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Special Issue on DPCO 2013

Newsletter of Tamilnadu Pharmaceutical Sciences Welfare Trust

Apr. - May. - Jun. 2013

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EDITORIAL

Dear Readers,

It is a great pleasure to publish and release 18th issue of our Pharma Web Newsletter – Apr – June 2013. Our Trust Chairman and Governing body members desired to publish the Drugs Price Control Order 2013 (DPCO 2013) in order to benefit the pharma community. Hence it was decided to Publish and release this current News letter containing the DPCO order 2013 along with parliament Question & Answers and News paper news items on this subject.

We hope readers will preserve this book in order to know the rules and regulations of latest DPCO order and its implication. The Prices of formulation under the National List of Essential Medicines (NLEM) issued by Ministry of Health & family welfare are controlled as per the New DPCO order. Nearly 652 formulations under 27 therapeutic segments of NLEM are covered under new DPCO. It seems nearly 20% price reduction in 60% of formulations & even prices may fall upto 70% in some cases under NLEM. It is hoped that that new order may enhance the innovation & R&D work .The order is covering18% of US 13.6 billion Dollars of their domestic market. We hope that consumers will benefit out of this order.

I hope members may be benefitted by reading the new DPCO order and its implications.

With Best Regards
R. Narayanaswamy
Chief Editor

Editorial Policy and Disclaimer

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

GLOBAL PHARMA CHALLENGES – ARE WE READY?

By
Mr. Samson K. Wilson, K.K. College of Pharmacy, Chennai

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

The Pharmaceutical industry is a $ 500 billion global business that requires a tight, safe, and efficient supply chain. Modern pharmaceutical products rely on ingredients and materials from across the globe. It is estimated that 80% of the active ingredients for drugs sold in the United States originates in the global sourcing chain outside the country.

Estimated at USD 554.00 billion in 2004, the global pharmaceuticals market is forecast to register an annual growth rate of 8.2 percent from 2004 to 2011 to reach USD 967.00 billion. Such expansion is expected, however, to be based on the ability of pharmaceuticals companies to adapt to changes in patient population, and target diseases of unmet medical need to maximize revenue potential.

High clinical development costs coupled with declining drug discovery success rates are causing productivity levels to fall in the global pharmaceuticals industry. The imminent patent expiry of several major blockbuster drugs and the related rise of cheaper generic alternatives is further exacerbating the situation.

The global pharmaceutical industry offers significant growth opportunity for participants that can build new strategic business models. For instance, an ageing global population is poised to drive pharmaceutical drugs for indications such as macular degeneration and Alzheimer disease. Drugs that address rising multi-factorial disorders such as cancer as well as lifestyle disorders such as obesity are also likely to experience strong revenue growth. Moreover, as patient groups become more fragmented and diagnostic methods improve, the demand for evidence-based personalized treatments is likely to increase making a challenge for the Pharma area and the pharmacists to cope up with it.

Challenges faced by the companies Globally!!!

The Challenges faced by the company are many but the future lies in the leadership and the team development.

As Pharmaceutical companies have grown and globalised, they have faced increased challenges to sustain innovation with global teams and to be nimble and stay ahead of ever more diverse competitors. They are constantly challenged to accelerate the process of bringing new drugs to the market that are medically effective and differentiated from the competition. While meeting these challenges, they must continuously manage the very difficult balance between market driven “need for speed” and the absolute need for scientific rigor and safety. It is essential for major pharmaceuticals companies to move from the blockbuster model and adopt new strategies that cater to specific diseases areas and populations.

To grow in this new era of evidence-based personalized medicine, companies should generate a sustainable product characterized by improved productivity and diversity.

Market participants need to replace their dependence on a limited number of highly lucrative drug candidates with a more comprehensive and diverse product portfolio. Innovative products that focus on areas of unmet medical need and cover a broad range of disease indications are likely to underpin a strong, sustainable product pipeline. Furthermore, companies need to examine reformulations and investigate new indications for existing blockbuster drugs.

The use of computer modeling and biomarker discovery to aid the discovery of promising drug candidates is likely to facilitate an enhanced understanding of the clinical development process and help them to make more informed investment decisions. As large pharmaceuticals companies try to enhance their drug development pipelines, mergers, acquisitions and licensing agreements for individual compounds are likely to gain appeal.

Mergers and strategic collaborations to invest in existing leads are also likely to diffuse the cost of potential failures, thereby preventing the draining of companies. The production of pharmaceutical products requires validating every aspect of the receiving, analysis, storage, and handling of drug actives, excipients and other raw materials, following FDA regulation.

It is unacceptable for chemicals or excipients to expire before the manufacturing process takes place, such as when their transport was delayed or they were not transported with proper temperature and humidity control. Additionally, every state has its own licensing requirements covering drug production. Meeting these requirements is a major challenge for both suppliers and third-party logistics partners that build and implement pharmaceutical supply chains.

A strong working relationship with a freight forwarding logistics expert can be essential to helping pharmaceutical producers build an efficient global supply chain. A proficient logistics company designs supply-chain solutions to save money and improve efficiency. Expediters and their customers should use freight forwarders at the vanguard of cutting-edge methodology that includes a comprehensive electronic tracking system. Freight forwarders consistently solve problems in a non-traditional way that adds value, addressing challenges such as refrigeration, theft, customs, regulations, and product tracking.

The other newer challenges faced globally by the industries are:

1. Novel drug delivery system

2. Patent drugs.

3. Nanoparticles

In case of patent drugs the companies has to innovate new type of drugs with the same ingredient to cope up with the revenue and to be in the market as a successful product. The companies when invents a new drug they have a time limit of 20 years of patent act. Till the time of expiry of the latent period no other company can sell the drugs with the same ingredient. This might provide economy to the inventor company but not the other companies which will play a major role in the revenue of Pharma field.

The other area concerning about the future is novel drug delivery system. In a country like India where the funds are provided less for Pharma field its too hard to be in the top list in case of NDDS. To be globally in the ranks, revenue should be provided to the Pharma industry so that there will be a brighter future ahead for pharmacy.

Drugs Price Control Order 2013, Published by Government of India.

To be published in the Gazette of India,
Extraordinary, Part II, Section 3, Sub-section(ii) dated 15th May 2013

Ministry of Chemicals and Fertilizers
(Department of Pharmaceuticals)

New Delhi
Dated 15th May 2013
25 Vaisakha Saka 1935

ORDER

S.O. 1221(E).– In exercise of the powers conferred by section 3 of the Essential Commodities Act, 1955, (10 of 1955), and supersession of the Drug (Prices Control) Order, 1995, except as respect to things done or omitted to be done before such supersession, the Central Government hereby makes the following Order, namely:-

1. **Short title and commencement.–** (1) This Order may be called the Drugs (Prices Control) Order, 2013.

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

2. Definitions.– (1) In this Order, unless the context otherwise requires,–

(a) **"Act"** means the Essential Commodity Act, 1955 (10 of 1955);

(b) **"active pharmaceutical ingredients or bulk drug"** means any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and which is used as such or as an ingredient in any formulation;

(c) **"brand"** means a name, term, design, symbol, trademark or any other feature that identifies one seller's drug as distinct from those of other sellers;

(d) "**ceiling price**" means a price fixed by the Government for Scheduled formulations in accordance with the provisions of this Order;

(e) "**dealer**" means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and includes his agent;

(f) "**distributor**" means a person engaged in the work of distribution of drugs and includes an agent or a stockist for stocking drugs for sale to a dealer;

(g) **"existing manufacturer"** means manufacturer existing on the date of publication of this order in the Official Gazette.

(h) "**Form**" means a form specified in the Second Schedule;

(l) "**formulation**" means a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include –

(i) any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines;

(ii) any medicine included in the Homeopathic system of medicine; and

(iii) any substance to which the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) do not apply;

(j) **"generic version of a medicine"** means a formulation sold in pharmacopeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name;

(k) "**Government**" means the Central Government;

(l) "**import**" with its grammatical variations and cognate expressions means bringing a drug into India from a place outside India for its sale;

(m) **"local taxes"** means any tax or levy (except excise or import duty included in retail price) paid or payable to the Government or the State Government or any local body under any law for the time being in force by the manufacturer or his agent or dealer;

(n) "**manufacturer**" for the purpose of this Order means any person who manufactures, imports and markets drugs for distribution or sale in the country;

(o) **"market share"** means the ratio of domestic sales value (on the basis of moving annual turnover) of a brand or a generic version of a medicine and the sum of total domestic sales value of the all brands and generic versions of that medicine sold in the domestic market having same strength and dosage form;

(p) **"margin to retailer"** for the purposes of this Order shall mean a percentage of price to retailer;

(q) **"market based data"** means the data of sales related to a drug collected or obtained by the Government as deemed fit, from time to time;

(r)**"maximum retail price"** means the ceiling price or the retail price plus local taxes and duties as applicable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack;

(s) **"moving annual turnover"** in a particular month means cumulative sales value for twelve months in domestic market, where the sales value of that month is added and the corresponding sales of the same month in the previous year are subtracted;

(t) **"National List of Essential Medicines"** means National List of Essential Medicines, 2011 published by the Ministry of Health and Family Welfare as updated or revised from time to time and included in the first schedule of this order by the Government through a notification in the Official Gazette;

(u) **"new drug"** for the purposes of this Order shall mean a formulation launched by an existing

manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines by combining the drug with another drug either listed or not listed in the National List of Essential Medicines or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the National List of Essential Medicines.

(v) **"non-scheduled formulation"** means a formulation, the dosage and strengths of which are not specified in the First Schedule;

(w) **"pharmacoeconomics"** means a scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another;

(x) **"price list"** means a price list referred to in paragraphs 24 and 25 and includes a supplementary price list;

(y) **"price to retailer"** means the price of a drug at which it is sold to a retailer which includes duties and does not include local taxes;

(z) **"retail price"** means the price fixed by the Government for a new drug under paragraph 5 ;

(za) **"retailer"** means a dealer carrying on the retail business of sale of drugs to customers;

(zb) **"scheduled formulation"** means any formulation, included in the First Schedule whether referred to by generic versions or brand name;

(zc) **"schedule"** means a Schedule appended to this Order;

(zd) **"wholesaler"** means a dealer or his agent or a stockist engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational or research institution or any other agency;

(ze) **"wholesale price index"** means annual wholesale price index of all commodities as announced by the Department of Industrial Policy and Promotion, Government of India, from time to time.

3. Directions to manufacturers of active pharmaceutical ingredients or bulk drugs or formulations.– The Government may, -

(i) with a view to achieve adequate availability and to regulate the distribution of drugs, in case of emergency or in circumstances of urgency or in case of non-commercial use in public interest, direct any manufacturer of any active pharmaceutical ingredient or bulk drug or formulation to increase the production and to sell such active pharmaceutical ingredient or bulk drug to such other manufacturer(s) of formulations and to direct formulators to sell the formulations to institutions, hospitals or any agency as the case may be;

(ii) for the purpose of giving any direction under sub-paragraph (i), call for such information from manufacturers of active pharmaceutical ingredients or bulk drugs or formulations, as it may consider necessary and such manufacturer shall furnish the required information within such time the Government may fix.

4. Calculation of ceiling price of a scheduled formulation.– (1) The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under:

Step1. First the Average Price to Retailer of the scheduled formulation i.e. P(s) shall be calculated

as below:

Average Price to Retailer, P(s) = (Sum of prices to retailer of all the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.)

Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as below:

P(c) = P(s).(1+M/100), where

P(s) = Average Price to Retailer for the same strength and dosage of the medicine as calculated in step1 above.

M = % Margin to retailer and its value =16

(2) The ceiling price calculated as per sub-paragraph (1) and notified by the Government shall be applicable to scheduled imported formulations also.

5. Calculation of retail price of a new drug for existing manufacturers of scheduled formulations.– (1) The retail price of the new drug available in domestic market shall be calculated as provided in sub-paragraph (1) of paragraph 4.

(2) (i) the price to retailer of a new drug, not available in domestic market, shall be fixed by the Government on the principles of "Pharmacoeconomics" of the new drug, on the recommendation of a Standing Committee of Experts formed under paragraph 15.

(ii) the retail price of such new drug shall be fixed by adding sixteen percent margin to retailer on the price to retailer as fixed in item (i):

6. Ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition.– (1) where the average price to retailer of a scheduled formulation, arrived at as per the formula specified in sub-paragraph (1) of paragraph 4, has the effect of,-

(a) no reduction in average price to retailer with respect to the prices to retailer of the schedule formulation; and

(b) there are less than five manufacturers for that formulation having one percent or more market share,

the ceiling price shall be calculated as under:-

(i) in the event of other strengths or dosage forms of the same scheduled formulation is available in the list of scheduled formulation, the average price to retailer shall be calculated as under:

Step1: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

P(s) = Pm{1-(Pi1+Pi2+…)/(N*100)} Where,

Pm = Price to Retailer of highest priced scheduled formulation under consideration.

Pi = % reduction in Average Price to Retailer of other strengths and dosage forms (calculated as in step1 of sub-paragraph (1) of paragraph 4) in the list of schedule formulations w.r.t the highest priced formulation taken for calculating the average price to retailer of such strengths and dosage forms.

N = Number of such other strengths or dosage forms or both in the list of schedule formulations

Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

P(c) = P(s).(1+M/100), where

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step1 hereinabove and

M = % Margin to retailer and its value=16

(ii) in the event of other strengths or dosage forms of the scheduled formulation is not available in the schedule but there are other scheduled formulations in same sub-therapeutic category as that of the scheduled formulation, then the Ceiling Price shall be calculated as under:

Step1: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

P(s) = Pm{1-(Pi1+Pi2+…)/(N*100)}, Where,

Pm = Price of highest priced formulation taken for calculating the average price to retailer of the formulation under consideration..

Pi = % reduction in Average Price to Retailer of other schedule formulations (calculated as in step1 of sub-paragraph (1) of paragraph 4) in same sub-therapeutic category as that of the scheduled formulation under consideration w.r.t the highest priced formulation taken for calculating the average price to retailer.

N = Number of such other schedule formulations in same sub-therapeutic category as that of the scheduled formulation under consideration.

Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

P(c) = P(s)*(1+M/100), where

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step1 above and

M = % Margin to retailer and its value=16

Explanation.- where the scheduled formulation under consideration is coming under more than one sub-therapeutic category, the Average Price to Retailer of the scheduled formulation shall be calculated after taking into consideration the percentage reduction in Average Price to Retailer of other schedule formulations under all such sub-therapeutic categories and the lowest average price to retailer shall be taken for calculating the ceiling price of the scheduled formulation under consideration;

(iii) in case the other strengths or dosage forms of the scheduled formulation are not available in the schedule and there is no sub therapeutic category of the scheduled under consideration, the ceiling price shall be calculated as under:

Step1: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under:

P(s) = Pm{1-(Pi1+Pi2+…)/(N*100)} Where,

Pm = Price of highest priced formulation taken for calculating the average price to retailer of the formulation under consideration.

Pi = % reduction in Average Price to Retailer of other schedule formulations (calculated as in step1 sub-paragraph (1) of paragraph 4) in same therapeutic category as that of the scheduled formulation under consideration w.r.t the highest priced formulation taken for calculating the average price to retailer.

N = Number of such other schedule formulations in same therapeutic category as that of the scheduled formulation under consideration.

Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under:

P(c) = P(s).(1+M/100), where

P(s) = Average Price to Retailer of the scheduled formulation as calculated in step1 above and

M = % Margin to retailer and its value=16

Explanation.- where the scheduled formulation under consideration is coming under more than one therapeutic category, the Average Price to Retailer of the scheduled formulation shall be calculated after taking into consideration the percentage reduction in Average Price to Retailer of other schedule formulations under all such therapeutic categories and the lowest average price to retailer shall be taken for calculating the ceiling price of the scheduled formulation under consideration.

2) Notwithstanding anything contained in this paragraph, where the price has been fixed and notified by the Government under the Drugs (Prices Control) Order, 1995 the provisions of sub-paragraph (1) shall not apply.

7. Margin to retailer.– While fixing a ceiling price of scheduled formulations and retail prices of new drugs, sixteen percent of price to retailer as a margin to retailer shall be allowed.

8. Maximum retail price.– (1) The maximum retail price of scheduled formulations shall be fixed by the manufacturers on the basis of ceiling price notified by the Government plus local taxes wherever applicable, as under:

Maximum Retail Price = Ceiling price + Local Taxes as applicable

(2) The maximum retail price of a new drug shall be fixed by the manufacturers on the basis of retail price determined by the Government plus local taxes wherever applicable, as under:

Maximum Retail Price = Retail Price + Local Taxes as applicable

9. Reference data and source of market based data.– (1) Initially, the source of market based data shall be the data available with the pharmaceuticals market data specializing company – IMS Health (IMS) and if the Government deems necessary, it may validate such data by appropriate survey or evaluation.

(2) The Government may in the due course of time come out with other appropriate mechanism of collecting or obtaining the market based data related to drugs and the decision of Government with respect to collection or obtaining of data shall be final.

(3) The market based data, for fixing the ceiling price of scheduled formulations for the first time after the notification of this order, shall be the data of May, 2012.

(4) The market based data for fixing the retail price of new drugs available in the market, shall be the data available for the month ending immediately before six months of receipt of application for fixing the price of the new drug.

(5) The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six month of notification of revision in the first schedule.

(6) Notwithstanding anything contained in this order, the reference date for the formulations which are part of the Drugs (Prices Control) Order, 1995 shall be as per the provisions of paragraph 10 of this Order.

10. Pricing of the formulations covered under Drugs (Prices Control) Order, 1995.– (1) The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of the said order, up to 31st May, 2012, shall remain effective for further one year i.e. up to 30th May' 2013 and the manufacturers may revise the prices of such scheduled formulations as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and thereafter the formula as in sub- paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such formulations.

(2) The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of Drugs (Prices Control) Order,1995 after 31st May,2012, shall remain effective for one year from the date of notification of such prices under Drugs (Prices Control) Order,1995 and immediately thereafter the manufacturers may revise the prices as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and on the 1st April of succeeding financial year, the formula as in sub-paragraph (1) of paragraph 4 of this Order shall be applied for fixing the ceiling prices of such schedule formulations.

(3) The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, up to 31st May,2012, shall remain effective for further one year i.e. up to the 30thMay'2013 and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order.

(4) The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, after 31st May,2012, shall remain effective for one year from the date of notification of such prices and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in

paragraph 20 of this Order.

11. Ceiling price or retail price of a pack.– (1) The average price to retailer calculated as per the provisions in paragraphs 4, 5 and 6 shall be on the dosage basis, (per tablet, per capsule or injection in volume as listed in first schedule) and the ceiling price or retail price of a pack shall be reached by multiplying the same with the number or quantity in the pack as the case may be.

(2) In the event of the unit of the dosage for a scheduled formulation not available in the first schedule, the lowest pack size for that category of medicine, as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules thereunder, shall be taken as unit dosage for calculating the ceiling price or retail price as the case may be, for that scheduled formulation and this shall be applicable while calculating the per unit price of even non-scheduled medicines for arriving at the retail price in case of paragraph 5.

12. Price of formulations (branded or generic version) listed in the National List of Essential Medicines, launched by a manufacturer.– (1) A manufacturer, launching a scheduled formulation, shall be free to fix the price of the scheduled formulation equal to or below the ceiling price fixed for that schedule formulation by the Government.

(2) Where an existing brand is re-launched by another manufacturer the provisions of paragraph 13 shall be applicable.

13. Price of scheduled formulations for the existing manufacturers.– (1) All the existing manufactures of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price (plus local taxes as applicable):

Provided, that in case of scheduled formulations produced or available in the market before the date of notification of ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of such notification that the maximum retail price of such scheduled formulation does not exceed the ceiling price (plus local taxes as applicable).

(2) All the existing manufactures of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price lower than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government shall maintain their existing maximum retail price.

(3) Annual increase in maximum retail price may be carried out as per the increase in the wholesale price index with respect to previous year as per the provision of sub-paragraphs (2) and (3) of paragraph 16.

Provided that in case of decline in wholesale price index, a corresponding reduction in the prices shall be made as per the provision of sub-paragraph (4) of paragraph 16.

14. Fixation of ceiling price of scheduled formulations.– (1) The Government shall fix and notify the ceiling prices of the scheduled formulations in accordance with the provisions of the paragraphs 4 and 6, as the case may be, and no manufacturer shall sell the scheduled formulations at a price higher than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government.

(2) Where any manufacturer sells a scheduled formulation at a price higher than the ceiling price (plus local taxes as applicable) fixed and notified by the Government, such manufacturers shall be liable to deposit the overcharged amount along with interest thereon from the date of such overcharging.

15. Fixation of retail price of a new drug for existing manufacturers of scheduled formulations.– (1)

The Government shall form a Standing Committee of such Experts, as it may deem fit, within sixty days of notification of this order with a view to recommend the retail prices of new drugs on the principles of "Pharmacoeconomics".

(2) Where an existing manufacturer of a drug with dosages and strengths as specified in National List of Essential Medicines launches a new drug, such existing manufacturers shall apply for prior price approval of such new drug from the Government in Form-I specified under Schedule-II of this Order.

(3) On receipt of the application under sub-paragraph (2), in the event of the new drug available in domestic market, the Government shall fix the retail price of the new drug in accordance with the provision of sub-paragraph(1) of paragraph 5 and in the event of the new drug not available in domestic market, the Government shall forward the same to the Standing Committee of Experts who shall examine the application on the principles of "Pharmacoeconomics" and make recommendations of retail price of the new drug to the Government within thirty days of the receipt of application.

(4) The Government shall, on receipt of recommendation under sub-paragraph (3), within thirty days, fix the retail price of such new drug and such price shall be applicable to such applicant of such new drug.

(5) Where existing manufacturer of scheduled formulation fails to apply for prior approval of the price of the new drug in Form-I, such manufacturer shall be liable to deposit the overcharged amount over and above such price fixed and notified by the Government, if any, along with interest thereon from the date of launch of the new drug, in addition to the penalty.

(6) No existing manufacturer of a scheduled formulation shall sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government for such new drug and in case such a manufacturer is found to sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government, such manufacturer of the new drug shall be liable to deposit the overcharged amount along with interest from the date of overcharge, in addition to the penalty.

16. Revision of ceiling price of scheduled formulations.– (1) The Government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding calendar year on or before 1st April of every year and notify the same on the 1st day of April every year.

(2) The manufacturers may increase the maximum retail price (MRP) of scheduled formulations once in a year, in the month of April, on the basis of the wholesale price index with respect to previous calendar year and no prior approval of the Government in this regard shall be required.

(3) Information about the revision, if carried out, shall be forwarded to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision and non-submission of information under this sub-paragraph shall be construed as non revision of maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the pre-revised maximum retail price (MRP), alongwith interest thereon from the date of overcharging.

(4) In case of decline in wholesale price index, there shall be a corresponding reduction in the maximum retail price and in case of scheduled formulations produced or available in the market before the date of notification of revised ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of such notification that the maximum retail price (MRP) of such scheduled formulation does not

exceed the revised ceiling price (plus local taxes as applicable) and information about the revision shall be sent to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision.

(5) Non-submission of information under the sub-paragraph (4) shall be construed as non reduction in maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the maximum retail price revised based on decline in wholesale price index, alongwith interest thereon as overcharged amount from the date of overcharging.

17. Amendment of the list of scheduled formulation.– (1) A decision to amend the first schedule, clearly stating the reasons thereof, shall be taken by the Government within sixty days of receipt of communication from the Ministry of Health and Family Welfare and the amendment(s) or revision, if required, in the first schedule shall be notified and thereafter, the ceiling price(s) for the medicine(s) added in the first schedule shall be fixed as per the provisions of this order within a period of sixty days from the date of the notification.

(2) The medicines omitted from the first schedule shall fall under the category of non-scheduled formulations.

18. Revision of ceiling price on the basis of moving annual turnover (MAT).– The revision of ceiling prices on the basis of moving annual turnover value shall be carried out,-

(i) as and when the National List of Essential Medicines is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier;

(ii) when the number of manufacturers of a scheduled formulation, having price of a scheduled formulation more than or equal to seventy five percent of the ceiling price fixed and notified by the Government, has decreased by twenty five percent or more than the number of manufacturers as existing on the reference date;

(iii) when the number of manufacturers of a scheduled formulation, having prices of their scheduled formulation equal to or lower than twenty five percent of the ceiling price fixed by the Government, has increased by twenty five percent or more than the number of manufacturers as existing on the reference date.

Explanation.- For the purpose of items (ii) and (iii) the "reference date" shall be for first revision of ceiling price May, 2012 and for second or subsequent revision the date of previous revision of the ceiling price.

19. Fixation of ceiling price of a drug under certain circumstances.- Notwithstanding anything contained in this order, the Government may, in case of extra-ordinary circumstances, if it considers necessary so to do in public interest, fix the ceiling price or retail price of any Drug for such period, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year.

20. Monitoring the prices of non-scheduled formulations.– (1) The Government shall monitor the maximum retail prices (MRP) of all the drugs, including the non-scheduled formulations and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it

shall reduce the same to the level of ten percent of maximum retail price for next twelve months.

(2) The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase in price in addition to the penalty.

21. Monitoring the availability of scheduled formulations.– (1) The Government shall monitor the production and availability of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulation and the manufacturer of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulation shall furnish the information as stated in Form-III of schedule-II of this Order quarterly.

(2) Any manufacturer of scheduled formulation, intending to discontinue any scheduled formulation from the market shall issue a public notice and also intimate the Government in Form-IV of schedule-II of this order in this regard at least six month prior to the intended date of discontinuation and the Government may, in public interest, direct the manufacturer of the scheduled formulation to continue with required level of production or import for a period not exceeding one year, from the intended date of such discontinuation within a period of sixty days of receipt of such intimation.

22. Recovery of dues accrued under the Drugs (Prices Control) Order, 1979 and to deposit the same into the Drugs Prices Equalisation Account.– (1) Notwithstanding anything contained in this order, the Government may by notice, require a manufacturer, importer or distributor as the case may be, to deposit the amount which has accrued under the provisions of the Drugs (Prices Control) Order, 1979 on or before the commencement of this order, into the Drugs Prices Equalisation Account and the manufacturer, importer or distributor, as the case may be, shall deposit the said amount into the said account within such time as the Government may specify in the said notice.

(2) The existing amount, if any, in the Drugs Prices Equalisation Account on or before the date of commencement of this Order, and the amount deposited under sub-paragraph (1) shall be utilised for;-

(a) paying to the manufacturer, importer or distributor, as the case may be, the shortfall between his retention price and the common selling price or, as the case may be, the pooled price for the purpose of increasing the production, or securing the equitable distribution and availability at fair prices, of drugs;

(b) meeting the expenses incurred by the Government in discharging the functions under this paragraph; and

(c) promoting higher education and research in Pharmaceutical Sciences and Technology and for the purposes incidental thereto.

23. Recovery of overcharged amount under Drugs Prices Control Orders 1987 and 1995.– Notwithstanding anything contained in this order, the Government shall by notice, require the manufacturers, importer or distributor or as the case may be, to deposit the amount accrued due to charging of prices higher than those fixed or notified by the Government under the provisions of Drugs (Prices Control) Order, 1987 and Drugs (Prices Control) Order, 1995 under the provisions of this Order.

24. Carrying into effect the price fixed or revised by the Government, its display and proof thereof.– (1) For all the scheduled formulations having maximum retail price (MRP) higher than ceiling price (plus local taxes as applicable), the manufactures shall revise the maximum retail price (MRP) not exceeding the ceiling price (plus local taxes as applicable):

Provided that in case of scheduled formulations produced or available in the market before the date of notification of ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of the notification that the maximum retail price of such scheduled formulation does not exceed the ceiling price (plus local taxes as applicable).

(2) Every manufacturer of a schedule formulation intended for sale shall display in indelible print mark, on the label of container of the formulation and the minimum pack thereof offered for retail sale, the maximum retail price of that formulation based on the ceiling price notified in the Official Gazette or ordered by the Government in this behalf with the words "Maximum Retail Price" preceding it and the words 'inclusive of all taxes' succeeding it.

(3) Every manufacturer shall issue a price list and supplementary price list, if required, in Form V to the dealers, State Drugs Controllers and the Government indicating reference to such price fixation or revision as covered by the order or Gazette notification issued by the Government, from time to time.

(4) Every retailer and dealer shall display the price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

25. Display of prices of non-scheduled formulations and price list thereof.– (1) Every manufacturer of a non-Scheduled formulation intended for sale shall display in indelible print mark, on the label of container of the formulation and the minimum pack thereof offered for retail sale, the maximum retail price of that formulation with the words "Maximum Retail Price" preceding it and the words 'inclusive of all taxes' succeeding it.

(2) Every manufacturer shall issue a price list and supplementary price list, if required, of the non-Scheduled formulations in Form-V to the dealers, State Drugs Controllers and the Government indicating changes, from time to time.

(3) Every retailer and dealer shall display the price list and the supplementary price list, if any, as furnished by the manufacturer or importer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.

26. Control of sale prices of formulations.– No person shall sell any formulation to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whichever is less.

27. Sale of split quantities of formulations.– No dealer shall sell loose quantity of any formulation at a price which exceeds the pro-rata price of the formulation.

28. Manufacturer, distributor or dealer not to refuse sale of drug.– Subject to the provisions of the Drug and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder, -

(a) no manufacturer or distributor shall withhold from sale or refuse to sell to a dealer any drug without good and sufficient reasons;

(b) no dealer shall withhold from sale or refuse to sell any drug available with him to a customer intending to purchase such drug.

29. Maintenance of records and production thereof for inspection.– Every manufacturer shall maintain records relating to the sales of individual active pharmaceutical ingredients or bulk drugs manufactured or imported and marketed by him, as the case may be, and the sales of formulations units and packs and also such other records as may be directed from time to time by the Government and the Government shall have the power to call for any record and to inspect such records at the premises of the manufacturer.

30. Power of entry, search and seizure.– (1) Any Gazetted Officer of the Central Government or of a State Government, as the case may be, authorised by a general or special order by the Central Government or by the State Government, as the case may be, in this behalf may, with a view to securing compliance with this Order or to satisfy himself that the provision of this Order have been complied with–

(a) enter and search any place;

(b) seize any drug, alongwith the containers, packages or coverings in which the drug is found, in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened, and thereafter take all measures necessary for securing production of the drug, containers, packages or coverings, so seized, in a court of law and for their safe custody pending such production;

(c) seize any document, such as, cash memo or credit memo books, books of account and records of purchase and sale of the drugs in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened.

(2) The provisions of Code of Criminal Procedure, 1973 (2 of 1974), relating to search and seizure shall, so far as may be, apply to searches and seizures under this Order.

31. Power to review.– Any person aggrieved by any notification issued or order made under paragraphs 4, 5 and 6 of this Order, may apply to the Government for a review of the notification or order within a period of thirty days of the date of publication of the notification in the Official Gazette or the receipt of the order by him, as the case may be, and the Government may make such order on the application as it may deem proper:

Provided that pending a decision by the Government on the application submitted under the above paragraph, no manufacturer shall sell a scheduled formulation or a new drug, as the case may be, at a price exceeding the ceiling price or retail price, as the case may be, fixed by the Government of which a review has been applied for.

32. Non–application of the provisions of this order in certain cases.- The provisions of this order shall

not apply to, -

(I) a manufacturer producing a new drug patented under the Indian Patent Act, 1970 (39 of 1970) (product patent) and not produced elsewhere, if developed through indigenous Research and Development, for a period of five years from the date of commencement of its commercial production in the country.

(ii) a manufacturer producing a new drug in the country by a new process developed through indigenous Research and Development and patented under the Indian Patent Act, 1970 (39 of 1970) (process patent) for a period of five years from the date of the commencement of its commercial production in the country.

(iii) a manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India:

Provided that the provision of this paragraph shall apply only when a document showing approval of such new drugs from Drugs Controller General (India) is produced before the Government.

Explanation.- Notwithstanding anything contained in this Order, for the purpose of this paragraph "new drug" shall have the same meaning as is assigned to under rule 122E of the Drugs and Cosmetics Rules, 1945;

File No.31011/17/2012-PI-II

(Shambhu Kallolikar)

Joint Secretary to the Government of India

Schedule-I

(See Paragraphs-2(t),2(zb))

Symbols P, S and T appearing in NLEM 2011 denote essentiality at Primary, Secondary and Tertiary levels respectively.

NATIONAL LIST OF ESSENTIAL MEDICINES 2011			
Section: 1 – Anesthesia			
1.1 General Anesthetics and Oxygen			
Medicines	**Category**	**Route of Administration**	**Strengths**
Ether	S, T	Inhalation	--
Halothane with vaporizer	S, T	Inhalation	
Isoflurane	S, T	Inhalation	
Ketamine Hydrochloride	P, S, T	Injection	10 mg / ml, 50 mg / ml
Nitrous Oxide	P, S, T	Inhalation	
Oxygen	P, S, T	Inhalation	
Thiopentone Sodium	S, T	Injection	0.5 g, 1 g powder
Added Medicines			
Sevoflurane	T	Inhalation	
Propofol	P,S,T	Injection	1% oil suspension
1.2 Local Anesthetics			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Bupivacaine Hydrochloride	S, T	Injection	0.25%, 0.5%, 0.5% to be mixed with 7.5% glucose solution

Lignocaine Hydrochloride	P, S, T	Topical Forms, Injection, Spinal	2-5%, 1-2%, 5% +7.5% Glucose
Lignocaine Hydrochloride + Adrenaline	P, S, T	Injection	1%, 2% + Adrenaline1:200,000
Added Medicines			
EMLA cream	T	Cream	
1.3 Preoperative Medication and Sedation for Short Term Procedures			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Atropine Sulphate	P, S, T	Injection	0.6 mg / ml
Diazepam	P,S,T S, T	Tablets Injection, Syrup, Suppository	5 mg 5 mg / ml 2mg/5ml 5 mg
Midazolam	P, S, T	Injection	1 mg / ml 5 mg / ml
Morphine Sulphate	S, T	Injection	10 mg / ml
Promethazine	P, S, T	Syrup	5 mg / 5 ml
Section: 2 - Analgesics , Antipyretics, Nonsteroidal Anti- inflammatory Medicines, Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders			
2.1: Non-Opioid Analgesics, Antipyretics and Nonsteroidal Anti-inflammatory Medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Acetyl Salicylic Acid	P, S, T	Tablets	325, 350 mg
Diclofenac	T	Tablets	50 mg
	T	Injection	25 mg / ml
Ibuprofen	P, S, T	Tablets Syrup	200 mg, 400 mg 100mg/5ml

Paracetamol	P, S, T	Injection	150 mg / ml
	P, S, T	Syrup	125 mg / 5ml
	P, S, T	Tablets	500 mg
	P, S, T	Suppository	80 mg, 170 mg
2.2 Opioid Analgesics			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Morphine Sulphate	S, T	Injection	10 mg / ml
		Tablets	10 mg
Added medicines			
Tramadol	S,T	Injection Cap	50 mg/ml 50 mg,100 mg
Fentanyl	S,T	Injection	50ug/ml 2ml ampoule
2.3 Medicines used to treat Gout			
Allopurinol	S, T	Tablets	100 mg
Colchicine	S, T	Tablets	0.5 mg
2.4 Disease modifying agents used in Rheumatoid disorders			
Azathioprine	S, T	Tablets	50 mg
Methotrexate	S,T	Tablets	5mg, 7.5mg, 10mg
Sulfasalazine	S, T	Tablets	500 mg
Added medicines			
Hydroxychloroquine phosphate	S,T	Tablets	200 mg
Leflunomide	S,T	Tablets	10mg, 20 mg tab
Section: 3 – Antiallergics and Medicines used in Anaphylaxis			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**

Adrenaline Bitartrate	P, S, T	Injection	1 mg / ml
Chlorpheniramine Maleate	P, S, T	Tablets	4 mg
Dexchlorpheniramine Maleate	P, S, T	Syrup	0.5 mg / 5 ml
Dexamethasone	P, S, T	Tablets	0.5 mg
		Injection	4 mg / ml
Hydrocortisone Sodium Succinate	P, S, T	Injection	100 mg
Pheniramine Maleate	P, S, T	Injection	22.75 mg / ml
Prednisolone	P, S, T	Tablets	5 mg, 10 mg, 20 mg
Promethazine	P, S, T	Tablets	10 mg, 25 mg
		Syrup	5 mg / 5 ml
Added Medicines			
Cetrizine	P,S,T	Tablets Syrup	10mg 5 mg/ml
Section: 4 - Antidotes and Other Substances used in Poisonings			
4.1: Nonspecific			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Activated Charcoal	P,S,T	Oral	
4.2: Specific			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Atropine Sulphate	P,S,T	Injection	1 mg/ml
Specific Antisnake venom	P,S,T	Injection Polyvalent Solution/ Lyophilyzed Polyvalent Serum	
Calcium gluconate	P,S,T	Injection	100mg/ml
Desferrioxamine mesylate	S, T	Injection	500mg
Methylthioninium chloride (Methylene blue)	S, T	Injection	10 mg / ml
Penicillamine	S, T	Tablets or Capsules	250 mg

Dimercaprol	S, T	Injection in oil	50 mg / ml
Flumazenil	T	Injection	0.1 mg / ml
Sodium Nitrite	S, T	Injection	30 mg / ml
Sodium Thiosulphate	S, T	Injection	250 mg/ ml
Naloxone	P,S,T	Injection	0.4mg/ml
Pralidoxime Chloride(2-PAM)	P,S,T	Injection	25 mg/ml
Added medicines:			
N-acetylcysteine	P,S,T	Injection	200 mg/ml(5 ml)
Section: 5 – Anticonvulsants/ Antiepileptics			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Carbamazepine	P, S, T	Tablets Syrup	100mg 200mg 100 mg/5ml
Diazepam	P,S,T	Injection	5 mg / ml
Magnesium sulphate	S,T	Injection	500 mg /ml
Phenobarbitone	P,S,T ST P,S,T	Tablets Injection Syrup	30 mg, 60 mg 200 mg/ml 20 mg/5ml
Phenytoin Sodium	P,S,T	Capsules or Tablets Syrup Injection	50 mg, 100mg 25mg/ml 50 mg/ml
Sodium Valproate	P,S,T	Tablets Syrup	200 mg, 500mg 200 mg/5ml
	T	Injection	100 mg/ml
Added Medicines			
Lorazepam	T	Injection	2mg/ml
Section: 6 – Anti-infective Medicines			

6.1 Anthelminthics			
6.1.1 Intestinal Anthelminthics			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Albendazole	P,S,T	Tablets Suspension	400 mg 200 mg/ 5 ml
Added Medicines			
Piperazine	P,S,T	Tablets Solution	4.5 gm 750mg/5ml
6.1.2 Antifilarials			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Diethylcarbamazine citrate	P,S,T	Tablets	50 mg
6.1.3 Antischistosomals and Antitrematode Medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Praziquantel	S, T	Tablets	600 mg
6.2 Antibacterials			
6.2.1 Beta lactam medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Amoxicillin	S,T	Powder for suspension Capsules	125 mg / 5 ml 250 mg, 500 mg
Ampicillin	P,S,T	Capsules Powder for suspension Injection	250 mg, 500 mg 125 mg / 5 ml 500 mg
Benzathine Benzylpenicillin	P,S,T	Injection	6 lacs, 12 lacs units
Cefotaxime	S, T	Injection	125 mg, 250 mg 500 mg
Ceftazidime	S, T	Injection	250mg, 1g
Ceftriaxone	S, T	Injection	250 mg, 1 g
Cephalexin	P,S,T	Syrup	125 mg / 5 ml

		Capsules	250 mg, 500 mg
Cloxacillin	P,S,T	Capsules Injection Liquid	250 mg, 500 mg 250 mg 125mg/ 5 ml
Added Medicines			
Amoxicillin+Clavulinic acid	T	Tablets Powder for suspension Injection	625 mg 228.5mg/5ml 600mg, 1.2gm
Cefixime	T	Tablet	100, 200mg
6.2.2 Other antibacterials			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Amikacin	S, T	Injection	250 mg / 2 ml
Azithromycin	S,T	Tablets Suspension Injection	100, 250,500mg 100mg/5ml 500mg
Ciprofloxacin Hydrochloride	P,S,T	Injection Tablets	200 mg /100 ml 250 mg, 500 mg
Co-Trimoxazole (Trimethoprim + Sulphamethoxazole)	P,S,T	Tablets Suspension	80 + 400 mg 160+800 mg 40 + 200 mg / 5 ml
Doxycycline	P,S,T	Tablets	100 mg
Erythromycin Estolate	P,S,T	Syrup Tablets	125 mg / 5 ml 250 mg, 500 mg
Gentamicin	P,S,T	Injection	10 mg/ml, 40 mg/ml
Metronidazole	P,S,T	Tablet Injection Syrup	200mg,400mg 500mg/100ml 100mg/5ml
Nitrofurantoin	P,S,T	Tablets	100 mg
Sulphadiazine	S, T	Tablets	500 mg
Vancomycin Hydrochloride	T	Injection	500 mg, 1 g
6.2.3 Antileprosy medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Clofazimine	P,S, T	Capsules	50 mg, 100 mg
Dapsone	P,S, T	Tablets	50 mg, 100mg
Rifampicin	P,S, T	Capsules or Tablets	150 mg, 300 mg

6.2.4 Antituberculosis medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Ethambutol	P,S,T	Tablets	200 mg, 400 mg, 600 mg, 800 mg
Isoniazid	P,S,T	Tablets Syrup	50 mg, 100 mg, 300 mg 100 mg/5ml
Ofloxacin	S, T	Tablets	100 mg, 200 mg
		Syrup	50 mg / 5 ml
Pyrazinamide	P,S,T	Tablets	500 mg, 750 mg, 1000 mg, 1500 mg
Rifampicin	P,S,T	Capsules/Tablets Syrup	50 mg, 150 mg, 300 mg,450 mg 100 mg / 5 ml
Streptomycin Sulphate	P,S,T	Injection	0.75 g, 1 g
6.3 Antifungal medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Amphotericin B	S, T	Injection	50 mg
Clotrimazole	P,S,T	Pessaries Gel	100 mg, 200 mg, 2%
Fluconazole	S, T	Capsules or Tablets	50 mg, 100 mg, 150 mg, 200 mg
Griseofulvin	P,S,T	Capsules or Tablets	125 mg, 250 mg
Nystatin	P,S,T	Tablets Pessaries	500,000 IU 100,000 IU
6.4 Antiviral medicines			
6.4.1 Antiherpes medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Acyclovir	S, T	Tablets Injection Suspension	200 mg, 400 mg 250 mg, 500 mg 400 mg / 5 ml
6.4.2 Antiretroviral medicines			
6.4.2.1 Nucleoside reverse transcriptase inhibitors			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**

Didanosine	S, T	Tablets	250 mg, 400 mg
Lamivudine	S, T	Tablets	150 mg
Lamivudine + Nevirapine + Stavudine	S, T	Tablets	150 mg + 200 mg+ 30 mg
Lamivudine + Zidovudine	S, T	Tablets	150 mg + 300 mg
Stavudine	S, T	Capsules	15 mg, 30 mg, 40 mg
Zidovudine	S, T	Tablets	100 mg, 300 mg
ADDED MEDICINES			
Stavudine+ Lamivudine	S,T	Tablets	30mg+ 150mg
Zidovudine+ Lamivudine+ Nevirapine	S,T	Tablets	300mg+ 150mg+ 200mg
6.4.2.2 Non-nucleoside reverse transcriptase inhibitors			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Efavirenz	S, T	Capsules	200 mg, 600 mg
Nevirapine	S, T	Capsules Suspension	200 mg 50 mg / 5 ml
6.4.2.3 Protease inhibitors			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Indinavir	S, T	Capsules	200 mg, 400 mg
Nelfinavir	S, T	Capsules	250 mg
Ritonavir	S, T	Capsules Syrup	100 mg, 400 mg / 5ml
Saquinavir	S, T	Capsules	200 mg
6.5 Antiprotozoal Medicines			
6.5.1 Antiamoebic and Antigiardiasis medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Diloxanide Furoate	P,S,T	Tablets	500 mg
Metronidazole	P,S,T	Tablets Injection	200 mg, 400 mg 500 mg /100 ml

6.5.2 Antileishmaniasis medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Amphotericin B	S, T	Injection	50 mg
Pentamidine Isothionate	S, T	Injection	200 mg
Sodium Stibogluconate	S, T	Injection	100 mg / ml
6.5.3 Antimalarial Medicines			
6.5.3.1 For curative treatment			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Artesunate (To be used only in combination with Sulfadoxine +Pyrimethamine)	P,S,T	Tablets	50 mg
Chloroquine phosphate	P,S,T	Tablets Injection Syrup	150 mg base 40 mg / ml 50 mg / 5 ml
Primaquine	P,S,T	Tablets	2.5 mg, 7.5 mg
Pyrimethamine	P,S,T	Tablets	25 mg
Quinine sulphate	P,S,T ST	Tablets Injection	300 mg 300 mg / ml
Sulfadoxine + Pyrimethamine	P,S,T	Tablets	500 mg + 25 mg
Medicines added			
Clindamycin	S,T	Tablet	150, 300mg
6.5.3.2 For prophylaxis			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Medicines added			
Mefloquine	S,T	Tablet	250 mg base
6.5.4 Antipneumocystosis and Antitoxoplasmosis medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Co-Trimoxazole (Trimethoprim + Sulphamethoxazole)	P,S,T	Tablets Suspension	80 + 400 mg 160+800 mg 40 + 200 mg / 5 ml
Pentamidine Isothionate	S, T	Injection	200 mg

Section: 7 – Antimigraine medicines			
7.1: For treatment of acute attack			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Acetyl Salicylic Acid	P,S,T	Tablets	300 - 350 mg
Dihydroergotamine	S, T	Tablets	1 mg
Paracetamol	P,S,T	Tablets	500 mg
7.2: For Prophylaxis			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Propranolol hydrochloride	P,S,T	Tablets	10 mg, 40 mg
Section: 8 – Antineoplastic, immunosuppressives and medicines used in palliative care			
8.1: Immunosuppressive medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Azathioprine	T	Tablets	50 mg
Cyclosporine	T	Capsules	10 mg, 25 mg, 50 mg, 100 mg
		Concentrate for Injection	100 mg/ml
8.2: Cytotoxic medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Actinomycin D	T	Injection	0.5 mg
Alpha Interferon	T	Injection	3 million IU
Bleomycin	T	Injection	15 mg
Busulphan	T	Tablets	2 mg
Cisplatin	T	Injection	10 mg / vial 50 mg / vial
Cyclophosphamide	T	Tablets Injection	50 mg, 200 mg 500 mg
Cytosine	T	Injection	100 mg/vial
arabinoside			500 mg/vial 1000 mg/vial
Danazol	T	Capsules	50 mg, 100 mg
Doxorubicin	T	Injection	10 mg, 50 mg

Etoposide	T	Capsules Injection	100 mg 100 mg/ 5 ml vial
Flutamide	T	Tablet	250 mg
5-Fluorouracil	T	Injection	250 mg / 5 ml
Folinic Acid	T	Injection	3 mg / ml
Gemcitabine hydrochloride	T	Injection	200 mg 1 gm
L- Asparaginase	T	Injection	5000 KU.
Melphalan	T	Tablet	2 mg, 5 mg
Mercaptopurine	T	Tablet Injection	50 mg 100 mg / ml
Methotrexate	T	Tablet Injection	2.5 mg 50 mg / ml
Mitomycin-C	T	Injection	10 mg
Paclitaxel	T	Injection	30 mg / 5 ml
Procarbazine	T	Capsules	50 mg
Vinblastine sulphate	T	Injection	10 mg
Vincristine	T	Injection	1 mg / ml
Added medicines			
Carboplatin	T	Injection	150 mg, 450 mg vial
Dacarbazine	T	Injection	500 mg
Daunorubicin	T	Injection	20 mg vial
Ifosfamide	T	Injection	1 gm/2ml vial
Mesna	T	Injection	200 mg
Oxaliplatin	T	Injection	50 mg vial
Imatinib	T	Tablets	100 mg, 400 mg
Chlorambucil	T	Tablets	2 mg
8.3: Hormones and antihormones			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Prednisolone	S, T	Tablets	5 mg
		Injection	20 mg, 25 mg (as sodium phosphate or succinate)
Raloxifene	T	Tablets	60 mg
Tamoxifen Citrate	T	Tablets	10 mg, 20 mg

8.4: Medicines used in palliative care			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Morphine Sulphate	T	Tablets	10 mg
Ondansetron	S, T	Tablets	4 mg, 8 mg
		Injection	2 mg/ml
		Syrup	2 mg/5 ml
Added Medicines			
Filgrastim	T	Injection	1 ml vial
Allopurinol	T	Tablets	100 mg

Section: 9 –Antiparkinsonism medicines

Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Bromocriptine Mesylate	S, T	Tablets	1.25 mg, 2.5 mg
Levodopa+ Carbidopa	P,S,T	Tablets	100 mg+10 mg 250 mg+25 mg 100 mg+25 mg
Trihexyphenidyl Hydrochloride	P,S,T	Tablets	2 mg

Section: 10 –Medicines affecting the blood

10.1: Antianaemia medicines

Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Cyanocobalamin	P, S,T	Injection	1 mg/ml
Ferrous Sulphate/ Fumrate	P,S,T	Tablets	Tablets equivalent to 60 mg elemental iron
		Oral solution	25mg elemental iron (as sulphate)/ml
Folic Acid	P,S,T	Tablets	1 mg , 5mg
Iron Dextran	S, T	Injection	50 mg iron/ml
Pyridoxine	P,S,T	Tablets	10 mg

10.2: Medicines affecting coagulation

Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Heparin Sodium	S, T	Injection	1000 IU/ml 5000 IU/ ml

Protamine Sulphate	S, T	Injection	10 mg/ml
Phytomenadione	P, S, T	Injection	10 mg/ml
Warfarin sodium	S, T	Tablets	5 mg
Added Medicines			
Enoxaparin	T	Injection	40mg, 60mg

Section: 11 –Blood products and Plasma substitutes

11.1: Plasma Substitutes

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Dextran-40	P,S,T	Injection	10%
Dextran-70	P,S,T	Injection	6%
Fresh frozen plasma	T	Injection	
Hydroxyethyl Starch (Hetastarch)	S, T	Injection	6%
Polygeline	S, T	Injection	3.5%

11.2: Plasma fractions for specific use

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Albumin	S, T	Injection	5%, 20 %
Cryoprecipitate	S, T	Injection	
Factor VIII Concentrate	S, T	Injection	Dried
Factor IX Complex (Coagulation Factors II,VII, IX, X)	S, T	Injection	Dried
Platelet Rich Plasma	S, T	Injection	

Section: 12 –Cardiovascular medicines

12.1: Antianginal medicines

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Acetyl salicylic acid	P,S,T	Tablets	75mg, 100mg, 350 mg soluble/dispersible
Diltiazem	S, T	Tablets	30 mg, 60 mg
Glyceryl Trinitrate	P,S,T	Sublingual Tablets Injection	0.5 mg 5mg/ml

Isosorbide 5 Mononitrate/ Dinitrate	P,S,T	Tablets	10 mg, 20 mg
Metoprolol	P,S,T	Tablets Injection	25 mg, 50 mg 1mg/ml
Added Medicines			
Clopidogrel	T	Tablets	75 mg
12.2: Antiarrhythmic medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Adenosine	S,T	Injection	3 mg/ml
Amiodarone	S, T	Tablets Injection	100 mg, 200 mg 50 mg/ml (3 ml ampoule)
Diltiazem	S, T	Tablets	30 mg, 60 mg
	T	Injection	5 mg/ ml
Esmolol	T	Injection	10 mg / ml
Lignocaine Hydrochloride	S, T	Injection	1%, 2%
Procainamide Hydrochloride	T	Tablets Injection	250 mg 100mg/ml
Verapamil	S, T	Tablets Injection	40 mg, 80 mg 2.5mg/ml
12.3: Antihypertensive medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Amlodipine	P,S,T	Tablets	2.5 mg, 5 mg
Atenolol	P,S,T	Tablets	50 mg, 100 mg
Enalapril Maleate	P,S,T T	Tablets Injection	2.5 mg, 5mg 1.25mg/ml
Losartan Potassium	S, T	Tablets	25 mg, 50 mg
Methyldopa	P,S, T	Tablets	250 mg
Nifedipine	S, T	Capsules Tablets Sustained release tablets or capsules	5 mg, 10mg 10mg, 20mg 10mg, 20mg
Sodium Nitroprusside	T	Injection	50 mg/ 5 ml
Added Medicines			
Hydrochlorthiazide	P,S,T	Tablets	12.5, 25 mg

12.4: Medicines used in heart failure

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Digoxin	S, T	Tablets Injection Elixir	0.25 mg 0.25 mg/ml 0.05 mg/ml
Dobutamine	S, T	Injection	50 mg / ml
Dopamine Hydrochloride	S,T	Injection	40 mg / ml

12.5: Antithrombotic medicines

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Acetyl salicylic acid	P,S,T	Tablets	75mg, 100mg, 350 mg soluble/dispersible
Heparin Sodium	S, T	Injection	1000 IU /ml 5000 IU/ml
Streptokinase	S, T	Injection	750,000 IU 15,00,000 IU
Urokinase	T	Injection	500,000 IU/ml 10,00,000 IU/ml

New Category - ADDED

12.6 Hypolipidemic Medicines

Atorvastatin	P,S,T	Tablets	5 mg, 10 mg

Section: 13 –Dermatological medicines (Topical)

13.1: Antifungal medicines

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Miconazole	P,S,T	Ointment or Cream	2%

13.2: Antiinfective medicines

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Acyclovir	S, T	Cream	5%
Framycetin Sulphate	P,S,T	Cream	0.5%
Methylrosanilinium Chloride (Gentian Violet)	P,S,T	Aqueous solution	0.5%

Neomycin + Bacitracin	P,S,T	Ointment	5 mg + 500 IU / g
Povidone Iodine	P,S,T	Solution or Ointment	5%
Silver Sulphadiazine	P,S,T	Cream	1%
13.3: Antiinflammatory and antipruritic medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**S trengths**
Betamethasone Dipropionate	P,S,T	Cream / Ointment	0.05%
Calamine	P,S,T	Lotion	
13.4: Astringent Medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Zinc Oxide	P,S,T	Dusting Powder	
13.5: Medicines affecting skin differentiation and proliferation			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Coal Tar	P,S,T	Solution	5%
Dithranol	T	Ointment	0.1-2%
Glycerin	P,S,T	Solution	
Salicylic Acid	P,S,T	Solution	5%
13.6: Scabicides and Pediculicides			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Benzyl benzoate	P,S,T	Lotion	25 %
Added Medicines			
Permethrin	S,T	Cream Lotion	5% 1%, 5%
Section: 14 –Diagnostic agents			
14.1: Ophthalmic medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Fluorescein	S, T	Eye drops	1%
Lignocaine	S, T	Eye Drops	4%
Tropicamide	S, T	Eye drops	1%

14.2: Radiocontrast media

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Barium Sulphate	S, T	Suspension	100% w/v, 250% w/v
Calcium Ipodate	S, T	Injection	3 g
Iopanoic Acid	S, T	Tablets	500 mg
Meglumine Iothalamate	S, T	Injection	60% w/v (iodine =280 mg / ml)
Meglumine Iotroxate	S, T	Solution	5-8 g iodine in 100-250 ml
Propyliodone	S, T	Oily, suspension	500-600 mg / ml
Sodium Iothalamate	S, T	Injection	70% w/v(Iodine =420 mg / ml)
Sodium Meglumine Diatrizoate	S, T	Injection	60% w/v(Iodine conc. =292 mg / ml), 76% w/v(Iodine conc. =370 mg / ml)

Section: 15 –Disinfectants and antiseptics

15.1: Antiseptics

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Acriflavin+Glycerin	P, S, T	Solution	
Benzoin Compound	P, S, T	Tincture	
Cetrimide	P, S, T	Solution	20% (conc. for dilution)
Chlorhexidine	P, S, T	Solution	5% (conc. for dilution)
Ethyl Alcohol 70%	P, S, T	Solution	
Gentian Violet	P, S, T	Paint	0.5%, 1%
Hydrogen Peroxide	P, S, T	Solution	6%
Povidone Iodine	P, S, T	Solution	5%, 10%

15.2: Disinfectants

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Bleaching Powder	P, S, T	Powder	Contains not less than 30 % w/w of available chlorine (as per I.P)
Formaldehyde Solution	P, S, T	Solution	Dilute 34 ml of formaldehyde solution with water

			to produce 100 ml (As per I.P)
Glutaraldehyde	S,T	Solution	2%
Potassium Permanganate	P, S, T	Crystals for solution	

Section: 16 –Diuretics

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Furosemide	P,S,T	Injection Tablets	10 mg/ ml 40mg
Hydrochlorothiazide	P,S,T	Tablets	25 mg, 50 mg
Mannitol	P,S,T	Injection	10%, 20%
Spironolactone	P,S,T	Tablets	25 mg

Section: 17 – Gastrointestinal medicines

17.1: Antacids and other Antiulcer medicines

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Aluminium Hydroxide + Magnesium Hydroxide	P,S,T	Tablet Suspension	
Omeprazole	P,S,T	Capsules	10 mg, 20 mg, 40 mg
Ranitidine	P,S,T	Injection	25 mg / ml
Added Medicines			
Pantoprazole	T	Injection	40 mg
Famotidine	P,S,T	Tablets	20 mg

17.2: Antiemetics

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Domperidone	P,S,T	Tablets Syrup	10 mg 1 mg / ml
Metoclopramide	P,S,T	Tablets Syrup Injection	10 mg 5 mg / 5 ml 5 mg / ml
Promethazine	P,S,T	Tablets Elixir or Syrup Injection	10 mg, 25 mg 5 mg / 5 ml 25 mg / ml
Added Medicines			
Ondansetron	S,T	Tablet Syrup Injection	4mg, 8 mg 2 mg/ml 2mg/ml

17.3: Antiinflammatory Medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Added Medicines			
5-Amino salicylic Acid (5-ASA)	S,T	Tablets	400mg
17.4: Antispasmodic medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Dicyclomine Hydrochloride	P,S,T	Tablets Injection	10 mg 10 mg / ml
Hyoscine Butyl Bromide	P,S,T	Tablets Injection	10 mg 20 mg / ml
17.5: Laxatives			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Bisacodyl	P,S,T	Tablets, Suppository	5 mg
Ispaghula	P,S,T	Granules	
17.6: Medicines used in diarrhorea			
17.6.1 Oral dehydration salts			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Oral Rehydration Salts	P,S,T	Powder for solution	Glucose: 13.5 g/L Sodium chloride: 2.6 g/L Potassium chloride: 1.5 g/L Trisodium citrate dihydrate+: 2.9 g/L Powder for dilution in 200ml; 500 ml; 1000ml. (As per I.P)
17.6.2 Antidiarrhoeal medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Medicines added			
Zinc Sulfate	P,S,T	Syrup	20 mg/5ml

Section: 18 –Hormones, other endocrine medicines and contraceptives

18.1: Adrenal hormones and synthetic substitutes

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Dexamethasone	S,T	Tablets Injection	0.5mg 4mg/ml
Hydrocortisone Sodium Succinate	P, S,T	Injection	100 mg / ml
Methyl Prednisolone	S,T	Injection	40 mg/ ml
Prednisolone	P, S,T	Tablets	5mg, 10mg, 20mg

18.2: Androgens

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Testosterone	P,S,T	Capsules Injection	40mg(as undecanoate) 25mg/ml(as propionate)

18.3: Contraceptives

18.3.1: Hormonal Contraceptives

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Ethinylestradiol + Levonorgesterol	P,S,T	Tablets	0.03 mg +0.15 mg
Ethinylestradiol + Norethisterone	P,S,T	Tablets	0.035 mg +1.0 mg
Hormone Releasing IUD	T	Levonorgesterol Releasing	IUD

18.3.2: Intrauterine devices

Medicines	Category	Route of Administration/ Dosage Form	Strengths
IUD containing Copper	**P,S,T**		

18.3.3: Barrier Methods

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Condoms	**P,S,T**		

18.4: Estrogens

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Ethinylestradiol	P,S,T	Tablets	0.01mg 0.05mg
18.5: Medicines used in Diabetes mellitus			
18.5.1: Insulins and other Antidiabetic agents			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Glibenclamide	P,S,T	Tablets	2.5 mg, 5mg
Insulin Injection (Soluble)	P,S,T	Injection	40 IU / ml
Intermediate Acting(Lente/NPH Insulin)	P,S,T	Injection	40 IU / ml
Metformin	P,S,T	Tablets	500mg
Added medicines			
Premix Insulin 30:70 injection	P,S,T	Injection	40IU/ml
18.5.2 Medicines used to treat hypoglycemia			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Glucagon	T	Injection	1mg/ml
Added medicines			
25% Dextrose	P,S,T	Injection	100 ml
18.6 Ovulation Inducers			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Clomiphene citrate	T	Tablets	50mg, 100mg
18.7 Progestogens			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Medroxy Progesterone Acetate	P,S,T	Tablets	5mg, 10mg
Norethisterone	P,S,T	Tablets	5mg
18.8 Thyroid and antithyroid medicines			

Medicines	Category	Route of Administration / Dosage Form	Strengths
Carbimazole	P,S,T	Tablets	5mg, 10mg
Levothyroxine	P,S,T	Tablets	50µg, 100 µg
Iodine	S,T	Solution	8 mg / 5 ml
Section: 19 Immunologicals			
19.1: Diagnostic agents			
Drugs	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Tuberculin, Purified Protein derivative	P,S,T	Injection	1 TU, 5 TU
19.2: Sera and immunoglobins			
Drugs	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Anti-D immunoglobin (human)	S, T	Injection	300 µg
Polyvalent Antisnake Venom	P,S,T	Injection	10 ml
Antitetanus Human immunoglobin	P,S,T	Injection	250 IU, 500 IU
Diphtheria Antitoxin	S, T	Injection	10,000 IU
Rabies immunoglobin	P,S,T	Injection	150 IU / ml
19.3: Vaccines			
19.3.1: For Universal Immunisation			
Drugs	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
B.C.G Vaccine	P,S,T	Injection	
D.P.T Vaccine	P,S,T	Injection	
Hepatitis B Vaccine	P,S,T	Injection	
Measles Vaccine	P,S,T	Injection	
Oral Poliomyelitis vaccine (LA)	P,S,T	Solution	
19.3.2: For Specific Group of Individuals			

Drugs	Category	Route of Administration/ Dosage Form	Strengths
Rabies Vaccine	P,S,T	Injection	
Tetanus Toxoid	P,S,T	Injection	
Section: 20 – Muscle Relaxants (Peripherally acting) and Cholinesterase Inhibitors			
Drugs	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Atracurium besylate	S, T	Injection	10 mg / ml
Neostigmine	S,T	Tablets, Injection	15 mg, 0.5mg/ml
Pyridostigmine	S, T	Tablets, Injection	60 mg, 1mg/ml
Succinyl choline chloride	S,T	Injection	50 mg/ml
Added drugs			
Vecuronium	P,S,T	Injection	2 mg/ml
Section: 21 – Ophthalmological Preparations			
21.1: Anti-infective agents			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Chloramphenicol	P,S,T	Drops/Ointment	0.4%, 1%
Ciprofloxacin Hydrochloride	P,S,T	Drops/Ointment	0.3%
Gentamicin	P,S,T	Drops	0.3%
Miconazole	P,S,T	Drops	1%
Povidone Iodine	S,T	Drops	0.6%
Sulphacetamide Sodium	P,S,T	Drops	10%,20%
21.2: Antiinflammaory agents			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Prednisolone Acetate	P,S,T	Drops	0.1%
Prednisolone Sodium Phosphate	P,S,T	Drops	1%
21.3: Local Anaesthetics			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**

Tetracaine Hydrochloride	P,S,T	Drops	0.5%
21.4: Miotics and Antiglucoma medicines			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Acetazolamide	S,T	Tablets	250 mg
Betaxolol Hydrochloride	T	Drops	0.25%, 0.5%
Pilocarpine	S,T	Drops	2%, 4%
Timolol Maleate	P, S, T	Drops	0.25%, 0.5%,
21.5: Mydriatics			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Atropine Sulphate	P,S,T	Drops/Ointment	1%
Homatropine	P,S,T	Drops	2%
Phenylephrine	P,S,T	Drops	5%
21.6: Ophthalmic Surgical Aids			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Methyl Cellulose	T	Injection	2%
Section: 22 – Oxytocics and Antioxytocics			
22.1: Oxytocics			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Methyl Ergometrine	P,S,T	Tablets Injection	0.125mg 0.2mg/ml
Mifepristone	T	Tablets	200mg
Oxytocin	S,T	Injection	5 IU/ ml, 10IU/ml
Added medicines			
Misoprostol	T	Tablets	100ug
22.2: Antioxytocics			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**

Terbutaline Sulphate	S,T	Tablets Injection	2.5 mg 0.5 mg/ml
Added Medicines			
Nifedipine	S,T	Tablets	10 mg
Betamethasone	P,S,T	Injection	4 mg/ml
Section: 23 – Peritoneal Dialysis Solution			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Intraperitoneal Dialysis Solution	T		4Of approximate composition
Section: 24 – Psychotherapeutic Medicines			
24.1: Medicines used in Psychotic Disorders			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**S trengths**
Chlorpromazine hydrochloride	P,S,T	Tablets Syrup Injection	25 mg, 50mg, 100mg 25mg/5ml 25mg/ml
Haloperidol	S, T	Injection	**5mg/ml**
Added medicines			
Olanzapine	T	Tablets	5mg,10mg
24.2: Medicines used in mood disorders			
24.2.1: Medicines used in Depressive disorders			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Amitriptyline	P,S,T	Tablets	25 mg
Fluoxetine hydrochloride	P,S,T	Capsules	20 mg
Imipramine	P,S,T	Tablets	25 mg, 75 mg
24.2.2: Medicines used in Bipolar disorders			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Lithium Carbonate	T	Tablets	300 mg
Added Medicines			
Sodium Valproate	P,S,T	Tablets	200 mg, 500mg

24.3: Medicines used for Generalized Anxiety and Sleep Disorders

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Alprazolam	P,S,T	Tablets	0.25 mg, 0.5 mg
Diazepam	P,S,T	Tablets	2 mg, 5mg

24.4: Medicines used for obsessive compulsive disorders and panic attacks

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Added Medicines			
Fluoxetine hydrochloride	P,S,T	Capsules	20 mg

Section: 25 – Medicines acting on the respiratory tract

25.1: Antiasthmatic medicines

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Beclomethasone Dipropionate	P,S,T	Inhalation	50 µg, 250µg/dose
Hydrocortisone sodium succinate	P,S,T	Injection	100 mg, 200mg, 400 mg
Salbutamol sulphate	P,S,T	Tablets Syrup Inhalation	2mg, 4mg 2mg/5ml 100µg/dose
Added Medicines			
Ipratropium bromide	P,S,T	Inhalation	20µg/metered dose

25.2: Antitussives

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Codeine phosphate	S,T	Tablets Syrup	10mg 15mg/ 5ml
Dextromethorphan	P,S,T	Tablets	30mg

Section: 26 – Solutions correcting water, electrolyte and acid-base disturbances

26.1: Oral

Medicines	Category	Route of Administration/ Dosage Form	Strengths
Oral Rehydration Salts	P, S, T	Powder for Solution	As per IP

26.2: Parenteral			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Glucose	P, S, T	Injection	5% isotonic, 10%, 15%.
Glucose with sodium chloride	P, S, T	Injection	5% + 0.9%
Normal Saline	P, S, T	Injection	0.9%
N/2 Saline	S, T	Injection	
N/5 Saline	S, T	Injection	
Potassium Chloride	P, S, T	Injection	11.2% Sol.
Ringer Lactate	P, S, T	Injection	As per IP
Sodium Bicarbonate	P, S, T	Injection	As per IP
26.3: Miscellaneous			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Water for Injection	P, S, T	Injection	2 ml, 5 ml, 10 ml
Section: 27 – Vitamins and Minerals			
Medicines	**Category**	**Route of Administration/ Dosage Form**	**Strengths**
Ascorbic Acid	P,S,T	Tablets	100 mg, 500 mg
Calcium carbonate	P,S,T	Tablets	250 mg, 500 mg
Multivitamins (As per Schedule V of Drugs and Cosmetics Rules)	P,S,T	Tablets	
Nicotinamide	P,S,T	Tablets	50 mg
Pyridoxine	P,S,T	Tablets	25 mg
Riboflavin	P,S,T	Tablets	5 mg
Thiamine	P,S,T	Tablets	100 mg
Vitamin A	P,S,T	Tablets Capsules	5000 IU, 50000 IU, 100000 IU,
		Injection	50000 IU/ml
Vitamin D (Ergocalciferol)	P,S,T	Capsules	0.25 mg, 1 mg
Added Medicines			
Calcium gluconate	P,S,T	Injection	100mg/ml in 10 ml ampoule

SCHEDULE-II

FORM - I

PROFORMA FOR APPLICATION FOR PRICE FIXATION / REVISION OF A NEW DRUG FORMULATION RELATED TO NLEM FORMULATION

(See paragraphs 2(u),5,7,8,9,15)

1. Name of the formulation:
2. Name and address of the manufacturer/importer :
3. Name of the Marketing Company, if any:
4. Composition as per label claimed and approved by Drug Control Authorities:
5. Drugs Control Authority Permission Number and Date (copy to be enclosed):
6. Date of commencement of production / import:
7. Type of formulation (Tablets/ Capsules/ Syrup/ Injection/ Ointment/ Powder etc.):
8. Size of packs (10's/ 100's/ 1 ml/ 2 ml/ 10 ml/ 5 gms/ 10 gms etc.)
9. Therapeutic category/ use of the formulation.
10. The Retail Price claimed for approval
11. Reason for submission of application for price fixation / revision.
12. Any other information relevant to product and its process of manufacturing/ packaging/ distribution.

The information furnished above is correct and true to the best of my knowledge and belief.

Place: **Authorized Signatory:**

Name:

Date: **Designation:**

SCHEDULE-II
FORM - II

PROFORMA FOR SUBMISSION OF REVISED-PRICES FOR SCHEDULED FORMULATIONS

(See paragraph 16)

1. Name and address of the manufacturer / importer / distributor.
2. Name and address of the marketing company, if any.

Sl. No.	Name of the Product (Formulation and its dosage forms)	Composition of scheduled formulation/ new drug	Pack Size	WPI change w.r.t preceeding Year	Price to retailer (incl. of E.D.) (Rs.)		Maximum Retail Price (incl. of E.D.&Taxes) (Rs.)		Ceiling Price (Notified) (Rs.)	Effective Batch No. and date
					Pre-Revised	Revised	Pre-Revised	Revised		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
	Scheduled Formulations									
	Own Manufactured Formulations									
	Purchased/Imported Formulations									

Notes:- In case of purchased formulation, name of the manufacturer shall be indicated.

The information furnished above is correct and true to the best of my knowledge and belief.

Place:

Date:

Authorised Signatory:
Name:
Designation:

SCHEDULE-II
FORM – III

PROFORMA FOR QUARTERLY RETURN IN RESPECT OF PRODUCTION/IMPORT AND SALE OF NLEM DRUGS
(See paragraphs 21(1))

1. Name and address of the manufacturer/importer:
2. Name and address of marketing company, if any:
3. Details of production/import and sale for the Quarter of a Year: .....

TABLE-A

Name of the Scheduled Formulation	Composition /Strength	Dosage Form	Unit(No/ kg/Ltr)	Production/Import Level					Domestic Sale				
				Previous Year	Current Year				Previous Year	Current Year			
					1st Quarter	2nd Quarter	3rd Quarter	4th Quarter		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)

TABLE-B

Name of the Bulk Drug/API used in Scheduled Formulation	Unit (Kg/ Ltr)	Installed Capacity	Production/Import Level					Domestic Sale				
			Previous Year	Current Year				Previous Year	Current Year			
				1st Quarter	2nd Quarter	3rd Quarter	4th Quarter		1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)

Constraints, if any:

Note: (1) Production outsourced / carried out on job work basis should also be included

The information furnished above is correct and true to the best of my knowledge and belief.

Place:
Date:

Authorised Signatory:
Name:
Designation:

SCHEDULE-II

FORM - IV

PROFORMA FOR SUBMISSION OF THE DETAILS IN RESPECT OF DISCONTINUATION OF THE PRODUCTION AND/ OR IMPORT OF SCHEDULED FORMULATION

(See paragraphs 21(2))

1. Name of the formulation:
2. Name and address of the manufacturer/importer :
3. Name of the Marketing Company, if any:
4. Composition as per label claimed and approved by Drug Control Authorities:
5. Drugs Control Authority Permission Number and Date (copy to be enclosed):
6. Celling Price and date of notification:
7. Existing maximum retail price (MRP) and its effective date:
8. Therapeutic category as per NLEM:
9. Date of commencement of production / import
10. Proposed date of discontinuation:
11. Reasons for discontinuation of production / import:
12. Year-wise Production/Import during the last 5 years including current year
13. Year-wise sale during the last 5 years including current year
14. Whether any new drug as defined under Proviso of Definition of “New Drug” under DPCO, 2013 has been launched or intended to be launched. If so, the details thereof:
15. Any other information relevant to discontinuation of scheduled formulation:

Authorized Signatory:

Place:

Name:

Date:

Designation:

SCHEDULE-II
FORM - V

PROFORMA FOR PRICE LIST

(See paragraphs 2(x),24,25,26)

1. Name and address of the manufacturer / importer / distributor.
2. Name and address of the marketing company, if any.

TABLE-A

Sl. No.	Name of the Product (Formulation and its dosage forms)	Composition approved by Drug Control Authorities	Pack Size	Price to retailer (incl. of E.D.) (Rs.)	Maximum Retail Price (incl. of E.D.&Taxes) (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Scheduled Formulations				
	Own Manufactured Formulations				
	Purchased/Imported Formulations				

TABLE-B

Sl. No.	Name of the Product (Formulation and its dosage forms)	Composition approved by Drug Control Authorities	Pack Size	Price to retailer (incl. of E.D.) (Rs.)	Maximum Retail Price (incl. of E.D.&Taxes) (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Non-Scheduled Formulations				
	Own Manufactured Formulations				
	Purchased/Imported Formulations				

Notes:- In case of purchased formulation, name of the manufacturer shall be indicated.

The information furnished above is correct and true to the best of my knowledge and belief.

Authorised Signatory:

Place:

Date:

Name:

Designation:

NEWS

Chemists Protest

Members of the Tamil Nadu Chemists and Druggists Association went on a day-long fast on Friday.

The association is worried reducing the price of 348 drug molecules to benefit the consumers will adversely affect their profits.

The association, with Statewide presence, has around 40,000 members. “We have repeatedly sent representations to the Central and State governments but there has been no reprieve,” said association president K.K. Selvan.

“The government had cut the price of 74 drugs but now with the additional burden of 274 drugs going of the list, it will be difficult to remain in the business,” he said.

While the price of a drug will fall by 30 per cent for the consumer, the pharmacist will face a four per cent cut in profit. The State currently has 40,000 retail shops and 2,000 wholesale medical shops.

Source: *The Hindu, 11th May 2013*

Govt Close To Notifying Drug Price Policy

Consumers can finally look forward to a reduction in medicine prices. The long-awaited **National Pharmaceutical Pricing Policy** is finally close to being implemented with the government expected to issue the **Drug Price Control Order** (DPCO) over the next couple of days.

The DPCO will give teeth to the already-approved national pharma policy — which has not yet led to the regulation of drug prices — and may be issued as early as May 16, sources told TOI. The order has already received approval from all ministries, they added. The policy, which caps prices of 652 formulations under 27 therapeutic areas like anti-infectives (cetrizine), cardiac (aten), gastro-intestinal medicines (ocid) , pain-killers (paracetamol) and anti-diabetic drugs (insulin), was cleared by the Union Cabinet in November last year. Once implemented, it will result in prices of drugs coming down by around 20%.

Significantly, the changes in prices will be effective after 45 days from the date of issue (of notification) to allow the trade (chemists) to liquidate stocks with existing prices. So assuming that the notification is issued on May 16, the new prices would be effective from July 1. The retail prices in May 2012 will be taken as the cut-off for calculation of ceiling prices, sources added.

The DPCO 2013 — issued under the Essential Commodities Act,1955— will lay the framework of the drug policy, mechanism of regulating prices and list the 652 commonly-used drug formulations which are being brought under the price control policy, sources said. It will replace the existing DPCO 1995 which regulates prices of 74 medicines in the country at present.

It will also list penalties for violation of provisions.

The policy uses a market-based pricing method — 'the simple average method' — for determining the ceiling price of all the molecules (drugs) under a particular therapeutic area with over 1% market share. The scope of the policy is around 18% of the Rs 72,000-crore pharmaceutical market. The coverage increases to around 30% after coupling the policy with existing medicines already under price control.

The government is expected to submit the DPCO 2013 before the Supreme Court when it meets to hear the public interest litigation filed in 2003 to bring down prices of essential medicines.

Source: *The Times of India, 16th May 2013*

Too Much Control on Too Many Drugs

The new price control regime has gaping holes

The number of **drugs** under **price control** has gone up from 74 to 652. The size of the spurious drug trade, estimated to be huge, remains absolutely unchanged.Why put these two seemingly unrelated parts of the pharma story together? Because of the wrong focus of policy action. Rather than unaffordability of off-patent generic drugs, what hits healthcare in India is wide distribution of fake and substandard drugs, packaged to look like the real thing.

The administrative resources of the government are to be expended on keeping tabs on the prices of as many as 652 drugs, each with multiple producers in India's fragmented pharma industry.

Each producer is entitled to a price cap that is the lower of its own legacy pricing and the simple arithmetic mean of all brands with more than 1% market share, and has a strong incentive to launch a new brand of the same drug that can be priced at, rather than below, the capped price.

In this scenario, fake drugs would receive very little attention. Why not at least a weighted average of the prices of producers with a market share more than 1%? Why not the median price or the modal? How can drug prices be allowed to go up in proportion with the wholesale price index?

Suppose food prices go up sharply in a year, thanks to a drought or mismanagement of the food stocks by a KV Thomas-type minister; why should the prices of drugs, which have low labour content in their manufacture and so are relatively insulated from any inflation-indexation of wages, go up in tandem?

Why discount efficiency improvements that might warrant a price reduction? Patented drugs, rather than generic drugs from producers who have to compete intensely with other producers, raise the challenge of affordability. Eight years after India heralded a product patent regime, we are yet to see a policy to control patented drugs.

This is policymaking lethargy. The government needs more holistic thinking, more vigorous public consultation and a larger public healthcare system, to hold drug prices down. That's a small part of curtailing healthcare costs.

Source: *The Economic Times, 17th May 2013*

New Drug Price Regime To Alter Structure

The Indian consumer will benefit under the new Drug Pricing Control Order 2013 (DPCO 2013) which has been notified and will replace the DPCO 1995. The new order will bring 652 drugs under price control and will enable the National Pharmaceutical Pricing Policy 2012 to regulate prices of 348 drugs covered under the National List of Essential Medicines (NLEM) 2011.

“Consumers will be the biggest beneficiaries as prices of some brands may fall by up to 70 per cent,” D.G. Shah, Secretary General, Indian Pharmaceutical Alliance (IPA) said. “It will bring about a structural change ,” Mr. Shah said.

The new policy differs from the existing DPCO 1995 in that it is based on the simple average price (SAP) for all brands with a market share above 1 per cent in their segment. The new policy also uses a market-based pricing mechanism against the earlier proposed cost-plus method.

TWO-THIRDS

Analysts estimate that the policy will cover two-thirds of the Rs. 60,000 crore domestic industry. "The larger companies with established brands may be able to sustain better but there could be some loss of market share. There will no doubt be an initial spurt in volumes when prices decline," Rahul Sharma, pharma analyst with Karvy Stock Broking told *The Hindu.*

In the long-term, the policy proposes to reduce the bandwidth of prices of the same molecule and this will have an impact on manufacturers in the mid and lower segments, analysts feel.

Mr. Shah estimated the average impact on industry profitability to be around 20 per cent. "So in the short-term, industry profitability could decline by around Rs. 1,500 crore. It will have a 2 percentage point impact on margins and this could come down to 8 per cent," he said.

However, despite the initial hit on profitability, volume growth over the next few years and price indexation to inflation will help companies recover. "The policy has moved away from the intrusive and opaque cost-plus pricing mechanism to a more transparent market-based pricing regime," Mr. Shah said.

Source: *The Hindu, 19th May 2013*

PARLIAMENT QUESTION – ANSWERS

LOK SABHA

Unstarred Question No. 5763

Answered on 02.05.13

FIXATION OF CEILING PRICES FOR IMPORTED FORMULATIONS

5763 Shri A.K.S. VIJAYAN

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

(a) whether the Organisation of Pharmaceutical Producers of India has asked the Government to fix the ceiling prices separately for imported formulations because making the same drugs outside the country is more costly; and

(b) if so, the details thereof and the reaction of the Government thereto?

ANSWER

MINISTER OF STATE (INDEPENDENT CHARGE) IN THE MINISTRY OF CHEMICALS AND FERTILIZERS AND MINISTER OF STATE (INDEPENDENT CHARGE) IN THE MINISTRY OF STATISTICS AND PROGRAMME IMPLEMENTATION (SHRI SRIKANT KUMAR JENA)

(a) & (b) The Organisation of Pharmaceutical Producers of India (OPPI) had given the following suggestions/inputs on draft National Pharmaceutical Pricing Policy 2011 (NPPP-2011):

"Import products have different cost-structure and are not comparable to locally manufactured drugs, consequently, imported formulations included in National List of Essential Medicines-2011 (NLEM)-2011) should be placed in a separate category and a separate ceiling price should be fixed for them."

These suggestions of OPPI were placed before the Group of Ministers(GoM). Based on the recommendations of GoM, National Pharmaceutical Pricing Policy 2012 (NPPP-2012) was formulated and placed before the Cabinet. The Cabinet considered NPPP-2012 in its meeting held on 22.11.2012 and based on the approval of the Cabinet the NPPP-2012 was notified on 712.2012.

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