Tamilnadu Pharmaceutical
Sciences Welfare Trust

Pharma Web

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

ISSUE : 29 Jan. - Feb. - Mar. 2016

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TAMILNADU PHARMACEUTICAL SCIENCES WELFARE TRUST
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EDITORIAL

Dear Readers,

We are happy to publish the 29th issue of Pharma Web Newsletter for Jan – Mar 2016. We are also happy to announce our Chairman Mr. S. V. Veerramani, have been unanimously elected as president 68th IPC to be held at Visakhapatnam in December 2016.

The following articles are published in this issue

a. Indian Pharmaceutical Industry – Challenges & Way Forward by **Mr. S. V. Veerramani,** President – IDMA, CMD M/s. Fourrts (Inida) Labs Pvt Ltd & Chairman of our Trust

b. Quality Control & Calibration of Equipments by **Dr. R. Venkidesh,** General Manager, Quality Control, Sai Mirra Innopharm, Chennai

Essay competition article about "Pharmacist Role: Safety First with Medicines" by Mr. M. Vigneshwar, College of Pharmacy, Jaya College of Paramedical Sciences, Thiruninravur, Chennai

We have also published the following Gazette Notifications pertaining to the amendment of Drugs & Cosmetics Act & Rules.

a. Three notification on Clinical Trials

b. Inclusion of "Ablation device" as a notified medical device

c. Notification for inclusion of various sea ports & Air ports for Import of Drugs and Pharmaceuticals.

d. A notification regarding exemption under Schedule K for Zinc Sulphate, Custom made device & Homeopathic hair oil.

e. List of Fixed Dose Combination banned by Government of India (344 combinations)

Important news items appeared in various national News papers on various technical issues are also published in this issue. Various events held in Pharmacy colleges of Tamilnadu are published

Important Parliament Question & Answers belong to Lok Sabha & Rajya Sabha during the winter session.

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

INDIAN PHARMACEUTICAL INDUSTRY – CHALLENGES & WAY FORWARD

by

S. V. Veerramani

President – IDMA, CMD M/s. Fourrts (Inida) Labs Pvt Ltd.,
Lecture delivered B.V. Patel Memorial Lecture, 18th December 2015,
67th Indian Pharmaceutical Congress, Mysuru

INDIAN PHARMACEUTICAL INDUSTRY

SEVERAL CHALLENGES FROM VARIOUS FRONTS

May be Bottlenecks or Opportunities for Growth

REGULATORY	SMEs
TECHNOLOGY	APIs
INTERNATIONAL MARKET	SUPPLY CHAIN
DOMESTIC MARKET	RESEARCH & DEVELOPMENT
COST	

REGULATORY - CHALLENGES

- Observations from USFDA and other regulatory authorities have indicated the need for improvements in systems documentation and compliance and deficiencies in GMP practices and data integrity.
- This has led to stoppage of production in few plants, loss of revenue and loss of prestige.
- Lack of efficient internal control, lab control, computer systems and failure to follow written procedures and investigation failures have been considered some of the reasons for the same.

REGULATORY - WAY FORWARD

- Need for In-house training of all cadres on all the above observations. The training should be practical need based on Regulatory requirements and compliance.
- There should be more accent on quality culture and documentation. Adherence to SOPs and building a risk mitigation frame work.
- There is an urgent need to establish and build the credibility of Pharmaceuticals from India.

REGULATORY - CHALLENGES

EVERCHANGING REGULATIONS

- Yesterday's recommendation becomes today's expectations. Today's expectations become tomorrow's requirements.
- Product specifications (for testing requirements) is increasing with the release of every edition of Pharmacopoeia.
- Efforts in demonstrating quality exceeds that of building quality in the product.

REGULATORY - WAY FORWARD

- There is a need for constant updating and training of personnel to meet the ever changing global requirements.
- Need to be alert on current changes in regulations and the action to be taken.
- There needs to be a forum of collaborative discussions between Industry and Regulators to optimise regulatory requirements and remove unnecessary procedures.

TECHNOLOGY - CHALLENGES & WAY FORWARD

- Need for improving our techniques, cost efficiencies and machinery utilization.
- Need to adopt more of automation packaging innovation, IT based approaches and software validation. Need for foolproof system.
- Need for application of LEAN manufacturing techniques to improve operational excellence and reduce wastages.
- Need for better utilization of man-power.
- If we cannot improve operational excellence, we cannot sustain price advantage.

INTERNATIONAL MARKET - CHALLENGES

ROW MARKETS

- Regulatory requirements and approval for registration of products are increasing with the requirement for CTD dossiers.
- Local Clinical Trials / BA / BE studies are insisted in certain countries.
- Product specifications also differ in certain countries.
- Inspections from Ministry of Health of various countries have become more stringent.
- There seems to be an increasing emphasis on pharmaco-vigilance studies.

INTERNATIONAL MARKET - WAY FORWARD

ROW MARKETS

- There is a need for spending resource and time to prepare CTDs for various products. WHO-GMP units need to think in terms of PICS approvals and constantly upgrade their plants.
- It would be better for companies to concentrate on few countries and focus and specialize on few products
- Need for constant updating of current requirements and take prompt action.

COST - A BIG CHALLENGE

- Cost of compliance
- High cost of rejection and loss of reputation is a serious issue.
- Changes in regulatory requirement add financial burden to the Industry, more so, when the market is highly competitive and price sensitive.
- The cost of machinery, laboratory equipments like GC / HPLC and utility cost need to be considered.
- Accessory cost for automation and checks seems to be more than cost of the main machine.

COST - A BIG CHALLENGE

- Cost of carrying multiple inventories due to different language and labeling requirement.
- Establishment and approval of new facility for regulated markets and attainment of breakeven levels take up to 7 years, which adds a great burden on cost. International prices offered are so low, that there is not enough return on investment.

COST – WAY FORWARD

- Need for vigil in costing of the product, productivity, control of process loss, manpower cost, regulatory compliance cost and interest cost.
- Cost consciousness and efficiency is the need of the hour.
- Adequate funding and investments are necessary.
- Government support is welcome.

DOMESTIC MARKET - CHALLENGES

DPCO

- There is a pricing pressure constraining the marketing efforts.
- The traditional market and sales model are becoming in adequate.
- An increase in field force has not yielded expected productivity.
- Increase in the sale of patented products is worrying Indian companies.
- UCPMP may become mandatory – can lead to changes in marketing and selling approach.

DOMESTIC MARKET - WAY FORWARD

- Pharmaceutical companies need to be vigilant about the current scenario and make strategies keeping in mind the future trends.
- Need for increased attention from Acute to Chronic segment and from Urban to Rural markets
- Apart from anti-diabetic and Cardiovascular segments, there is an increase incidence of Dementia and Obesity. Geriatric population on the increase
- Accent on prevention of disease has lead to increased use of Nutraceuticals.

DOMESTIC MARKET - WAY FORWARD

- Introduce products with Incremental Innovation.
- Collaboration with MNCs for marketing patented products in India
- Launching patient programs
- Re-aligning field force strategy
- For price controlled products, cay think of higher volumes through lower price.
- Voluntarily adapt ethical marketing practice.

PUBLIC PERCEPTION

CHALLENGES

- There is a perception on the part of the public and consumer organisation that pharmaceutical industry is enjoying exorbitant profits and following no ethical practices.

WAY FORWARD

- There is a need for educating the public and NGOs that Indian Pharmaceutical Industry is offering quality products at the lowest price in the world and contributing to healthcare.
- Indian Pharma companies also need to do more on CSR in order to make public aware about the value of the Indian Pharmaceutical Industry.

SMEs – THE GROWTH ENGINE

CHALLENGES

- Large number of SMEs are in India – SMEs at varying levels.
- Need for sustenance and growth in face of increased regulatory requirements and plant upgradation cost.
- Fragmentation and Competition in the market.

SMEs – THE GROWTH ENGINE

WAY FORWARD

- There is a need for investment in upgrading plant and travelling from Schedule M compliance to GMP-WHO compliance. This will help them to tap the Export market as well as become Contract Manufacturers for larger companies.
- Need for Government support in funding SMEs for plant upgradation.
- SMEs should concentrate on Regional marketing and specialize in few therapeutic segments.
- Participate more in hospital and Institutional supplies.

APIs – NEED FOR URGENT SUPPORT

CHALLENGES

- Over dependence on China for API can affect Formulation industry in times to come.
- China scores over India in reduced land cost, transaction cost, electricity subsidy and other increased subsidies and support from Chinese Government.

WAY FORWARD

- Needs urgent support from Government of India for API sector in the form of reduced land cost, electricity subsidy, common effluent treatment plant and interest subsidy.
- Approval from Ministry of Environment need to be speeded up

SUPPLY CHAIN (LOGISTICS)

CHALLENGES

INDIA

- Varying temperature zones in India and different modes of transportation as well as inadequate storage practices is challenging the Quality and Integrity of the Product. There is a need for improving transportation and good storage practices.

INTERNATIONAL

- Raw materials are often sourced in one country, processed in another with finished product being sold in a 3rd country. There is a need for controlling the supply chain to ensure quality and integrity of the product.

RESEARCH & DEVELOPMENT

CHALLENGES

- Innovate, Manufacture and Deliver is supposed to be the role of Pharma companies. But, Indian companies concentrate more on Manufacturing and Delivery.
- Over dependence on Generics have taken away the attention on Innovation and R&D.
- Indian pharmaceutical industry are investing less on R&D as compared to MNCs, more due to pricing pressures.
- India can lose to MNCs for slowness in introduction of new drugs and therapies.

RESEARCH & DEVELOPMENT

WAY FORWARD

- Increased investment in R&D and if necessary get special funding for the same.
- Identify key drug categories of significant disease burden in India.
- Concentrate on incremental innovation and increase the number of Patent filings.
- Collaborating with MNCs on New Drug Research
- Industry Academy interaction need to be strengthened. Academic institutions should become base for Industrial Research.
- There is a need for strengthening of NIPERs.

CHALLENGES & WAY FORWARD

BIO-TECHNOLOGY

- The Indian Biotech Industry comprising of Vaccines, Therapies and Diagnostics are growing at 20% and likely to step up their growth rate to almost 50%.

MEDICAL DEVICE

- The Medical Device Industry is likely to grow exponentially and need proper regulation for its growth.

HERBAL INDUSTRY

- The Indian Herbal Industry has also got great potential for growth and need to be tapped with accent of standardization for global market.

GOVERNMENT

- The Prime Minister slogan on "MAKE IN INDIA" is apt for Indian Pharmaceutical Industry. But, there is a need for improving Ease of doing business.
- Time for regulatory approvals in general need to be reduced.
- MOUs with Regulatory Authorities of other countries can iron out differences in regulatory perceptions and boost growth of Indian Pharma Sector.
- Encouragement to Clinical Trials and removal of bottlenecks, so as to bring back India as an important base for Clinical Research.

GOVERNMENT

- Increase in span of price control can hurt the Industry and availability of drugs.
- Government need to announce API Package quickly.
- There is a urgent need to provide funding for SMEs for upgradation. Bottlenecks in financing need to be removed
- Government need to provide funding for R&D and Drug Discovery
- Approval of Foreign Direct Investment in Brown field sector to be encouraged.

GENERAL – WAY FORWARD

- 72 Billion US Dollars worth of drugs are going out of Patent in the next 3 years. India need to encash on the same.
- India need to encash on CRAMS (Contract Research & Manufacturing Services) considering its developed capabilities in manufacturing and research.

GENERAL – WAY FORWARD

- There is a need for massive attention on Skill development and training in order to tap the increasing opportunities in the Indian and Global Market.
- There is a need to capitalize the advances in Information Technology and Digital Innovation in the pharmaceutical industry and consider increased usage of IT in all segments of manufacturing, R&D, Marketing and Logistics.

GENERAL – WAY FORWARD

- Consider increased usage of IT in all segments of manufacturing, R&D, Marketing and Logistics.
- Low prices cannot be sustained for long. There is a need for increased accent on Quality and Timely delivery.
- We need to decide whether we will be Pharmacy of the World catering to varied therapeutic segments or concentrate and specialize in few therapeutic segments.

COLLABORATION – WAY FORWARD

- There is a need for harmonization of various pharmacopoeias.
- There is a need for collaborative forums between industry and regulators to optimize the regulatory requirements and remove barriers in technology utilization and change
- There is an important need for collaborations between Industry and Academic Institutions.
- There is a need for increased collaboration between Indian and Multi-national companies.

- End -

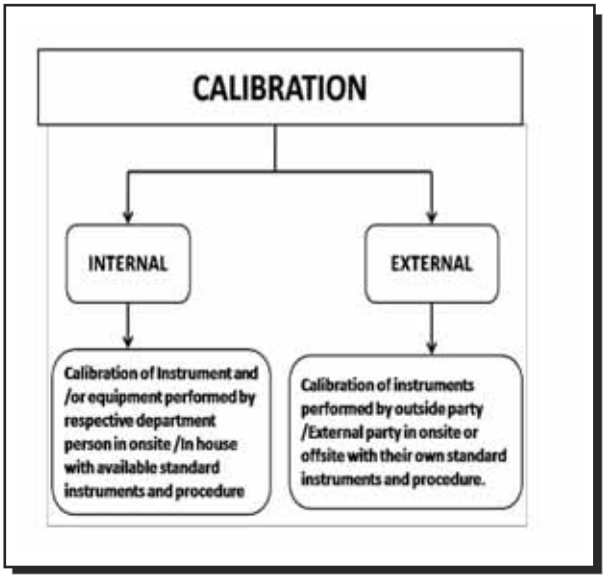
QUALITY CONTROL & CALIBRATIONS OF EQUIPMENT

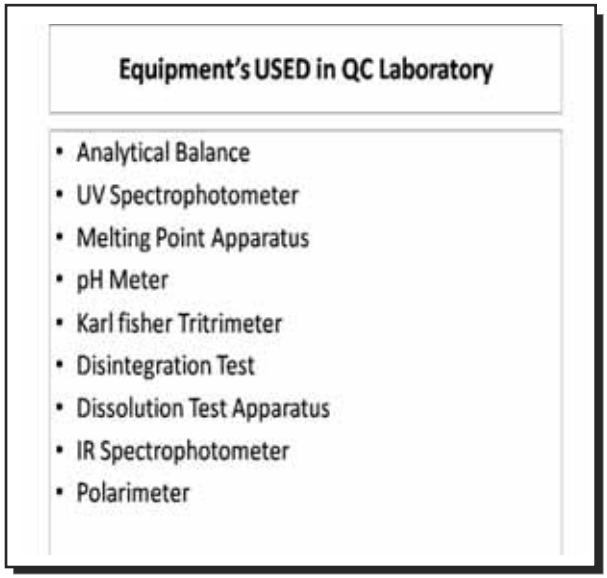
by

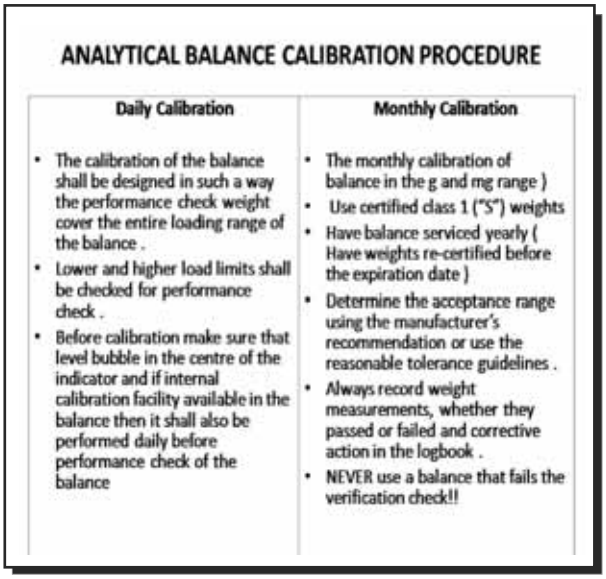
Dr. R. Venkidesh,

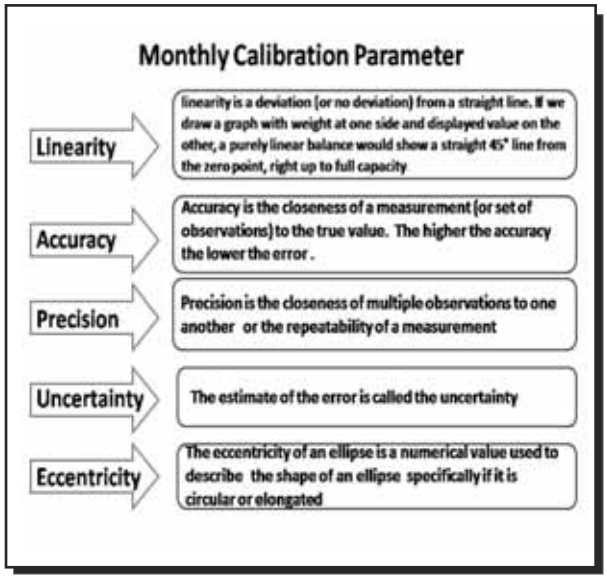
General Manager, Quality Control, Sai Mirra Innopharm, Chennai

(Lecture Delivered on 24th October 2015, during the Training Program on Quality Control, conducted by TNPSWT)









LINEARITY

- Instrument Shall be calibrated by using 200 g,100 g, 50 g, 20 g, 10 g, 5 g, 2 g, 1 g, 500 mg, 200 mg, 100 mg, 50 mg,20 mg and 10 mg by calibrated weight.

- Weigh the each weight for 3 times and calculate the average value and Correlation coefficient
- Limit : Correlation coefficient Should be less than 0.995

ACCURACY

- Instrument Shall be calibrated by using 10 g, 100 g, 200 g (for 200gm & 220gm capacity balance) by calibrated weight.
- Weigh the each weight for 5 times for all weights.
- Limit: ± 0.1 % of Reported Standard Weight

PRECISION

- Instrument Shall be calibrated by using 100g, 10g, calibrated weight. (for 200 g & 220 g capacity balance)
- Measurement is performed 5 times for all weights.
- Reset the balance to zero and then confirm that the indicator value is zero.
- Load a weight equivalent to the test load on the centre of the pan, and then record the indicator value.
- Limit : ± 0.1% of Reported standard weight .

MEASUREMENT UNCERTAINITY

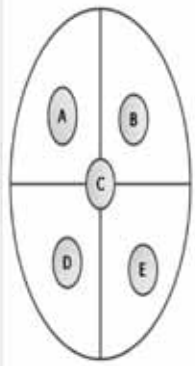
- Instrument shall be calibrated using 100 g calibrated weight .
- Measurement is performed 10 times for all weights
- vReset the balance to zero ,and then confirm that indicator value is zero.
- Load the weight equivalent to the load on the center of the pan, and then record the indicate value.
- Limit : 0.001

Calculations:

$$\text{Uncertainty} = \frac{3X \text{ Standard Deviation}}{\text{Reported standard mass weight (g)}}$$

ECCENTRICITY

- The mass(100 g) is placed in the centre of the balance pan, C, and the balance tarred so that it displays zero weight.
- The weight is then moved to test points A, B, D and E, in turn and the deviation from zero recorded.
- Before measurement, reset the balance to zero, and then confirm that the indicator value is zero.
- Load a 100g weight for 200g & 220 g capacity balance, which is equivalent to the test load, on the centre of the pan (Position C) and then record the indicator.
- Place the same weight at position A, and then record the indicator value.
- Place the same weight at position B,D and E in turn ,while recording the respective indicator value
- Limit : Related standard deviation (RSD) - NMT 0.05%



Eccentricity test position on square round balance pan

INSRUMENTATION AND WORKING OF UV SPECTROPHOMETER

- Instrumentation and working of the UV spectrometers can be studied simultaneously. Most of the modern UV spectrometers consist of the following parts

Light Source: Tungsten filament lamps and Hydrogen-Deuterium lamps are most widely used and suitable light source as they cover the whole UV region. Tungsten filament lamps are rich in red radiations; more specifically they emit the radiations of 375 nm, while the intensity of Hydrogen-Deuterium lamps falls below 375 nm.

Monochromator: Monochromators generally composed of prisms and slits. The most of the spectrophotometers are **double beam spectrophotometers**. The radiation emitted from the primary source is dispersed with the help of rotating prisms. The various wavelengths of the light source which are separated by the prism are then selected by the slits such the rotation of the prism results in a series of continuously increasing wavelength to pass through the slits for recording purpose. The beam selected by the slit is monochromatic and further divided into two beams with the help of another prism.

INSRUMENTATION AND WORKING OF UV SPECTROPHOMETER

Sample and reference cells- One of the two divided beams is passed through the sample solution and second beam is passé through the reference solution. Both sample and reference solution are contained in the cells. These cells are made of either silica or quartz. Glass can't be used for the cells as it also absorbs light in the UV region.

Detector- Generally two photocells serve the **purpose of detector in UV spectroscopy**. One of the photocell receives the beam from sample cell and second detector receives the beam from the reference. The intensity of the radiation from the reference cell is stronger than the beam of sample cell. This results in the generation of pulsating or alternating currents in the photocells.

Amplifier- The alternating current generated in the photocells is transferred to the amplifier. The amplifier is coupled to a small servometer. Generally current generated in the photocells is of very low intensity, the main purpose of amplifier is to amplify the signals many times so we can get clear and recordable signals.

Recording devices- Most of the time amplifier is coupled to a pen recorder which is connected to the computer. Computer stores all the data generated and produces the spectrum of the desired compound.

CALIBRATION TEST PARAMETERS

- Control of Absorbance → Check the absorbance using a solution of potassium dichromate
- Control of Wavelength → Verify the wavelength scale using the absorption maxima
- Limit of Stray light → Stay light may be detected at a given wavelength with suitable solution
- Resolution power → When stated in monograph record the spectrum of 0.02% v/v solution of toluene in hexane

CONTROL OF ABSORBANCE

- Control of absorbance is done 0.006% w/v with 0.06% w/v of potassium dichromate in 0.005M sulphuric acid
- Check the absorbance of the solution, using 0.005M Sulphuric acid as blank, in the range 200 to 600 nm for each wavelength indicated in the following table.
- Calculate the A (1% 1 cm) value.

$$A(1\%\ 1cm) = \frac{E}{CX1}$$

- where, E - Absorbance of the solution at the particular wavelength.
  C - Concentration of $K_2Cr_2O_7$ expressed in % w/v
  l - Thickness of the absorbing layer in cm i.e. 1 cm.

Wave length	A (1% 1 cm)	Maximum Tolerance
235 nm	124.5	122.9 - 126.2
257nm	144.5	142.8 - 146.2
313nm	48.6	47.0 - 50.3
350nm	107.3	105.6 – 109.0
430nm	15.9	15.7 - 16.1

CONTROL OF WAVELENGTH

- Transfer accuracy 1.00 ± 0.005 g of Holmium oxide (99.5%) into a 256mL volumetric flask.
- Add about 15 mL of 1.4 M Perchloric acid, warm to dissolve, cool, dilute to volume with 1.4 M perchloric acid and mix.
- Check the wavelength of the absorption peaks in the range 200nm to 600nm ,using 1.4 M perchloric acid as blank ,against the values in the following table

Peak	Maximum Tolerance
1.	240.15 - 242.15 nm
2.	286.15 - 288.15 nm
3.	360.50 - 362.50 nm
4.	533.30 - 539.30 nm

LIMIT OF STRAY LIGHT

- Dry about 2g of Potassium Chloride AR grade by heating to constant weight at 130ºC .
- Transfer accurately 1.2 ± 2% g of potassium chloride in to a 100 mL volumetric flask, add about 25 mL of water, dissolve, dilute to volume with water and mix.
- On running spectrum absorbance increase steeply between 220 nm and 200 nm and is greater than 2.0 at 198 nm.

RESOLUTION POWER

- The resolution power of UV is checked by using 0.02% v/v solution of toluene in hexane solution.
- Record the spectrum of 0.02% v/v solution of toluene in hexane solution.
- The ratio of the absorbance at the maximum at about 269nm to that at about 266 nm should not less than 1.5.

MELTING POINT APPARATUS

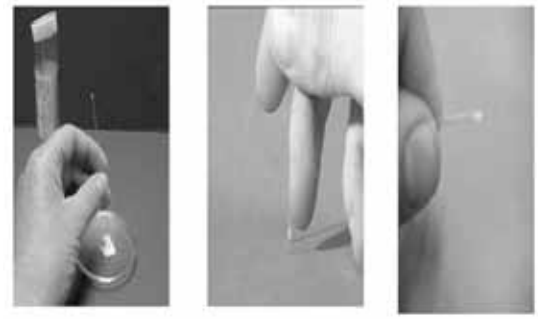
CALIBRATION PROCEDURE

- Ensure that all the connection of the instrument are proper.
- Operate the instrument as per the operating instructions and determine the melting point of the following substances.

Reference substances	Standard range
Vanillin	80 ºC to 80ºC
Benzoic acid	121 ºC to 123ºC
Sulphanilamide	164.5 ºC to 166.5ºC
Caffeine	234ºC to 237ºC

How to take sample in capillary tube

1 2 3



pH METER

BUFFER SOLUTION

pH 6.87 ⟹	PH Limit ± 0.05 (6.82 – 6.92)
pH 4.01 ⟹	PH Limit ± 0.05 (3.96 – 4.06)
pH 9.18 ⟹	PH Limit ± 0.05 (9.13 – 9.23)

Clean the pH meter with purified water and wipe the moisture, using lint free tissue paper.

Initially, take buffer 7.00 containing beaker and dip the electrode and calibrated ATC Probe connected into instrument stir for a while. Press "CAL" button and automatically calibrated buffer solution, the display shows the buffer pH (7.00±0.05). Once the standard pH value is displayed, go to check the confirm calibration

BUFFER SOLUTION

- Take buffer 4.01 containing beaker and dip the electrode and calibrated ATC Probe connected into instrument stir a while. Press "CAL" button and automatically calibrated buffer solution, the display shows the buffer pH (4.01±0.05). Once the standard pH value is displayed, go to check the confirm calibration. During Calibration NIST Standard, DIN, USA, own standard can be used.
- Take buffer 10.01 containing beaker and dip the electrode and calibrated ATC Probe connected into instrument stir for a while. Press "CAL" button and automatically calibrated buffer solution, the display shows the buffer pH (10.01±0.05). Once the standard pH value is displayed, go to check the confirm calibration. Note down the value .
- In this way calibrate the pH meter using the buffer solutions to read the pH 4.01, 7.00 and 10.01 respectively at 25°C. pH limit is ±0.05.
  - The electrode is activated with 0.1N HCl at the end of every week.
  - After calibration the electrode should be stored in 3M KCl
  - If the calibration deviates from the standard, report the results to the departmental head for appropriate action to be taken.

SLOPE TEST

- The millivolt reading when observed at pH 7.00 must near to zero, as there will be no electrical conduction at that pH. So when a pH 7.00 buffer is kept, a zero reading will be observed.
- Now place a 4.01 pH standard buffer and observe the mill volts.
- Divide the observed mill volt by three.
- Calculate the percentage of the slope by considering 59.2 as a standard value.
- The limit of slope obtained should be between 95% and 105%.
- The same can also be done by taking the pH 10.01 standard buffer value and the above calculation done.

Calculation: $\frac{y}{3} = z$

To get the slope in percentage:

$\frac{z}{59.2} \times 100$

x - Observed millivolt at pH 7.00 standard buffer solution

y - Observed millivolt at pH 4.01 buffer

CALIBRATION FOR ATC PROBE

- Clean the pH meter with purified water and wipe the moisture, using lint free tissue paper
- Switch on the instrument
- Take water containing beaker at 20°C, 25°C, 30°C and 40ºC and dip the electrode and calibrated ATC Probe connected into solution.
- The display shows the temperature in the instrument and check with calibrated thermometer.
- Acceptance criteria ± 0.5º C

- ATC- Automatic Temperature controller

KARL FISCHER TITRIMETER

DAILY CALIBRATION

- switch on the instrument.
- Set medium rotation speed for magnetic stirrer.
- Standardization is performed with Water.
- Take approximate quantity of methanol in the titration vessel and position the vessel in such a manner that the electrode just dips into the methanol.
- Fill the KFR reagent in the burette up to '0' level.
- Methanol is neutralised by titration.
- For titration, if necessary press the reset button and then start button.
- A beep denotes the end point.
- Take (NLT 25 mg) water in 1 mL syringe and weigh. Inject 2 to 3 drops of water through the side neck of the titration vessel containing neutralised methanol.
- Again refill the burette with KFR reagent up to the '0' mark.
- Press reset button and start button and titrate it.

DAILY CALIBRATION

- Again a beep is heard when the end point is attained.
- Calculate the KFR factor with respect to the quantity of KFR reagent consumed (titre value):
- Press reset button and start button and titrate it.
- A beep sound is heard when the end point is attained.
- Calculate the KFR factor with respect to the quantity of KFR reagent consumed (titre value)

$$\text{Factor} = \frac{\text{weight taken (in mg)}}{\text{Titre value}}$$

- Limit: 4 to 7 mg/mL.

SYSTEM SUITABILITY TEST

- **System suitability is done by Standardization of K.F. reagent with water or Disodium tartrate dihydrate.**

- For disodium tartrate dihydrate:

- Take approximate quantity of methanol in the titration vessel and position the vessel in such a manner that the electrode just dips into the methanol.
- Fill the KFR reagent in the burette up to '0' level.
- Methanol is neutralised by titration.
- For titration press the reset button and then start button.
- A beep denotes the end point.
- Take 150mg to 350mg Disodium tartrate dihydrate in the titration vessel containing neutralised methanol.
- Again refill the burette with KFR reagent up to the '0' mark.
- Press reset button and start button and titrate it.

Calculation

WATER	Disodium tartrate dihydrate
Factor = $\frac{\text{weight taken (in mg)}}{\text{Titre value}}$	Equivalent factor for Disodium tartrate dihydrate = 0.1566
Limit: 4-7 mg/mL	Factor = $\frac{\text{Equivalent factor X weight taken (in mg)}}{\text{Titre value}}$
	Limit: 4-7 mg/mL

SYSTEM SUITABILITY TEST

- Again a beep is heard when the end point is attained.

- Calculate the KFR factor with respect to the quantity of KFR reagent consumed (titre value).

Equivalent factor for Disodium tartrate dihydrate = 0.1566

- Factor = $\frac{\text{Equivalent factor X weight taken (in mg)}}{\text{Titre value}}$

- Do the same procedure for 5 times.

- Calculate the average value .The average value must be within the specified limit.

- Limit: 4-7 mg/mL

DISINTEGRATION TIME

What is Tablet disintegration Time

- For a drug to be readily available to the body it must be in solution.
- For most tablets ,the first important step toward solution is break down of the tablet into smaller particles (or) granules ,a process called Disintegration.

Calibration parameter

- Number of stokes
- Distance travelled
- Temperature

Distance travelled

- Attach the basket rack assembly firmly.
- Switch on the main and instrument.
- Attach the basket rack assembly firmly.
- Press enter key once to start the test.
- Note down the travelling distance of the basket rack assembly on the device from a calibrated scale.
- Repeat the test two more times to confirm the results
- Limit : 53mm to 57 mm

Number of Strokes

- Measure the number of strokes per minute using a calibrated stop watch.
- Repeat the same for further three times
- Find out the average number of strokes per minute.
- All the results should meet the requirement.
- Limit:28 - 32 Strokes/minute

TEMPERATURE

- Suspend the assembly in a beaker containing purified water .
- Set the temperature to 37± 2°C.
- After attaining the temperature check water temperature using calibrated thermometer.
- Repeat the operation for further 3 times.
- Find out the average temperature.
- All the results should meet the requirement.
- Limit :37 ± 2ºC

Note :If the calibration deviates from the standard, report the results to the departmental head for appropriate action to be taken.

DISSOLUTION TEST

What is dissolution

- Drug should be released from tablet in a controlled & reproducible way .
- Tablets or capsules taken orally remain one of the most effective means of treatment available. The effectiveness of such dosage forms relies on the drug dissolving in the fluids of the gastrointestinal tract prior to absorption into the systemic circulation. The rate of dissolution of the tablet or capsule is therefore crucial.
- The administration of drugs via oral dosage forms is one of the most common and effective means of delivering treatments to patients. When a dosage form is swallowed, the rate at which it releases the active ingredient is critical to ensure that the drug is delivered properly. The rate at which the drug is released is called the dissolution rate.

Calibration PARAMETERS

- Temperature
- Time
- Rotation per minutes

Factors that may affect reliability of the test

Proper alignment/geometry of dissolution apparatus	• Depth • Centering • wobbling
Proper conditions during dissolution test	• Temperature • Rotation per minutes • Time

Mechanical Caibtration Equipment Needed

Tachometer	Measures resolution per minutes with sensitivity less than 0.5 rpm
Centring Gauge	Determines centering of the apparatus shaft within the vessel.Distance given by this gauge are checked with a caliber
Digital protractor	Determine the angle of a surface relative to horizantal or vertical
Centering	Determine the centering of the stirring element shaft within the vessel for each position.
Digital Thermometers	Measure the temperature of any particular device or living body and displays the reading. A thermometer scale can be in Fahrenheit or Celsius.

TEMPERATURE

- set the temperature to 37°C.
- Check the temperature of each vessel with calibrated thermometer and record.
- **Acceptance criteria:** The difference should be within 37 ±0.5°C.

TIME

- Adjust the set time to '20' minutes in the instrument and start the instrument.
- Simultaneously start the calibrated stop watch.
- When beep sound is heard, immediately check the time on stopwatch and record the time.
- Follow the same procedure to calibrate at 30, 45, 60, 120 and 180 minute intervals.
- **Acceptance criteria:** The difference should not be more than 10 seconds .

ROTATION PER MINUTES

- Set the RPM to 50 in the instrument.
- Start the instrument and check the RPM using a calibrated tachometer.
- Repeat the procedure at 75, 100 and 150 rpm.
- **Acceptance criteria:** The difference should not be more than ± 4%.

DEPTH

- Measure the depth of paddle and basket in the bowel with the help of depth gauge.
- Fix the shafts with paddles / baskets.
- Fix the depth gauge in lower and upper part of shaft with paddle or basket.
- Press the platform down ▼ key. Measure depth for paddle/basket with suitable device.
- **Acceptance criteria: NMT ±2mm**

CENTERING

- Measure the diameter of the vessel in (mm) with vernier caliper.
- Place the centering device in the middle of each shaft and adjust the screws until the device fit with the vessel.

WOBBLING

- Measure the wobble of each shaft having paddle /basket with the help of wobbling gauge.
- Fix the wobbling gauge on ¾ part of shaft connected with paddle / basket and measure the reading in mm
- Press the platform down ▼ key .Fix the wobbling gauge on upper part of shaft with paddle/ basket and measure the reading in mm.
- Acceptance criteria: **NMT ±2mm**

APPARATUS SUITABILITY

- Check the suitability of the instrument as per apparatus test of USP apparatus 1 & 2 and follow the procedure as given along with the USP system suitability reference standard
- Parameters

➢ Apparatus : USP Apparatus I & II

➢ Medium : De-aerated water

➢ Volume : 500mL

➢ RPM : 50

➢ Time : 30 minutes

➢ Absorbance at : 242 nm

PROCEDURE

- **Preparation of standard Solution :**
  Transfer 25mg of prednisone USP RS in a clean and dry volumetric flask Add 50 mL of ethanol mix and dilute to 100 mL with dissolution media. Dilute 2 mL to 25 mL with dissolution media.
- **Preparation of Standard Solution:**
  Add one tablet to 500 mL of de-aerated water and carry out dissolution for 30 minutes.

* Measure the absorbance of standard and sample solution in a 1cm cell on suitable UV spectrophotometer at 242 nm, using dissolution medium as blank.

* Calculate the amount of Prednisone dissolved in the dissolution medium by using the formula:

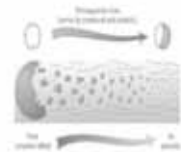
$$\frac{\text{Spl.Abs} \times \text{Std.Weight in mg} \times 2 \times 500 \times \text{Purity of prednisone}}{\text{Std.Abs} \times 100 \times 25 \times \text{Label Claim}}$$

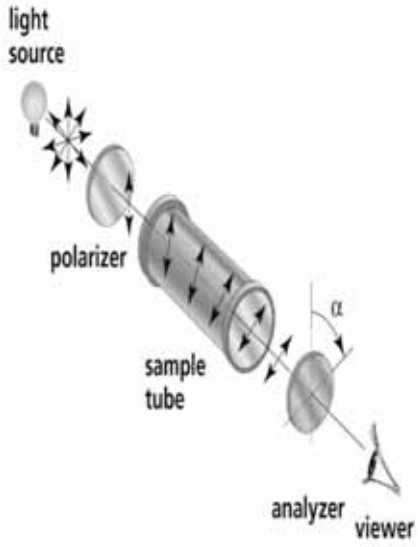
- Testing should be carried out on 7 units and 8th unit is considered as control.
- calculate the % of prednisone dissolved in the medium.
- After calculating the % of Prednisone dissolved, convert the results into a log scale.
- Run in each apparatus for two times and name them as set I and set 2. Determine the mean and variance for set-1 and set-2 individually.
- Convert the results to a geometric mean (GM) and percent coefficient of variation (%CV) and round both to one decimal place. Record the results in format number: Annexure–II
- **Acceptance criteria:** The dissolution of USP reference standard should be within the limit mentioned on the certificate of the USP reference standard.

POLARIMETER

What is Difference between Disintegration and dissolution

Disintegration time is the time required for a dosage form to **break up** in to granules of specified size (or smaller) under carefully specified conditions.





PROCEDURE

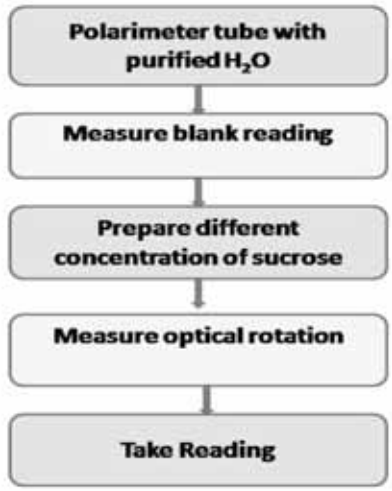
- Switch on the mains wait till sodium lamp glows with full intensity of yellow light.
- Rinse the Polarimeter tube with distilled water.
- Adjust the vernier scale and main dial scale to zero.
- If two halves intensity is not metering then adjust it by turning knurled screw of the prism box slightly. If not possible then adjust the field by rotating milled knob and vernier scale note the reading (+) or (-) side as a zero and to be consider while calibrating.
- Fill the purified water in Polarimeter tube. Clean the sides of the tube with tissue paper.
- Entrap any air bubble in space at center of the tube. Keep the Polarimeter tube in the place provided in the Polarimeter.
- Adjust the zero with the help of control knob. Focus circular disc of light with the help of field telescope.

- Observe the fields, which is divided into two halves, light and dark. Adjust the control knob to get equal intensity of the two halves.
- Measure optical rotation of the blank solution.
- Remove the Polarimeter tube from Polarimeter & discard the purified water from the tube.
- Prepare the following concentrations of Sucrose (AR Grade) solution (which has been dried at 105°C for 3 hours) and measure the optical rotation in a 2-dm tube at 25°C. The expected readings are given below.

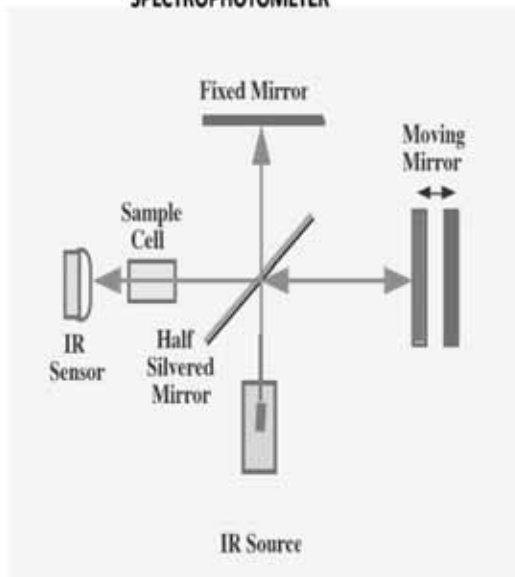
Concentration (g/100mL)	Angle of Rotation (+) at 25°C
10.00	+13.08° to +13.58°C
20.00	+26.36° to +26.86°C
30.00	+39.61° to +40.11°C
40.00	+52.81° to +53.31°C
50.00	+65.98° to +66.48°C

- Rinse the tube with sucrose solution (10g/100mL) and fill the solution in Polarimeter tube. Clean the sides of the tube with tissue paper.
- Entrap any air bubble in the space at the center of tube.
- Keep the Polarimeter tube in the space provided in the Polarimeter and measure the optical rotation of sample solution.
- Note the reading in degree of rotation.
- Remove the tube from Polarimeter & discard the solution from the tube.
- Repeat the procedure with (20g/100mL), (30g/100mL), (40g/100mL) and (50g/100mL) solution after rinsing with the same solutions.
- Note the readings of each concentration The values should comply with specified limits.
- Remove the tube from Polarimeter and discard the solution from the tube.
- Wash the tube with purified water and rinse with acetone and keep in Polarimeter tube box.

FLOW CHART



FOURIER TRANSFORMER INFRARED SPECTROPHOTOMETER



Calibration Procedure

- Double click on the "IR Solution" icon.
- IR Solution (default) windows will appear on the monitor.
- Switch ON the instrument as per operation Procedure
- Go to "Measure" and click. Then go to Measurement and click on "EP" Validation.
- "Previous background data" will display on screen and then "Remove the marked data" will display on screen. Then click "yes".
- Select method file will display. Click Measurement on the method file.
- Enter the parameter and click OK and "Form of power spectrum" will appear and then "Remove sample from sample chamber " will appear then click ok. These operations are automatic.
- By default it takes 45 scans two times and after completion of the scanning it will ask printing option followed by displaying "Now printing" then Result.

Calibration Procedure

- Display shows "Set Polystyrene film in to the sample chamber", insert the polystyrene film (thickness: 0.05mm) and click on OK.
- By default it takes 45 scans two times and after completion of the scanning it will ask printing option followed by displaying "Now printing" then Result ,
  - Pass (1) form of power spectrum,
  - Pass (2) Correctness of resolution and Wave number by polystyrene film
- Will appear on the screen then click "OK".
- The printout of the background spectrum, Polystyrene spectrum and the Validation report will come automatically.
- The validation report shows power spectrum, Control of Resolution, Wave number accuracy, Reproducibility of wave number and reproducibility of Absorbance.

ACCEPTANCE CRETERIA

- Resolution

Range	Limit
Between 2850.00 to 2870.00	Not Less than 0.33
Between 1582.00 to 1589.00	Not less than 0.08

Wave number	Tolerance (±1.0cm^{-1})
3060.0	3059.0 - 3061.0
2849.5	2848.5 - 2850.5
1942.9	1941.9 - 1943.9
1601.2	1600.2 - 1602.2
1583.0	1582. 0 - 1584.0
1154.5	1153.5 - 1155.5
1028.3	1027.3 - 1029.3

- Enter all the data's in the calibration protocol and compare the results for its compliance against the values generated by the system.
- Attach the printout of both the spectrum and the validation report with the calibration protocol.
- Ensure Polystyrene film is calibrated every year against standard NIST traceable film.

- End-

PHARMACIST ROLE : SAFETY FIRST WITH MEDICINES

by

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

INTRODUCTION:

Pharmacist is a part of Health care team who is "solely responsible for manufacturing, storage, dispensing, and all other matters related to drugs". Pharmacist must perform his work legally, coordinately and professionally to achieve rational drug use and to ensure medicine safety.

AIM OF WORK:

Is it possible to produce medicine safety?

YES, it is possible if a pharmacist performs all the works related to medicine. Only a pharmacist must be engaged in **Manufacturing, Storage, Dispensing, Counseling, Educating** about the drugs. The following are the some of the safety measures to be taken by a pharmacist to produce medicine safety:

ROLE OF PHARMACIST IN MEDICINE SAFETY IN MANUFACTURING:

It is the sole duty of pharmacist to follow **'GOOD MANUFACTURING PRACTICE' (GMP)** for production of safe and efficacious medicines thereby to ensure rational drug use. All the medicines must comply with the limits of pharmacopoeia. No medicines which are qualitatively or quantitatively substandard should be sent to market. The medicines therapeutic effect should overweigh side effect then only it should be manufactured.

Pharmacist must ensure that all the drugs which are manufactured are packed in proper and safe way for further process. The packaging should also comply with the pharmacopoeia.

ROLE OF PHARMACIST IN MEDICINE STORAGE:

The medicines should be properly handled and stored by the Pharmacist to prevent the degradation of medicine. **Ex: Certain drugs like IV INJECTIONS should be refrigerated while**

others should be kept in dark place. The medicines should be stored in a concrete walled well ventilated place. All the medicines must be categorized **as poisonous and non poisonous** and should be kept under lock and key. No person should be authorized to enter into the pharmacy other than the pharmacist. Medicines **which lost their Shelf life** must be carefully **disposed** as soon as possible. All the medicines should be categorized according to their category and property.

ROLE OF PHARMACIST IN MEDICINE SAFETY DURING TO DISPENSING:

Pharmacist must ensure **FIFO-FIRST IN FIRST OUT (FIFO)** while dispensing of medicines to minimize the dispensing of expired drugs. Medicines should be double checked weather right medicine is given to right person. Pharmacist must enquire and record the details **like patient family detail, medication history, hereditary disorder, immunity deficiency, any allergic condition, pregnancy.** While dispensing of medicine pharmacist should educate the **Right time, Right route, Right dose and dosage form** the medicine should be taken by the patient.

Pharmacist should not dispense a medicine incase of any discrepancy over the medicine it should be clarified with senior Pharmacist or Physician then only the drug should be dispensed. In no case the drug should not dispensed in an assumption. Since **SOUND ALIKE LOOK ALIKE (SALA)** drugs can cause medication accident.

Pharmacist should not dispense the drugs through the counter other than OTC drugs in any situation. **Ex: Incase of drugs like NSAIDS counseling regarding their side effects like gastric irritation, heart burns must be give to the patients.** Pharmacist must counsel to improve the medication compliance.

Pharmacist must counsel patient about the medicines effect weather it is for therapeutic or diagnostic or preventive nature. Then the drugs property, its adverse effect, its interactions, its contra indications should be clearly indicated.

ROLE OF PHARMACIST IN MEDICINE SAFETY AFTER DISPENSING:

A Pharmacist must perform **Therapeutic drug monitoring (TDM)** to ensure safety to the patient. Pharmacist must record the details of patients who are using **Schedule X drugs.** No such drug should be **early or late refilled without the permission of physician.** Pharmacist must help **the patient incase of missed or overdosing of medicine** since he/she only knows about **the Pharmacological and adverse effects clearly.** He must educate patient what to do incase of emergency conditions. **Ex: Incase of allergic reaction what should be done to prevent**

further accident.

Incase of narcotic medicine the records separately maintained which should include details of patient, physician, dose, and lot and batch number. All these records should be maintained properly by the pharmacist in the pharmacy itself it should be verified incase of any discrepancy.

ROLE OF HOSPITAL PHARMACIST IN MEDICINE SAFETY:

Pharmacist in the hospital should be allowed to **Ward round** and to **directly interact** with patients to minimize the medication incidents. He or she must take part in investigation of medication errors to prevent them in future and also he/she should **prevent the use of investigational medicine use** inside the hospital. A pharmacist must be consulted prior to admitting in hospital to prevent duplication of medicine, over dose, allergy. A pharmacist plays important role in **Reconciliation of medicine.**

ROLE OF PHARMACIST IN EDUCATING ABOUT MEDICINE SAFETY:

Pharmacist must gain knowledge about the ways to medicine safety and prevention of errors. A pharmacist should educate his fellow and junior pharmacist regarding the safe use of medicines. It is his duty to educate the patients regarding the safest use of medicines. Pharmacist should arrange for **Handouts, Posters, audio and Visual sessions for patients regarding medicine.**

CONCLUSION:

The pharmacist is the one of **the health care team** person who possessing important role in **drug safety** a patient sees before leaving the hospital so he must professionally perform his **duty and responsibility to bring out the medicine safety.** Pharmacist must give special campaign over medicine safety and prevention of errors so that they need to be will be well educated in recent trends of medicinal accident prevention and safety measures to **safe guard the patient.**

“We the pharmacist must be the medication safety person”
“Ask pharmacist: to know about your drugs”

NOTIFICATIONS

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 6th January, 2016

G.S.R. 11(E).— The following draft rules further to amend the Drugs and Cosmetics Rule s, 1945, which the Central Gover nment proposes to make, in exercise of the powers confe rred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after c onsultation with the Drugs T echnical Advisory Board, is hereby p ublished for information of all persons likely to be affected thereby, a nd notice is hereby given that the said draft rules shall be taken into considerati on on or after the expiry of a period of forty-five days from the date on which the c opies of the Gazette of I ndia c ontaining these draft rules are made available to the public.

The objections and suggestions which may be received from any person with respect to the said draft rules within the period specified above, will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414-A, D Wing, Nirman Bhawan, New Delhi- 110011.

Draft rules

1. (1) These rules may be called the Drugs and Cosmetics (9th Amendment) Rules, 2016.

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

2. In the Drugs and Cosmetics Rules, 1945, (hereinafter referred to as the said rules), in rule 122DA, in sub-rule (3), before the *Explanation*, the following sub-rule shall be inserted, namely:-

   "(4) No permission for conduct of clinical trial intended for academic purposes in respect of approved drug formulation shall be required for any new indication or new route of administration or new dose or new dosage form where,-

   (a) the trial is approved by the Ethics Committee; and
   (b) subject to the provisions of sub-rule (5), the data generated is not intended for submission to the licensing authority.

   (5) The Ethics Committee shall however inform the licensing authority about the cases approved by it and also about cases where there could be an overlap between the clinical trials for academic and regulatory purposes and where the said authority does not convey its comments to the Ethics Committee within a period of thirty days from the date of receipt of communication from the Ethics Committee, it shall be presumed that no permission from the licensing authority is required.".

3. In Schedule Y to the said rules, in Appendix I, in item 4, after sub-item 4.8, the following note shall be inserted, namely:-

   "Note.- Where data on animal toxicity as per the specification of Appendix III has been submitted and the same has been considered by the regulatory authority of the country which had earlier approved the drug, the animal toxicity studies shall not be required to be conducted in India except in cases where there are specific concerns recorded in writing.".

[F. No. X.11035/289/2015-DFQC]

K. L. SHARMA, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification number F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number GSR 918(E) dated 30.11.2015.

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MINISTRY OF HEALTH AND FAMILY WELFARE

(Deaprtment of Health and Family Welfare)

NOTIFICATION

New Delhi, the 25th January, 2016

S. O. 237(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, after consultation with the Drugs Technical Advisory Board, hereby specifies the following device intended for use in human beings as drug with immediate effect, namely:-

"Ablation device"

[F. NO. X -11035/275/2015-DFQC]
K. L. SHARMA, Jt. Secy.

397 GI/2016

Printed by the Manager, Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 1st March, 2016

G.S.R. 268(E).—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of thirty days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public.

Objections and suggestions which will be received with respect to the said draft rules within the period specified above will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi- 110011.

Draft rules

1. (1) These rules may be called the Drugs and Cosmetics (…..Amendment) Rules, 2016.

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

2. In the Drugs and Cosmetics Rules, 1945, in rule 43 A, for the words "Chennai, Kolkata, Mumbai, Cochin, Nhava Sheva, Kandla, Inland Container Depots at Tuglakabad and Patparganj in Delhi, Tuticorin in

Tamil Nadu and Marmugao port in Goa: in respect of drugs imported by sea into India. Chennai, Kolkata, Mumbai, Delhi, Ahmedabad, Hyderabad, Goa and Bengaluru in respect of drugs imported by air into India", the following words shall be substituted, namely:-

"Chennai, Kolkata, Mumbai, Cochin, Nhava Sheva, Kandla, Inland Container Depots at Tuglakabad and Patparganj in Delhi, Tuticorin in Tamil Nadu, Marmugao port in Goa and Visakhapatnam in Andhra Pradesh:

in respect of drugs imported by sea into India;

Chennai, Kolkata, Mumbai, Delhi, Ahmedabad, Hyderabad, Goa, Bengaluru and Visakhapatnam:

in respect of drugs imported by air into India.".

[F. No. X-11014/1/2015-DFQC]

K. L. SHARMA Jt. Secy.

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

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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 8th March, 2016

G.S.R. 287 (E).-Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare), number G.S.R. 559(E), dated the 17th July, 2015, published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), dated the 17th July, 2015, inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And Whereas copies of the Gazette were made available to the public on 17th July, 2015;

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

Now, therefore, in exercise of the powers conferred under section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (First Amendment) Rules, 2016.

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

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

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

"4. Post Marketing Surveillance.-

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

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

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

(ic) The applicant shall furnish Periodic Safety Update Reports (PSURs) in order to-

(a) report all relevant new information from appropriate sources;

(b) relate the data to patient exposure;

(c) summarise the market authorisation status in different countries and any significant variations related to safety; and

(d) indicate whether changes shall be made to product information in order to optimise the use of product.";

(B) in Appendix III, in paragraph 1.8, in the table,-

(i) under the heading 'Systemic Toxicity Studies', for sub-heading "Oral or Parenteral or Transdermal" and entries relating thereto, the following shall be substituted, namely:-

"Oral, or parentral or transdermal	Single dose or several doses in one day, Upto 1 wk	I,II,III	2sp, 2wks
	>1 wk but upto 2 wks	I,II,III	2sp; 2wks
	Upto 2 wks	Marketing permission	2 sp; 4 wks
	>2 wks but upto 4 wks	I, II,III	2 sp; equal to duration of human exposure
		Marketing permission	2 sp; 12 wks
	> 4 wks but upto 12 wks	I,II,III	2 sp; equal to duration of human exposure
		Marketing permission	2 sp; 24 wks
	> 12 wks but upto 24 wks	I,II,III	2 sp; equal to duration of human exposure
		Marketing permission	2 sp; Rodent 24 wks, non-rodent 36 wks
	> 24 wks	I,II,III	2 sp; Rodent 24 wks, non-rodent 36 wks
		Marketing permission	2 sp; Rodent 24 wks, non-rodent 36 wks";

(ii) under the heading "Male Fertility Study", for entries thereunder, the entries "Phase III in male volunteers/patients" shall be substituted.

[F.No. X 11014/12/2011-DFQC]

K. L. SHARMA, 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 GSR 918(E) dated the 30th November, 2015.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health & Family Welfare)

NOTIFICATION

New Delhi, the 16th March, 2016

G.S.R. 312(E).— The following draft rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), after consultation with the Drugs Technical Advisory Board, is hereby published for information of persons likely to be affected thereby, and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Gazette of India containing these draft rules are made available to the public.

The objections and suggestions which may be received from any person with respect to the said draft rules within the period specified above, will be considered by the Central Government.

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414'A' D-Wing, Nirman Bhawan, New Delhi-110011.

Draft rules

1. (1) These rules may be called the Drugs and Cosmetics (Third Amendment) Rules, 2016.

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

2. In the Drugs and Cosmetics Rules, 1945, in Schedule K, for serial numbers 35 and 35 and the entries relating there to, the following serial numbers and entries shall be substituted, namely:-

Class of Drugs	Extent and Conditions of Exemptions
"35. Homeopathic hair oils having active ingredients up to 3X potency only.	The provisions of Chapter IV of the Act and the rules made thereunder which require them to be regulated with a sale license subject to the condition that such products have been manufactured under a valid manufacturing license and sold in the original sealed packing of the licensed manufacturers.
36. Custom made devices.	All provisions of Chapter IV of the Act and the rules made thereunder, subject to the condition that the device being specifically made in accordance with a duly qualified medical practitioner's written prescription under his responsibility, in accordance with specific design, characteristics and the same is intended for the sole use of a particular patient and the label contain the words

	'custom made device'. Explanation.- Mass produced devices, which only need adoption to meet the specific requirement of a medical practitioner or any other professional user, shall not be considered as custom made device.
37. Zinc sulphate tablets and oral solutions having 10 mg and 20 mg of elemental zinc.	The provisions of Chapter IV of the Act and the rules made thereunder which require them to be regulated by a sale license, subject to the condition that such products have been manufactured under a valid drug manufacturing license.".

[F. No. X. 11014/5/2012-DFQC]

K. L. SHARMA, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification number F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number GSR 287(E) dated the 08.03.2016.

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MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 16th March, 2016

G.S.R. 313(E).— Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), vide notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare), number G.S.R. 11(E), dated the 6th January, 2016, published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), dated the 6th January, 2016, inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette were made available to the public on 06.01.2016;

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

Now, therefore, in exercise of the powers conferred under section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (Second Amendment) Rules, 2016.

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

2. In the Drugs and Cosmetics Rules, 1945, (hereinafter referred to as the said rules), in rule 122 DA, after sub-rule (3), before the Explanation, the following shall be inserted, namely:-

"(4) No permission for conduct of clinical trial intended for academic purposes in respect of approved drug formulation shall be required for any new indication or new route of administration or new dose or new dosage form where,-

(a) the trial is approved by the Ethics Committee; and

(b) subject to the provisions of sub-rule 5, the data generated is not intended for submission to licensing authority.

"(5) The Ethics Committee shall however inform the licensing authority about the cases approved by it and also about cases where there could be an overlap between the clinical trial for academic and regulatory purposes and where the said authority does not convey its comments to the Ethics Committee within a period of thirty days from the date of receipt of communication from the Ethics Committee, it shall be presumed that no permission from the licensing authority is required.".

3. In Schedule Y to the said rules, in Appendix I, in item 4, after sub-item 4.8, the following note shall be inserted, namely:-

"Note.- Where the data on animal toxicity as per the specifications of Appendix III has been submitted and the same has been considered by the regulatory authority of the country which had earlier approved the drug, the animal toxicity studies shall not be required to be conducted in India except in cases where there are specific concerns recorded in writing.".

[F. No. X.11035/289 /2015-DFQC]

K. L. SHARMA, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification number F.28-10/45-H (1) dated 21st December 1945 and last amended vide notification number GSR 287(E) dated 08.03.2016.

List of Fixed Dose combination Drugs banned by Ministry of Health and Family Welfare, as on 10th March 2016.

S. No.	Gazette No.	Drug Name
1.	S.O. 705 (E)	Aceclofenac + Paracetamol + Rabeprazole
2	S.O.706(E)	Nimesulide + Diclofenac
3	S.O. 707(E)	Nimesulide + Cetirizine + Caffeine
4	S.O. 708 (E)	Nimesulide + Tizanidine
5	S.O. 709 (E)	Paracetamol + Cetirizine + Caffeine
6	S.O. 710 (E)	Diclofenac + Tramadol + Chlorzoxazone
7	S.O. 711 (E)	Dicyclomine + Paracetamol + Domperidone
8	S.O. 712 (E)	Nimesulide + Paracetamol dispersible tablets
9	S.O. 713 (E)	Paracetamol + Phenylephrine + Caffeine
10	S.O. 714 (E)	Diclofenac + Tramadol + Paracetamol
11	S.O. 715 (E)	Diclofenac + Paracetamol + Chlorzoxazone + Famotidine
12	S.O. 716 (E)	Naproxen + Paracetamol
13	S.O. 717 (E)	Nimesulide + Serratiopeptidase
14	S.O. 718 (E)	Paracetamol + Diclofenac + Famotidine
15	S.O. 719 (E)	Nimesulide + Pitofenone + Fenpiverinium + Benzyl Alcohol
16	S.O. 720 (E)	Omeprazole + Paracetamol + Diclofenac
17	S.O. 721 (E)	Nimesulide + Paracetamol injection
18	S.O. 722 (E)	Tamsulosin + Diclofenac
19	S.O. 723 (E)	Paracetamol + Phenylephrine + Chlorpheniramine + Dextromethorphan + Caffeine
20	S.O. 724 (E)	Diclofenac + Zinc Carnosine
21	S.O. 725 (E)	Diclofenac + Paracetamol + Chlorpheniramine Maleate + Magnesium Trisillicate

22	S.O. 726 (E)	Paracetamol + Pseudoephedrine + Cetrizine
23	S.O. 727 (E)	Phenylbutazone + Sodium Salicylate
24	S.O. 728 (E)	Lornoxicam + Paracetamol + Trypsin
25	S.O. 729 (E)	Paracetamol + Mefenamic Acid + Ranitidine + Dicyclomine
26	S.O. 730 (E)	Nimesulide + Dicyclomine
27	S.O. 731 (E)	Heparin + Diclofenac
28	S.O. 732 (E)	Glucosamine + Methyl Sulfonyl Methane + Vitamin D3 + Manganese + Boron + Copper + Zinc
29	S.O. 733 (E)	Paracetamol + Tapentadol
30	S.O. 734 (E)	Tranexamic Acid + Proanthocyanidin
31	S.O. 735 (E)	Benzoxonium Chloride + Lidocaine
32	S.O. 736 (E)	Lornoxicam + Paracetamol + Tramadol
33	S.O. 737 (E)	Lornoxicam + Paracetamol + Serratiopeptidase
34	S.O. 738 (E)	Diclofenac + Paracetamol + Magnesium Trisilicate
35	S.O. 739 (E)	Paracetamol + Domperidone + Caffeine
36	S.O. 740 (E)	Ammonium Chloride + Sodium Citrate + Chlorpheniramine Maleate + Menthol
37	S.O. 741 (E)	Paracetamol + Prochlorperazine Maleate
38	S.O. 742 (E)	3 tablets of Serratiopeptidase (enteric coated 20000 units) + Diclofenac Potassium & 2 tablets of Doxycycline
39	S.O. 743 (E)	Nimesulide + Paracetamol Suspension
40	S.O. 744 (E)	Aceclofenac + Paracetamol + Famotidine
41	S.O. 745 (E)	Aceclofenac + Zinc Carnosine
42	S.O. 746 (E)	Paracetamol + Disodium Hydrogen Citrate + Caffeine
43	S.O. 747 (E)	Paracetamol + DL Methionine
44	S.O. 748 (E)	Disodium Hydrogen Citrate + Paracetamol
45	S.O. 749 (E)	Paracetamol + Caffeine + Codeine
46	S.O. 750 (E)	Aceclofenac (SR) + Paracetamol
47	S.O. 751 (E)	Diclofenac + Paracetamol injection

48	S.O. 752 (E)	Azithromycin + Cefixime
49	S.O. 753 (E)	Amoxicillin + Dicloxacillin
50	S.O. 754 (E)	Amoxicillin 250 mg + Potassium Clavulanate Diluted 62.5 mg
51	S.O. 755 (E)	Azithromycin + Levofloxacin
52	S.O. 756 (E)	Cefixime + Linezolid
53	S.O. 757 (E)	Amoxicillin + Cefixime + Potassium Clavulanic Acid
54	S.O. 758 (E)	Ofloxacin + Nitazoxanide
55	S.O. 759 (E)	Cefpodoxime Proxetil + Levofloxacin
56	S.O. 760 (E)	Azithromycin, Secnidazole and Fluconazole
57	S.O. 761 (E)	Levofloxacin + Ornidazole + Alpha Tocopherol Acetate
58	S.O. 762 (E)	Nimorazole + Ofloxacin
59	S.O. 763 (E)	Azithromycin + Ofloxacin
60	S.O. 764 (E)	Amoxycillin + Tinidazole
61	S.O. 765 (E)	Doxycycline + Serratiopeptidase
62	S.O. 766 (E)	Cefixime + Levofloxacin
63	S.O. 767 (E)	Ofloxacin+ Metronidazole+Zinc Acetate
64	S.O. 768 (E)	Diphenoxylate + Atropine + Furazolidone
65	S.O. 769 (E)	Fluconazole Tablet, Azithromycin Tablet and Ornidazole Tablets
66	S.O. 770 (E)	Ciprofloxacin + Phenazopyridine
67	S.O. 771 (E)	Amoxycillin + Dicloxacillin + Serratiopeptidase
68	S.O. 772 (E)	Azithromycin + Cefpodoxime
69	S.O. 773 (E)	Lignocaine + Clotrimazole + Ofloxacin + Beclomethasone
70	S.O. 774 (E)	Cefuroxime + Linezolid
71	S.O. 775 (E)	Ofloxacin + Ornidazole + Zinc Bisglycinate
72	S.O. 776 (E)	Metronidazole + Norfloxacin
73	S.O. 777 (E)	Amoxicillin + Bromhexine
74	S.O. 778 (E)	Ciprofloxacin + Fluticasone + Clotrimazole + Neomycin
75	S.O. 779 (E)	Metronidazole + Tetracycline

76	S.O. 780 (E)	Cephalexin + Neomycin + Prednisolone
77	S.O. 781 (E)	Azithromycin + Ambroxol
78	S.O. 782 (E)	Cilnidipine + Metoprolol Succinate + Metoprolol Tartrate
79	S.O. 783 (E)	L-Arginine + Sildenafil
80	S.O. 784 (E)	Atorvastatin + Vitamin D3 + Folic Acid + Vitamin B12 + Pyridoxine
81	S.O. 785 (E)	Metformin + Atorvastatin
82	S.O. 786 (E)	Clindamycin + Telmisartan
83	S.O. 787 (E)	Olmesartan + Hydrochlorothiazide + Chlorthalidone
84	S.O. 788 (E)	L-5-Methyltetrahydrofolate Calcium + Escitaloprami
85	S.O. 789 (E)	Pholcodine + Promethazine
86	S.O. 790 (E)	Paracetamol + Promethazine
87	S.O. 791 (E)	Betahistine + Ginkgo Biloba Extract + Vinpocetine + Piracetam
88	S.O. 792 (E)	Cetirizine + Diethyl Carbamazine
89	S.O. 793 (E)	Doxylamine + Pyridoxine + Mefenamic Acid + Paracetamol
90	S.O. 794 (E)	Drotaverine + Clidinium + Chlordiazepoxide
91	S.O. 795 (E)	Imipramine + Diazepam
92	S.O. 796 (E)	Flupentixol + Escitalopram
93	S.O. 797 (E)	Paracetamol + Prochloperazine
94	S.O. 798 (E)	Gabapentin + Mecobalamin + Pyridoxine + Thiamine
95	S.O. 799 (E)	Imipramine + Chlordiazepoxide + Trifluoperazine + Trihexyphenidyl
96	S.O. 800 (E)	Chlorpromazine + Trihexyphenidyl
97	S.O. 801 (E)	Ursodeoxycholic Acid + Silymarin
98	S.O. 802 (E)	Metformin 1000/1000/500/500mg + Pioglitazone 7.5/7.5/7.5/7.5mg + Glimepiride 1/2/1/2mg
99	S.O. 803 (E)	Gliclazide 80 mg + Metformin 325 mg
100	S.O. 804 (E)	Voglibose + Metformin + Chromium Picolinate
101	S.O. 805 (E)	Pioglitazone 7.5/7.5mg + Metformin 500/1000mg
102	S.O. 806 (E)	Glimepiride 1mg/2mg/3mg + Pioglitazone 15mg/15mg/15mg + Metformin 1000mg/ 1000mg/1000mg

103	S.O. 807 (E)	Glimepiride 1mg/2mg+ Pioglitazone 15mg/15mg + Metformin 850mg/850mg
104	S.O. 808 (E)	Metformin 850mg + Pioglitazone 7.5 mg + Glimepiride 2mg
105	S.O. 809 (E)	Metformin 850mg + Pioglitazone 7.5 mg + Glimepiride 1mg
106	S.O. 810 (E)	Metformin 500mg/500mg+Gliclazide SR 30mg/60mg + Pioglitazone 7.5mg/7.5mg
107	S.O. 811 (E)	Voglibose + Pioglitazone + Metformin
108	S.O. 812 (E)	Metformin + Bromocriptine
109	S.O. 813 (E)	Metformin + Glimepiride + Methylcobalamin
110	S.O. 814 (E)	Pioglitazone 30 mg + Metformin 500 mg
111	S.O. 815 (E)	Glimepiride + Pioglitazone + Metformin
112	S.O. 816 (E)	Glipizide 2.5mg + Metformin 400 mg
113	S.O. 817 (E)	Pioglitazone 15mg + Metformin 850 mg
114	S.O. 818 (E)	Metformin ER + Gliclazide MR + Voglibose
115	S.O. 819 (E)	Chromium Polynicotinate + Metformin
116	S.O. 820 (E)	Metformin + Gliclazide + Piogllitazone + Chromium Polynicotinate
117	S.O. 821 (E)	Metformin + Gliclazide + Chromium Polynicotinate
118	S.O. 822 (E)	Glibenclamide + Metformin (SR)+ Pioglitazone
119	S.O. 823 (E)	Metformin (Sustainded Release) 500mg + Pioglitazone 15 mg + Glimepiride 3mg
120	S.O. 824 (E)	Metformin (SR) 500mg + Pioglitazone 5mg
121	S.O. 825 (E)	Chloramphenicol + Beclomethasone + Clomitrimazole + Lignocaine
122	S.O. 826 (E)	Clotrimazole + Ofloxaxin + Lignocaine + Glycerine and Propylene Glycol
123	S.O. 827 (E)	Chloramphennicol + Lignocaine + Betamethasone + Clotrimazole + Ofloxacin + Antipyrine
124	S.O. 828 (E)	Ofloxacin + Clotrimazole + Betamethasone + Lignocaine
125	S.O. 829 (E)	Gentamicin Sulphate + Clotrimazole + Betamethasone + Lignocaine
126	S.O. 830 (E)	Clotrimazole + Beclomethasone + Ofloxacin + Lignocaine

127	S.O. 831 (E)	Becloemthasone + Clotrimazole + Chloramphenicol + Gentamycin + Lignocaine Ear drops
128	S.O. 832 (E)	Flunarizine + Paracetamole + Domperidone
129	S.O. 833 (E)	Rabeprazole + Zinc Carnosine
130	S.O. 834 (E)	Magaldrate + Famotidine + Simethicone
131	S.O. 835 (E)	Cyproheptadine + Thiamine
132	S.O. 836 (E)	Magaldrate + Ranitidine + Pancreatin + Domperidone
133	S.O. 837 (E)	Ranitidine + Magaldrate + Simethicone
134	S.O. 838 (E)	Magaldrate + Papain + Fungul Diastase + Simethicone
135	S.O. 839 (E)	Rabeprazole + Zinc + Domperidone
136	S.O. 840 (E)	Famotidine + Oxytacaine + Magaldrate
137	S.O. 841 (E)	Ranitidine + Domperidone + Simethicone
138	S.O. 842 (E)	Alginic Acid + Sodium Bicarbonate + Dried Aluminium Hydroxide + Magnesium Hydroxide
139	S.O. 843 (E)	Clidinium + Paracetamol + Dicyclomine + Activated Dimethicone
140	S.O. 844 (E)	Furazolidone + Metronidazole + Loperamide
141	S.O. 845 (E)	Rabeprazole + Diclofenac + Paracetamol
142	S.O. 846 (E)	Ranitidine + Magaldrate
143	S.O. 847 (E)	Norfloxacin + Metronidazole + Zinc Acetate
144	S.O. 848 (E)	Zinc Carnosine + Oxetacaine
145	S.O. 849 (E)	Oxetacaine + Magaldrate + Famotidine
146	S.O. 850 (E)	Pantoprazole (as Enteric Coated Tablet) + Zinc Carnosine (as Film Coated Tablets)
147	S.O. 851 (E)	Zinc Carnosine + Magnesium Hydroxide + Dried Aluminium Hydroxide + Simethicone
148	S.O. 852 (E)	Zinc Carnosine + Sucralfate
149	S.O. 853 (E)	Mebeverine & Inner HPMC capsule (Streptococcus Faecalis + Clostridium butyricum + Bacillus mesentricus + Lactic Acid Bacillus)
150	S.O. 854 (E)	Clindamycin + Clotrimazole + Lactic Acid Bacillus
151	S.O. 855 (E)	Sildenafil + Estradiol Valerate

152	S.O. 856 (E)	Clomifene Citrate + Ubidecarenone + Zinc + Folic Acid + Methylcobalamin + Pyridoxine + Lycopene + Selenium + Levocarnitine Tartrate + L-Arginine
153	S.O. 857 (E)	Thyroxine + Pyridoxine + Folic Acid
154	S.O. 858 (E)	Gentamycin + Dexamethasone + Chloramphenicol + Tobramycin + Ofloxacin
155	S.O. 859 (E)	Dextromethorphan + Levocetirizine + Phenylephrine + Zinc
156	S.O. 860 (E)	Nimesulide + Loratadine + Phenylephrine + Ambroxol
157	S.O. 861 (E)	Bromhexine + Phenylephrine + Chlorepheniramine Maleate
158	S.O. 862 (E)	Dextromethorphan + Bromhexine + Guaiphenesin
159	S.O. 863 (E)	Paracetamol + Loratadine + Phenylephrine + Dextromethorphan + Caffeine
160	S.O. 864 (E)	Nimesulide + Phenylephrine + Caffeine + Levocetirizine
161	S.O. 865 (E)	Azithromycin + Acebrophylline
162	S.O. 866 (E)	Diphenhydramine + Terpine + Ammonium Chloride + Sodium Chloride + Menthol
163	S.O. 867 (E)	Nimesulide + Paracetamol + Cetirizine + Phenylephrine
164	S.O. 868 (E)	Paracetamol + Loratadine + Dextromethophan + Pseudoepheridine + Caffeine
165	S.O. 869 (E)	Chlorpheniramine Maleate + Dextromethorphan + Dextromethophan + Guaiphenesin + Ammonium Chloride + Menthol
166	S.O. 870 (E)	Chlorpheniramine Maleate + Ammonium Chloride + Sodium Citrate
167	S.O. 871 (E)	Cetirizine + Phenylephrine + Paracetamol + Zinc Gluconate
168	S.O. 872 (E)	Ambroxol + Guaiphenesin + Ammonium Chloride + Phenylephrine + Chlorpheniramine Maleate + Menthol
169	S.O. 873 (E)	Dextromethorphen + Bromhexine + Chlorpheniramine Maleate + Guaiphenesin
170	S.O. 874 (E)	Levocetirizine + Ambroxol + Phenylephrine + Guaiphenesin
171	S.O. 875 (E)	Dextromethorphan + Chlorpheniramine + Chlorpheniramine Maleate
172	S.O. 876 (E)	Cetirizine + Ambroxol + Guaiphenesin + Ammonium Chloride + Phenylephrine + Menthol
173	S.O. 877 (E)	Chlorpheniramine + Phenylephrine + Caffeine

174	S.O. 878 (E)	Dextromethorphan + Triprolidine + Phenylephrine
175	S.O. 879 (E)	Terpinhydrate + Dextromethorphan + Menthol
176	S.O. 880 (E)	Dextromethorphan + Phenylephrine + Zinc Gluconate + Menthol
177	S.O. 881 (E)	Chlorpheniramine + Codeine + Sodium Citrate + Menthol Syrup
178	S.O. 882 (E)	Enrofloxacin + Bromhexin
179	S.O. 883 (E)	Bromhexine + Dextromethorphan + Phenylephrine + Menthol
180	S.O. 884 (E)	Levofloxacin + Bromhexine
181	S.O. 885 (E)	Levocetirizine + Ranitidine
182	S.O. 886 (E)	Levocetirizine + Phenylephrine + Ambroxol + Guaiphenesin + Paracetamol
183	S.O. 887 (E)	Cetirizine + Dextromethorphan + Phenylephrine + Zinc Gluconate + Paracetamol + Menthol
184	S.O. 888 (E)	Paracetamol + Pseudoephedrine + Dextromethorphan + Cetirizine
185	S.O. 889 (E)	Diphenhydramine + Guaiphenesin + Ammonium Chloride + Bromhexine
186	S.O. 890 (E)	Chlorpheniramine + Dextromethorphan + Phenylephrine + Paracetamol
187	S.O. 891 (E)	Dextromethorphen + Promethazine
188	S.O. 892 (E)	Diethylcabamazine Citrate + Cetirizine + Guaiphenesin
189	S.O. 893 (E)	Pseudoephedrine + Dextromethorphan + Cetirizine
190	S.O. 894 (E)	Chlorpheniramine + Phenylephrine + Dextromethophan + Menthol
191	S.O. 895 (E)	Ambroxol + Terbutaline + Dextromethorphan
192	S.O. 896 (E)	Dextromethorphan + Chlorpheniramine + Guaiphenesin
193	S.O. 897 (E)	Terbutaline + Bromhexine + Guaiphenesin + Dextromethorphan
194	S.O. 898 (E)	Dextromethorphan + Tripolidine + Phenylephirine
195	S.O. 899 (E)	Paracetamol + Dextromethorphan + Chlorpheniramine
196	S.O. 900 (E)	Pholcodine + Phenylephrine + Promethazine
197	S.O. 901 (E)	Codeine + Levocetirizine + Menthol
198	S.O. 902 (E)	Dextromethorphan + Ambroxol + Guaifenesin + Phenylephrine + Chlorpheniramine
199	S.O. 903 (E)	Cetirizine + Phenylephrine + Dextromethorphan + Menthol
200	S.O. 904 (E)	Roxithromycin + Serratiopeptidase
201	S.O. 905 (E)	Paracetamol + Phenylephrine + Triprolidine

202	S.O. 906 (E)	Acetaminophen + Loratadine + Ambroxol + Phenylephrine
203	S.O. 907 (E)	Cetirizine + Acetaminophen + Dextromethorphan + Phenyephrine + Zinc Gluconate
204	S.O. 908 (E)	Diphenhydramine + Guaifenesin + Bromhexine + Ammonium Chloride + Menthol
205	S.O. 909 (E)	Chlopheniramine Maleate + Codeine Syrup
206	S.O. 910 (E)	Cetirizine + Dextromethorphan + Zinc Gluconate + Menthol
207	S.O. 911 (E)	Paracetamol + Phenylephrine + Desloratadine + Zinc Gluconate + Ambroxol
208	S.O. 912 (E)	Levocetirizine + Montelukast + Acebrophylline
209	S.O. 913 (E)	Dextromethorphan + Phenylephrine + Ammonium Chloride + Menthol
210	S.O. 914 (E)	Dextromethorphan + Bromhexine + Guaiphenesin + Menthol
211	S.O. 915 (E)	Acrivastine + Paracetamol + Caffeine + Phenylephrine
212	S.O. 916 (E)	Naphazoline + Carboxy Methyl Cellulose + Menthol + Camphor + Phenylephrine
213	S.O. 917 (E)	Dextromethorphan + Cetirizine
214	S.O. 918 (E)	Nimesulide + Paracetamol + Levocetirizine + Phenylephrine + Caffeine
215	S.O. 919 (E)	Terbutaline + Ambroxol + Guaiphenesin + Zinc + Menthol
216	S.O. 920 (E)	Codeine + Chlorpheniramine + Alcohol Syrup
217	S.O. 921 (E)	Dextromethorphan + Phenylephrine + Guaifenesin + Triprolidine
218	S.O. 922 (E)	Ammomium Chloride + Bromhexine + Dextromethorphan
219	S.O. 923 (E)	Diethylcarbamazine + Cetirizine + Ambroxol
220	S.O. 924 (E)	Ethylmorphine + Noscapine + Chlorpheniramine
221	S.O. 925 (E)	Cetirizine + Dextromethorphan + Ambroxol
222	S.O. 926 (E)	Bromhexine + Dextromethorphan + Ammonium Chloride + Menthol
223	S.O. 927 (E)	Ambroxol + Guaifenesin + Phenylephrine + Chlorpheniramine
224	S.O. 928 (E)	Paracetamol + Phenylephrine + Chlorpheniramine + Zinc Gluconate
225	S.O. 929 (E)	Dextromethorphan + Phenylephrine + Cetirizine + Paracetamol + Caffeine
226	S.O. 930 (E)	Dextromethophan + Chlorpheniramine + Guaifenesin + Ammonium Chloride
227	S.O. 931 (E)	Levocetirizine + Dextromethorphan + Zinc
228	S.O. 932 (E)	Paracetamol + Phenylephrine + Levocetirizine + Caffeine

229	S.O. 933 (E)	Chlorphaniramine + Ammonium Chloride + Sodium Chloride
230	S.O. 934 (E)	Paracetamol + Dextromethorphan + Bromhexine + Phenylephrine + Diphenhydramine
231	S.O. 935 (E)	Salbutamol + Bromhexine + Guaiphenesin + Menthol
232	S.O. 936 (E)	Chlorpheniramine + Ammonium Chloride + Noscapine + Sodium Citrate
233	S.O. 937 (E)	Cetirizine + Dextromethorphan + Bromhexine + Guaifenesin
234	S.O. 938 (E)	Diethyl Carbamazine + Chlorpheniramine + Guaifenesin
235	S.O. 939 (E)	Ketotifen + Cetirizine
236	S.O. 940 (E)	Terbutaline + Bromhexine + Etofylline
237	S.O. 941 (E)	Ketotifen + Theophylline
238	S.O. 942 (E)	Ambroxol + Salbutamol + Theophylline
239	S.O. 943 (E)	Cetriritzine + Nimesulide + Phenylephrine
240	S.O. 944 (E)	Chlorpheniramine + Phenylephrine + Paracetamol + Zink Gluconate
241	S.O. 945 (E)	Acetaminophen + Guaifenesin + Dextromethorphan + Chlorpheniramine
242	S.O. 946 (E)	Cetirizine + Dextromethorphan + Phenylephrine + Tulsi
243	S.O. 947 (E)	Cetirizine + Phenylephrine + Paracetamol + Ambroxol + Caffeine
244	S.O. 948 (E)	Guaifenesin + Dextromethorphan
245	S.O. 949 (E)	Levocetirizine + Paracetamol + Phenylephirine + Caffeine
246	S.O. 950 (E)	Caffeine + Paracetamol + Phenylephrine + Chlorpheniramine
247	S.O. 951 (E)	Ketotifen + Levocetrizine
248	S.O. 952 (E)	Paracetamol + Levocetirizine + Phenylephirine + Zink Gluconate
249	S.O. 953 (E)	Paracetamol + Phenylephrine + Triprolidine + Caffeine
250	S.O. 954 (E)	Caffeine + Paracetamol + Phenylephrine + Cetirizine
251	S.O. 955 (E)	Dextromethorphan + Phenylephirin + Guaifenesin
252	S.O. 956 (E)	Ambroxol + Levocetirizine + Phenylephrine + Guaiphenesin +Menthol
253	S.O. 957 (E)	Pseudoephedrine + Cetirizine
254	S.O. 958 (E)	Dextromethorphan + Chlorpheniramine + Ammonium Chloride + Menthol
255	S.O. 959 (E)	Paracetamol + Caffeine + Phenylephrine + Chlorpheniramine
256	S.O. 960 (E)	Salbutamol + Aminophylline + Guaifenesin
257	S.O. 961 (E)	Salbutamol + Thoephylline + Bromhexine

258	S.O. 962 (E)	Chlorpheniramine + Dextromethorphan + Guaifenesin + Phenylephrine
259	S.O. 963 (E)	Caffeine + Paracetamol + Chlorpheniramine
260	S.O. 964 (E)	Ammonium Chloride + Dextromethorphan + Cetirizine + Menthol
261	S.O. 965 (E)	Dextromethorphan + Paracetamol + Cetirizine + Phenylephrine
262	S.O. 966 (E)	Chlorpheniramine + Terpin + Antimony Potassium Tartrate + Ammonium Chloride + Sodium Citrate + Menthol
263	S.O. 967 (E)	Terbutaline + Etofylline + Ambroxol
264	S.O. 968 (E)	Paracetamol + Codeine + Chlorpheniramine
265	S.O. 969 (E)	Paracetamol+Pseudoephedrine+Certirizine+Caffeine
266	S.O. 970 (E)	Chlorpheniramine+Ammonium Chloride + Menthol
267	S.O. 971 (E)	N-Acetyl Cysteine + Ambroxol + Phenylephrine + Levocertirizine
268	S.O. 972 (E)	Dextromethorphan + Phenylephrine + Tripolidine + Menthol
269	S.O. 973 (E)	Salbutamol + Certirizine + Ambroxol
270	S.O. 974 (E)	Dextromethorphan + Phenylephrine + Bromhexine + Guaifenesin + Chlorpheniramine
271	S.O. 975 (E)	Nimesulide + Certirizine + Phenylephrine
272	S.O. 976 (E)	Naphazoline + Chlorpheniramine + Zinc Sulphate + Boric Acid + Sodium Chloride + Chlorobutol
273	S.O. 977 (E)	Paracetamol + Bromhexine + Phenylephrine + Chlorpheniramine + Guaifenesin
274	S.O. 978 (E)	Salbutamol + Bromhexine
275	S.O. 979 (E)	Dextromethorphan + Phenylephrine + Guaifenesin + Certirizine + Acetaminophen
276	S.O. 980 (E)	Guaifenesin + Bromhexine + Chlorpheniramine + Paracetamol
277	S.O. 981 (E)	Chlorpheniramine + Ammonium Chloride + Chloroform + Menthol
278	S.O. 982 (E)	Salbutamol + Choline Theophylinate + Ambroxol
279	S.O. 983 (E)	Chlorpheniramine + Codeine Phosphate + Menthol Syrup
280	S.O. 984 (E)	Pseudoephedrine + Bromhexine
281	S.O. 985 (E)	Certirizine + Phenylephrine + Paracetamol + Caffeine + Nimesulide
282	S.O. 986 (E)	Dextromethorphan + Cetirizine + Guaifenesin + Ammonium Chloride
283	S.O. 987 (E)	Ambroxol + Salbutamol + Choline Theophyllinate + Menthol
284	S.O. 988 (E)	Paracetamol + Chlorpheniramine + Ambroxol + Guaifenesin + Phenylephrine

285	S.O. 989 (E)	Chlorpheniramine + Vasaka + Tolubalsm + Ammonium Chloride + Sodium Citrate + Menthol
286	S.O. 990 (E)	Bromhexine + Cetrizine + Phenylephrine IP+Guaifenesin + Menthol
287	S.O. 991 (E)	Dextromethorphan + Ambroxol + Ammonium Chloride + Chlorpheniramine + Menthol
288	S.O. 992 (E)	Dextromethorphan + Phenylephrine + Cetirizine + Zinc + Menthol
289	S.O. 993 (E)	Terbutaline + N-Acetyl L-Cysteine + Guaifenesin
290	S.O. 994 (E)	Calcium Gluconate + Levocetirizine
291	S.O. 995 (E)	Paracetamol + Levocetirizine + Pseudoephedrine
292	S.O. 996 (E)	Salbutamol + Choline Theophylinate + Carbocisteine
293	S.O. 997 (E)	Chlorpheniramine + Vitamin C
294	S.O. 998 (E)	Calcium Gluconate + Chlorpheniramine + Vitamin C
295	S.O. 999 (E)	Chlorpheniramine + Paracetamol + Pseudoephedrine + Caffeine
296	S.O. 1000(E)	Guaifenesin + Bromhexine + Chlorpheniramine + Phenylephrine + Paracetamol + Serratiopeptidase (as enteric coated granules) 10000 SP Units
297	S.O. 1001(E)	Paracetamol + Pheniramine
298	S.O.1002(E)	Betamethasone + Fusidic Acid + Gentamycin + Tolnaftate + Iodochlorhydroxyquinoline (ICHQ)
299	S.O. 1003 (E)	Clobetasol + Ofloxacin + Miconazole + Zinc Sulphate
300	S.O. 1004 (E)	Clobetasole + Gentamicin + Miconazole + Zinc Sulphate
301	S.O. 1005 (E)	Levocetirizine + Ambroxol + Phenylephrine + Paracetamol
302	S.O. 1006 (E)	Permethrin + Cetrimide + Menthol
303	S.O. 1007 (E)	Beclomethasone + Clotimazole + Neomycin + Iodochlorohydroxyquinone
304	S.O. 1008 (E)	Neomycin + Doxycycline
305	S.O. 1009 (E)	Ciprofloxacin + Fluocinolone + Clotrimazole + Neomycin + Chlorocresol
306	S.O. 1010 (E)	Clobetasol + Ofloxacin + Ketoconazol + Zinc Sulphate
307	S.O. 1011 (E)	Betamethasone + Gentamicin + Tolnaftate + Iodochlorhydroxyquinoline
308	S.O. 1012 (E)	Clobetasol + Gentamicin + Tolnaftate + Iodochlorhydroxyquinone + Ketoconazole
309	S.O. 1013 (E)	Allantoin + Dimethieone + Urea + Propylene + Glycerin + Liquid Paraffin
310	S.O. 1014 (E)	Acriflavine + Thymol + Cetrimide

311	S.O. 1015 (E)	Betamethasone + Neomycin + Tolnaftate + Iodochlorohydroxyquinoline + Cholorocresol
312	S.O. 1016 (E)	Clobetasol + Neomycin + Miconazole + Clotrimazole
313	S.O. 1017 (E)	Ketoconazole + Tea Tree oil + Allantion + Zinc Oxide + Aloe Vera + Jojoba oil + Lavander oil + Soa noodels
314	S.O. 1018 (E)	Clobetasol Propionate + Ofloxacin + Ornidazole + Terbinafine
315	S.O. 1019 (E)	Clobetasol + Neomycin + Miconazole + Zinc Sulphate
316	S.O. 1020 (E)	Beclomethasone Diproprionate + Neomycin + Tolnaftate + Iodochlorhydroxyquinoline + Chlorocresol
317	S.O. 1021 (E)	Betamethasone + Gentamycin + Zinc Sulphate + Clotrimoazole + Chlorocresol
318	S.O. 1022 (E)	Borax + Boric Acid + Naphazoline + Menthol + Camphor + Methyl Hydroxy Benzoate
319	S.O.1023(E)	Bromhexine + Dextromethorphan
320	S.O. 1024 (E)	Dextromethorphan + Chlopheniramine +Bromhexine
321	S.O.1025(E)	Menthol + Anesthetic Ether
322	S.O.1026(E)	Dextrometharphan + Chlopheniramine + Ammonium + Sodium Citrate + Menthol
323	S.O. 1027 (E)	Ergotamine Tartrate + Belladona Dry Extract+Caffeine + Paracetamol
324	S.O. 1028 (E)	Phenytoin + Phenobarbitone
325	S.O. 1029 (E)	Gliclazide 40mg + Metformin 400mg
326	S.O. 1030 (E)	Paracetamol + Ambroxol + Phenylephrine + Chlorpheniramine
327	S.O. 1031 (E)	Oflaxacin + Ornidazole Suspension
328	S.O. 1032 (E)	Albuterol + Etofylline + Bromhexine + Menthol
329	S.O. 1033 (E)	Albuterol + Bromhexine + Theophylline
330	S.O. 1034 (E)	Salbutamol+Hydroxyethyltheophylline (Etofylline) + Bromhexine
331	S.O. 1035 (E)	Paracetamol+Phenylephrine+Levocetirizine+Sodium Citrate
332	S.O. 1036 (E)	Paracetamol + Propyphenazone + Caffeine
333	S.O. 1037 (E)	Guaifenesin + Diphenhydramine + Bromhexine + Phenylephrine
334	S.O. 1038 (E)	Dried Alumnium Hydroxie Gel + Prophantheline + Diazepam

335	S.O. 1039 (E)	Bromhenxine + Phenylephrine + Chlorpheniramine + Paracetamol
336	S.O. 1040 (E)	Beclomethasone + Clotrimazole + Gentamicin + Iodochlorhydroxyquinoline
337	S.O. 1041 (E)	Telmisartan + Metformin
338	S.O. 1042 (E)	Ammonium Citrate + Vitamin B 12 + Folic Acid + Zinc Sulphate
339	S.O. 1043 (E)	Levothyroxine + Phyridoxine + Nicotinamide
340	S.O. 1044 (E)	Benfotiamine + Metformin
341	S.O. 1045 (E)	Thyroid + Thiamine + Riboflavin + Phyridoxine + Calcium Pantothenate + Tocopheryl Acetate + Nicotinamide
342	S.O. 1046 (E)	Ascorbic Acid + Manadione Sodium Bisulphate + Rutin + Dibasic Calcium Phosphate + Adrenochrome mono Semicarbazone
343	S.O. 1047 (E)	Phenylephrine + Chlorpheniramine + Paracetamol + Bromhexine + Caffeine
344	S.O. 1048 (E)	Clotrimazole + Beclomethasone + Lignocaine + Ofloxacin + Acetic Aicd + Sodium Methyl Paraben + Propyl Paraben

INFORMATION

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

Profile of 1st Rank Projects

PHARMACEUTICS

Name: Ms. V. P. Shilpa

Project Title: "Formulation and Evaluation of matrix-based sustained release tablets of quetiapine fumarate using citrus pomelo fruit peel as a natural polymer"

College: College of Pharmacy, SRIPMS, Coimbatore

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

PHARMACEUTICAL CHEMISTRY

Name: Ms. R. Kalaiselvi

Project Title: Design, Synthesis, Characterisation and Biological evaluation of some new heterocyclic derivatives as anti-tubercular agents

College: Madras Medical College, Chennai

Guide's Name: Dr. A. Jerad Suresh

PHARMACEUTICAL ANALYSIS

Name: Ms. K. Arthi

Project Title: "Development of validated stability indicating HPTLC method for the determination of Roflumilast in tablet dosage form and its application to accelerated stability studies"

College: College of Pharmacy, SRIPMS, Coimbatore

Guide's Name: Dr. A. Suganthi

PHARMACOLOGY

Name: Mr. Raj Kumar Pradhan

Project Title: Mechanistic Evaluation of Antiparkinson effects of sigma-1 receptor against , Fabomotizole, in 6- OHDA induced rat model.

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. K. Elango

PHARMACOGNOSY

Name: Mr. M. Asuvathaman

Project Title: Phytochemical characterization of potential Anti-filarial fractions isolated from various extracts of leaves of vitex negundo and lantana camera linn (verbenance)

College: Mother Theresa Post Graduate & Research Institute of Health Sciences, Puducherry

Guide's Name: Prof. Dr. V. Gopal

PHARMACY PRACTICE

Name: Ms. A. Sravanthi

Project Title: A Randomized, Double-blind, Placebo Controlled Trial of OBERAY (Ayurvedic Medicine) in overweight and obese adult population

College: SRM College of Pharmacy, Kattangulathur

Guide's Name: Dr. T. M. Vijaya Kumar

PHARM D- PHARMACY PRACTICE

Name: Ms. Ria Rose Roy, Ms. Subitha Babu, Ms. Shilpa Cyril, Mr. Mohammad Kamal

Project Title: Public Perception and Knowledge on Medication Errors

College: JSS College of Pharmacy, Ooty

Guide's Name: Dr. Ponnusankar

PHARM D- CLINICAL PHARMACY

Name: Ms. DesuSwathi, Ms. Kshitiji Sharma, Ms. Ponaki Lakshmi, Ms. Reeba Elizabeth Royce

Project Title: Ethnographic study to evaluate the role of Mid-regional pro-Adrenomedullin as a cardiac biomarker and to study the cost of illness in Acute Coronary Syndrome.

College: SRM College of Pharmacy, Kattangulathur

Guide's Name: Dr. S. Venkatraghavan

EVENTS

National Level Seminar at S. A. Raja Pharmacy College, Tirunelveli

S. A. Raja Pharmacy College, Tirunelveli, organized the National Level Seminar on "Analytical and Bio analytical techniques in plant Research" on 23rd January 2016. The seminar was inaugurated under the Chairmanship of Dr. S. A. Jacob Raja, and Dr. Mrs. Ajitha Das Aruna, Joint Director of Medical Education (Pharmacy) as chief guest.

Dr. S. N. Meyyanathan, Professor & Head Dept. of Pharmaceutical Analysis, JSS, Ooty, gave a lecture on the topic "Bio-Analytical method development theory and applications" and the scientific session was presented by Dr. K. B. Ramesh Kumar M.Sc.,Ph.D, Scientist "C" Phyto Chemistry Division, Jawaharlal Nehru Tropical Garden Research Institute, Trivandrum on "Advances in Phytochemical Analytical Techniques". Around 700 delegates participated from various colleges and universities from various parts of India. Poster presentation was also held and best three posters were awarded with certificates and cash prizes.

Lecture on Viral Diseases at Periyar College of Pharmaceutical Sciences, Trichy

An invited lecture was arranged by Periyar Health Club of Periyar College of Pharmaceutical Sciences, Trichy on 27th Feb. 2016 to create awareness about the various fatal viruses that anchor more than a million people to death. Dr. R. Senthamarai, Principal welcomed the gathering. Dr. S. Dhanapaul, Professor & Head, Dept. of Microbiology, KAPV Govt. Medical College and Hospital, Tiruchirappalli delivered a lecture on "Emerging Viral Diseases". In his lecture he deliberated on the unrestrained devastation and misery caused by different types of viruses including plague, swine flu, dengue, ebola and zika viruses. He anecdote on the various causative factors and ill effects of these worldwide pandemic diseases through power point presentation in a lucid manner. He added that by removing the major health threats, eradication of disease provides one of the greatest health benefits for humankind. In the future, the biotechnology revolution will likely yield numerous new vaccines, even for diseases considered chronic and degenerative, thus it is very important that we continue to search for those diseases that could eventually be eradicated. He also stressed on the precautionary measures to be taken by the individual and Government to avoid getting infected by the emerging viral diseases. Dr. A.M. Ismail, Professor and Dr. G. Krishnamoorthy, Vice Principal graced the programme. Staff of Periyar Centenary Educational Complex, Senior Citizens of Samy Kaivalyam Home and Faculty & students of the institution attended the programme.

One Day Workshop at Periyar College of Pharmaceutical Sciences, Trichy

A one day workshop on "Traditional Medicines - Current Approach" was organized by Periyar Technology Business Incubator (PTBI), Trichy Centre of Periyar College of Pharmaceutical Sciences, Trichy on 13th February 2016. The workshop began with Inaugural function. Dr. T. Shri Vijaya Kirubha, Head, Dept. of Pharmacognosy welcomed the gathering. Prof. Dr. R. Senthamarai, Principal delivered the Presidential address. In her address, she charted out how traditional medicines serve as an important element of our National healthcare system. She also explicated on the ill effects of Fast food and portrayed on the effectiveness of traditional medicine. Prof. Dr. V. Gopal, Principal, College of Pharmacy, Mother Theresa Post graduate and Research Institute of Health Sciences, Puducherry inaugurated the workshop and highlighted the importance of traditional medicines. He stressed on the importance of documenting and protecting these medicines. One of the renowned alumnae Mrs. Nagalakshmi Gopal graced the occasion.

As a part of the programme, Dr. S. Ashok, Managing Director, Saravana Hospitals, Salem delivered a lecture on "Innovations in Global Herbal Health Industry" followed by Mr. N. Kanagasabapathy, President of The Tiruchirappalli District Tiny and Small Scale Associations (TIDITSSIA) spoke on "Global Marketing of Herbal Medicines". Dr. C. Shahul Hameed, IMCOPS (Indian Medical Practitoners Co-operative Pharmacy & Stores Ltd.) Consultant, Trichy Branch prepared some herbal formulations during the demo session.

Dr. S. Ashok, MD, Saravana Hospitals, Salem delivered the Valedictory address in the evening. In his address he attributed on the current situation of traditional medicine in terms of providing basic health coverage and stressed about the concrete steps to be taken to globalise traditional medicine. Prof. Dr. R. Senthamarai, Principal delivered the presidential address and called upon the delegates to actively involve in traditional medicine research. Nearly 214 delegates from various Universities, Pharmacy, Arts and Science Colleges, Siddha practioners and Entrepreneurs from TamilNadu & Puducherry actively took part in the Workshop. Dr. C. Shahul Hameed, IMCOPS Consultant, Trichy Branch, Mr. G. Sebastian, Correspondent, Dr. A. M. Ismail, Emeritus Professor and Dr. G. Krishnamoorthy, Vice Principal graced the occasion.

NEWS

Implementation of Track and Trace System For Export of Pharmaceuticals and Drug Consignments

PUBLIC NOTICE NO. 52/2015-2020, Dated: January 5, 2016

In exercise of the powers conferred under Paragraph 2.04 of the Foreign trade Policy, 2015-20, as amended from time to time, the Director General of Foreign Trade hereby amends Para 2.89A of Handbook of Procedure, 2015-20, as notified vide Public Notice No. 4/2015-20 dated 1.04.2015 (as amended), as under, for laying down the procedure for implementation of the Track and Trace system for export consignments of drug formulations:

2. "2.89A

Procedure for Implementation of the Track and Trace system for export drug formulations

i. The manufacturer or the exporter of drug formulations will print the barcode as per GSI Global Standard at different packaging levels to facilitate tracking and tracing of their products. The details are as follows:

a) Primary Level:

Incorporation of two dimensional (2D) barcode encoding unique and universal global product identification code in the format of 14 digits Global Trade Item Number (GTIN) along with batch number, expiry date and a unique serial number of the primary pack. The bar code labeling at primary level is exempted till further notification, however, the above mentioned details are required to be printed in human readable form on optional basis till further notification.

b) Secondary level:

Incorporation of one or two dimensional (1D or 2D) barcode encoding unique and universal global product identification code in the format of 14 digits Global Trade Item Number (GTN) along with batch number, expiry date and a unique serial number of the secondary pack. However, in case of mono cartons manufacturer or exporter shall affix bar code on mono carton containing one primary pack on optional basis till further notification.

c) Tertiary Level:

Incorporation of one dimensional (1D) barcode encoding unique and universal global product identification code in the format of 14 digits Global Trade Item Number (GTIN) along with batch number, expiry date and a unique serial number of the tertiary pack i.e. Serial Shipping Container Code (SSCC).

ii) Parent – Child Relationship / Effective dates for SSI and Non - SSI Manufacturers:

The manufacturer or exporter shall maintain the data in the parent-child relationship for three levels of packaging i.e. Primary, Secondary and Tertiary packaging and their movement in its supply chain.

a) All Manufacturers (SSI & Non-SSI Manufacturers):

As one time exemption all manufacturers are exempted from maintenance of Parent-Child relationship in packaging and its uploading on central portal (http://dava.gov.in) till 31.03.2016. However, the requirements of printing of bar-coding on the different levels or packaging will be applicable as prescribed.

b) Extended date of Exemption to SSI Manufacturers:

All SSI drug manufactures are exempted from requirement of maintaining Parent-Child relationship in packaging levels for a further period up to 31.03.2017. However, they are required to upload Tertiary level data on the central portal mandatorily as prescribed in public notice no. 13/2015-2020 dated 22.05.2015.

iii) The data mentioned in (ii) above shall be uploaded on the central portal of the Government of India by the manufacturer or exporter or its designated agency before release of the drug formulations for sale or distribution.

iv) The responsibility of the correctness, completeness and ensuring timely upload of data on the central portal shall be with the manufacturer or exporter.

v) The above rules (i) to (iv) will not be applicable to those drug formulations manufactured for export purposes, where the government of the importing country has mandated or formally notified its intention to mandate a specific requirement and the exporter intends to avail the option of printing the barcodes in their format after duly obtaining the permission of DCGI or its nominee. However, the tertiary level of packaging will have additional printing of barcode as per (i) (c) above in addition to importing country's requirement, if any.

vi) Export of drugs manufactured by non-SSI units and having manufacturing date prior to 31.03.2016 and export of the drugs manufactured by SSI units and having manufacturing date prior to 31.03.2017 are exempted from requirement of data uploading on Central Portal.

vii) All drugs manufactured by non SSI units with manufacturing date on or after 01.04.2016 and all drug manufactured by SSI units with manufacturing date on or after 01.04.2017 can be exported only if both tertiary and secondary packaging carry bar-coding as applicable and the relevant data as prescribed by DGFT is uploaded on the Central Portal.

Explanation:

(a) For the purpose of this rule,

(i) Drug formulation means a formulation manufactured with a license from Drug Control Authority under the provisions of Drugs & Cosmetics Act and Rules made there under and registered as “Drug with the FDA of importing country.

(ii)Primary packaging means the package which is in direct physical contact with the active ingredient.

Secondary packaging means a carton containing one or more primary packs and includes a mono carton containing one primary pack.

The tertiary packaging means a shipper containing one or more secondary packs.

(b) All relevant guidelines regarding grant of specific exemption(s) if any, procedure of data requirement / maintenance / upload on central portal and clarifications issued under this notification etc., will be available on the central portal i.e. http://dava.gov.in

(c) It will be the responsibility of the drug manufacturers/exporters as the case may be, to satisfy the customs authorities that the export consignment satisfies the conditions of the notification”.

3. Effect of this Public Notice:

In suppression of the earlier Public Notice no. 13/2015-2020 dated 22.05.2015, the dates for implementation of Track and Trace system for export of drug formulations along with maintaining the Parent-Child relationship in packaging have been extended to 01.04.2016 for non SSI manufactured drugs and to 01.04.2017 for SSI manufactured drugs.

(Issued from F.No.01/91/180/648/AM09/Export Cell)

(Anup Wadhawan)

Director General of Foreign Trade

Source: *Small Industry, Volume: 25 - Issue 01, January – 2016*

F.No. 7-5/2016/BC/005
Directorate General of Health Services
Office of drugs Controller General(India)

To

07 MAR 2016

Director General Foreign Trade,
Department of Commerce,
Ministry of Commerce & Industry,
Udyog Bhawan, New Delhi

Subject: Implementation of track & trace system for export of pharmaceuticals and drug consignments – regarding

Sir,

Reference is invited to your public notice no. 52/2015-2020 dated 5.01.2016 pertaining to the captioned subject. The notification prescribes certain barcoding requirements for export of drug formulations. However, provisions from 2(i) to 2(iv) of the aforesaid notification will not be applicable to those drug formulation manufactured for export purposes, where the government of importing country has mandated or formally notified its intention to mandate a specific requirements and the exporter intends to avail the option of printing the barcode in their format after duly obtaining permission from the office of DCGI or its nominee. However, the tertiary level of packaging will have additional printing of barcode as per (i) (c) above in addition to importing country's requirement, if any.

We have received various applications from importer requesting waiver of the aforementioned barcoding requirements on formulations for export. The applications have been examined along with the provisions of the public notice issued by the DGFT. The aforesaid exemption has to be accorded under the provision of Handbook of Procedures, 2015-2020 regulated by the DGFT. Further, this office does not have a mechanism to verify the claim of the exporter that the Government of the importing country has actually issued a specific requirement for printing of the barcode. Therefore, it is opined that it would be appropriate if the exemptions are issued by the DGFT which is the competent authority rather than the DCGI. This office would extend all its cooperation required in this regard.

Yours faithfully
07-03-16
(Dr. G.N. Singh)
Drugs Controller General (India)

Copy to: PPS to JS (R) for information

Sun Plans to Sell a Few Ranbaxy Brands

Drug maker Sun Pharmaceuticals has put on the block a bundle of Ranbaxy brands which are low priority in its domestic market strategy or which may overlap with its own products, top industry executives said.

The country's largest drug maker completed acquisition of Ranbaxy last year from its Japanese owner, Daiichi Sankyo, as part of a $4 billion all-stock deal. The Ranbaxy brands that Sun is looking to sell rake in about Rs 115 crore in annual sales and the company is expecting a valuation of about 2.5x or Rs 250-270 crore for them, they said.

Sun declined to comment on the matter. The persons quoted earlier said the deal has been in the market for over two months but the response has been lukewarm as some drugs on offer are seeing declining sales.

But the bigger hurdle to the deal being attractive, according to them, is that the products belong to a wide range of segments from orthopedics, anti-infective, urology, oncology, respiratory, anti-diabetes and dermatology. A broad product basket makes it tough for a single buyer to take a consolidated marketing approach, they said.

Among the products on Sun's sale list is Fortwin, a narcotic-based drug used to treat severe pain conditions. The drug generated Rs 35 crore revenue last year, down 30 per cent from the previous year, industry executives said.

The government has tightened regulations on sale of drugs in this category, making it difficult for the distribution chain to store and maintain records, which is one of the reasons cited for the shrinking sales of the product. However, a few other brands that form part of the offer are showing strong growth. For instance, Romilast, which is used in respiratory conditions, and Mobiswift, a drug used to relieve muscle spasm, are showing an uptrend, executives said.

Sun has also put up for sale Insucare, one of the many insulins in the market, according to one executive who said, "Insulin is heavily dominated by big multinationals and the product is fetching low margins."

Broadly, Ranbaxy's brands in the cardiovascular and diabetes segment saw sales of Rs 21 crore last year, while orthopedic drugs brought in Rs 52 crore. Sale of drugs in the respiratory, urology, oncology and dermatology segments stood at Rs 19 crore, Rs 8 crore, Rs 9 crore and Rs 3.5 crore, respectively.

Last week, the Competition Commission of India cleared Strides Shasun's Rs 165-crore deal to acquire two divisions of Sun Pharma that deal in neurology products.

Offer List for Sale

Key Brands:

- Fortwin - Pain conditions
- Romilast - Respiratory conditions
- Mobiswift - Muscle Spasm relief
- Insucare - Type I diabetes
- Pioglar - Anti-diabetes

Key Therapy Areas:

- Cardiovascular and diabetes : Rs 21 cr
- Orthopedic : Rs 52 cr
- Respiratory : Rs 19 cr
- Urology : Rs 8 cr
- Dermatology : Rs 3.5 cr
- Oncology : Rs 9 cr

Sun market Share

(Dec 2015 MAT)

9.2% of Rs 97,000 cr market size

Source: *The Economic Times, 29th January 2016*

USFDA Red-flags Lack of Controls at Wockhardt Unit

The US Food and Drug Administration's inspection at Indian drug maker Wockhardt's plant at Shendra earlier this month found a series of violations, including lack of controls to ensure that only authorised personnel could make changes to records and a bag of unaccounted shredded documents in a laboratory.

Wockhardt's Shendra unit near Aurangabad, which supplies products to some developed markets, was inspected from January 4 to 12, ahead of initiating supplies to the US. The FDA had listed nine observations related to processes followed at the plant, which Wockhardt later clarified were not of a serious nature. The details of the observations were not known until now.

One observation noted by FDA investigators in Form 483 showed that appropriate controls had not been exercised over computers and related systems to ensure that changes in master production and control records are instituted only by authorised personnel, according to the regulator's document available with ET Now, the business news channel of ET.

The FDA observed that written production and process control procedures had not been documented at the time of performance. The FDA officials said they discovered one bag of unaccounted shredded documents next to a shredder machine located inside the microbiology quality control laboratory. The bag included indistinguishable controlled documents, signed laboratory worksheets and work reports containing uncontrolled notes about work being performed and schedule planning for the quality control testing laboratory.

The FDA made nine observations, for which appropriate reply would be submitted to the inspecting authority in due course, Wockhardt said in a stock exchange filing on January 15. Chairman Habil Khorakiwala said on January 19 that some of the observations could be addressed in the short term and a few may take a couple of months.

One observation in Form 483 signed by investigators Daniel J Roberts and Dipesh K Shah noted that the aseptic processing areas were deficient regarding the system for monitoring environmental conditions.

Source: *The Economic Times, 29th January 2016*

WHO Certifies Vaccine Maker GreenSignal Bio

Geneva-based World Health Organisation (WHO) has accorded PQP (Pre-qualification of Medicines Programme) certification to the city-based GreenSignal Bio Pharma Pvt. Ltd., a BCG vaccine-making firm.

GreenSignal is the second Indian company to get PQP certification from WHO.

PQP certification helps GreenSignal to participate in the global immunisation programme, which is facilitated through international procurement agencies such as UNICEF and others. These global institutions go by the WHO's list of pre-qualified products while making a decision on procurement for medicines for distribution in resource-limited nations.

Headed by former Chief Election Commissioner, Mr. N. Gopalaswamy, GreenSignal has a full-fledged BCG vaccine production facility at

Gummidipondy in Thiruvallur district. Set up on a two-acre land, the facility has the capacity to churn out 60 lakh vials. At the moment, the company has been supplying BCG vaccine to the Government of India and Indonesia, The WHO certification will provide GreenSignal access to 5-7 countries with UNICEF setting it year-wise allotment target for supply of BCG vaccine.

Mr. P. Murali, Managing Director, said the company was in the process of setting up a greenfield project near Thiruvallur to expand its product range. He expected the project to go on stream in a year or so. The upcoming facility would produce new vaccines such as MMR, DTP, HepB, TT and HPV

Source: *The Hindu, 5th February 2016*

Stem Cell Therapy Safer for Skin Care : Docs

At 20, all Sharmila wanted was a lighter skin and for her, the only solution to get that fairer look was the cream her classmate suggested. It would lighten the pigmentation on her skin and she could finally fulfill her dream. Within days, she saw a remarkable difference with the topical steroids.

However, her happiness was short lived. In less than six months, Sharmila had red patches and pimples. Her dermatologist told her the steroids had made her skin thinner and caused serious damage to the cells. Sharmila was put on a long-term therapy to rejuvenate her skin cells.

Sharmila is not the only one. Sadly , at least 10% of patients that dermatologists see at their clinics have been opting for unsafe treatment to have a "glowing, young and lighter" skin. Senior dermatologists Dr Sarveshwari and Dr Shobana, said doctors' bodies like Indian Dermatology Association have been lobbying with the government to ensure that pharmacists do not offer topical steroids over the counter. "Steroids are given as a treatment for some medical problems. It is not to lighten skin," she said.

The doctors pushed for non-invasive "safer" options such as topical stem-cell therapy, which can repair dry skin, dull complexion, wrinkles and pigmentation.

Some creams can also reverse grey hair.

These topical creams contain bone-marrow-derived-stem-cell-stimulating peptides and enzymes that aid epidermal growth factors. "We have been using them for three years and we have seen no adverse skin reactions. Everyone wants to look young and beautiful and we tell them to opt for safer options," said Dr Sarveshwari, consultant dermatologist, Sundram Medical Foundation.

They admitted that stemcell based topical creams are so far considered safe because they have been in use only for the past few years and there has been no detailed evidence to show it is "unsafe".

The treatment costs anywhere between Rs 1,000 and Rs 3,000 for topical creams and the course may take up to two years. "At present it is not covered by insurance companies but we recommend it to our patients because we know it is safer than self prescribed steroids," said Dr Shobana.

Source: *The Times of India, 13th February 2016*

Ranbaxy Whistle Blower may Bat for Drug Quality in India

Dinesh Thakur, who rattled the generic drug industry in India through his expose of malpractices in Ranbaxy as a whistleblower, may be looking to address issues related to the quality of pharmaceutical products in the country.

He's considering plans to set up a patient advocacy group that will aim to increase transparency and accountability among drug makers in India, according to people aware of the matter. Thakur is said to have approached public relations companies in India to initiate the campaign that will try to raise matters related to drug safety standards.

Thakur, however, denied any such plans in an email to ET. However, others said Thakur has shared his ideas with a few people on how the process could be taken forward.

Such a move, if it does come about, would take place at a time when top Indian drug makers face US Food and Drug Administration strictures over non-compliance with the quality standards.

Since November 2015, the US FDA has issued warning letters to leading Indian drugmakers Sun, Dr Reddy's and Cadila for not complying with good manufacturing practices. Though warning letters are not uncommon in the drug business, observations on data integrity and quality of manufacturing are serious matters, experts said.

Also, since the Ranbaxy scandal, there has been increased scrutiny of drug makers in India by the US FDA. Nearly 40% of drugs consumed by US patients is manufactured by Indian generic makers. The companies are in firefighting mode as 40% of revenue at large Indian generic makers comes from the US market.

If Thakur was to indeed launch such an initiative, the Indian Drug Controller may be nudged into establishing similar standards of quality as practiced by global regulators, experts said. In 2012, a parliamentary committee report on health and family welfare revealed mismanagement at the Central Drug Control Board and alluded to collusion with pharmaceutical companies.

"The committee is of the firm opinion that most of the ills besetting the system of drugs regulation in India are mainly due to the skewed priorities and perceptions of CDSCO (Central Drugs Standard Control Organisation)," the committee had noted. "For decades together it has been according primacy to the propagation and facilitation of the drugs industry, due to which, unfortunately, the interest of the biggest stakeholder i.e. the consumer has never been ensured."

Experts have repeatedly called into question inspection norms followed by Indian agencies for enforcement of quality standards at local sites. Although the Drug Controller General of India puts up a periodic list of the companies that are found supplying drugs that are not of standard quality in the country, experts feel the system needs to be tightened further to scale up to global standards

Source: *The Economic Times, 16th February 2016*

Tweak Rules to Aid 'Brand Pharma'

After 'Brand India' drug companies need to create 'Brand Pharma' for which the government should tweak laws, create a robust infrastructure which fosters innovation, and strengthen regulatory compliance to world standards. This will accelerate growth and help industry to achieve the $ 55 billion turnover by 2020, industry bigiwgs at the Make in India session said.

Kicking off the inaugural session on 'Indian Pharmaceuticals Industry – Aligning with Make in

India Vision', here on Tuesday, Pankaj Patel CMD Zydus Cadila, said the Indian pharmaceutical industry is poised to reach $55 billion, of which $30 billion will be exports. The crucial factors to make this happen are affordability, strong infrastructure, and, most important, the ease of doing business. "We need to think how to create ease of doing business without comprising quality and affordability", he said, adding, regulation of prices is welcome, but only those of essential medicines.

Agreeing with his views on a simpler duty structure and quality standards, Rajiv Modi, CMD, Cadila Pharma said the domesitc pharma industry can become a global manufacturing hub, and a future global innovation hub.

He said "Brand pharmaceuticals made in India should be created just like 'Brand India'. Let Indian standards be escalated to be better than the best".

The Centre is coordinating closely with the states to improve productivity, Hansraj Gangaram Ahir, Minister of State, Department of Pharmaceuticals assured the industry, adding, a constructive dialogue is on (with industry) to address all issues, including that of price control, procuring land and environmental clearances. Dr V.K. Subburaj, Secretary Department of Pharmaceuticals said local reach of medicines is poor, with only 20% of patients accessing medicines.

Source: *The Times of India, 17th February 2016*

Fix Compliance Woes, Say Pharma Honchos

Some of India's top pharmaceutical entrepreneurs have urged the industry to fix their compliance issues with regulators to create India's image as the producer of best quality medicines and give fillip to the government's Make in India initiative.

Dilip Shanghvi, Managing Director of the country's largest drug maker Sun Pharma; Pankaj Patel, Chairman and MD of Zydus Cadila, and Rajiv Modi, CMD of Cadila Pharmaceuticals, also urged drug makers to innovate to leap to the next level of growth in the sector. " I see India as the potential pharmacy hub of the world, if we make a few changes to the way we do business in India and the way we manage our business in India week in Mumbai on Tuesday. " We should focus on fixing the compliance. If we achieve the regulatory capability where mutual recognition of manufacturing in India is accepted globally, it will significantly improve the perception of quality of Indian products, " he said.

Shanghvi said companies need to move beyond being mere generic players and look to innovate to capture the potential $800 billion pharmaceuticals market. His statements come at a time when the Indian generic industry, which manufactures nearly half of the drugs consumed across the world, has been battling a perception issue of not being quality compliant.

Shanghvi said there is a need to fix the curriculum of pharmacy colleges in India where many of the current pains of the pharma sector, such as data integrity, is not given priority.

Modi of Cadila Pharmaceuticals said India's regulatory standard should be raised at par with global agencies, a move that would quash any doubts about the quality of drugs coming from India. He also gave a bold call of abolishing price control. Modi's thoughts were echoed by Pankaj Patel of Zydus Cadila who said the government should control only prices of essential drugs. Patel also lashed out at the clinical research guidelines of India, calling it the "worst guidelines in the world".

Source: *The Economic Times, 17th February 2016*

Ban Unregulated Sale of Online Drugs, Says PIL

A businessman has moved the Madras high court, seeking a ban on online portals selling scheduled drugs without doctors' prescription, and without any regulatory mechanism.

The first bench comprising Chief Justice Sanjay Kishan Kaul and Justice M M Sundresh issued notices to state and central drug standard and control authorities, on the PIL filed by N Ruthramoorthy of Salem, on Tuesday . The court posted the case to April 4 for further hearing.

"Medicines are not simple tems of commerce, they are essential components [for] health. They must be administered in a timely manner, as prescribed by [a doctor]," Ruthramoorthy said, adding that as on date, India had no tele-medicine law for online sale of medicine.

The petition said Schedule-H and H1drugs, which cannot not be sold without a prescription, were being sold by at least 3,000 drug stores online in violation of Rule 65 of Drugs and Cosmetic Rules, 1945.

Besides seeking a ban on these online stores, the PIL wanted action against the websites concerned for having allowed such sale network and a committee to find the total number of websites in India selling schedule H, H1 and X medicines.

These 3,000 websites offer attractive discounts which are impossible in open market sale, he said. Some websites offer even money back guarantee in case of problems, he added. Many of these websites function from outside the country , violating laws of India, he said.

The petitioner said, "It is necessary to have a strict ehealth laws and regulations in our country , and it is also necessary to have dedicated laws for websites selling drugs online."

Source: *The Times of India, 17th February 2016*

Bulk Drug Policy to be Unveiled

Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers is expected to come out with a new bulk drug policy in less than a month with an objective to grow the Indian pharmaceuticals sector to a $200 billion industry by 2030.

Under this policy, the government wants to build an ecosystem to help pharma companies to move up in the value chain and develop new molecules through innovations.

“We are coming out with a new policy. This policy should been announced six months back. Now it will be unveiled in less than a month,” said Dr V K Subburaj, Secretary, Department of Pharmaceutical, Ministry of Chemicals and Fertilizers said.

The industry which grew in the last 15 years has potential to be a $200 billion industry and can be the world's largest if it scales up and moves up the value-chain.

Until 1970 India was dependent on other countries for its pharmaceutical requirements and in 20 years' time, it became self sufficient to meet its own requirements, he said.

“India has now become a superpower as far as generic drugs are concerned. India can become a $300 billion industry including medical devices by 2030,” he said quoting a FICCI report.

As per this report the country's pharmaceutical industry has the potential to touch $200 billion by

2030 from the present $32 billion. And the medical devices segment can grow from $5 billion now to $100 billion.

“This is a herculean task, but possible. We must get into development of new molecules and have new drug discovery which is currently lacking. We should reach this level,” he said.

“If we concentrate on states where growth is less, we should be able to achieve the infrastructure requirements of the pharmaceutical industry,” he added.

The industry is growing at 8-9 per cent per annum at present, and even if we maintain the same growth rate, we can reach $110 billion by 2030, Subburaj said, adding that we need to overcome several challenges to achieve this herculean task.

“To overcome the quality problems, we need to have our own APIs manufacturing capacities. The new bulk drug policy will help in increasing the domestic bulk drug production and reduce dependence on Chinese imports,” he said.

Union Minister Hansraj Ahir while speaking at this seminar said that the new policy is aiming at bringing down imports of bulk drugs and increasing the domestic output.

Bulk Drugs otherwise called APIs are active raw materials that provide therapeutic effect to drugs. India is dependent on China for APIs and there is a concern on quality.

Dilip Shanghvi, Managing Director, Sun Pharmaceuticals said industry must focus on innovation and adopt international practice.

“I see India as a potential pharmacy hub for the world,” he said, adding, “If we make a few changes in the way we do and manage business in India, we can accelerate that process.”

He said the regulatory framework must be strengthened and brought on par with international practices.

Source: *The Hindu, 18th February 2016*

Cipla Acquires Two U S Generic Drug Companies

Cipla Ltd., acquired two U.S. generic drug companies, InvaGen Pharmaceuticals Inc., and Exelan Pharmaceuticals Inc., to increase its revenue and introduce new products for oncology and diabetes in the world's largest pharmaceutical market, according to a company statement. The Mumbai-headquartered Cipla closed the transaction through its wholly-owned subsidiary, Cipla (EU) Ltd., according to the statement.

The combined revenue for the two companies for the year ended 2015 was over $230 million.

“The acquisition will further strengthen Cipla's presence in the U.S. pharmaceutical market. InvaGen's balanced portfolio, robust manufacturing base and strong R&D capabilities will act as lever to expand Cipla's reach in the U.S. market,” Umang Vohra, Global Chief Operating Officer, Cipla Ltd said in the statement.

The acquisitions will give scale to Cipla's US business — currently 8 per cent of total revenue — as well as providing a launch pad to introduce Cipla's pipeline of products in respiratory and injectables, among others, in the coming years, according to the statement. This is the second large scale acquisition in Cipla's 80 year history — the first was Cipla Medpro, South Africa.

“Combined with the pipeline of InvaGen products, the overall portfolio will be wide-ranging and will cover chronic therapies like CVS, CNS, respiratory, oncology and diabetes among others,” according to the company.

The acquisition of InvaGen pharmaceuticals also provides Cipla with about 40 approved Abbreviated New Drug Application (ANDA), a U.S. generic drug approval for an existing licensed medication or approved drug., 32 marketed products, and 30 pipeline products which are expected to be approved over the next four years. In addition, InvaGen has filed five first-to-file products.

Dosage forms include immediate release, modified release and extended release tablets and capsules.

Source: *The Hindu, 19th February 2016*

Prices of Essential Drugs to be Cut By 3% From April

There may be good news for patients at the start of new financial year. Prices of all essential medicines, including painkillers, anti-infectives, anti-diabetes, cardiac and antibiotics, are expected to be revised downwards in April by nearly 3%, resulting in substantial savings in treatment costs.

This will be the first time that prices of nearly 750-odd essential formulations (part of the National List of Essential Medicines) will witness a price drop across the board, since the National Pharmaceutical Policy was implemented in 2013. The drop in prices will be in line with the change in annual wholesale price index, which was -2.75% (negative) for the January-December period.

Drug companies have already been sounded out by the government, sources said, adding, while a majority are agreeable, a few are not in favour. An industry body has already taken up the issue with the government, requesting it to drop the move.

The DPCO (Drug Price Control Order) 2013 lays down the provision for price revision in drugs, where manufacturers can change the maximum retail price (MRP) of scheduled formulations once a year, in April, on the basis of the WPI of the preceding calendar year, and, for this, no prior approval of government shall be required. Also, in case of a decline in wholesale price index, there shall be a corresponding reduction in the maximum retail price, it adds.

The DPCO 2013 covers about 18-20% of the organized pharmaceutical retail market valued at around Rs 96,000 crore.

Source: *The Times of India, 20th February 2016*

Antibiotics May Trigger Mental Confusion: Study

Common antibiotics may be linked to a serious disruption in brain function, called delirium, and other brain problems, researchers including one of Indian-origin have claimed.

Delirium causes mental confusion that may be accompanied by hallucinations and agitation. Medications are often the cause of delirium, but antibiotics are not necessarily the first medications doctors may suspect. "People who have delirium are more likely to have other complications, go into a nursing home instead of going home after being in the hospital and are more likely to die than people who do not develop delirium," said Shamik Bhattacharyya, of Harvard Medical School and Brigham and Women's Hospital in Boston. "Any efforts we can make to help identify the cause of delirium have the potential to be greatly beneficial," said Bhattacharyya.

For the study, researchers reviewed all available scientific reports and found case reports on 391 patients, over seven decades, who were given antibiotics and later developed delirium and other brain problems.

Source: *The Times of India, 22th February 2016*

MNC's Demand for Patent Irks Patients

Over the past week, hepatitis C patients have been protesting outside India's patent office in Dwarka here, against the American multinational pharmaceutical major Gilead Sciences and the United States government for pressuring the Indian government "to blindly and speedily grant patents".

The patent office has been hearing the 'companys patent claim on the blockbuster drug Sovaldi, which is priced at a staggering $84,000 (about Rs.57 lakh) in the U.S.

The proceedings will have major implications for millions of hepatitis C patients across the world who will be able to access the drug if open generic production of sofosbuvir is possible in India.

"Gilead is charging exorbitant prices in many countries and using patents to block people in other countries from buying low-cost, yet equally effective versions of this medicine", said Loon Gangte of DNP+ (Delhi Network of Positive Persons). "This is global treatment rationing. I feel like I'm back in the early days of the battle for HIV treatment, where you live or die based on where you live", he said.

On January 14, 2014, India's Deputy Controller General of Patents had rejected the company's patent claim, allowing generic drug makers to manufacture affordable versions of the drug.

The verdict was set aside by the Delhi High Court on January 30.

It is estimated that 150 million people are infected by hepatitis C globally, and 700,000 die of the disease each year. Untreated, it can cause liver cirrhosis and cancer.

Source: *The Hindu, 28th February 2016*

530 Essential Medicines to get Cheaper

In what could bring some relief to patients, 530 essential medicines including those of cancer, diabetes and hypertension are set to become cheaper by from April1.

The National Pharmaceutical Pricing Authority (NPPA) has revised price caps for all the essential medicines and notified new price ceilings based on the annual average inflation. According to estimates by the Central Statistical Office, the average annual inflation rate as measured by the WPI has fallen from 7.4% in 2012-13 to 2% in 2014-15 and further 2.8% in 2015-16 (up to January 2016)

The move assumes significance as this is for the first time the regulator has lowered the ceiling on essential medicines since the existing market-based drug pricing policy came into place in 2013.The downward revision by 2.7% is also expected to impact major pharmaceutical companies, mainly those with substantial share in essential drug segments such as GlaxoSmithKline pharma, Abbott , Lupin, Cipla and Dr Reddy's Laboratories. The local pharmaceutical retail market is pegged at over Rs 1 lakh crore annually. Around 18-20% of the market is presently under price control.

As per the National Pharmaceutical Pricing Policy,2013, MRP of all the scheduled or essential medicines are fixed by the NPPA based on the average price of all drugs in a particular therapeutic segment with at least 1% market share.

The policy also has a provision that provides for an annual increase or decrease in the ceiling price of such drugs based on the Wholesale Price Index, NPPA has used the provision to lower the prices of 530 medicines by 2.7%.

According to the NPPA notification, issued on March 3, the price revision is exclusive of local taxes which may be applicable to certain medicines. Recently, the government had withdrawn customs duty exemption and imposed excise duty on a host of life saving medicines. While the move attracted a lot of criticism as well as notices by the National Human Rights Commission (NHRC) to the finance and health ministries, the government meanwhile restored duty exemption of three of the 74 drugs involved. Experts say the latest price reduction on 530 essential medicines may not be enough to offset the hike due to duty revision.

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

The Antibiotic Red Line of Control

India faces a twin challenge of overconsumption of antibiotics breeding drug-resistant bacteria while ensuring that the poor and vulnerable have easy access

A much-needed public awareness campaign to highlight the dangers of misuse and irrational use of antibiotics was recently launched by the Ministry of Health and Family Welfare.

Called 'Medicines with the Red Line', it comes at a time when the consumption of antibiotics in India has increased sharply while the effectiveness of these drugs to treat bacterial infections has been steadily declining.

High disease burden, rising income, cheap, unregulated sales of antibiotics and poor public health infrastructure are some of the reasons for the sharp increase in antibiotic use. A report (August 2014) in the journal The Lancet Infectious Diseases, said that in 2010, India consumed 13 billion units of antibiotics, the highest in the world. Between 2005 and 2009, consumption shot up by 40 per cent.

A case of contradictions

And the impact of this unregulated usage is already showing. Between 2008 and 2013, E.colibacteria resistant to third-generation cephalosporins increased from 70 to 83 per cent; it went up from 8 to 13 per cent in the case of carbapenems and 78 to 85 per cent in the case of fluoroquinolone, notes a paper published on March 3, 2016 in PLOS Medicine.

The consequences of increased prevalence of antimicrobial resistance are best illustrated in the case of neonatal sepsis. On average 57,000 neonates die each year in India, the highest in the world, due to sepsis infection that is resistant to first-line antibiotics; in 2012, India had the highest neonatal deaths (nearly 7,79,000).

The irony is that at the same time, the lack of access or delayed access to effective antibiotics is causing more deaths in India than from drug-resistant bacteria. This is best revealed in the case of pneumonia in children under five years of age. Most of the 1,70,000 pneumonia deaths that occurred in this age group in India in 2013 could have been averted had these children had access to effective antibiotics, notes a paper published on November 18, 2015 in the journal The Lancet. Only 12.5 per cent of affected children received antibiotic treatment for pneumonia.

One way to reduce the dependence on antibiotics, particularly in the case of pneumonia, is by increasing the coverage of immunisation, which is currently hovering around 72 per cent for DTP (diphtheria-tetanus-pertussis).

So like many other developing countries, India has to turn the spotlight on ensuring sustainable access even while maintaining sustainable effectiveness of all antibiotics. The only way to achieve this twin objective is by ensuring that all stakeholders — government, patients, veterinarians, doctors, pharmacists, pharmaceutical companies and

health-care facilities — play their respective roles more responsibly.

First, people should be made aware that stopping antibiotics midway, missing doses, taking suboptimal dosages, or consuming antibiotics for cold and other viral infections, to name a few, makes them resistant to antibiotics; when ill the next time, their only recourse will be more expensive drugs or probably nothing at all. This is best exemplified in the case of multidrug-resistant tuberculosis that requires longer period of treatment using very toxic drugs that are more expensive.

Cracking down

For the government, the top priority should be to crack down on drug companies manufacturing irrational fixed-dose combination drugs. "A recent study reported fixed dose combinations and loose antimicrobials for tuberculosis. Loose antimicrobials come without packaging and do not mention the name of the drug, its manufacturer, the date of manufacture, or the date of expiry," notes the PLOS Medicine paper.

The government should also urgently regulate drug companies discharging antimicrobial waste into the environment and regulate the use of antibiotics in animal feed to combat antibiotic resistance and obtain healthier animal products — misuse of antibiotics in food animals is linked to the antibiotic resistance problems we face today. Better sanitation and effective infection control measures in health-care settings will also drastically cut the spread of drug-resistant strains.

As a 2013 study in Indian Journal of Medical Ethics revealed, knowledge of antibiotic resistance was "reasonable among doctors, but low in priority". Inadequate diagnostic facilities, lack of antibiotic guidelines and patients' demand for quick relief often determined doctors' prescription habits, besides incentives from drugs companies and chemists to push certain products.

The collusion of drug companies and chemists is also apparent in the rampant over-the-counter (OTC) sale of antibiotics, particularly carbapenems (that is among the highest in the world), even for ailments where they are not indicative. The introduction of Schedule H1 category from March 2014 to prevent the sale of 24 third- and fourth-generation antibiotics without prescription is a step in the right direction. Licences of 213 retail pharmacies have been cancelled for non-compliance.

But restricting OTC sales of antibiotics, particularly the commonly used ones, is a double-edged sword. Any intervention to limit access by enforcing prescription-only laws unwittingly cuts off a vast majority of the population, particularly in the rural areas, that lacks access to doctors.

Source: *The Hindu, 6th March 2016*

Higher Duty on Medical Devices may be Counter-Productive

The Union Budget exempted dialysis equipment from some customs duties to make the procedure more affordable. On the other hand, the costs of other critical, life-saving medical devices have risen by 17-18 per cent and are set to climb further, thanks to a flurry of recent government decisions that include a steep increase in customs duties, notified a month before the Budget.

Seventy five per cent of the medical devices used in India, including stents, catheters and cancer-treating equipment, are imported, and duty hikes are seen as a measure to prod global device manufacturers to make their products in India.

The industry, however, has warned the Prime Minister's Office, the ministries of Finance, Health, Industry and Commerce and the Department of

Pharmaceuticals, that the move will have dire implications on the healthcare costs of citizens, besides medical tourism. So far, their demand for a "complete and immediate" rollback of the duty increases, especially on products that cannot be manufactured in India, has been met with silence, rue industry representatives.

"Why are poor patients being made to pay for Make In India? The Budget has cut some duties on raw materials for medical equipment, but duties on devices were raised ahead of the Budget," said Pavan Choudary, Managing Director at Vygon and chairman of the medical equipment division at the Confederation of Indian Industry (CII). "You can't support Make In India at the cost of unsupporting Heal In India." Customs duties were raised by 7.3 percentage points for most medical device imports in January, taking the effective rates to the range of 18 per cent to 28 per cent. Taken together with the rupee depreciating by more than 10 per cent since January 2015, it means an effective increase of 17 per cent to 18 per cent in the cost of imported devices that is likely to be passed on to patients.

There was no nuanced look at what devices can be made in India and what cannot, while raising the duties, and lower duties (in the range of zero to five per cent) in neighbouring countries could spur a rise in smuggling of medical devices, industry officials argue.

"A blanket approach has been used to raise duties," Mr. Choudary said. The "protectionist step will deter new technologies from entering the Indian market, patients will be at risk if small bulk items are imported at cheaper rates from India's neighbourhood without any legal or service guarantees," he said. Separately, registration cost for medical device makers, which is currently at $1,000 per product category, is proposed to be raised to a range of $8,000 to $10,000. The registration costs are to be paid once in every three years.

On Tuesday, the Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers issued a draft notification proposing a 35 per cent cap on trade margins for pharma products and medical devices.

"How will this help Make In India? The government's policy on medical devices, starting from its decision to allow 100 per cent foreign direct investment last January, has gone from good to worse," said Himanshu Baid, Chairman of Poly Medicure Limited.

"You can't force people to make in India by raising customs duties, registration costs and stipulating what margins they can earn," said Mr. Baid, who heads CII's medical technology division.

"The government has announced many things, including the National Medical Devices Policy in April 2015, pursuing the passage of the Drugs and Cosmetics Amendment Bill (pending since 2013), but we are yet to see any movement on the ground," Mr. Baid said, adding that India's fledgling medical device industry was struggling in the "confusing policy environment".

Industry representatives expressed surprise at the government's move to relax duties on dialysis equipment and were curious as to how it would ensure that dialysis costs would actually reduce for patients as hospitals would not be obliged to pass on the cost savings on the equipment.

A dialysis machine costs Rs.7 lakh to Rs.10 lakh and India has an estimated 25,000 such machines. No Indian firm is in a position to manufacture dialysis equipment.

Source: *The Hindu, 10th March 2016*

U.S.Industry Body Says India Agreed to not Issue 'Compulsory' Drug Licences

India has given private assurances that it will not grant licences allowing local firms to override patents and make cheap copies of drugs by big Western drugmakers, a US business advocacy group said.

The comments were revealed in a submission last month by the US-India Business Council (USIBC) to the US Trade Representative (USTR), which is reviewing global intellectual property laws for an annual report identifying trade barriers to US companies.

The USTR has placed India on its "priority watch" list for two years in a row saying the country's patent laws unfairly favour local drug makers. A bone of contention has been a legal provision that allows the overriding of patents on original drugs and granting of 'compulsory licences' to local firms to make cheaper copycat medicines.

India can grant such licences under certain conditions, such as public health emergencies, to ensure access to affordable medicines for its mostly poor people. It granted the first such licence in 2012, allowing local firm Natco Ltd to sell a copy of German drugmaker Bayer's cancer medicine Nexavar at a tenth of the price.

Since that ruling, big Western pharmaceutical companies have criticised India's patent law and lobbied for it to be changed.

In its submission to the USTR, a copy of which was seen by Reuters, the USIBC said the government "privately reassured" the group that it would not grant such licences to firms for commercial purposes.

The government has made no such statements publicly. Officials have said they are committed to protecting the interests of patients.

Commerce Minister Nirmala Sitharaman, her joint secretary in charge of pharmaceuticals, and the USIBC did not respond to requests for comment.

Washington-based non-profit Knowledge Ecology International (KEI) expressed concern over the USIBC submission.

“If such an agreement in fact exists, this is extremely troubling news ... this sort of pressure is basically a declaration of war on poor cancer patients," KEI said in its own submission to the USTR last week. It called for details of the agreement to be made public.

Under Prime Minister Narendra Modi, India has been undertaking a review of its intellectual property (IP) policy. A revised policy is due to be released imminently.

Health activists have criticised the review, saying India is buckling under U S pressure and comprising patients.

The Medicine Sans Frontieres (MSF) charity, which largely depends on India to supply antibiotics and drugs to combat HIV, hepatitis C and tuberculosis for the developing world, called India's position “a deep concern”.

“India should take note that today globally patent monopolies are considered as the core reason for the ever-upward spiral of drug prices”, said Leena Menghaney, the South Asia head of MSF's access campaign.

Source: *The Hindu, 10th March 2016*

Pharmacy to the World Can't Make Diapers, Hospital Beds'

India is lagging in manufacturing medical devices and the recent increase in import duties on such devices are a 'corrective step' to create an ecosystem for manufacturing them locally, according to a top government official.

While India is known as the pharmacy of the world, exporting to over 200 countries, it is falling behind in medical devices whose regulation was recently entrusted with the Department of Pharmaceuticals, Union Pharmaceuticals Secretary V. K. Subburaj said

“We are producing so many things, sending even satellites to Mars in a very cost-effective way. But we are not able to produce ordinary medical devices. You go to any hospital you will find that all the equipment is coming from other countries, even the ordinary monitors, hospital beds. Can't we produce hospital cots and beds here?” Mr. Subburaj asked.

Citing the example of linear accelerator machines used in radiation therapy for cancer patients, the secretary said these devices cost over Rs.5 crore so the 1.5 million new cancer patients every year in India can only go to 'corporate hospitals' for treatment. “If you manufacture such a technology within India, and it is available, it will cost Rs.1.5 crore.

But we don't manufacture in India. We all think only foreign equipment will work that are available only in top most tertiary care hospitals.

“Suppose you manufacture them here, even district hospitals can have this equipment and treat cancer,” he said. Imports from Ireland or China are not only convenient but also cheaper owing to inverted duty structures that hamper domestic manufacturing activity, he said referring to the decision to hike duties on several medical devices in January.

“Recently, we initiated correction of duty structures. If you import the equipment as it is, it is cheaper, it is convenient to get (them) into the hospital from Ireland or China.

“If you manufacture the same thing in India, duty is there. So it is convenient for all of us, but we want to rectify this… It wouldn't happen overnight,” Mr. Subburaj said. He said this approach will help in manufacturing medical devices in India over time.

“You will be surprised baby diapers used by the millions of babies born in our country, are also called a medical device.

“We import Rs.200 crore of diapers, (but) now, a few companies have come into India. We will create an ecosystem that even large medical devices are made in India over a period of time,” Mr. Subburaj said arguing that there was no reason why India should import ordinary medical devices, including hospital beds and even diapers.

Mr. Subburaj said the government is working on standards for medical devices rather than rely on USFDA norms currently prescribed in government procurements for medical equipment. He was speaking at an event to introduce a voluntary certification process for domestically-produced medical devices organised by the Quality Council of India with the Association of Indian Medical Device Industry.

Mr. Subburaj said such a certification would help create confidence among doctors and consumers about the reliability of locally manufactured products.

The government is also prodding all pharma producers to adapt World Health Organisation (WHO) standards to reassure the world that Indian drugs are not only cost-effective but are also of good quality.

"Whatever be the quality constraints that people keep complaining of (in pharma products), that's not a major issue. Our own people undermine our own products," he said.

Mr. Subburaj said though Indian standards are sufficient, the move to WHO standards would help bolster quality perception.

According to India Ratings, a Fitch company, the Indian pharmaceutical industry is estimated to grow at 20 per cent compound annual growth rate over the next five years.

The Indian pharmaceutical industry, which is expected to grow over 15 per cent every year between 2015 and 2020, will outperform the global pharmaceutical industry, which is set to grow at an annual rate of five per cent between the same period.

Presently the market size of the pharmaceutical industry in India stands at U.S. $ 20 billion. As on March 2014, Indian pharmaceutical manufacturing facilities registered with the U.S. Food and Drug Administration (FDA) stood at 523, highest for any country outside the U.S.

By 2020, India is likely to be among the top three pharmaceutical markets by incremental growth and sixth largest market globally in absolute size. India's cost of production is significantly lower than that of the US and almost half of that of Europe. It gives a competitive edge to India over others, according to a report by the Indian Brand Equity Foundation.

Source: *The Hindu, 16th March 2016*

Pharma Firms Breathe Easy After Court Intervention

A number of Indian and multi-national pharmaceutical companies on Tuesday got temporary relief from the Delhi High Court, which stayed a government order banning nearly 350 drugs on safety grounds. This was a day after Pfizer got a similar relief.

Abbott India, the local arm of American pharmaceutical multinational Abbott Healthcare, said that it had obtained an interim injunction suspending the operation of the government notification that prohibited the manufacture, sale and distribution of several fixed dose combinations already approved for use, till the next date of hearing.

"Abbott reviewed the Drug Controller General of India (DCGI) notification regarding fixed dose combinations and approached the Delhi High Court for relief, as we were not informed, consulted or allowed a representation by the authority for some important products," a company spokesperson said in a statement.

The banned Phensedyl received DCGI approval in 1995 and had been on the market in India since the 1980s, the statement said, and claimed that the syrup had been used safely and effectively by physicians and patients alike.

"Some of the other formulations in our petition are in use globally, including the US, UK and Australia, and are approved by regulatory bodies such as the US FDA (Food and Drug Administration)," according to a statement issued by the company.

Source: *The Hindu, 16th March 2016*

Kerala Chemists Get 2 Weeks to Retun Banned Drug Combos

The Kerala High Court has granted chemists and druggists in the state more time to return the brands banned by a recent government order on 344 fixed dose combination (FDC) drugs. FDCs are a mix of two or more drug ingredients combined into one dose.

Industry executives said chemist in other states are following suit. For instance, the Tamil Nadu Chemist and Druggist Association (TNCDA) is set to file a petition in a few days, they said.

In an interim order on Friday, the Kerala High Court directed the state's drug controller not to initiate action in this matter against the members of the All Kerala Chemists and Druggists Association (AKCDA) for two weeks, in which period they are expected to take steps to return the banned drugs, said AKCDA general secretary Thomas Raju. "For the time being, it is enough," Raju said.

The state drug controller had sent AKCDA a letter on March 15 directing return of all banned drugs to the distributors by March 21. Pointing out that the deadline was too short, Raju, said, "We have 15,000 retailers and wholesalers under AKCDA, and each of them will have at least 2,000 brands with these FDCs to return."

Other chemist and druggist associations, including those in Andhra Pradesh, Telangana, Tamil Nadu and Mumbai are said to be contemplating similar moves.

S Ramachandran, president of TNCDA, which will be filing its petition on March 21, said the group is looking for a stay of one month instead of two weeks.

Source: *The Economic Times, 19th March 2016*

New Medicine For Drug-Resistant TB Launched

On the eve of World Tuberculosis Day, Health Minister J.P. Nadda launched Bedaquiline — new drug for Drug Resistant TB — as part of the national programme. The drug will be introduced in 104 districts across five States.

Speaking at a press briefing, Mr. Nadda said the “process of fighting TB is continuous. Hence there can be no dilution and no diversion. Our attention needs to be steadfast and aggressive.” The programme would not suffer on account of budgetary allocation.

The new class of drug is a diarylquinoline that specifically targets Mycobacterial ATP synthase, an enzyme essential for the supply of energy to Mycobacterium tuberculosis and most other mycobacteria.

Bedaquiline is being introduced at six tertiary care centres across India. These sites have advanced facilities for laboratory testing and intensive care for patients. Bedaquiline will be given to multi-drug resistant TB patients with resistance to either all fluoroquinolone and/or all second line injectables and extensive drug resistant TB.

The national programme will also benefit from the introduction of over 500 Cartridge-Based Nucleic Acid Amplification Test (CBNAAT) machines — a revolutionary rapid molecular test which detects Mycobacterium tuberculosis and rifampicin drug resistance, simultaneously. This test is fully automated and provides results within two hours. It

is a highly sensitive diagnostic tool and can be used in remote and rural areas without sophisticated infrastructure or specialised training.

Emphasising on the need for collective commitment from all stakeholders, B.P. Sharma, Union Health Secretary, said the Revised National Tuberculosis Control Program (RNTCP) was one of the most successful programmes. “The programme has made significant impact on prevalence and treatment of TB. The quality of treatment has to be even over the public and private sectors. It has to be well supported by a strong procurement so that it can be sustained till 2030. But we need new tools for diagnostics and new research,” Mr. Sharma said.

Source: *The Hindu, 22nd March 2016*

Govt Defers Implementation of Pharma Code of Ethics Yet Again

The government has postponed by another three months the implementation of a statutory code of principles to curb unethical practices by the pharmaceutical industry, mainly involving winning prescriptions from doctors to generate higher revenue.

A March 17 note from the Department of Pharmaceuticals informed industry bodies about the latest deferment, the fourth since the code was to be made effective in January 2015. The government is now giving the final touches to the set of binding principles to check practices such as gifting and facilitating overseas travel, which companies sometimes use to push prescriptions through doctors.

The "Uniform Code of Pharmaceutical Marketing Practices" includes penal provisions and was meant to come into force following a period of voluntarily implementation, which has been lax.

"The process for self-implementation did not work. We have continued to receive complaints of breaches. We hope to set the code for drug companies in a few months," a senior government official told ET. For medical devices, too, the same stringencies may apply although the details aren't finalised.

The rules for the code were kicked off on January 1last year for a period of six months and were subsequently extended until March 31, 2016. The government, industry groups, the Medical Council of India and representatives from patient advocacy groups have been consulted on the broad guidelines.

The Organisation of Pharmaceutical Producers of India, a lobby group of most large global drug makers, said it supports the code, which "will increase accountability in the Indian pharma industry."

"We hope the Department of Pharmaceutical's extensive consultations with all stakeholders will result in a robust code," OPPI director general Ranjana Smetacek said. "OPPI members already adhere to a stringent code, based on the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations).

Ethical marketing remains a core area of focus for us. We would like to see our industry being known across the world for ethical business practices that contribute to responsible treatments for patients." Hansraj Ahir, minister of state for chemicals and fertilisers, said in a statement in Parliament last week that the code has been reviewed and it has

been decided to make it statutory. Marketing experts told ET the voluntary code was loosely implemented by the industry and lacked commitment.

Drug companies found ways to deviate and influence the decisions of doctors. Others, however, called for a balance in the new rules to take into account genuine costs incurred on "continuous medical education" events for doctors. Most said a tight law is needed.

"The collusion between some drug companies and doctors, particularly in chronic therapy areas (hypertension, cardiac, neurology) where prescriptions extend for the entire life of the patient, is not a secret," a senior medical consultant said, conceding that the links now are not as blatant as before.

Some companies, experts said, outsourced the task of coordinating with doctors to independent agencies, mainly to facilitate visits overseas for conferences and meetings. Others have assigned a certain amount of spending on doctors and earmarked a sales target from them.

In such cases, it is difficult for regulators to put the companies under the radar. The revised version of the statutory code may incorporate penal provisions, besides tougher conditions such as a limit on free samples, a clear process of registrations of doctors for conferences and a cap on the number of conferences that doctors can attend.

According to industry experts, the penal provisions include reprimanding companies found to be in violation of the code. It will require companies to pay fines of “multiple of hundreds” of the value of items given and licences of manufacturers can be suspended for one to three years.

Source: *The Economic Times, 23rd March 2016*

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PARLIAMENT QUESTION - ANSWERS
LOK SABHA
MINISTRY OF HEALTH AND FAMILY WELFARE

Question No: 2153
Answered on: 11.12.2015
BAR-CODING OF MEDICINE STRIPS

2153 SHIVAJI ADHALRAO PATIL, DHARMENDRA YADAV, CHANDU BARNE SHRIRANG, R. PARTHIPAN, ANANDRAO ADSUL

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether the Government has issued directives to the pharmaceutical companies to affix bar-codes on medicine strips and containers, if so, the details thereof and the reasons there for;

(b) whether the Government has received any representation/request from drug manufacturers/exporters with regard to mandatory bar-code provision, if so, the details thereof along with the response of the Government thereto;

(c) whether the Government has assessed the likely impact of the mandatory bar-code provision on the small and medium sized pharmaceutical companies which risk to be out of business, and if so, the details thereof; and

(d) the corrective measures being taken by the Government in this regard?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) While no such direction has been issued, a draft Notification G.S.R.449(E) dated 03-06-2015 was published to obtain the suggestions and objections of the stakeholders regarding mandatory bar-coding of drugs manufactured in India.

(b) to (d): A number of representations have been received from the stakeholders on the above referred draft rules indicating financial and technical difficulties in implementing the proposal. Keeping these in view, these Rules have not been finalized as yet.

Question No: 2263
Answered on: 11.12.2015
DRUG REGULATIONS

2263 GAURAV GOGOI, RAJENDRA AGRAWAL, JYOTIRADITYA MADHAVRAO SCINDIA

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether the Government has taken note of ban on import of certain Indian drugs and warnings issued to a number of Indian drug manufacturers by American/ European drug regulators and the World Health Organisation (WHO) in the recent past;

(b) if so, the details thereof and the extent to which Indian drug industry and export are affected as a result thereof during the last three years and the current year;

(c) whether the Government has identified certain flaws in the drug regulation regime ranging from inadequate testing facilities and a lack of database to insufficient training to regulatory officials, and if so, the details thereof; and

(d) the steps taken/proposed to be taken by the Government to strengthen the drug regulation regime and raise the standards of

pharmaceutical products as per global and WHO standards; and

(e) the other measures taken/proposed to be taken by the Government to raise the credibility of Indian drugs and drug manufacturers in the global market?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) & (b): In case of export of drugs, Indian Pharmaceutical companies are required to comply with the regulatory provisions of the importing country. Isolated reports of the drugs not meeting the prescribed standards have appeared in the media and on the websites of the regulatory authorities of foreign countries, etc. from time to time. As per the recent media reports, regulatory action has been taken by USFDA against nine Indian Pharmaceutical Companies. Such instances impact our exports only marginally.

(c) & (d): The gaps and weaknesses of our regulatory structures have been identified and the Government has, with a view to strengthen the regulatory regime, approved a proposal to strengthen the drug regulatory structures both at the Centre and in the States at a total cost of Rs.1750/- crore. The strengthening will include construction of new offices and laboratories, re-equipping existing laboratories, additional manpower, training, e-governance modules and IT infrastructure.

(e): With a view to raise the credibility of our drugs, the Department of Commerce has introduced bar coding on secondary and tertiary packs for exports for tracking and tracing the medicines. Once fully implemented, it will remove the chances of someone else selling medical products that are not genuine.

Question No: 3298
Answered on: 18.12.2015

SAFETY OF DRUGS

3298 PREM DAS RAI, SANJAY JAISWAL, K. KAMARAAJ, RANGASWAMY DHRUVANARAYANA,

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether use of untested liposomal amphotericin B reportedly poses a threat to life of patients and if so, the details thereof along with the corrective measures being taken by the Government in this regard;

(b) whether certain approved fixed dose combinations of drugs are reportedly unsafe and not recommended internationally, if so, the details thereof along with the reasons for their approval and the remedial steps being taken by the Government to test/screen all drug combinations in order to ensure their safety;

(c) whether the Government proposes to introduce a centralized prescription drug system which can serve as a valuable investigative and preventive for the health care community, regulatory boards and law enforcement and if so, the details thereof;

(d) the other steps taken/proposed to be taken by the Government to ensure safety and standards of drugs; and

(e) the measures taken/proposed to be taken by the Government to avoid misappropriation in supply of drugs and the action taken against the offenders in this regard during the last three years?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a): Any untested drug poses risk to patients and liposomal amphotericin B is no exception. As per Drugs and Cosmetics Act, 1940 and Rules, 1945 thereunder, manufacturers are required to test each batch of the drugs either in their own laboratory or in any laboratory approved by the Licensing Authority.

(b): New Drugs including Fixed Dose Combinations (FDCs) are approved as per the provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder. However, some FDCs considered as New Drugs under the Drugs & Cosmetics Rules, 1945 for which approval of the Drugs Controller General (India), is required, have been manufactured and marketed with the approval of the State Drug Controllers / Regulators. DCG (I) had on 15.01.2013 requested all State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months. Notices had been issued to all manufacturers of such FDCs and the responses received from them have been analysed by a Committee of experts, which has submitted its report to the Government. Action as per decision taken by the Government has been initiated in respect of all such cases except 294 FDCs, the matter relating to which is currently sub-judice in the Hon'ble High Court at Chennai.

(c): No such proposal is under consideration of the Government at present.

(d): For evaluation of the safety and efficacy of New Drugs, the Government has approved 25 panels of experts of various therapeutic areas. Further, Pharmacovigilance Programme of India has been launched on 14.07.2010 for monitoring, recording and reporting of Adverse Drug Reactions (ADRs) in the country.

(e): No case of misappropriation in the supply of drugs has been reported during the last three years in Medical Store Organisation/Government Medical Store Depots and Central Government Health Scheme. Standard Operating Procedures have been developed to avoid any misappropriation in the supply of drugs.

Question No: 3377
Answered on: 18.12.2015
ILLEGAL DRUG LICENSE AND HEALTH CENTRES/CLINICS

3377 RAVINDRA VISHWANATH GAIKWAD, SONA RAM CHOUDHARY

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether attention of the Government has been drawn towards reported instances of prevalence of fake drug license in various States/UTs;

(b) if so, the details thereof indicating the number of such cases reported and the action taken by the Government against the offenders during the last three years and the current year, State/UT-wise;

(c) the steps taken/proposed to be taken by the Government for periodic review of the policy governing issue of drug license and defection of fake licences them; and

(d) the actions taken/proposed to be taken by the Government against the illegal health centres/clinics during the said period, State/UT-wise indicating the rules formulated therefor?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) & (b): A few instances where licenses had been issued without jurisdiction by State Licensing Authorities have come to the notice of the Central Government recently. The State Licensing

Authorities have, in such cases, been directed to cancel such licenses.

(c): Issues relating to the practices followed for issuances of licenses, enforcement, etc., are considered regularly in the meetings of the Drug Consultative Committee (DCC) and the DCC makes suitable recommendations to the Government. The Government has also approved a proposal to strengthen the drug regulatory structures at a total cost of Rs.1750/- crore to be spent over next three years. This includes organization wide e-Governance. In the networked environment, the entire information will be available online and necessary corrective measures can be taken.

(d): Health is a State subject. The Central Government has enacted the Clinical Establishments (Registration and Regulation) Act, 2010 and made rules thereunder. Action can be taken by the State Governments, where the Act has been adopted. However, the Act has been adopted only in 9 States and Union Territories (except Delhi).

Question No: 3425
Answered on: 18.12.2015

TESTING NORMS FOR CLINICAL TRIALS OF DRUGS

3425 Dr. Bhola Singh, Sudheer Gupta, Sunil Baliram Gaikwad, G. Hari Gajanan Chandrakant Kirtikar, Kunwar Haribansh Singh, V. Panneer Selvam, Ashok Shankarrao Chavan

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether the Government proposes to ease the norms for clinical trials of new drugs including those already approved in other countries and fast track their approvals in the country;

(b) if so, the details thereof and the reasons therefor;

(c) whether the Ethics Committee has been given more freedom and responsibilities to monitor clinical trials of new drugs;

(d) if so, the details thereof along with the trials approved by the Ethics Committee till date; and

(e) the other steps taken/proposed to be taken by the Government to ensure patient safety while approving clinical trials of new drugs?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) & (b): The process of approval of new drugs and conduct of clinical trials has been rationalized by the Government with a view to ensure a careful assessment of the risk versus benefit to the patients, innovation vis-à-vis existing therapeutic options and unmet medical needs in the country. These criteria have been made an integral part of the approval process. Besides, a module for online submission of Clinical Trial applications has been operationalized. Further, the pool of Subject Experts has been increased manifold and time-lines fixed for all activities. At the same time, adequate measures have been put in place to ensure the safety and welfare of patients / clinical trial subjects. It has also been decided that due consideration will be given to the fact that the drug has been approved and is in use in other countries.

(c) & (d): In order to put the clinical trial processes on a scientific footing and ensure closer supervision of such trials Ethics Committees are now required to be registered with the Drugs Controller General (India) [DCG(I)]. These Committees are entrusted with the responsibility to analyse Serious Adverse Events during Clinical Trials. As on 15/12/2015, 1027 Ethics Committee(s) are registered with the DCG (I). Most of the permissions granted for conduct of clinical trials by Central Drugs Standard

Control Organization (CDSCO) are in multiple sites across the country. Clinical Trial on a new drug at any site can be initiated only after permission has been granted by the Licensing Authority and the approval obtained from the respective Ethics Committee(s). The number of permission(s) granted by CDSCO for clinical trial of new drug(s) during year 2012, 2013, 2014 and current year (as on 27/11/2015) is 253, 73, 198 and 191, respectively.

(e): Other steps taken include laying down the formulae for determining compensation in all cases of Serious Adverse Events of injury or death, obligation to pay compensation where payable within the stipulated time-frame and recording of audio-visual informed consent of the trial subject.

RAJYA SABHA - MINISTRY OF HEALTH AND FAMILY WELFARE

Question No: 274
Answered on: 01.12.2015
FRAMING OF A SUITABLE ANTIBIOTIC POLICY

274 Prof. M.V. Rajeev Gowda

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether the Ministry is aware that in a recent report India has been declared to have one of the highest rates of antibiotic resistance in the world;

(b) whether the Ministry will consider developing a suitable antibiotic policy with a framework to curb rampant use of antibiotics in livestock; and

(c) if so, the details of plans thereof, and if not, the reasons therefor?

ANSWER

(a): As per the recent report (2015) released by Global Antimicrobial Resistance Partnership (GARP), it is reported that resistance among common pathogens is increasing worldwide though regional patterns of resistance vary.

(b) & (c): A National Policy for containment of Antimicrobial Resistance (AMR) in the country was formulated in the year 2011 and has been widely disseminated. The said policy envisages enforcement and enhancement of regulatory provisions for use of antibiotics for humans as also for veterinary use. An insertion has also been made in the Drugs and Cosmetics Rules, 1945 to specify the withdrawal period of antibiotics in case of egg, milk, poultry and fish before these enter the human food chain. The Department of Animal Husbandry, Dairying and Fisheries has also issued Advisories in 2014 addressed to all States and Union Territories regarding judicial use of antibiotics to prevent AMR.

Question No: 278
Answered on: 01.12.2015
DRUG INSPECTORS AND SPECIALISTS FOR REGULATORY WORK

278 Dr. Chandan Mitra

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) the total requirement of drug inspectors and specialists for regulatory work in the country vis-a-vis their present strength;

(b) whether Government has taken any steps to meet the huge requirement of drug inspectors and specialists for regulatory work; and

(c) if so, the details thereof, and if not, the reasons therefor?

ANSWER

(a): Keeping in view the size of Indian Pharma Industry and consumer base / number of sales units, over 3000 drug inspectors are required both at the Central and State levels. The strength of drug inspectors in the country as compiled by Central Drugs Standard Control Organization in September, 2015, was 1467.

(b): Yes.

(c): The Central Government has increased the number of sanctioned posts of drugs inspectors in CDSCO from 32 in April, 2008 to 279 in November, 2015. The Government has approved a proposal to strengthen the Drug Regulatory Structures both in the Centre and the States at a cost of Rs.1750 Crore. This will include augmentation of human resources at different levels both for regulatory functions and laboratories.

Question No: 279
Answered on: 01.12.2015
CHECK ON MISUSE OF DICLOFENAC

279 Dr. Chandan Mitra

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether Government is aware that despite ban on use of Diclofenac for veterinary use, the multi dose vials available in the market for human use are widely misused for veterinary purposes resulting in 99 per cent decline in the population and 3 species of Vultures;

(b) if so, the reasons for inaction in this regard; and

(c) the steps taken by Government to restrict the pack of Diclofenac for human use in single dose only in order to avoid its misuse?

ANSWER

(a): The use of diclofenac and its formulations for animal use had been prohibited by the Government with effect from 04.07.2008. Further, vide notification dated 17.07.2015, diclofenac injection for human use is permitted only in single dose pack inter alia to avoid its possible misuse.

(b): Does not arise.

(c): As stated in reply to (a) above, Drugs and Cosmetics Rules, 1945 have been amended and the amended rules are being enforced strictly.

Question No: 295
Answered on: 01.12.2015
OPENING OF DRUG DATABASE TO FOREIGN REGULATORS

295 Shri Anand Sharma

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether it is a fact that Government is proposing to open drug database to foreign regulators;

(b) if so, whether it will dispel campaign of spurious drugs emanating from India; and

(c) the status of implementation of the decision on bar-coding of pharma product consignments meant for exports?

ANSWER

(a): India is a major supplier of medicines to the world. Regulators of countries importing drugs from India observe due diligence before permitting such imports. Any data that is not barred from disclosure under the law/rules, etc., can be shared with such regulators.

(b): Yes.

(c): Bar coding has been made mandatory for exports with effect from 01.10.2015.

Question No: 300
Answered on: 01.12.2015
CURTAILING USE OF ANTIBIOTICS IN LIVESTOCK FARMING

300 Shri Sukhendu Sekhar Roy

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether Government is aware of a study of American researchers' report published in 'Proceedings of the National Academy of Sciences' which predicts India will be fourth largest consumer of antibioticlaced chicken by 2030;

(b) if so, what steps Government has initiated to curtail use of antibiotics for subtherapeutic purpose in livestock farming; and

(c) if so, the details of remedial measures adopted so far?

ANSWER

(a): The Government is aware of the findings as reported in the print media.

(b) & (c): Anti-microbial resistance is a major concern and the Government has taken a series of steps to ensure rational use of antibiotics both for human and veterinary use. The Drugs & Cosmetics Rule, 1945 have been amended to regulate manufacture and sale of antibiotics and habit forming drugs with a view to ensure that these are not misused. A new Schedule H1 containing 46 drugs has been added to these rules. These drugs are required to be sold in the country with the following conditions:

(I) To be labelled with the symbol Rx which shall be in red and conspicuously displayed on the left top corner of the label. It shall also be labelled with the following words in a box with a red border: "Schedule H1 Drug-Warning: -It is dangerous to take this preparation except in accordance with the medical advice. -Not to be sold by retail without the prescription of a Registered Medical Practitioner."

(II) The supply of a drug specified in Schedule H1 shall be recorded in a separate register at the time of the supply giving the name and address of the prescriber, the name of the patient, the name of the drug and the quantity supplied and such records shall be maintained for three years and be open for inspection.

Further, the Department of Animal Husbandry, Dairying and Fisheries issued a circular on 03/06/2014 to the Animal Husbandry Departments of all States and Union Territories requesting them to advise the veterinarians, feed manufacturers and the persons involved in treatment of animal to ensure judicious use of antibiotics and hormones and stop their use in animal feed. The Drugs Controller General (India) has also requested all State/UT Drugs Controllers on 06/06/2014 to advise all Animal Husbandry Departments in their respective States/UTs for compliance of the above referred circular issued by Department of Animal Husbandry, Dairying and Fisheries. DCGI has also issued an advisory to all States/ Union Territories on 12/09/2014 that use of antibiotics and hormones in animal feed be stopped.

RAJYA SABHA - MINISTRY OF CHEMICALS AND FERTILIZERS

Question No: 1095
Answered on: 08.12.2015

ONLINE SALE OF MEDICINES

1095 Dr. K.P. Ramalingam

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether Government is considering allowing online sale of medicines;

(b) whether the All India Organization of Chemists and Druggists have expressed their opposition to such decision; and

(c) whether Government has clarified to the said association that no decision has been taken by Government with regard to the sale of medicine online, if so, the details thereof?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) & (b): A number of representations have been received from chemists and druggist associations against the online sale of prescription drugs. Similarly, a number of representations have also been received to permit such sales. However, no decision has been taken to allow online sale of medicines.

(c): Yes.

Question No: 1116
Answered on: 08.12.2015

REGULARISATION OF E PHARMACIES

1116 Shri Derek O Brien

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether it is a fact that Government is considering regularizing the sale of medicines through e-pharmacies if so, the reasons therefor;

(b) whether the current laws will be amended to include the provisions for e-pharmacies;

(c) if not, the details of the alternatives, if any, as envisaged by Government; and

(d) whether Government has plans to consult the various stakeholders across the nation for the same?

ANSWER

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI JAGAT PRAKASH NADDA)

(a) to (c): The sale and distribution of drugs in the country is regulated as per the provisions under the Drugs & Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 made thereunder. As per said Rules, Drugs specified in Schedule H, H1 or Schedule X can't be sold except on and in accordance with the prescription of a Registered Medical Practitioner. The supply of prescription drugs can be effected only by or under the personal supervision of a registered pharmacist from a licensed premises.

A number of representations have been received from chemists and druggist associations against the online sale of prescription drugs. Similarly, a number of representations have also been received to permit such sales. The representations received were discussed in detail in the 48th meeting of the Drugs Consultative Committee (DCC), held on 24th July, 2015. The DCC has constituted a 7 - Member

Sub-Committee to examine the issue of sale of drugs on the internet, while taking care of the risks and concerns related to such sales.

(d): Government always follows the normal process of inviting objections and suggestions from the stakeholders before making any rules.

Question No: 1485
Answered on: 11.12.2015

PRICING OF DRUGS MEDICINES

1485 Shri C.P. Narayanan

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:-

(a) whether Government has a clear policy regarding pricing of medicines;

(b) whether it is weighed in favour of pharmaceutical companies or in favour of patients from ordinary/poor families; and

(c) whether Government has ensured that life saving drugs are made available at reasonable cost to them by producing them in public sector companies?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a) & (b): The Department of Pharmaceuticals has notified the National Pharmaceutical Pricing Policy-2012 under which the prices of medicines included in the National List of Essential Medicines-2011 are to be controlled and regulated. The objective is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines – "Essential Medicines" – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of the industry, thereby meeting the goals of employment and shared economic well being for all.

(c): Life saving drugs is not mentioned in the Drugs (Prices Control) Order-2013. It only finds mentioned in the custom and excise tariff. Some full/partial exemptions/concessions from payment of duties on specified drugs and medicines are presently in force. However, essential medicines as mentioned in the reply to Parts (a) and (b) above, are made available at reasonable prices in accordance with the National Pharmaceutical Pricing Policy-2012 and the Drugs (Price Control) Order-2013.

Question No: 1486
Answered on: 11.12.2015
REVIEW OF DRUG PRICING POLICY

1486 Smt. Kanak Lata Singh

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to satate :-

(a) & (b): The Department of Pharmaceuticals has notified the National Pharmaceutical Pricing Policy-2012 under which the prices of medicines included in the National List of Essential Medicines-2011 are to be controlled and regulated. The objective is to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines –

"Essential Medicines" – at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of the industry, thereby meeting the

goals of employment and shared economic well being for all.

(c): Life saving drugs is not mentioned in the Drugs (Prices Control) Order-2013. It only finds mentioned in the custom and excise tariff. Some full/partial exemptions/concessions from payment of duties on specified drugs and medicines are presently in force. However, essential medicines as mentioned in the reply to Parts (a) and (b) above, are made available at reasonable prices in accordance with the National Pharmaceutical Pricing Policy-2012 and the Drugs (Price Control) Order-2013.

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a): The Government has been reviewing/re-evaluating the policy whenever required. It is an ongoing process.

(b): Pursuant to the announcement of National Pharmaceutical Pricing Policy, 2012, Government notified Drugs (Prices Control) Order, 2013 (DPCO, 2013) on 15th May, 2013. All the medicines specified in the National List of Essential Medicines 2011 (NLEM) have been included in the First Schedule of DPCO, 2013 and brought under price control. Out of total 680 NLEM medicines (628 net medicines) under scheduled category of DPCO, 2013, NPPA has fixed the ceiling prices in respect of 530 medicines based on market price data under provisions of the said order. In addition, maximum retail price (MRP) has been capped in respect of 106 non scheduled medicines.

(c): In view of (b) above, does not arise.

Question No: 1490
Answered on: 11.12.2015

SUPPLY OF LOW COST GENERIC MEDICINES AND PRODUCTION OF APIS

1490 Dr. V. Maitreyan

Will the Minister of CHEMICALS AND FERTILIZERS be please to state:

(a) whether Government proposes to start more Pharmaceutical companies to provide generic and cheap medicines and drugs to the needy poor people, if so, the details thereof;

(b) whether Government has taken up the issue with the drug manufacturers and pharmaceutical industries to produce and use Active Pharmaceutical Ingredients (APIs) indigenously than to depend heavily on China; and

(c) if so, the outcome thereof along with the further steps taken by Government in this regard?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a) No, Sir.

(b) and (c): The Government had constituted a Committee headed by Secretary, Health Research to look into the issues of Active Pharmaceuticals Ingredient (API)/ Bulk Drugs produced in the country. The recommendations of this committee which have since been submitted to the Government are being examined in consultation with all stake holders including manufacturers. These recommendations, once implemented would provide a roadmap for the growth of domestic Bulk Drug / API industry.

Question No: 2279
Answered on: 18.12.2015

HIGH PRICES OF LIFE SAVING DRUGS

2279 Dr. R. Lakshmanan

Will the Minister of CHEMICALS AND FERTILIZERS be pleased to state:

(a) whether there is no clear definition of Life Saving Drugs in Drugs (Prices Control) Order (DPCO), 2013;

(b) whether due to this lacuna Life Saving Drugs are very costly and are out of reach of poor patients; and

(c) whether Government will come forward to rectify this lacuna, if so, the details thereof and if not, the reasons therefor?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a), (b) & (c): "Life saving drugs" are not defined in the Drugs (Price Control) Order, 2013. However, pursuant to the announcement of National Pharmaceutical Pricing Policy (NPPP), 2012, Government notified Drugs (Prices Control) Order, 2013 (DPCO, 2013) on 15th May, 2013. All medicines specified in the National List of Essential Medicines 2011 (NLEM) have been included in the First Schedule of DPCO, 2013 and brought under price control. Under DPCO, 2013. Prices of drugs are fixed on 'Market based pricing' methodology. 'Market based pricing' methodology has been adopted in accordance with the principles outlined in the NPPP, 2012.

Out of total 680 NLEM medicines (628 net medicines) under scheduled category of DPCO, 2013, National Pharmaceutical Pricing Authority (NPPA) has fixed the ceiling prices in respect of 530 medicines based on market price data under provisions of the said order. Ceiling prices so fixed in accordance with the provisions of DPCO, 2013 are uniformly applied in retail marketing across the country for all medicines sold in either brand name or generic name. These also include medicines used for treatment of cardiovascular/heart disease, diabetes, HIV/AIDS, cancer, tuberculosis and kidney disease, specified in the Schedule-I of DPCO, 2013. Consequent to the price fixation of drugs under this order, affordability of the medicines has improved considerably.

Question No: 2282
Answered on: 18.12.2015

OPENING OF MORE JAN AUSHADHI STORES

2282 Shri Ranjib Biswal

Will the Minister of CHEMICALS AND FERTILIZERS be please to state:

(a) the total number of Jan Aushadhi Stores opened in the country as on 31 October, 2015 particularly in Maharashtra along with their locations;

(b) whether Government proposes to open more such stores in Odisha particularly in its tribal and left wing extremism affected districts;

(c) if so, the targets fixed in this regard for the remaining period of Twelfth Five Year Plan, year-wise; and

(d) the steps taken by Government to render necessary assistance to the individuals/agencies to open these stores in the far-flung areas of the State?

ANSWER

MINISTER OF STATE IN MINISTRY OF CHEMICALS AND FERTILIZERS (SHRI HANSRAJ GANGARAM AHIR)

(a) As on 31st October, 2015, 184 Jan Aushadhi Stores (JAS) had been opened across 17 State/UTs, out of which 103 Jan Aushadhi Stores were operational. Out of these 103 Jan Aushadhi Stores 1 store is functional in Maharashtra as on 31st October, 2015. This store is located at: Jan Aushadhi Store, HAL Colony, Pimpri, Pune.

(b) In Odisha, 23 Jan Aushadhi Stores are functional as on date. Seven (7) more applications for new Jan Aushadhi Stores in Odisha have been approved and are now in the process of obtaining Drug Licenses and agreement signing. Efforts are on to open even more Jan Aushadhi Stores.

(c) As per the original plan, the objective was to open one Jan Aushadhi Store in each of the 630 districts of the country. Later, a new business plan was prepared in August, 2013 and the objective was revised to open 3000 stores across the country by the end of the 12th Five Year Plan period 2012-2017. As per the new action plan of opening of Jan Aushadhi Stores, they can be opened anywhere in the country.

(d) JAS run by private entrepreneurs/ pharmacists/NGOs & Charitable organizations that are linked with Bureau of Pharma PSUs of India (BPPI) headquarters through internet will get incentive up to Rs. 1.5 lakhs. This will be given @10% of monthly sales subject to a ceiling of Rs. 10,000/- per month up to a limit of Rs. 1.5 lakhs. In NE sates, Naxal affected areas and tribal areas, the rate of incentive will be 15% and subject to a monthly ceiling of Rs. 15,000 and total limit of Rs. 1.5 lakhs.