods containing Probiotics

- Food containing prebiotics specified in Schedule VIII

Novel Foods

- Food may not have a history of human consumption; or may have any ingredient used in it which or the source from which it is derived, may not have a history of human consumption
- No novel food shall be manufactured or imported for commercial purpose without the prior approval of the Food Authority

Schedules under the Regulation

Schedule I	Vitamins, Minerals and their components	Table A - Vitamins Table B – Minerals Table C - Permissible overages
Schedule II	Amino acids	Table A -Essential Amino Acids Table B – Non- Essential Amino Acids Table C - Nucleotides
Schedule III	Vitamins, minerals and trace elements allowed to be used in FSDU / FSMP	Table 1 - Vitamins Table 2 - Minerals
Schedule IV	Plant or botanical ingredients (400 ingredients in regulation)	
Schedule V	Schedule VA to VF – List of permissible Additives	
Schedule VI	Ingredients as nutraceuticals	Part A – Ingredients with Purity Criteria Part B – Ingredients alone
Schedule VII	Probiotics compounds	
Schedule VIII	Prebiotic compounds	

More ingredients approved under Implementation_Health_Suppliments, F. No. Stds/Nutra(DCGI)/FSSAI/2017(Pt1) dated 29/12/2017

Ingredient and Additives permissibility for Functional Food

S.No	Name of the Food Supplement	Permitted Ingredient	Permitted Additive
1	**Health Supplement**	From Schedule I or II or IV or VII, VIII or Enzymes only of Schedule VI.	Schedule VA or VE or VF only
2	**Nutraceutical**	From Schedule II, IV, **VI**, VII, VIII, or I.	Schedule VA or VE or VF only
3	**Food for Spl. Dietary Purpose (other than infants and those products intended to be taken under medical advice)**	From Schedule I or II or III or IV or VI or VII or VIII	Schedule VB or VE or VF only
4	**Food for Spl. Medical Purpose**	From Schedule I or II or III or IV or VII or VIII or Enzymes only of Schedule VI	Schedule VC or VD or VE or VF only

Ingredient and Additives permissibility for Functional Food

S.No	Name of the Food Supplement	Permitted Ingredient	Permitted Additive
5	**Food Added with Probiotic Ingredients**	Probiotic Culture specified in Schedule VII and or also in Addition of permitted PreBiotics	Schedule VA TO VF only
6	**Food Added with Prebiotic Ingredients**	Prebiotic Culture specified in Schedule VIII.	Schedule VA TO VF only.
7	**Specialty Food Containing Plant or botanical ingredients**	Only Plant or botanical ingredients specified in Schedule IV.	Schedule VE OR VF only
1-7	**All Categories in S.No 1-7**	**ADDITIONAL INGREDIENTS OTHER THAN ANY ADDITIVES** In addition to the Ingredients as mentioned in the Column 3, it may contain the Additional Ingredients OTHER THAN ADDITIVES either Standardized item or permitted for use in Standardized Item as per FSS(FPS& FA) R 2011.	**ADDITIONAL ADDITIVES NOT PERMITTED**

Prohibition

- Implied claims for curing disease or claims of drug like efficacy such as 'Prevents bone fragility in post menopausal women'
- Disease claims by the name of the product such as cancer cure or through a pictures, symbols, namely, electrocardiogram tracing, lipid profile

Limelight on the Regulation

- Mere combination of vitamins and minerals are not covered under these regulations unless there is an inclusion of an element of food
- Products may also contain standardized or permitted ingredients specified in FSS (FPS & FA) regulation, 2011.
- Overages of vitamins and minerals are permissible as per Schedule I - table C, however label declaration shall be provided for such products
- 10% variation form that of label declaration is permissible during analysis of functional food samples
- Heavy metals – as per FSS (Contaminants, Toxins and Residues) Regulation, 2011
- Hormones/Steroids/Psychotropic ingredients - not allowed under these regulations

Claims

Nutrition Claims

Claim for Energy, Fat, Cholesterol, Fat, Sugar, Protein, vitamin and Minerals

Nutrient/ component	Claim	Conditions
Energy/Calorie	Low	Not more than 40 kcal# per 100 g for solids 20 kcal per 100 ml for liquids.
	Free	Not more than 4 kcal per 100 ml for liquids.

Health Claims

Nutrient – Health Condition:

Sodium – Hypertension, Saturated fat-blood cholesterol

Nutrient/Food-Health Relationship	Conditions for claim	Claim Statement
Calcium or Calcium and Vitamin D and osteoporosis	○ the food is a source or high in calcium or in calcium and vitamin D and ○ a statement that the beneficial effect is obtained with a daily recommended intake (RDA)	Adequate Calcium (or Calcium and Vitamin D) intake throughout life, through a balanced diet are essential for bone health and to reduce the risk of osteoporosis

Claims

Health claim- relationship exists between the constituent of that nutrient and specific health related benefits

Types of health claims

- (i) ingredients (nutrient or nutritional) function claims;
- (ii) enhanced function claims;

- Adequate level of documentation and scientific proof made available for review by the Food Authority when called for

- Other claims - may be allowed - prior approval of the Food Authority - no drug claims

product led claims

Valid data and suitable statistical design proving the benefit for disease risk reduction - human intervention studies;

- The product compatibility for the proposed claim benefit and suitable qualifiers
- The use of word “shown” can be used as when a single human intervention study shows significant benefit:
- The use of word “Proven" can be used as when more than one human intervention studies
- Health Claims where scientific support does not exist, or if a novel ingredient is to be introduced, there shall be a prior approval of the Authoity

- I am a manufacturer of API like Paracetamol, Acetaminophen,.. will FSSAI issues license for me??
    - Drugs are not covered under FSSAI Act & Regulations, License will be issued for any standardized Food article/ingredients/additives only

- I have sun dried leaf/fruit powders, can I categorize it under Health Supplements?
    - Mere forms of food such as fruits, vegetables, minimally processed, shall not constitute HS or Nutra., or FSDU or FSMP ü May be categorized as botanicals

- I am a manufacturer of Ingredients/additives which are not covered under these regulations how can I get a FSSAI license?
    - Check out FSS (Approval for non specified food and food ingredients) regulation, 2017

- I am manufacturer of intermediates and not the final product, which food category should I apply under?
    - Premixes and Intermediates to be applied under food category 99

Food categories

FLRS has several food categories; 1-16 & 99..
Where do I fit the functional foods??

13.3 Dieteic foods intended for special medical purposes (excluding products of food category 13.1)

13.4 Dieteic formulae for slimming purposes and weight reduction

13.5 Dieteic foods (e.g. supplementary foods for dietary use) excluding products of food categories13.1 – 13.4 and 13.6

13.6 Food Supplements/health supplements; Nutraceuticals; Speciality food containing plant botanical ingredients with safe history of usage; and prebiotics/probiotics (excluding foods containing prebiotics/probiotics covered under any other category)

Examples for the Product format – Form B

Other food processing units

Sl.No.	Food Category	Name of Food Item(s)	Quantity (MT/Day)	Kind of Business
1	13.6 - Food Supplements/health supplements; Nutraceuticals; Speciality food containing plant botanical ingredients with safe history of usage; and prebiotics/probiotics (excluding foods containing prebiotics/probiotics covered under any other category)	Nutraceutical (Ingredients Soya Protein Isolate Retinyl acetate,cholecalciferol, D-alpha-tocopherol, Phylloquinone, L-ascorbic acid , Thiamine mononitrate, Riboflavin, Pyridoxine hydrochloride, Cyanocobalamin, Niacin, Folic acid D-pantothenate, Calcium sulphate, Potassium phosphate monobasic, Magnesium carbonate, Sodium carbonate, with permitted list of additives) XXXXX	0.5	Manufacturer
2	13.6 - Food Supplements/health supplements; Nutraceuticals; Speciality food containing plant botanical ingredients with safe history of usage; and prebiotics/probiotics (excluding foods containing prebiotics/probiotics covered under any other category)	Health supplement (Ingredients Sodium Chloride, Potassium Chloride, Sodium citrate, Calcium lactate, Magnesium sulphate, L- Lysine, Ascorbic acid, with permitted list of additives) YYYYY	0.5	Manufacturer

Model Format for Submission of Ingredients and Additives for Food Category 13.3 to 13.6

(ONLY FOR ILLUSTRATION PURPOSE)

Name of the Food Item: AABBCCDD
Name of the Product Category: 13 – Foods Stuffs for Intended Nutritional Purpose
Name of the Sub Food Category: Between 13.3 to 13.6
Name of Food: 13.6 - Food Supplement- **Nutraceutical- AABBCCDD**

Ingredient (Other than Additive) Details [ILLUSTRATION]

S.No	Name of the Ingredient	Quantitative Composition in Finished Good (Ex- 100gm) (Units as per the concerned Schedule)	Regulation Number as per the Gazette Notification vide FSSAI Order dated 06-01-2014 **(Mandatory)**	Regulation Number as per FSS(FPS) Regulation 2011 (if Applicable)
1	AbelmoschusMoshatusSeed	4 g	Schedule IV – S.No 4	NA
2	Corn Flour	94 gm	NA	2.4.7 of FSS(FPS) Regulations 2011.

Note: if it is Not Applicable, enter as NA.

Model Format for Submission of Ingredients and Additives for Food Category 13.3 to 13.6

Contd. -

[ILLUSTRATION]

S.No	Name of the Additive	INS Number	Regulation Number as per the Gazette Notification vide FSSAI Order dated 06-01-2014 (Schedule V only)	Quantitative Composition in Finished Good (Example 100 GM) (Units as per the concerned Schedule)
1	Acesulfame Potassium	INS 950	Schedule VA – S.No 1	190 mg

(if the No additive is used , the same shall be mentioned clearly)

NAME AND SIGNATURE OF THE AUTHORISED SIGNATORY

******

For Exports

Declaration by Exporting FBO
Involving in Export of NON-STANDARDIZED PRODUCTS
(including Proprietary Food and Other Health Supplement / Nutraceuticals)

Name of the Product	
Name of the Importing Country	
Whether Product falls under the Food Category of Indian Regulation	**IF YES** , Choose/ Mention the Food Category from the following 1. Proprietary Food 2. a. Health Supplement b. Nutraceuticals, c. Food for Special Medical Purpose d. Food for Special Dietary Purpose e. Specialty foods containing botanical ingredients f. Pre-Biotic Food / Pro-biotic Food.
IF No, Mention the Food Category as per the Regulation **of the Importing Country**	

Name Of the Ingredient and Additive	Complying as per Indian FSS Regulation (If yes , **Mention the Regulation Number in FSSR)**	If **NOT Permissible in the Indian FSSR,** Mention the **Regulation Number of the Importing Country**	Enclose the Copy of the Specification of the Importing Country (Yes/ No)
A	B	C	D

Declaration :

I /We hereby declare that the Information including the copy of the Specification of the importing country as given above is authentic and truthful. The applied product is Food only and it is in compliance with the Regulations of the Importing Country and this product will not sold in the Domestic Market in any form.

Name and Signature of the Authorized Signatory

For office use	**(Remark based on the above Input by EFBO and Tick any one)**	
1	Ingredients and Additives are as per FSSR , To be included in Domestic KoB also	
2	Ingredients and Additives are NOT as per FSSR , Foreign Country Specification enclosed and Declaration given by EFBO, To be included in ONLY EXPORT KOB	

Other points to keep in mind

- What are the document I need to provide?
  - Annexure 2 of FSS (L & R) Regulations, 2011
- License Fee? How to make payment?
  - Application procedure is completely online including payment – 7500/year for FSSAI Central License
- I have submitted the application, when will I get my License??
  - 15 Days for scrutiny of your application
  - Issued license can be Downloaded from your bin

I Got a License, what else FSSAI expects?

- Always provide safe and wholesome food for your customers
- Check the Annexure 3 – Conditions of the License of FSS (L & R) Regulation, 2011
- Basic hygiene, GMP, GHP as prescribed in the Schedule IV of FSS (L & R) Regulation, 2011
- Have your product periodically analysed and maintain proper records
- Have through knowledge of standards, keep updating it with new amendments and orders
- FoSTaC - Food Safety Training & Certification – Mandatory for all licensee - at least one trained and certified Food Safety Supervisor under FoSTaC for every 25 food handlers in each premise
- Submission of Annual Returns before the prescribed time

Take Home

- Technical team shall ensure that product is formulated in line with the FSS Regulations to avoid delay due to any product related queries
- Have through knowledge of Regulations and standards, keep updating it with new amendments, notices and orders

REGULATORY PATHWAY FOR APPROVAL OF FIXED DOSE COMBINATIONS (FDCs)

by

Dr. K. Bangarurajan,
Joint Drugs Controller (India), CDSCO, FDA Bhawan, New Delhi
(Lecture Delivered during the Pharmac South Exhibition 2019,
organized by IDMA, TN held on 28th & 29th June 2019 at Chennai Trade Centre, Chennai.)

CONTENTS

Brief Background

- The combination of two or more drugs combined for the first time falls under the definition of New Drug.
- Prior permission from the office of DCG(I) is required for such FDCs since 21.9.1988. Even though the FDCs have been documented in Indian market since the 1960s, efforts to regulate them started in 1988.
- These processes were laid down under Schedule Y, which came into existence in 1988, under the Drug & Cosmetics Act, 1940. As per Rule 122E of the same law, CDSCO as Central Licensing Authority (CLA) approves the FDCs after reviewing relevant pharmacological studies such as bioequivalence, safety profile and clinical trials. Only after the approval from CLA for a particular FDC, the State Licensing Authorities (SLAs) can issue licences for its manufacturing, marketing and sales.
- However, one persistent problem has been the gap in having a systematic, transparent and efficient regulatory framework for FDCs in India

Brief Background

- It was observed that SLAs were granting license for manufacturing of FDCs, which fall under the ambit of New Drugs, without due approval from DCG(I).
- In order to address this issue, Ministry of Health and Family Welfare had also issued repeated statutory direction under section 33P to the State Governments to instruct their respective drugs licensing authorities to refrain from granting licenses for manufacture of new drugs and FDCs covered under the definition of the terms 'new drug' without due approval of the Drugs Controller General (India)
- A disconnected regulatory ecosystem, coupled with an aggressive pharmaceutical industry, gave rise to a challenging domestic pharmaceutical market one which is flooded with FDCs, including irrational FDCs, offered inappropriately for various ailments and stretched far beyond their therapeutic advantages.
- While 1306 FDCs have been approved officially from 1961 to till Feb 2019 by the CLA, their actual numbers in the Indian market including those approved by several SLAs is estimated to be around 6,000.

Rational Use of Drugs as on WHO:

"Rational use of drugs requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of time, and the lowest cost to them and their community."

Marketing Authorization Process of Fixed Dose Combinations

Fixed dose combinations (FDCs) refer to products containing one or more active ingredients used for a particular indication(s).

FDCs can be divided into following groups:

1. FDCs which contains one or more active ingredients as a new drug
2. FDCs which include active ingredients which are already approved individually and are combined for the first time for a particular claim
3. FDCs which are already marketed but now proposed to change the ratio of active ingredients or to make a new therapeutic claim
4. FDCs which includes active ingredients that are combined for convenience only.

Study required for FDCs

1. FDCs which contains one or more active ingredients as a new drug - [FDCs to be approved for marketing, data to be submitted will be similar to data required for any new drug including clinical trials]
2. FDCs which include active ingredients which are already approved individually and are combined for the first time for a particular claim – [*CT required where the ingredients are likely to have significant interaction of a pharmacodynamic or pharmacokinetic nature] [* If clinical trials have been carried out with the FDC in other countries, reports of such trials should be submitted. If the FDC is marketed abroad, the regulatory status in other countries should be stated] [* In case such a combination is not marketed anywhere in the world but these drugs are already in use concomitantly (not as a FDC but individually) for the said claim, marketing permission may be granted based on chemical and pharmaceutical data]
3. FDCs which are already marketed but now proposed to change the ratio of active ingredients or to make a new therapeutic claim [*For such FDCs, the appropriate rationale including published reports (if any) should be submitted to obtain marketing permission. Permission will be granted depending upon the nature of the claim and data submitted]
4. FDCs which includes active ingredients that are combined for convenience only [*It will have to be demonstrated that the proposed dosage form is stable and the ingredients are unlikely to have significant interaction of a pharmacodynamic or pharmacokinetic nature. No additional animal or human data are generally required for these FDCs, and marketing permission may be granted if the FDC has an acceptable rationale]

FORM CT-04- APPLICATION FOR GRANT OF PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

FORM CT-05- APPLICATION FOR GRANT OF PERMISSION TO CONDUCT BIOAVAILABILITY OR BIOEQUIVALENCE STUDY

FORM CT-06- PERMISSION TO CONDUCT CLINICAL TRIAL OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

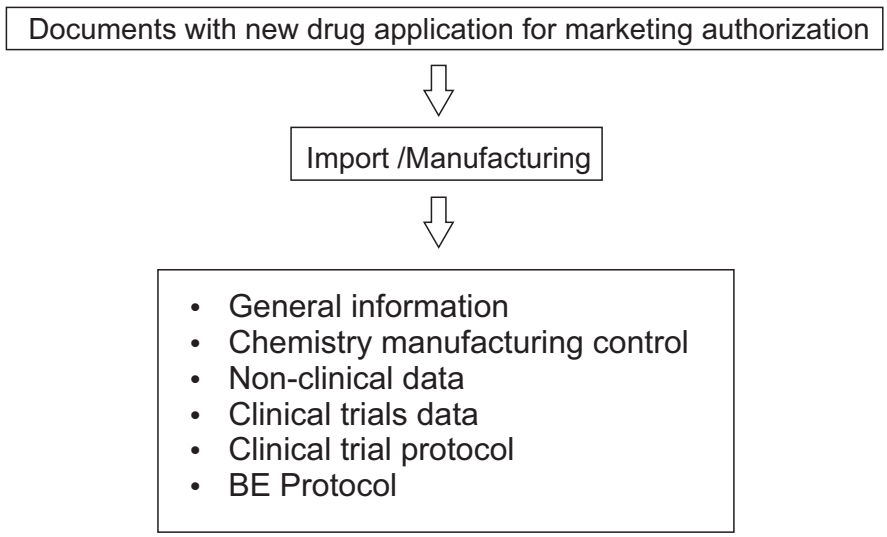
FORM CT-07- PERMISSION TO CONDUCT BIOAVAILABILITY OR BIOEQUIVALENCE STUDY OF NEW DRUG OR INVESTIGATIONAL NEW DRUG

FORM CT 18 - APPLICATION FOR GRANT OF PERMISSION TO IMPORT NEW DRUG FOR SALE OR FOR DISTRIBUTION

FORM CT 20- PERMISSION TO IMPORT PHARMACEUTICAL FORMULATIONS OF NEW DRUG FOR SALE OR FOR DISTRIBUTION

FORM CT 21- APPLICATION FOR GRANT OF PERMISSION MANUFACTURE NEW DRUG FORMULATION FOR SALE OR FOR DISTRIBUTION

FORM CT 23- PERMISSION TO MANUFACTURE PHARMACEUTICAL FORMULATION OF NEWDRUG FOR SALE OR FOR DISTRIBUTION



Data required

Chemical and Pharmaceutical information

Animal Pharmacology

Animal Toxicology

Phase III Clinical Trials

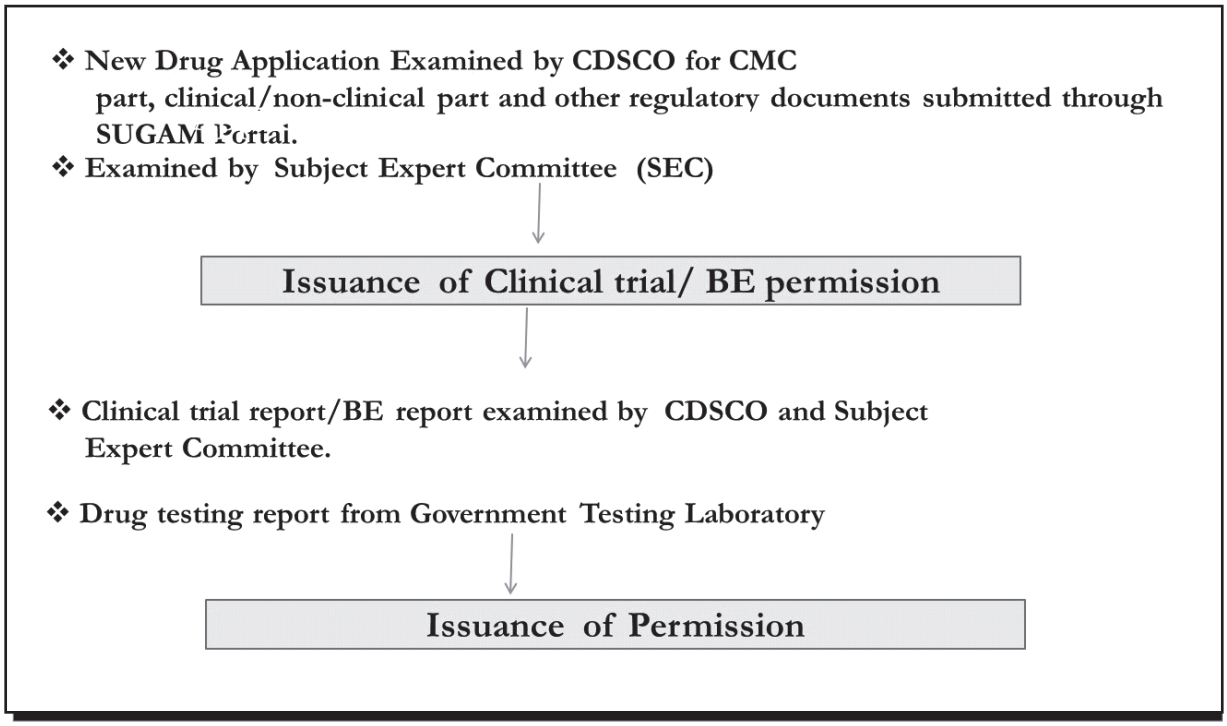
Regulatory Status in other country

COPP/FSC (in case of import)

Label, Prescribing information

Published literature including published clinical data

Advantages/disadvantages of the new drug over other marketed drugs of same therapeutic class



Fees payable for FDCs as per Sixth Schedule of New Drugs and Clinical Trial Rules, 2019

S. No.	Application	Fees (in Rs.)
1	Application for permission to import fixed dose combination having one or more of the ingredients as unapproved new molecules for marketing	5,00,000
2	Application for permission to import fixed Dose combination having approved ingredients for marketing	4,00,000
3	Application for permission to import fixed dose combination already approved for Marketing	2,00,000
4	Application for permission to import fixed dose combination for new claims, new indication or new dosage form or new route of administration or new strength for marketing	3,00,000
5	Application for permission to manufacture fixed dose combination having one or more of the ingredients as unapproved new molecules for sale or distribution	5,00,000
6	Application for permission to manufacture fixed dose combination having approved ingredients for sale or distribution	3,00,000
7	Application for permission to manufacture fixed dose combination already approved for sale or distribution	2,00,000
8	Application for permission to manufacture fixed dose combination for new claims, new indication or new dosage form or new route of administration or new strength for sale or distribution	3,00,000

Different type of Checklist for FDC Division of CDSCO SUGAM Portal

1. FDC - Marketed abroad

2. Not marketed anywhere but individual components used concomitantly

3. Approvals of a FDC already approved in the country (For subsequent approval)

4. Only for Convenience

5. Marketed in India but some changes are sought
   - i. New Indication Import/Manufacture
   - ii. New Dosage Form Import/Manufacture
   - iii. New Route of Administration Import/Manufacture
   - iv. Modified Release Dosage Form import/Manufacture
   - v. Additional Strength Import/Manufacture

Additional Information:-

Prescribing Information

The prescribing information shall comprise the following sections:-

Generic Name

Composition

Dosage Form

Indication

Dose and method of administration

Use in special population

Contra-indication

Warning, precaution, drug-interactions, undesirable effects, overdose, Pharmacodynamic and Pharmacokinetic properties

Incompatibilities, shelf-life, storage and handling instructions.

Label and Carton should be as per Rule 96 and 97 of the Drugs and Cosmetics Rules, 1945

Issues related to 294 FDCs

- 83 FDCs have been considered as rationale. Further, pathway for processing of these applications is still under consideration. However, draft pathway for issuance of NOC is already published on official website.

- Pathway with respect to 49 FDCs, which require further generation of Data in terms of safety and efficacy with detailed recommendation of experts, are already published on CDSCO website.

- Pathway with respect to 17 FDCs, which require to prove its rationality, safety and efficacy, are already published on CDSCO website along with Annexure A and B.
  - Annexure A- Name of FDCS
  - Annexure B- Format for submission of information.

Achievements:-

- Prohibited 328 FDCs on 07.09.2018 declared as irrational by the DTAB. However the matter is subjudice.
- Resolved 294 FDCs court cases issue pending since 2007 in Hon'ble Madras High Court.
- Prohibited 80 FDCs on 11.01.2019 which were considered as irrational by DTAB under 294 FDC list.
- Schedule H were amended on 26th April, 2018 w.r.t. footnote inserted, namely: - "4. The salts, esters, derivatives and preparations containing steroids for topical or external use are also covered by this Schedule."
- The restriction of sale and distribution on Buprenorphine sublingual tablet and FDC of Buprenorphine + Nalaxone sublingual tablets has been relaxed vide DCGI letter dated28.03.2019 allowing these drugs for supply to Psychiatric clinics and hospitals also so that the trained psychiatrists will have access to these medicines for treating their patients.
- DTAB in its meeting held on 29.11.2018 recommended de-notification of the ban imposed on Fixed Dose Combination of injectable preparation of synthetic Oestrogen and Progesterone. This will expand the choices of Injectable contraceptives available to Indian women for contraception.
- The approval power delegated to State Licensing Authorities in respect of FDCs declared as Rational by Prof. Kokate Committee under 18 months Policy decision and approved by DCGI.

MULTI FACETS OF A COMPETENT PHARMACIST

by
Ms. Rajambigai. S
Arulmigu Kalasalingam College of Pharmacy, Srivilliputhur

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

CONTENT:

INTRODUCTION:

"HEALTH IS A STATE OF COMPLETE PHYSICAL, MENTAL AND SOCIAL WELL-BEING, NOT MERELY THE ABSENCE OF DISEASE OR INFIRMITY". (WHO -1946)

Pharmacist is "a person prepared to formulate, dispense and provide clinical information on drugs or medication to health professionals and patients". Pharmacist is a one of the person in health care team, and plays a key role in providing quality health care and Pharmaceutical care to the public.

MULTI FACETS OF A COMPETENT PHARMACIST :

Pharmacist Role has been changed from Compounder and Dispensing Chemist to one of Drug therapy manager and his role expanded from pre clinical to clinical aspects, which include "MANUFACTURING, QUALITY CONTROL, DRUG DISCOVERY, REGULATORY PHARMACEUTICAL, DRUG DISPENSING, PATIENTS EDUCATION, PATIENT COUNSELING, HOSPITAL PHARMACY ADMINISTRATION AND COMMUNITY SERVICES "The Concept of 7 STAR PHARMACIST" was introduced by then WHO in march 2014 and covered these role. The following are the major roles a Pharmacist has to practice CAREGIVER, DECISIONMAKER, COMMUNICATOR, MANAGER, LIFELONG LEARNER, TEACHER and LEADER. The 7 star

Pharmacist was a landmark concept in terms of setting bench marks for Pharmacists to provide very high quality Pharmaceutical care to the patients. An addendum to the 7 star Pharmacist concepts has resulted in the inclusion of Two new criteria there are “RESEARCHER AND PHARAMAPRENEUR” thereby giving rise to the “9STAR PHARMACIST”.

CARE GIVER: Pharmacist provides patient care in their practice that optimizes therapy outcomes as well as promoting health wellness and disease prevention Pharmacist must view their practice as integrated and continuous with those of the healthcare system and other health professionals. “CARING ABOUT OTHERS RUNNING THE RISK OF FEELING AND LEAVING AN IMPACT ON PEOPLE BRINGS HAPPINESS”.

DECISION- MAKER: Ability to evaluate synthesizes data and provides efficacious safe and cost effective use of medicines. (For example medicines chemicals equipment procedures and practices) “SOMETIMES IT'S THE SMALLEST DECISIONS THAT CAN CHANGE YOUR LIFE FOREVER”.

COMMUNICATOR: Pharmacist is in an ideal position to provide a link between prescriber and patient and to communicate information on health and medicines to the public and other health professional .communication involves verbal, non- verbal listening and writing.”THE ART OF COMMUNICATION IS THE LANGUAGE OF LEADERSHIP”.

MANAGER: Pharmacists must be able to resources (HUMAN PHYSICAL and FINANCIAL) and information effectively; they must also be comfortable being managed by others, weather by an employer the manager/leader of the health care team.

LIFE-LONG-LEARNER: Pharmacists should learn how to keep their knowledge and skills up to date and how to put them into practice.The “lifelong process is active participation in learning activities that assists individuals in developing and maintaining continuing competence, enhance their professional practice and supporting achievement of their career goals”.

TEACHER: Every pharmacist has a responsibility to assist with the education and training of future generations of pharmacists and public. Participating as a teacher not only imparts knowledge to others it offers an opportunity for the practitioner to gain new knowledge and fine –tune existing skills.” IF YOU SALUTE YOUR DUTY YOU DON'T NEED TO SALUTE ANYBODY, BUT IF YOU POLLUTE YOUR DUTY,YOU HAVE TO SALUTE EVERYBODY”

LEADER: Pharmacist also plays a leadership role in the healthcare system to make decisions, communicate and manage effectively. A leader is one who can create an idea/vision and motivate other team members to achieve the vision .A leader is MISSION-DRIVEN without being egocentric effective pharmacy leaders are experts in DEMONSTRARTING and CREATING HIGH- PERFORMANCE PHARMACY PRACTICES CHARECTERIZED BY THE HIGH QUALITY PATIENTS CARE, IMPROVED MEDICATION SAFETY, and MAXIMUM PRODUCTIVITY.

RESEARCHER: Pharmacist must be able to use the evidence base (scientist, pharmacy practice, health system) effectively in order to advice on the rational use of medicines in the healthcare team. As a researcher the Pharmacist is able to increase the accessibility of unbiased-related information for the public and other healthcare professionals. “IT IS A EASY TO GET A THOUSAND PRESCRIPTIONS BUT HARD TO GET ONE SINGLE REMEDY”.

PHARMAPRENEUR: The concept of entrepreneur is still in its infancy because unfortunately the mindset of almost all fully registered Pharmacists (PHARMACY GRADUATE) is that their projection extends to only dry dispensing and its associated activities within a hospital or clinical setting. “THE ENTREPRENEUR ALWAYS SEARCHES FOR CHANGE RESPONDS TO IT AND EXPLOITS IT AS AN OPPORTUNITY”.

CONCLUSION:

Pharmacist must be elegant and should know every nook and corner of “NEWDISCOVERY OF DRUGS” and they shouldbe enough stable on their decision without any doubts arising with regards to physicians prescription. I AM NOT AN ENGINEER…… BUT I KNOW ENGINEERING. I AM NOT A LAWYER……BUT I KNOW LAW (JURISPRUDENCE). I AM NOT A B.Sc., STUDENT ……..BUT I KNOW ORGANIC CHEMISTRY. I AM MULTI TALENTED GUESS WHO I AM…….

“PHARMACIST” PROUD TO BE A PHARMACIST...

EVENTS

58th National Pharmacy Week Celebrations (NPW)

IPA TN State & Local Branch Report

58th National Pharmacy week was celebrated with the theme of **"Pharmacist: Your Medication Counselor"** at the Velammal Medical College Hospital & Research Centre, Madurai by IPA South TN Local Branch in association with IPA Tamilnadu State Branch on Tuesday, 19th November 2019. Shri. J. Jayaseelan, Vice President, IPA Tamil Nadu State Branch was presided over the celebration. Shri. M.V.Muthuramalingam, Chairman, Velammal Group of Institutions was the chief guest. Dr. G. Swaminthan, Retd. Dean, Madurai Medical College, Madurai, Board of Management, Kalasalingam Academy of Research and Education, Krishnankoil and Prof. Dr. K. Chinnaswamy, President, Indian Association of Colleges of Pharmacy, Chennai was the invited guest. Dr. Jacob Raja, Chairman, SA Raja Group of Institutions, Nagercoil, Dr. N. Manimaran, Chariman, Nallamani Group of Institutions, Tenkasi, CA. Dr. M. Karthikeyan, Chariman, Pannai Group of Institutions, Dindigul & Shri. P. Ponrajan, Managing Partner, Pharmafabrikon, Madurai, College of Allied Medical Sciences, Madurai was the guest of honor. Shri. K. Pandian, Jt. Secretary, IPA Tamilnadu & Dr. D. Babu Ananth, Governing Council member, The TN. Dr.MGR Medical University, Chennai were the special guest. Shri. R. Ilango, Asst. Director of Drugs Control, Virudhunagar Zone & Shri. N. C. Ravichandran, Asst. Director of Drugs Control, Madurai Zone were the special invitees. The celebration was inaugurated with prayer song followed by lightening of KuthuVillakku. Dr. N. Venkateshan, Secretary, South TN Local branch welcomed the gathering. The guests were adored by Shawl and memento. In the Chief guest address Shri. M.V. Muthuramalingam highlighted the role of pharmacist in the Health care team. Shri. J. Jayaseelan briefed about the role & responsibility of Pharmacist in the prevention of Drug interaction and importance of counseling. Prof. Dr. K. Chinnaswamy briefed about the Indian pharmacy scenario and role of pharmacist in Patient compliance. Shri.J.Anburaj, Treasurer, South TN Local branch was delivered the vote of Thanks. Shri. A. Sarangapani, President and other office bearers of South TN Local branch, Principal and faculty members from various pharmacy colleges were participated. Around 600 students from Arulmigu Kalasalingam College of Pharmacy, Krishnankoil , College of Pharmacy, Madurai Medical College, Madurai, S.A. Raja Pharmacy College, Vadakangulam, Sriram Nallamani Yadava College of Pharmacy, Tenkasi , K.M.College of Pharmacy, Madurai, Ultra College of Pharmacy, Madurai , Pannai College of Pharmacy, Dindigul, College of Allied sciences, Madurai, RVS Padmavathy Institute of Pharmacy & Research Center, Dindigul & Nadar Mahajana Sangam College of Pharmacy, Marthandam were participated and benefitted. The seminar was concluded with the lunch.

Indian Pharmaceutical Association, Coimbatore and Nilgiris Local Branch in association with **IPA Tamil Nadu State Branch** celebrated the **58th National Pharmacy Week Celebrations (NPW)** in a grand manner at Coimbatore. This year the program was organized by KMCH College of Pharmacy, Coimbatore at NGP auditorium on 20th November 2019.

The function was presided over by Dr. Nalla G. Palaniswami, Chairman & Managing Director, Kovai Medical Center and Hospital Coimbatore. Prof. (Dr).K. Chinnasamy, President –Indian Association of College of Pharmacy was the Chief Guest and Dr. Thavamani D. Palaniswami Managing Trustee, Kovai Medical Center Research and Educational Trust was the Guest of Honor addressed the gathering on the theme. Thiru.T. Sathish, Hon. Secretary – Indian Pharmaceutical Association, Tamil Nadu State Branch delivered the key note address.

The President of IPA Coimbatore and Nilgiris Branch Dr. T.K. Ravi and Dr. R. Vadivelan addressed the students and emphasized the importance of Pharmacy profession The Secretary of IPA Coimbatore local branch Dr. M. Ramanathan stated the importance of IPA membership and encouraged the students to become member of the association. Dr. S. Mohan Treasurer IPA Coimbatore local branch delivered the vote of thanks. He thanked the IPA Tamil Nadu Branch for sponsoring the NPW 2019 function. Around 600 Students and faculty attended the function.

Indian Pharmaceutical Association, Salem Local Branch in association with **IPA Tamil Nadu State Branch** celebrated the **58th National Pharmacy Week Celebrations (NPW)** in a grand manner at The Vinayaka Mission's College of Pharmacy, Salem on 21st November 2019. Prof. K. Chinnaswamy, President, IACP was the chief guest, Dr. B. Jaykar, Registrar, Vinayaka Mission's Research Foundation (Deemed to be University) presided over the function and Mr. T. Sathish, Honorary Secretary, IPA Tamil Nadu State Branch was the guest of honour. Dr. B. S. Venkateswarlu, Principal welcomed the gathering. The Registrar emphasized the need of Pharmacist services to the society. Dr. B. Jaykar has delivered Key note Address on the theme **"Pharmacist's Role in Patient's Safety and Efficacy of Medicine"**. Dr. S. Suriyanarayanan, Deputy Director (Research) and Dr. R.S. Shanmugasundaram, Deputy Director (Academic) felicitated the program. Dr. M. Kumar, Professor & Head, Dept. of Pharmaceutical Chemistry, Vinayaka Mission's College of Pharmacy proposed the vote of Thanks. The Program was ended with cultural events by the students.

58th National Pharmacy Week Celebration valedictory function was organized by IPA TN State Branch on 22nd November 2019 at 4.00 PM at **The TN Dr MGR Medical University,** Guindy, Chennai, **Dr. C. Vijaya Baskar**, Minister for Health, Medical Education & Family Welfare, Govt of Tamilnadu, Chief Guest of the function. The Guest of Honour was Dr. Beela Rajesh, I.A.S., Secretary to Govt, Health & Family Welfare Department, Govt. f Tamil Nadu. Dr. S. Manivannan, President, IPA –TNSB, welcomed the gathering. Mr. J. Jayaseelan, Vice President, addressed the gathering on the theme "Pharmacist: Your Medication Counsellor". **Dr. C. Vijaya Baskar**, gave the address to the audience, Academia & Industry Needed issues were put-forth & Minister has assured for a Pharma Park at Chennai & Pharma Policy in place immediately.

"Best Pharmacist Award" instituted by TN IPA & sponsored by M/s. Lalchand Bhimraj, Chennai, this year was awarded to Prof. Dr. B. Jaykar, Registrar, Vinayaka Mission University, Salem, for the dedicated service to the profession of Pharmacy & academia of Pharma.

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

58th National Pharmacy Week (NPW) Celebration by various Local branches of Tamilnadu

Address by Mr. J. Jayaseelan
58th NPW celebration by IPA South TN Local branch
at Velammal Medical College Hospital & Research Centre, Madurai

Group photo - 58th NPW Celebration by IPA South TN Local branch
at Velammal Medical College Hospital & Research Centre, Madurai

Address by Prof. Dr. K. Chinnaswamy
58th NPW Celebration by IPA Coimbatore and Nilgiris Local branch
at KMCH College of Pharmacy, Coimbatore

Audience
58th NPW Celebration by IPA Coimbatore and Nilgiris Local branch
at KMCH College of Pharmacy, Coimbatore

Inauguration
58th NPW Celebration by IPA Salem Local branch
at The Vinayaka Mission's College of Pharmacy, Salem

Audience
58th NPW Celebration by IPA Salem Local branch
at The Vinayaka Mission's College of Pharmacy, Salem

58th National Pharmacy Week (NPW), Valedictory by IPA Tamilnadu State Branch

Dignitaries on the Dias

Address by Dr. S. Manivannan

Address by Mr. J. Jayaseelan

Address by Mr. S. V. Veerramani

Address by Dr. Beela Rajesh

Address by Prof. Dr. K. Chinnaswamy

Best Pharmacist award to Dr. B. Jaykar

Address by Dr. C. Vijaya Baskar

TNPSW Trust Prize Distribution

Group Photo

IPA - Best State Branch Award

For the year 2019(Consecutive 2nd year) best State branch award received for Tamilnadu State Branch, IPA during the 71st IPC held in Chennai.

IRF Life Time Achievement Award

Every year IPA is giving the IRF Life time achievement award to members of IPA, and scrutinized by the selection committee. For the year 2019 the awardees from our trust Mr. A. Krishna Dev, Vice Chairman, of Trust and Chairman, TANIPA Trust.

Two Days National Seminar

A two days national seminar (PHARMGREE'19) was organized by Faculty of Pharmacy, Dr MGR Educational and Research Institute in association with Indian Pharmaceutical Association, TN Branch and TANIPA Trust, on the theme 'An Insight into Current Drug Development and Research' on 12th and 13th November 2019.

PHARMGREE'19 was inaugurated on 12th November 2019 at the Basement Auditorium of ACS Medical College and Hospital Campus, the Chief Guests were Prof. K. Chinnasamy, President, IACP, Dr. K. Bangaruajan, Joint Drugs Controller, CDSCO, New Delhi. The guests of honours were, Shri. M.M. Yousuf, Secretary, TANIPA Trust, Dr. S. Manivannan, President, IPA, TN, Shri. J. Jayseelan, Vice President, IPA TN, Shri. T. Sathish, Secretary, IPA TN and Executives of Dr. MGR Educational and Research Institute. "Best Pharmacist Award" and "Life Time Achievement Award" were awarded to Dr. K. Bangarurajan and Prof. Dr. K. Chinnasamy by our Honourable Secretary Thiru. A. Ravikumar.

After inauguration, scientific lectures were given by Dr. K. Bangarurajan, Joint Drug Controller, Govt. of India and Dr. S. Manivannan, Deputy Drug Controller, Govt. of India. About 80 E-posters were presented by students and Faculty delegates in various sessions which were evaluated by eminent academicians from other Pharmacy Institutions.

On 13th November 2019, scientific lectures by Dr. S. Sriram, Sri Ramakrishna Institute of Paramedical Sciences and Smt. Judy Jays, MS Ramiah University of Applied Sciences. Parallel sessions of 40 oral presentations were conducted for faculties and students, which was evaluated by Judges from other institutions. Dr. N. Harikrishnan, Principal, presented a memento to our Hon. President as a token of Gratitude for the fervent interest and enthusiasm shown by him in every step of conduction of PHARMGREE'19. The day ended up with distribution of certificates to all students of various institutions who participated in the Seminar. About 350 delegates from other Pharmacy institutions and Industry who had registered for the seminar.

INFORMATION

PG PHARMACY RESEARACH FELLOWSHIP AWARDS 2019

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

This is the 22nd year of this project, we have received 154 (99+55) applications from 7 different branches, from 16 institutions. All synopses were sent to Dr. G. Krishna Mohan, Center for Pharmaceutical Sciences, Jawaharlal Nehru Technological University, Kukatpally, Hyderabad & his team for evaluation. Based on the ranking, 23 students have been selected for Awards as per the following details.

"G. Rangachari Memorial Award"

PG Pharmacy Research Fellowship Award 2019 - 2020 – RESULT

PHARMACEUTICS

Rank	Name	College	Prize Amount
I	Ms. S. Priya Dharshini	Periyar College of Pharmaceutical Sciences, Tiruchirappali	12,000/-
II	Ms. A. J. Mariyambee	Kamalakshi Pandurangan College of Pharmacy, Tiruvannamalai	10,000/-
III	Mr. S.R Aravind	JSS College of Pharmacy, Ooty	8,000/-

PHARMACEUTICAL CHEMISTRY

Rank	Name	College	Prize Amount
I	Ms. Vinodhini. M	College of Pharmacy, Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry	12,000/-
II	Mr. Vyshaag. C.M.	JSS College of Pharmacy, Ooty	10,000/-
III	Ms. Sowmiya. P	College of Pharmacy, Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry	8,000/-

PHARMACEUTICAL ANALYSIS

Rank	Name	College	Prize Amount
I	Ms. Tresa Thomas	College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore	12,000/-
II	Mr. Mohanakishore G.	College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore	10,000/-
III	Mr. Arup Bhattacharya	JSS College of Pharmacy, Ooty	8,000/-

PHARMACOLOGY

Rank	Name	College	Prize Amount
I	Ms. Arthy. M	College of Pharmacy, Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry	12,000/-
II	Ms. Anitta Augustine	KMCH College of Pharmacy, Coimbatore	10,000/-
III	Mr. Vikash R.S.	JSS College of Pharmacy, Ooty	8,000/-

PHARMACOGNOSY

Rank	Name	College	Prize Amount
I	Ms. R. Harini	College of Pharmacy, Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry	12,000/-
II	Mr. Sagar T.R.	JSS College of Pharmacy, Ooty	10,000/-
III	Ms. Archana. I	College of Pharmacy, Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry	8,000/-

PHARMACY PRACTICE

Rank	Name	College	Prize Amount
I	Ms. Dharani M	Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education & Research, Chennai	12,000/-
II	Mr. S. Abdul Gani	Faculty of Pharmacy, Sri Ramachandra Institute of Higher Education & Research, Chennai	10,000/-
III	Mr. Anandu M Das	JSS College of Pharmacy, Ooty	8,000/-

PHARM D

Rank	Name	College	Prize Amount
I	Ms. Ashna Chackochan, Ms. Mahima Maheshwari, Mr. Ajith JS	JSS College of Pharmacy, Ooty	15,000/-
II	Mr. Joyita Krishnamurthi	School of Pharmaceutical Sciences, Vels Institute of Science, Technology & Advanced Studies, Chennai	12,000/-
III	Mr. Anirudh .M, Ms. Fatema Juzer Haji, Ms. Keerthana G.C, Ms. Arthi M.	SRM College of Pharmacy, SRM Institute of Science & Technology, Chennai	10,000/-
IV	Mr. Bhaktraj Singh, Mr. Dinesh Kumar. N, Mr. Manikandan. P, Mr. Vivian D Cruz	JSS College of Pharmacy, Ooty	8,000/-
V	Mr. U. Sanvas	School of Pharmaceutical Sciences, Vels Institute of Science, Technology & Advanced Studies, Chennai	6,000/-

Essay Competition 2019 - Final Year B. PHARM Students

TNPSWT initiated a new activity from 2011 for Essay competition and this year subject being **"Multi Facets of a Competent Pharmacist"**. This awarded is in the name of **"Shri. G. Swaminthan Memorial Award"** -- Sponsored by M/s. Pharm Product Pvt Ltd. Thanjavur.

This year we have received 37 applications from 7 colleges and this was evaluated by Dr. A. Ramesh, Principal, Vishnu Institute of Pharmaceutical Education & Research, Hyderabad. Based on the rating -- 3 students have been awarded as below

Rank	Name	College	Prize Amount
I	Ms. Rajambigai. S	Arulmigu Kalasalingam college of Pharmacy, Srivilliputtur	10,000/-
II	Ms. Heena. S	Vinaya Mission's College of Pharmacy, Salem	8,000/-
III	Ms. Caroline. N	College of Pharmacy, Madras Medical College, Chennai	7,000/-

University Merit Award

From year 2015 M/s. Fourrts India ltd sponsored university merit award (Fourrts Merit Award) for topper candidates, who have scored high marks in B.Pharm examinations passed during August 2019 of The Tamilnadu Dr. MGR Medical University, Guindy, Chennai

Rank	Name	College	Prize Amount
I	Ms. Keerthi. K	College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore	10,000/-
II	Ms. Susmitha. D	College of Pharmacy, Jaya College of Paramedical Sciences, Chennai	8,000/-
III	Ms. Abirami. G	College of Pharmacy, Sri Ramakrishna Institute of Paramedical Sciences, Coimbatore	7,000/-
IV	Mr. Sesha Kumar. S.S.	K.M. College of Pharmacy, Madurai	5,000/-

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NOTIFICATION

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 6th November, 2019

G.S.R. 828(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published as required under sub-section (1) of section 12 and sub-section (1) of 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. 152(E), dated the 26th February, 2019, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (I), inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of said Official Gazette were made available to the public on the 27th February, 2019;

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 sections 12 and 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 (Thirteenth Amendment) Rules, 2019.

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

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as said rules), in rule 71, after subrule (8), the following sub-rule shall be inserted, namely:

   "(9) In case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.".

3. In the said rules, in rule 71A, after sub-rule (4), before the proviso, the following sub-rule shall be inserted, namely:

   "(5) In case the applicant intends to market the drug under a brand name or trade name, the

applicant shall furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.".

4. In the said rules, in rule 71B, after clause (iv), before the proviso, the following clause shall be inserted, namely:

"(v) in case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market:".

5. In the said rules, in rule 76, after sub-rule (10), the following sub-rule shall be inserted, namely:

"(11) In case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.".

6. In the said rules, in rule 76A, after clause (iv), before the proviso, the following clause shall be inserted, namely:

"(v) in case the applicant intends to market the drug under a brand name or trade name, the applicant shall furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market:".

7. In the said rules, in Schedule A, after Form 50, the following Form shall be inserted, namely:

"FORM 51

[See rules 71(9), 71A(5), 71B(v), 76(11) and 76A(v)]

Form of undertaking to the licensing authority for marketing a drug under a brand name or trade name

(1) I ..... of..... intend to market the drug specified below under a brand name or trade name - ……

(i) Name of the drug :

(ii) Dosage form :

(iii) Composition :

(2) I hereby give this undertaking that to the best of my knowledge based on search in trade marks registry, central data base for brand name or trade name of drugs maintained by Central Drugs Standard Control Organisation, literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.

Place……..

Date …….....

[Signature, Name, Designation Seal/Stamp of manufacturer or on behalf of the manufacturer].".
[F. No. X.11018/48/2018-DRS]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note: The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R. 653(E), dated the 13th September, 2019.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 27th December, 2019

S.O. 4671(E).—In pursuance sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby amends the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) No. S.O. 5980(E), dated the 3rd December, 2018 published in PART II, Section 3, Sub-section (ii) of the Gazette of India, Extraordinary, namely,

In the said notification, for the words and figures "the 1st day of January, 2020" the words and figures "the 1st day of January, 2021" shall be substituted.

[F. No. X.11014/33/2018-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note : The principal notification was published in the Gazette of India Extraordinary, Part II, Section 3, Sub-section (ii) vide number S.O. 5980(E), dated the 3rd December, 2018.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 27th December, 2019

S.O. 4672(E).—In pursuance of sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby amends the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) No. S.O. 775(E), dated the 8th February, 2019 published in PART II, Section 3, Sub-section (ii) of the Gazette of India, Extraordinary, namely,

In the said notification, for the words and figures "the 1st day of April, 2020", the words and figures "the 1st day of April, 2021" shall be substituted.

[F. No. X.11014/12/2018-DR]
Dr. MANDEEP K. BHANDARI, Jt. Secy.

Note : The principal notification was published in the Gazette of India Extraordinary, Part II, Section 3, Sub-section (ii) vide number S.O. 775(E), dated the 8th February, 2019.

NEWS

Only PCI Approved Medical Stores to be Eligible to Provide PTs to D Pharm Students from 2020

The Pharmacy Council of India (PCI) has decided that it will acknowledge practical training (PT) obtained by students of diploma in pharmacy (D Pharm) only from pharmacies/medical stores (chemists and druggists) which have got prior approval of the PCI for the purpose of giving PT to student pharmacists.

The 106th central council meeting of the PCI took the decision in this regard which will be implemented from the year 2020. From now on, only PCI-approved medical stores or hospital pharmacies will be eligible to provide PTs to student pharmacists.

According to a circular issued by PCI, this is part of strengthening Education Regulations 1991 and Pharmacy Practice Regulations 2015 with respect to running of D Pharm course in the country.

As per clause 20 (3) of the ER 1991 and Regulation 4.4 of the PPR 2015, a student of Diploma in Pharmacy course has to undergo 500 hours of practical training (spanning three months) in a pharmacy. If the student takes the training from a government hospital pharmacy, it does not need to seek approval of the PCI. But private institutions, whether they are medical colleges or hospitals, they should apply for approval for giving PT to student pharmacists, according to information from PCI.

The main objective of the central pharmacy council to become rigid in implementing the regulations is to weed out fake practical training pharmacies or chemists and druggists who are assigning students in their shops for three months under the pretext of giving training. Such shops may not have full time registered pharmacists. In future, PCI will acknowledge the training only given by experienced and registered pharmacists. This is a requirement as per ER 1991 and PPR 2015.

The central council felt that exposure to working knowledge about keeping of records required by various Acts covering the profession of pharmacy should be an essential part of the course. Further, diploma students must get practical experience in the manipulation of pharmaceutical apparatus in common use. Similarly, he must understand the reading, translation and copying of prescriptions including checking of doses.

A pharmacist is supposed to have knowledge in dispensing of prescription illustrating the commoner methods of administering medicaments and storage of drugs and medical preparations, says the circular issued by PCI following the PCI decision.

The pharmacies or chemists and druggists who intent to provide PTs should inform the PCI through their state councils the details of both the trainers and the trainees. The application for approval should consist of copies of qualification certificate and registration certificate of the working pharmacist (trainer) and name and address of the diploma student and of his college. The date of joining PT and completion of the course must also be informed the PCI.

Source: *Pharmabiz,* 3rd January 2020

Just 1 Dose of the HPV Vaccine may Prevent Infection: Study

Just one dose of the Human papillomavirus (HPV) vaccine may prevent infection from potential cancer-causing virus, suggests new research.

Results of the study, which included only women participants published in the journal JAMA Network Open, suggest that a single dose of HPV vaccine may be as effective as the currently recommended two- or three-dose series.

However, it is too early for people to rely on a single dose of the vaccine for protection, according to senior author Ashish Deshmukh, Assistant Professor at The University of Texas Health Science Center at Houston (UTHealth).

"HPV vaccine coverage is less than 10 per cent globally because of poor vaccine uptake rates in many resource-limited countries. Ensuring boys and girls receive their first dose is a big challenge in several countries and a majority of adolescents are not able to complete the recommended series due to a lack of intensive infrastructure needed to administer two or three doses," Deshmukh said.

"If ongoing clinical trials provide evidence regarding sustained benefits of a one-dose regimen, then implications of single-dose strategy could be substantial for reducing the burden of these cancers globally," he added.

According to the US Centers for Disease Control (CDC), 34,800 new cancer diagnoses are linked to HPV annually.

The virus is thought to account for more than 90 per cent of all cervical and anal cancers, more than 60 per cent of all penile cancers, and approximately 70 per cent of all oral cancers.

Although the study participants included only women, the CDC recommends a two-dose regimen for all children, starting the series before age 15, or a three-dose regimen if the series is started between ages 16 to 26. The latest generation of HPV vaccine can protect against nearly 90 per cent of cancer-causing HPV infections.

Yet, current vaccinations rates are less than ideal.

"The current HPV vaccine dosing regimen can be cumbersome for people to understand. If one dose is proven effective in trials, the vaccine regimen will be simplified," said UTHealth School of Public Health assistant professor and lead author Kalyani Sonawane.

Source:*ET Healthworld,* 30th December 2019

Department of Pharmaceutical Asks Industry to Regulate Promotional Practices

With concerns over the influence of offering gifts to medical professionals by pharmaceutical companies surging, the Department of Pharmaceutical (DoP) has asked the pharmaceutical industry to step up efforts at self-regulation or it will be compelled to bring in a law to regulate promotional practices in the pharmaceuticals industry. The DoP secretary held a meeting on 23 December to review the implementation of the uniform code of pharmaceutical marketing practices (UCPMP) which is being voluntarily adopted by the pharmaceutical companies since 2015.

Following recent complaints of unethical marketing practices by pharmaceutical companies, a committee is likely to be set up by the DoP which will keep a strict vigil on any such violations, shared one of the persons attending the meeting.

The DoP secretary has told both the domestic and multinational pharma lobby groups along with the medical device industry to "strictly" comply with the code of ethics, added the same people. The pharma lobby groups and the medical devices lobby group have been asked to share their comments on the issue within a week.

"A committee is also likely to be set up by the DoP pharma to check on any such violations by the pharma companies in future," added another person. Chaired by the DoP pharma, the meeting was also attended by the National Pharmaceutical Pricing Auhtority (NPPA) chairperson Shubhra Singh and senior officials in the DoP.

The meeting was necessitated following a recent study by non-governmental organisation (NGO) Sathi (Support for Advocacy and Training to Health Initiatives), which claimed that "promotional practices of the pharmaceutical industry and implementation of status of related regulatory codes in India lacked credibility". It revealed that medical representatives disclosed widespread use of bribes, including foreign trips, microwave ovens, expensive. Smart phones, jewellery and even women, by pharmaceutical companies.

The report also revealed that medical representatives (MRs) talked of the tremendous pressure exerted by companies on them through high sales targets. The report is based on in depth interviews with 50 MRs, areas sales managers, allopathic and Ayush doctors and pharma executives from six cities conducted last year.

Simultaneously, earlier this month another non government organisation also blamed well-known Swiss drug maker for providing inducements in the form of honorariums for participation in conferences, travel assistance, accomodaion, food expenses, all of which are strictly prohibited under the UCPMP as well as the Indian Medical Council (Professional conduct, Etiquette and Ethics), Regulations 2002. A complaint in this regard was sent to the DoP.

The DoP has been dragging its feet on the draft legislation aimed at increasing transparency in financial relationships between healthcare providers and

pharmaceutical manufacturers as well as deterring unethical practices since 2016.

According to the UCPMP, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to persons qualified to prescribe or supply drugs, by a pharmaceutical company or any of its agents i.e. distributors, wholesalers, retailers, etc.

Gifts for the personal benefit of healthcare professionals and family members, both immediate and extended, such as tickets to entertainment events, are also not to be offered or provided. However, there has been no headway on the proposed legislation.

The government had in 2011 come out with the voluntary marketing code and its amended version in 2015 following complaints of unethical marketing practices, like bribing doctors and pharmacists through foreign junkets, gifts and other incentives. However, voluntary code has failed to deter unethical practices.

"The Pharma secretary also warned that if there are more violations that come to the light in future, the department will be compelled to make it UCPMP mandatory, which has penal provisions for the violators," added the second person, quoted above.

Source: *ET Healthworld,* 26th December 2019

Natco Launches Cut Price Versions of Cancer Drug Ibrutinib in India

Hyderabad-based Natco Pharma has launched a cut price version of ibrutinib, an anti-cancer drug, under its own brand name Ibrunat. The patent for the drug is held by Pharmacyclics for three to four more years in India. Pharmacyclics was globally acquired by US giant AbbVie in 2015 in a massive USD21 billion deal. In India, the marketing right for ibrutinib is held by Johnson & Johnson. Ibrutinib is used to treat patients with leukemia and similar other indications of cancer.

A Natco official confirmed its launch but refused to divulge more details. It is learnt that the Indian drug maker has already dispatched the drug in distribution channels. The Natco drug will cost at approximately INR 38000 per month as opposed to INR 4 lakh course of the innovator. A patient is expected to take 4 tablets each day.

Sources informed ET that Pharmacyclics had filed for an injunction petition in Delhi High Court but no clear decision was handed out. Natco was directed to maintain data for its inventory and stocks sold.

Natco's latest move is consistent with its earlier launches and challenging the patents held on anti-cancer drugs by multinational drug companies. In July this year, the Delhi High Court had dismissed an injunction plea by Bayer to halt Natco from selling copies of its brand of regorafenib. Bayer's products in three versions, marketed since 2013 in India, were priced at INR36000 to INR40000 per bottle of 28 tablets, while Natco's product was made available at INR9000 per bottle.

Source: *ET Healthworld,* 20th December 2019

Pakistan to Import Polio Markers from India

The federal cabinet of Pakistan, decided to give a one-time permission for import of polio markers from India and reduce prices of 89 medicines by 15 per cent, Pakistan media reports said.

The markers, which are used to mark the fingers of children after administering them polio vaccine, are approved by the World Health Organisation (WHO).

Notably, Pakistan suspended all kinds of trade with India after abrogation of Article 370 in Jammu and Kashmir on August 5. However, since a large number of medicines and raw material are imported from India, Pakistan's pharmaceutical industry started demanding that the ban be lifted on them because otherwise Pakistan could face severe crisis of medicines, especially life-saving drugs, within a few weeks. Consequently, the Pakistan government in September lifted the ban on import of medicines and raw material from India.

National coordinator of the Emergency Operation Centre for Polio Dr Rana Safdar, while talking to Dawn, said that non-toxic markers were required for marking the fingers of children. "There are only two WHO pre-qualified manufacturers in the world, in India and China, which manufacture non-toxic markers as children can swallow the ink. Though WHO procures markers for us and, in the past, it had purchased markers from China, there were issues with the quality of markers. We had lodged a complaint that the marks faded before the post-monitoring team's visit," he said.

"WHO had started procurement from India and, before the announcement of ban, it had given order for 800,000 markers to the manufacturer, but the stock could not be delivered due to the ban. But now because of the decision of one-time lifting of the ban we will get the markers. Meanwhile, the Chinese manufacturer has been contacted to provide us quality markers," he added.

Source: *ET Healthworld,* 26th December 2019

1 in 3 Delhi Adults has High Blood Pressure, and Must Watch Out

But if you are among the one in three adults in Delhi with high blood pressure, you should also check your BP frequently that is usually higher in winter. This is because low temperature causes constriction of the blood vessels — which increases BP as more pressure is needed to force blood through the narrowed veins and arteries. Based on the blood pressure levels, one may need adjustments in lifestyle. Normal BP for young people is 120/80 mmHg, for older ones it's 140/90 mmHg.

Dr Rommel Tickkoo, senior consultant, internal medicine at Max hospital, Saket, said he had come across several patients with increased BP. “We advise patients to take medicine to control BP on time. In few cases, we have to increase the dosage of medication also,” he said.

If blood pressure rises to very high levels one may experience headache, dizziness and shortness of breath. The risk of having a heart attack or stroke also goes up among the high-risk patients, according to doctors.

"Checking BP regularly can help in early diagnosis and treatment. One should eat a healthy diet, which is low in fat and sodium and rich in fruits and vegetables," said a doctor.

Doctors said that the dip in temperature — as was being witnessed over the last few days — also increased the risk of pneumonia. They said that patients and their family members should look out for warning signs such as coughing, yellow sputum, chest pain, chest discomfort, shortness of breath and fever which are early signs of pneumonia.

"They should rush to the doctor in case of any complication. Vaccination for pneumonia and flu is advised," said a senior doctor.

Doctors said families should take special care of the elderly as they cannot always protect themselves from catching cold or infections.

"Elderly people often go for morning walks. This should be avoided or at least delayed. Also, if there is prolonged cough, breathing difficulty or infection, one should consult a doctor," said Dr Anoop Misra, director, Fortis C-Doc Center of Excellence for diabetes, metabolic diseases and endocrinology.

To avoid falls, another common casualty witnessed during winters, doctors suggested good lighting on walkways and support in bathrooms.

Source: *ET Healthworld,* 25th December 2019

Patient-Specific Implants Now Developed at Central Scientific Instruments Organisation

Patient-specific bone and jaw implants can now be designed and built within the country, inside IARM (innovative additive research and manufacturing) laboratory inaugurated at Central Scientific Instruments Organisation (CSIO).

The laboratory even has the patient-specific implant-testing facility. CSIO has made country's first indigenous patient-specific hip-joint socket implant for the All-India Institute of Medical Sciences (AIIMS), New Delhi. Patients received three maxillofacial (face and jaw) implants at the PGI in 2016 and another two in 2017.

CSIO's senior scientist Vijay Kumar Meena said: "We design our implants for single patient only. 'One patient, one implant' is our philosophy. These implants help treat bone cancer, bone fungal infection, and severe trauma."

The scientists are happy to have achieved the skill of designing, building, and testing human implants at a single, unique place.

Meena said: "We are developing spine implant next. Once it comes through testing and clinical trials, we can tie up with companies for mass production."

Implant scientists also into surgical models, surgical tools, custom-made prosthetics, tissues engineering, and organ printing etc.

Source: *ET Healthworld,* 25th December 2019

Biohaven Pharma Says Treatment for Acute Migraine Succeeds in Study

Biohaven Pharmaceutical Holding Company Ltd said, two doses of its experimental treatment for acute migraine were effective in reducing headaches in a pivotal study.

The drug, vazegepant, belongs to a new class of treatments for migraine called CGRP inhibitors.

Vazegepant is the first CGRP treatment delivered in an intranasal formulation, which benefits patients uncomfortable with needles, the company said.

The trial evaluated the drug in three separate doses. Two higher doses reduced pain, helping patients return to normal function within two hours.

The positive results allow Biohaven to accelerate the program with only one additional positive efficacy trial likely needed for submission, the company said.

Vazegepant could generate revenue of $27 million in late 2021, and sales could reach $431 million by 2025, Wedbush analyst Laura Chico said.

Biohaven is racing against Allergan Plc to introduce a CGRP inhibitor for treatment of acute migraine.

The FDA is due to decide on Allergan's application to market its oral treatment this month.

Injectable CGRP inhibitors such as Aimovig from Amgen Inc and Novartis AG, Emgality from Eli Lilly and Ajovy from Teva Pharmaceutical Industries Ltd recently won approval for use in migraine prevention.

Shares of Biohaven were trading down 1.14% at $54.51, reversing course after rising as much as 4%.

The FDA is scheduled to decide on the company's lead product for acute treatment of migraine, rimegepant, by the first quarter of 2020.

Rimegepant, which is another CGRP inhibitor, is also being tested for prevention of migraine.

Vazegepant is complementary to rimegepant and has synergies with the product in terms of marketing, resources, and sales force, SVB Leerink analyst Marc Goodman said.

Source: *ET Healthworld,* 18th December 2019

Hetero Launches Combination Drug for HIV Under Brand Name Taffic

Drug firm Hetero on Tuesday launched an antiretroviral combination drug, used to treat human immunodeficiency virus type (HIV-1), in the country. The Hyderabad-based company has introduced the 3-in-1 drug under the brand name 'Taffic' in India.

The company's product is a generic version of Gilead's Biktarvy and has been approved by the Drug Controller General of India (DCGI).

The product will be marketed and distributed by Hetero Healthcare Ltd in the country, the drug firm said in a statement.

"The launch of this product emphasises company's ongoing commitment to provide advanced and effective treatments to HIV patients worldwide," it added.

To further this mission, Hetero will be making the latest combination drug available in 116 low and middle-income countries upon approvals from the regulatory authorities there, the drug firm said.

Taffic, a once-a-day single pill, is a combination of three medicines -- Bictegravir (50mg), Emtricitabine (200mg) and Tenofovir Alafenamide (25mg).

It is indicated for treatment of HIV-1 infection in adults who have no antiretroviral treatment history.

The drug can also be used to replace the current antiretroviral regimen in those who have viral copies less than 50 per ml in the blood at least for three months with no prior treatment failure and resistance to any components.

Hetero would manufacture the product at its manufacturing facility in Hyderabad, which is approved by international regulatory bodies.

Hetero is a leading player in antiretrovirals with a product portfolio of over 30 drugs.

Source:*ET Healthworld,* 17th December 2019

Violation of Drug Price Control Order: Drug Cos Under NPPA Lens for Self-Exemption from Price Cap

Sun Pharmaceutical Industries, Abbott, AstraZeneca, Lupin and other big drugmakers have come under the scanner of India's drug pricing watchdog for excluding products from the price control regime without first applying for such an exemption, according to documents that ET has seen and people with knowledge of the matter. This is in violation of the Drug Price Control Order (DPCO).

The National Pharmaceutical Pricing Authority (NPPA) has found that companies such as Lupin and Boehringer Ingelheim, apart from those mentioned above, launched products bypassing the regulatory framework.

The NPPA noted that these drug companies had launched anti-diabetes drugs under para 32 of the DPCO, without submitting the requisite application. This allows the NPPA to exempt certain classes of drugs from price

control for a period of five years. It says that the price cap won't apply if a new drug is developed through a unique and indigenous process, is patented under the Indian Patents Act and is not produced elsewhere. Taking strong objection to "self-invoking" of para 32 of DPCO 2013, the authority called for action against "wilful defaulters," according to the minutes of a meeting held on December 9 that ET has seen.

Cos Asked to Provide Data

"Self-invoking of para 32 of DPCO 2013 would tantamount to bypassing the regulatory framework and lead to chaos in product pricing, grievously impacting choices before the hapless consumers," said the NPPA minutes. "Such attempts need to be checked forcefully in order to safeguard public health and safety."

The companies have been asked to provide data on manufacturing, import and sales since the launch of the products. "The NPPA shall take further necessary action as applicable," according to the minutes.

"The NPPA can direct the companies to get prices fixed, fix a price and recover if it is overpriced," said an official, one of the persons cited above.

The companies named above didn't respond to queries.

The authority noted that Glenmark Pharmaceuticals Ltd had previously applied to fix the retail price of its anti-diabetes drugs RemoM and RemoZenM tablets containing remogliflozin etabonate and metformin hydrochloride. The application was withdrawn before the retail price was fixed. Glenmark subsequently launched RemoM and RemoZenM tablets containing the same ingredients without seeking exemption from NPPA.

The NPPA noted that Lupin and Boehringer Ingelheim had launched empagliflozin-metformin combination tablets and Sun Pharma and AstraZeneca had launched dapagliflozin-metformin combination tablets without seeking prior approval.

Following Glenmark's representation, the NPPA analysed data from pharmaceutical audit agency Pharmatrac and it was observed that Abbott Healthcare had also launched dapagliflozin-metformin combination tablets without obtaining approval. Accordingly, the NPPA issued showcause notices to Glenmark, Lupin, Sun and Abbott.

In response to the showcause notices, the companies stated that the formulations are "patented products," which are within the purview of para 32 of DPCO 2013 and are therefore exempted.

The authority noted that para 32 stipulates that companies seeking exemption under it have to submit the requisite documents. "This has been the procedure that has been adopted by the authority in all the four exemptions given so far under para 32 of DPCO 2013," it added. The NPPA found "no room to assume ignorance of the procedure being adopted for all such cases."

"An exemption under para 32 of DPCO 2013 is not a one-time measure but also subsequent exemption from provisions relating to annual price increase," the minutes further said. "Therefore, self-invocation of para 32 of DPCO 2013 needs careful examination to safeguard public interest to obviate any possibility of misuse."

Source: *ET Healthworld,* 16th December 2019

Allergies Affect 33% of Indians, Most Don't Get Right Treatment

Allergies — one of the most common reasons worldwide for a patient to visit a doctor — affect every third Indian but treatment here may not always provide adequate relief from sniffles or wheezing.

A new medical study found nasal sprays that provide relief from allergic rhinitis was only advised to 26% of the 571 patients needing it. It also found that only four out of the 1,030 patients were given “allergy vaccines” that can provide relief for up to six months, said the study's author and allergy specialist Dr Wiqar Shaikh, who blames the shortage of allergy specialists for this epidemic of “poor treatment”.

“It is regrettable that both undergraduate and postgraduate medical students in India are not exposed to teaching and training in allergic diseases,” he said. Allergies are often seen as a minor ailment, but a Swedish study estimated that allergic rhinitis or hay fever — a type of inflammation in the nose due to allergens in the air — cost almost $5.3 billion every year in terms of holidays from work and medicinal cost.

'Allergy vaccines have not yet been validated thoroughly’

A quarter of those with allergic rhinitis are likely to develop asthma, a chronic lung disease characterised by shortness of breath and wheezing and a common reason for hospitalisation.

The study, published recently in the Journal of Evolution of Medical & Dental Sciences, looked at 1,030 patients who were previously treated for their allergies by specialists ranging from dermatologists to surgeons. “As they were not treated by allergy specialists, only half of the 386 asthma patients had previously been advised to use inhalers. Moreover, over 90% of the patients were prescribed a drug to prevent wheezing even though I felt no one needed it,” said Dr Shaikh, who is a professor at state-run J J Hospital in Byculla.

An online search for allergy specialists is likely to show up doctors following alternative medicine forms, especially homeopathy. “An allergy specialist has to know when to ask for skin tests and when to give a vaccine, both of which are the cornerstone in treatment of allergic diseases,” he said.

Not all experts agree though. The problem with the field of allergies, said Dr Lancelot Pinto from Hinduja Hospital, Mahim, is that it is still in its infancy, even in the West. “Allergy research is hampered by the fact that one cannot easily determine whether a person is suffering from allergy or an extreme reaction to local pollution,” he said. A visitor from Bengaluru to Mumbai could get humidity-related skin allergies while a Mumbaikar visiting Bengaluru may get affected by pollen allergy. “Allergies aren't a simple straightforward field,” he added.

A senior doctor said that allergy vaccines haven't yet been validated thoroughly. “The fish therapy offered in Hyderabad could be considered as an oral vaccine, but it hasn't been validated as a treatment. Many homeopathy practitioners provide oral vaccines,” he added.

Source: *ET Healthworld,* 15th December 2019

Excessive Antibiotic Prescriptions for Children Can Harm Their Health: Study

Children in low and middle countries (LMICs) are being prescribed an average of 25 antibiotics during their first five years of life, which is an excess and could resist their ability to fight pathogens, says a recent study.

Gunther Fink, lead author of the study and head of the Household Economics and Health Systems Research Unit at Swiss TPH, said: "We knew children in LMICs are sick more often, and we knew antibiotic prescription rates are high in many countries. What we did not know was how these elements translate into actual antibiotic exposure--and the results are rather alarming."

Antimicrobial resistance is considered as one of the global health and development threat today, according to the World Health Organisation (WHO). Excessive use of antibiotics worldwide is one such factor contributing to the threat.

Mid-low countries often have children who fall sick frequently and they visit the hospital only to be overprescribed by antibiotics.

In Tanzania, for instance, several studies have shown that over 90 per cent of children who visit a health facility receive an antibiotic, although only in about 20 per cent of the treatment of the case was actually required.

Swiss TPH and Harvard Chan School research team analyzed data from 2007-2017 from health facilities and household surveys from eight countries: Haiti, Kenya, Malawi, Namibia, Nepal, Senegal, Tanzania, and Uganda.

The study has found that on an average child received 25 antibiotic prescriptions through age five a 'remarkable estimate', the authors wrote, given that two antibiotic prescriptions per year are considered excessive in many high-income settings.

Results showed that antibiotics were administered in 81 per cent of cases for children with a respiratory illness, in 50 per cent for children with diarrhoea, and in 28 per cent for children with malaria.

The excessive intake of antibiotics can also result in a concrete health impact on children. Valerie D'Acremont said: "Excess antibiotic use destroys the natural gut flora which is essential to fighting pathogens."

The research team is currently comparing policies at a country level to identify best practices that lead to lower antibiotic prescription rates. (ANI)

Source: *ET Healthworld,* 15th December 2019

WHO: Drying Supply of New Antibiotics A Concern

Treating infections may soon become difficult with a drying pipeline of new antibiotics and declining investment by drug makers to develop new medicines to combat the worsening crisis of antibiotic resistance, the World Health Organisation said while issuing a fresh warning against 'super bugs'.

This assumes significance as India is the largest consumer of antibiotics and misuse of such drugs is also rampant.

The UN agency released two reports assessing a weak pipeline for antibiotic agents. “The 60 products in development (50 antibiotics and 10 biologics) bring little benefit over existing treatments and very few target the most critical resistant bacteria (Gram-negative bacteria). While pre-clinical candidates (those in early-stage testing) are more innovative, it will take years before they reach patients,” the WHO said.

Though the problem is global, the implications may be more critical in India where poor public health infrastructure, a high burden of disease, overuse and misuse of antibiotics in poultry and agriculture and cheap, unregulated sales of antibiotics has created ideal conditions for rapid rise in resistant infections.

In its two reports — one that analysed products being tested on patients and another that looked at therapies in the early stages of development — the UN agency highlighted the grim economic realities that have been shutting down investment in the field by big pharma companies and strangling the few remaining small companies that have come to dominate development of antimicrobial therapies.

While antibiotics are used for almost every treatment, from preventing infections during surgeries to protecting cancer patients undergoing chemotherapy, the use of these medicines is for a short period — a week or two — diminishing their profitability for drug makers. On the other hand, drugs that treat chronic conditions are taken for years. Hence, companies are increasingly finding it lucrative to invest in other segments than antibiotics.

“Never has the threat of antimicrobial resistance been more immediate and the need for solutions more urgent” WHO director general Tedros Adhanom Ghebreyesus said.

“Numerous initiatives are underway to reduce resistance, but we also need countries and the pharmaceutical industry to step up and contribute with sustainable funding and innovative new medicines,” he added.

Source: *The Times of India,* 20th January 2020

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