THE DRUGS (PRICES CONTROL) ORDER, 2013

(Notified by SO 1221 (E) dated 15.05.2013 and as amended up to vide SO 1192(E) dated 22-03-2016)

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;
(i) "**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 or imports or markets drugs for distribution or sale in the country;][1]
(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

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[1] *Substituted vide GSR 1233 (E), w.e.f. 08-05-2015*

the same drug of specified dosages and strengths as listed in the National List of Essential Medicines.

[(v) **"non-scheduled formulation**" means a formulation, which is not included in Schedule – 1.][2]

(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.

(2) All other words and expressions used herein and not defined but defined in the Act or the Drugs and Cosmetics Act, 1940 (23 of 1940) shall have the meanings respectively assigned to them in the said Acts.

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

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[2] *Substituted vide GSR 686(E), w.e.f. 09-03-2015*

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 30th May'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.

[(3) Notwithstanding anything contained in sub-paragraph (1) and (2), in the case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I of the Drugs (Prices Control) Order, 2013, the Government may fix and notify separate ceiling price or retail price for such formulations with specified therapeutic rationale, considering the type of packaging or pack size or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be, conforming to Indian Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder for the same formulation.

(4) The Government shall form a Committee of Experts, as it may deem fit, within a period of fifteen days from the date of issue of this order, to recommend fixing of separate ceiling price of scheduled formulations or retail price of a new drug as per the above parameter.][3]

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
Price list;
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.

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[3] *inserted vide S.O.1192(E), dated 22.03.2016*

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 months 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;

[SCHEDULE-I

National List of Essential Medicines 2015

[See paragraphs-2(t), 2(zb)]

(Symbols P, S and T appearing in this Schedule denote essentiality at Primary, Secondary and Tertiary levels respectively)			
Section 1-Anesthetic agents			
1.1-General Anesthetics and oxygen			
	Medicine	Level of Healthcare	Dosage form and strength
1.1.1	Halothane	S,T	Inhalation
1.1.2	Isoflurane	S,T	Inhalation
1.1.3	Ketamine	P,S,T	Injection 10 mg/ml Injection 50 mg/ml
1.1.4	Nitrous oxide	P,S,T	Inhalation
1.1.5	Oxygen	P,S,T	Inhalation (Medicinal gas)
1.1.6	Propofol	P,S,T	Injection 10 mg/ml
1.1.7	Sevoflurane	T	Inhalation
1.1.8	Thiopentone	P,S,T	Powder for Injection 0.5 g Powder for Injection 1 g
1.2-Local anesthetics			
	Medicine	Level of Healthcare	Dosage form and strength
1.2.1	Bupivacaine	S,T	Injection 0.25% Injection 0.5% Injection 0.5% with 7.5% glucose
1.2.2	Lignocaine	P,S,T	Topical forms 2-5% Injection 1% Injection 2% Injection 5% with 7.5% Glucose
1.2.3	Lignocaine (A) + Adrenaline (B)	P,S,T	Injection 1% (A) + 1 :200000 (5 mcg/ml) (B) Injection 2% (A) + 1 :200000 (5
1.2.4	Prilocaine (A) + Lignocaine (B)	T	Cream 2.5% (A) + 2.5% (B)
1.3-Preoperative medication and sedation for short term procedures			
	Medicine	Level of Healthcare	Dosage form and strength
1.3.1	Atropine	P,S,T	Injection 0.6 mg/ml
1.3.2	Glycopyrrolate	S,T	Injection 0.2 mg/ml

1.3.3	Midazolam	P,S,T	Tablet 7.5 mg Tablet 15 mg Oral liquid 2 mg/ml Injection 1 mg/ml Injection 5 mg/ml
1.3.4	Morphine	P,S,T	Injection 10 mg/ml Injection 15 mg/ml
Section 2- Analgesics, antipyretics, non steroidal anti inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders			
2.1- Non-opioid analgesics, antipyretics and no steroidal anti -inflammatory medicines			
	Medicine	Level of Healthcare	Dosage form and strength
2.1.1	Acetylsalicylicacid	P,S,T	Tablet 300 mg to 500 mg Effervescent/ Dispersible/ Enteric coated Tablet 300 mg to 500 mg
2.1.2	Diclofenac	P,S,T	Tablet 50 mg Injection 25 mg/ml
2.1.3	Ibuprofen	P,S,T	Tablet 200 mg Tablet 400 mg Oral liquid 100 mg/5 ml
2.1.4	Mefenamic acid	P,S,T	Capsule 250 mg Capsule 500 mg Oral liquid 100 mg/5 ml
2.1.5	Paracetamol	P,S,T	Tablet 500 mg Tablet 650 mg All licenced oral liquid dosage forms and strengths Injection 150 mg/ml Suppository 80 mg Suppository 170 mg
2.2-Opioid analgesics			
	Medicine	Level of Healthcare	Dosage form and strength
2.2.1	Fentanyl	S,T	Injection 50 mcg/ml
2.2.2	Morphine	P,S,T	Tablet 10 mg Injection 10 mg/ml Injection 15 mg/ml
2.2.3	Tramadol	S,T	Capsule 50 mg Capsule 100 mg Injection 50 mg/ml
2.3-Medicines used to treat gout			
	Medicine	Level of Healthcare	Dosage form and strength
2.3.1	Allopurinol	P,S,T	Tablet 100 mg Tablet 300 mg
2.3.2	Colchicine	P,S,T	Tablet 0.5 mg
2.4-Disease modifying agents used in rheumatoid disorders			
	Medicine	Level of Healthcare	Dosage form and strength
2.4.1	Azathioprine	S, T	Tablet 50 mg
2.4.2	Hydroxychloroquine	S,T	Tablet 200 mg Tablet 400 mg

2.4.3	Leflunomide	S,T	Tablet 10 mg Tablet 20 mg
2.4.4	Methotrexate	S,T	Tablet 5 mg Tablet 7.5 mg Tablet 10 mg Injection 25 mg/ ml
2.4.5	Sulfasalazine	S, T	Tablet 500 mg
Section 3-Antiallergics and medicines used in anaphylaxis			
	Medicine	Level of Healthcare	Dosage form and strength
3.1	Adrenaline	P,S,T	Injection 1 mg/ml
3.2	Cetirizine	P,S,T	Tablet 10 mg Oral liquid 5 mg/5ml
3.3	Chlorpheniramine	P,S,T	Tablet 4 mg Oral liquid 2 mg/5 ml
3.4	Dexamethasone	P,S,T	Tablet 0.5 mg
3.5	Hydrocortisone	P,S,T	Powder for Injection 100 mg
3.6	Pheniramine	P,S,T	Injection 22.75 mg/ml
3.7	Prednisolone	P,S,T	Tablet 5 mg Tablet 10 mg Tablet 20 mg Oral liquid 5 mg/5 ml Oral liquid 15 mg/5 ml
Section 4-Antidotes and other substances used in poisoning			
4.1- Nonspecific			
	Medicine	Level of Healthcare	Dosage form and strength
4.1.1	Activated charcoal	P,S,T	Powder (as licensed)
4.2-Specific			
	Medicine	Level of Healthcare	Dosage form and strength
4.2.1	Atropine	P,S,T	Injection 1 mg/ml
4.2.2	Calcium gluconate	P,S,T	Injection 100 mg/ml
4.2.3	Desferrioxamine	S,T	Powder for Injection 500 mg
4.2.4	Dimercaprol	S,T	Injection 50 mg/ml
4.2.5	Methylthioninium chloride (Methylene blue)	S,T	Injection 10 mg/ml
4.2.6	N-acetylcysteine	P,S,T	Sachet 200 mg Injection 200 mg/ml
4.2.7	Naloxone	P,S,T m	Injection 0.4 mg/ml
4.2.8	Neostigmine	P,S,T	Injection 0.5 mg/ml

4.2.9	Penicillamine	S,T	Capsule 250 mg
4.2.10	Pralidoxime chloride (2- PAM)	P,S,T	Injection 25 mg/ml
4.2.11	Snake venom antiserum a) Soluble/ liquid polyvalent	P,S,T	a) Injection b) Powder for Injection
4.2.12	Sodium nitrite	S,T	Injection 30 mg/ml
4.2.13	Sodium	S,T	Injection 100 mg/ml
Section 5-Anticonvulsants/Antiepileptics			
	Medicine	Level of Healthcare	Dosage form and strength
5.1	Carbamazepine	P,S,T	Tablet 100 mg Tablet 200 mg CR Tablet 200 mg Tablet 400 mg CR Tablet 400 mg Oral liquid 100 mg/5 ml Oral liquid 200 mg/5 ml
5.2	Clobazam	S,T	Tablet 5 mg Tablet 10 mg
5.3	Diazepam	P,S,T	Oral liquid 2 mg/5 ml Injection 5 mg/ml Suppository 5 mg
5.4	Levetiracetam	S,T	Tablet 250 mg Tablet 500 mg Tablet 750 mg ER Tablet 750 mg Oral liquid 100 mg/ml Injection 100 mg/ml
5.5	Lorazepam	P,S,T	Tablet 1 mg Tablet 2 mg Injection 2 mg/ml
5.6	Magnesium sulphate	S,T	Injection 500 mg/ml
5.7	Phenobarbitone	P,S,T	Tablet 30 mgTablet 60 mgOral liquid 20 mg/5 ml
		S,T	Injection 200 mg/ml
5.8	Phenytoin	P,S,T	Tablet 50 mg Tablet 100 mg Tablet 300 mg ER Tablet 300 mg Oral liquid 30 mg/5 ml Oral liquid 125 mg/5 ml Injection 25 mg/ml Injection 50 mg/ml
5.9	Sodium valproate	P,S,T	Tablet 200 mg Tablet 300 mg CR Tablet 300 mg Tablet 500 mg CR Tablet 500 mg Oral liquid 200 mg/5ml
		T	Injection 100 mg/ml
Section 6-Anti infective medicines			
6.1-Anthelminthics			
6.1.1-Intestinal anthelminthics			

	Medicine	Level of Healthcare	Dosage form and strength
6.1.1.1	Albendazole	P,S,T	Tablet 400 mg Oral liquid 200 mg/5 ml
6.1.1.2	Mebendazole	P,S,T	Tablet 100 mg Oral liquid 100 mg/5 ml
6.1.2- Antifilarial			
	Medicine	Level of Healthcare	Dosage form and strength
6.1.2.1	Diethy lcarbamazine	P,S,T	Tablet 50 mg Tablet 100 mg Oral liquid 120 mg/5 ml
6.1.3-Anti-schistosomal & anti-trematodal medicine			
	Medicine	Level of Healthcare	Dosage form and strength
6.1.3.1	Praziquantel	S,T	Tablet 600 mg
6.2-Antibacterials			
6.2.1-Beta lactam medicines			
	Medicine	Level of Healthcare	Dosage form and strength
6.2.1.1	Amoxicillin	P,S,T	Capsule 250 mg Capsule 500 mg Oral liquid 250 mg/5 ml
6.2.1.2	Amoxicillin (A) + Clavulanic acid (B)	P,S,T	Tablet 500 mg (A) + 125 mg (B) Oral liquid 200 mg (A) + 28.5 mg (B)/5 ml Dry Syrup 125 mg (A) + 31.25 (B)/5 ml
		S,T	Powder for Injection 500 mg (A) + 100 mg (B) Powder for Injection 1 g (A) + 200 mg (B)
6.2.1.3	Ampicillin	P,S,T	Powder for Injection 500 mg Powder for Injection 1 g
6.2.1.4	Benzathine benzylpenicillin	P,S,T	Powder for Injection 6 lac units Powder for Injection 12 lac units
6.2.1.5	Benzyl penicillin	P,S,T	Powder for Injection 10 lac units
6.2.1.6	Cefadroxil	P,S,T	Tablet 500 mg Tablet 1 g Oral liquid 125 mg/5 ml
6.2.1.7	Cefazolin	P,S,T	Powder for Injection 500 mg Powder for Injection 1 g
6.2.1.8	Cefixime	S,T	Tablet 200 mg Tablet 400 mg Oral liquid 50 mg/5 ml Oral liquid 100 mg/5 ml

6.2.1.9	Cefotaxime	S,T	Powder for Injection 250 mg Powder for Injection 500 mg Powder for Injection 1 g
6.2.1.10	Ceftazidime	S,T	Powder for Injection 250 mg Powder for Injection 1 g
6.2.1.11	Ceftriaxone	S,T	Powder for Injection 250 mg Powder for Injection 500 mg Powder for Injection 1 g Powder for Injection 2 g
6.2.1.12	Cloxacillin	P,S,T	Capsule 250 mg Capsule 500 mg Oral Liquid 125 mg/5 ml Powder for Injection 250 mg
6.2.1.13	Piperacillin (A) + Tazobactam (B)	T	Powder for Injection 1 g (A) + 125 mg (B) Powder for Injection 2 g (A) + 250 mg (B) Powder for Injection 4 g (A) + 500 mg (B)
6.2.2-Other antibacterials			
	Medicine	Level of Healthcare	Dosage form and strength
6.2.2.1	Azithromycin	P,S,T	Tablet 250mg Tablet 500mg Oral liquid 200 mg/5 ml Powder for Injection 500mg
6.2.2.2	Ciprofioxacin	P,S,T	Tablet **250**mg Tablet **500**mg Oral liquid 250mg/5ml Injection 200 mg/100ml
6.2.2.3	Clarithromycin	S,T	Tablet 250mg Tablet 500mg Oral liquid 125mg/5ml
6.2.2.4	Co-trimoxazole [Sulphamethoxazole (A) + Trimethoprim (B)]	P,S,T	Tablet 400 mg (A) + 80 mg (B) Tablet 800 mg (A) + 160 mg (B) Oral liquid 200 mg (A) + 40 mg (B)/5 ml
6.2.2.5	Doxycycline	P,S,T	Capsule 100 mg Dry Syrup 50 mg/5 ml
6.2.2.6	Gentamicin	P,S,T	Injection 10 mg/ml Injection 40 mg/ml
6.2.2.7	Metronidazole	P,S,T	Tablet 200 mg Tablet 400 mg Oral liquid 200 mg/5 ml Injection 500mg/100 ml
6.2.2.8	Nitrofurantoin	P,S,T	Tablet 100 mg Oral liquid 25 mg/5 ml
6.2.2.9	Vancomycin	T	Powder for Injection 250 mg Powder for Injection 500 mg Powder for Injection 1 g
6.2.3-Antileprosy medicines			

	Medicine	Level of Healthcare	Dosage form and strength
6.2.3.1	Clofazimine	P,S,T	Capsule 50 mg Capsule 100 mg
6.2.3.2	Dapsone	P,S,T	Tablet 25 mg Tablet 50 mg Tablet 100 mg
6.2.3.3	Rifampicin	P,S,T	Capsule 150 mg Capsule 300 mg
6.2.4-Antituberculosis medicines			
	Medicine	Level of Healthcare	Dosage form and strength
6.2.4.1	Capreomycin	P,S, T	Powder for Injection 1 g
6.2.4.2	Cycloserine	P,S, T	Capsule 125 mg Capsule 250 mg
6.2.4.3	Ethambutol	P,S,T	Tablet 200 mg Tablet 400 mg Tablet 600 mg Tablet 800 mg
6.2.4.4	Ethionamide	P,S, T	Tablet 125 mg Tablet 250 mg
6.2.4.5	Isoniazid	P,S,T	Tablet 50 mg Tablet 100 mg Tablet 300 mg Oral liquid 100 mg/5 ml
6.2.4.6	Kanamycin	P,S, T	Powder for Injection 500 mg Powder for Injection 750 mg Powder for Injection 1 g
6.2.4.7	Levofloxacin	P,S, T	Tablet 250 mg Tablet 500 mg Tablet 750 mg
6.2.4.8	Linezolid	P,S, T	Tablet 600 mg
6.2.4.9	Moxifloxacin	P,S, T	Tablet 200 mg Tablet 400 mg
6.2.4.10	Para- amino salicylic acid	P,S,T	Tablet 500 mg Granules (As licensed)
6.2.4.11	Pyrazinamide	P,S,T	Tablet 500 mg Tablet 750 mg Tablet 1000 mg Tablet 1500 mg Oral liquid 250 mg/5 ml
6.2.4.12	Rifabutin	S,T	Capsule 150 mg
6.2.4.13	Rifampicin	P,S,T	Capsule 150 mg Capsule 300 mg Capsule 450 mg Capsule 600 mg Oral liquid 100 mg/5 ml

6.2.4.14	Streptomycin	P,S,T	Powder for Injection 750 mg Powder for Injection 1 g
6.3-Antifungal medicines			
	Medicine	Level of Healthcare	Dosage form and strength
6.3.1	Amphotericin B a) Amphotericin B (conventional) b) Lipid Liposomal Amphotericin B	S,T	Powder for Injection 50 mg
6.3.2	Clotrimazole	P,S,T	Pessary 100 mg
6.3.3	Fluconazole	P,S,T	Tablet 100 mgTablet 150 mgTablet 200 mgTablet 400 mg Oral liquid 50 mg/5 ml
		S,T	Injection 200 mg /100 ml
6.3.4	Griseofulvin	P,S,T	Tablet 125 mg Tablet 250 mg Tablet 375 mg
6.3.5	Nystatin	P,S,T	Tablet 500,000 IU Pessary 100,000 IU Oral Liquid 100, 000 IU/ml
6.4-Antiviral medicines			
6.4.1-Antiherpes medicines			
	Medicine	Level of Healthcare	Dosage form and strength
6.4.1.1	Acyclovir	P,S,T	Tablet 200 mg Tablet 400 mg Powder for Injection 250 mg Powder for Injection 500 mg Oral liquid 400 mg/5 ml
6.4.2-Anti Cytomegalovirus (CMV) medicines			
6.4.2.1	Ganciclovir	S,T	Capsule 250 mg Powder for Injection 500 mg
6.4.3-Antiretroviral medicines			
6.4.3.1-Nucleoside reverse transcriptase inhibitors			
	Medicine	Level of Healthcare	Dosage form and strength
6.4.3.1.1	Abacavir	S,T	Tablet 60 mg Tablet 300 mg
6.4.3.1.2	Abacavir (A) + Lamivudine (B)	S,T	Tablet 60 mg (A) +30 mg (B) Tablet 600 mg (A)+ 300 mg (B)

6.4.3.1.3	Lamivudine (A) + Nevirapine (B) + Stavudine (C)	S,T	Dispersible Tablet 30 mg (A) + 50 mg (B) + 6 mg (C) Tablet 150 mg (A) + 200 mg (B) + 30 mg (C)
6.4.3.1.4	Lamivudine (A) + Zidovudine (B)	S,T	Tablet 30 mg (A) + 60 mg (B) Tablet 150 mg (A) + 300 mg (B)
6.4.3.1.5	Stavudine (A) + Lamivudine (B)	S,T	Dispersible Tablet 6 mg (A) + 30 mg (B) Tablet 30 mg (A) + 150 mg (B)
6.4.3.1.6	Tenofovir (A) + Lamivudine (B)	S,T	Tablet 300 mg (A) +300 mg (B)
6.4.3.1.7	Tenofovir (A) + Lamivudine (B) + Efavirenz (C)	S,T	Tablet 300 mg (A) + 300 mg (B) + 600 mg (C)
6.4.3.1.8	Zidovudine	S,T	Tablet 300 mg Oral liquid 50 mg/5 ml
6.4.3.1.9	Zidovudine (A) + Lamivudine (B) + Nevirapine (C)	S,T	Tablet 60 mg (A) + 30 mg (B) + 50 mg (C) Tablet 300 mg (A) + 150 mg (B) + 200 mg (C)
6.4.3.2-Non-nucleoside reverse transcriptase inhibitors			
	Medicine	Level of Healthcare	Dosage form and strength
6.4.3.2.1	Efavirenz	S,T	Tablet 50 mg Tablet 200 mg Tablet 600 mg
6.4.3.2.2	Nevirapine	S,T	Dispersible Tablet 50 mg Tablet 200 mg Oral liquid 50 mg/5 ml
6.4.3.3-Integrase inhibitors			
6.4.3.3.1	Raltegravir	S,T	Tablet 400 mg
6.4.3.4–Protease inhibitors			
	Medicine	Level of Healthcare	Dosage form and strength
6.4.3.4.1	Atazanavir (A) + Ritonavir (B)	S,T	Tablet 300 mg (A) + 100 mg (B)
6.4.3.4.2	Darunavir	S,T	Tablet 600 mg
6.4.3.4.3	Lopinavir (A) + Ritonavi (B)	S,T	Tablet 100mg (A) + 25 mg (B) Tablet 200mg (A) + 50 mg (B) Oral liquid 400mg (A)mg (B)/5ml
6.4.3.4.4	Ritonavir	S,T	Tablet 100 mg
6.4.4-Medicines for hepatitis B and hepatitis C			
6.4.4.1	Entecavir	S,T	Tablet 0.5 mg Tablet 1 mg

6.4.4.2	Pegylated interferon alfa 2a	S,T	Injection 180 mcg
		S,T	Injection 80 mcg Injection 100 mcg Injection 120 mcg
6.4.4.3	Ribavirin	S,T	Capsule 200 mg
6.4.4.4	Sofosbuvir	S,T	Tablet 400 mg
6.4.4.5	Tenofovir	S,T	Tablet 300 mg
Section 6.5-Antiprotozoal Medicines			
6.5.1-Antiamoebic and antigiardiasis medicines			
	Medicine	Level of Healthcare	Dosage form and strength
6.5.1.1	Diloxanide furoate	P,S,T	Tablet 500 mg
6.5.1.2	Metronidazole	P,S,T	Tablet 200 mg Tablet 400 mg Injection 500 mg/100 ml Oral liquid 200 mg/5 ml
6.5.2-Antileishmaniasis medicines			
	Medicine	Level of Healthcare	Dosage form and strength
6.5.2.1	Amphotericin B a) Amphotericin B (conventional) b) Lipid Liposomal Amphotericin B	S,T	Powder for Injection 50 mg
6.5.2.2	Miltefosine	P,S,T	Capsule 10 mg Capsule 50 mg
6.5.2.3	Paromomycin	P,S,T	Injection 375 mg/ml
6.S.3-Antimalarial medicines			
6.S.3.1-For curative treatment			
	Medicine	Level of Healthcare	Dosage form and strength
6.5.3.1.1	Artemether (A) + Lumefantrine (B)	P,S,T	Tablet 20 mg (A) + 120 mg (B) Tablet 40 mg (A) + 240 mg (B) Tablet 80 mg (A) + 480 mg (B) Oral liquid 80 mg (A) + 480 mg (B)/5 ml
6.5.3.1.2	Artesunate	P,S,T	Powder for Injection 60 mg Powder for Injection 120 mg

6.5.3.1.3	Artesunate (A) + Sulphadoxine - Pyrimethamine (B)	P,S,T	Combi pack (A+B) 1 Tablet 25 mg (A) + 1 Tablet (250 mg + 12.5 mg) (B) 1 Tablet 50 mg (A) + 1 Tablet (500 mg + 25 mg) (B) 1 Tablet 100 mg (A) + 1 Tablet (750 mg + 37.5 mg) (B) 1 Tablet 150 mg (A) + 2 Tablet (500 mg + 25 mg) (B) 1 Tablet 200 mg (A) + 2 Tablet (750 mg + 37.5 mg) (B)
6.5.3.1.4	Chloroquine	P,S,T	Tablet 150 mg Oral liquid 50 mg/5 ml
6.5.3.1.5	Clindamycin	P,S,T	Capsule 150 mg Capsule 300 mg
6.5.3.1.6	Primaquine	P,S,T	Tablet 2.5 mg Tablet 7.5 mg Tablet 15 mg
6.5.3.1.7	Quinine	P,S,T	Tablet 300 mg Injection 300 mg/ml
6.5.3.2-For prophylaxis			
	Medicine	Level of Healthcare	Dosage form and strength
6.5.3.2.1	Mefloquine	T	Tablet 250 mg *Only for use as chemoprophylaxis for long term travellers like military and travel troops, travelling from low endemic to high endemic area.
6.5.4-Antipneumocystosis and anti toxoplasmosis medicines			
	Medicine	Level of Healthcare	Dosage form and strength
6.5.4.1	Co-trimoxazole [Sulphamethoxazole (A) + Trimethoprim (B)]	P,S,T	Tablet 400 mg (A) + 80 mg (B) Tablet 800 mg (A) + 160 mg (B) Oral liquid 200 mg (A) + 40 mg (B)/5 ml
6.5.4.2	Pentamidine	S,T	Powder for Injection 200 mg
Section 7 -Antimigraine medicines			
	Medicine	Level of Healthcare	Dosage form and strength
7.1.1	Acetylsalicylic acid	P,S,T	Tablet 300 mg to 500 mg Effervescent/ Dispersible/ Enteric coated Tablet 300 mg to 500 mg
7.1.2	Paracetamol	P,S,T	Tablet 500 mg Tablet 650 mg
7.1.3	Sumatriptan		Tablet 25 mg Tablet 50 mg

		P,S,T	Injection 6 mg/ 0.5 ml

7.2-For prophylaxis			
	Medicine	Level of Healthcare	Dosage form and strength
7.2.1	Flunarizine	P,S,T	Tablet 5 mg Tablet 10 mg
7.2.2	Propranolol	P,S,T	Tablet 10 mg Tablet 40 mg Tablet 80 mg

Section 8 -Antineoplastic/immunosuppressives and medicines used in palliative care			
8.1-Antineoplastic medicines			
	Medicine	Level of Healthcare	Dosage form and strength
8.1.1	5- Fluorouracil	T	Injection 250 mg/5 ml
8.1.2	6- Mercaptopurine	T	Tablet 50 mg
8.1.3	Actinomycin D	T	Powder for Injection 0.5 mg
8.1.4	All-trans retinoic acid	T	Capsule 10 mg
8.1.5	Arsenic trioxide	T	Injection 1mg/ml
8.1.6	Bleomycin	T	Powder for Injection 15 units
8.1.7	Bortezomib	T	Powder for Injection 2mg
8.1.8	Calcium folinate	T	Tablet 15 mg Injection 3 mg/ml
8.1.9	Capecitabine	T	Tablet 500 mg
8.1.10	Carboplatin	T	Injection 10 mg/ml
8.1.11	Chlorambucil	T	Tablet 2 mg Tablet 5 mg
8.1.12	Cisplatin	T	Injection 1 mg/ml
8.1.13	Cyclophosphamide	T	Tablet 50 mg Tablet 200 mg Powder for Injection 500 mg
8.1.14	Cytosine arabinoside	T	Injection 100 mg/ ml Powder for Injection 500 mg Powder for Injection 1000 mg
8.1.15	Dacarbazine	T	Powder for Injection 500 mg Powder for Injection 200 mg
8.1.16	Daunorubicin	T	Injection 5 mg/ml

8.1.17	Docetaxel	T	Powder for Injection 20 mg Powder for Injection 80 mg
8.1.18	Doxorubicin	T	Injection 2 mg/ml
8.1.19	Etoposide	T	Capsule 50 mg Capsule 100 mg Injection 20 mg/ml
8.1.20	Gefitinib	T	Tablet 250 mg
8.1.21	Gemcitabine	T	Powder for Injection 200 mg Powder for Injection 1 g
8.1.22	Ifosfamide	T	Powder for Injection 1 g Powder for Injection 2 g
8.1.23	Imatinib	T	Tablet 100 mg Tablet 400 mg
8.1.24	L- Asparaginase	T	Powder for Injection 5000 KU. Powder for Injection 10000 KU
8.1.25	Melphalan	T	Tablet 2 mg Tablet 5 mg
8.1.26	Mesna	T	Injection 100 mg/ml
8.1.27	Methotrexate	T	Tablet 2.5 mg Tablet 5 mg Tablet 10mg Injection 50 mg/ml
8.1.28	Oxaliplatin	T	Injection 5 mg/ml
8.1.29	Paclitaxel	T	Injection 30 mg/5 ml Injection 100 mg/16.7 ml
8.1.30	Procarbazine	T	Capsule 50 mg
8.1.31	Rituximab	T	Injection 10 mg/ml
8.1.32	Temozolomide	T	Capsule 20 mg Capsule 100 mg Capsule 250 mg
8.1.33	Thalidomide	T	Capsule 50 mg Capsule 100 mg
8.1.34	Trastuzumab	T	Injection 440 mg/50 ml
8.1.35	Vinblastine	T	Injection 1 mg/ml
8.1.36	Vincristine	T	Injection 1 mg/ml
8.2-Hormones and antihormones used in cancer therapy			
	Medicine	Level of Healthcare	Dosage form and strength

8.2.1	Bicalutamide	T	Tablet 50 mg
8.2.2	Letrozole	T	Tablet 2.5 mg
8.2.3	Prednisolone	S, T	Tablet 10 mg Tablet 20 mg Tablet 40 mg Oral liquid 5 mg/5 ml Oral liquid 15 mg/5 ml Injection 20 mg/2 ml
8.2.4	Tamoxifen	T	Tablet 10 mg Tablet 20 mg
8.3-Immunosuppressive medicines			
	Medicine	Level of Healthcare	Dosage form and strength
8.3.1	Azathioprine	T	Tablet 50 mg
8.3.2	Cyclosporine	T	Capsule 10 mg Capsule 25 mg Capsule 50 mg Capsule 100 mg Oral liquid 100 mg/ml Injection 50 mg/ml
8.3.3	M ycophenolate mofetil	T	Tablet 250 mg Tablet 500 mg
8.3.4	Tacrolimus	T	Capsule 0.5 mg Capsule 1 mg Capsule 2 mg

S.4-Medicines used in palliative care			
	Medicine	Level of Healthcare	Dosage form and strength
8.4.1	Allopurinol	T	Tablet 100 mg
8.4.2	Amitriptyline	T	Tablet 10 mg Tablet 25 mg
8.4.3	Dexamethasone	T	Tablet 0.5 mg Injection 4 mg/ml
8.4.4	Diazepam	T	Tablet 2 mg Tablet 5 mg Injection 5 mg/ml
8.4.5	Filgrastim	T	Injection 300 mcg
8.4.6	Fluoxetine	T	Capsule 20 mg
8.4.7	Haloperidol	T	Tablet 1.5 mg Tablet 5 mg Injection 5 mg/ml

8.4.8	Lactulose	T	Oral liquid 10 g/15 ml
8.4.9	Loperamide	T	Tablet 2 mg
8.4.10	Metoclopramide	T	Tablet 10 mg Oral liquid 5 mg/5 ml Injection 5 mg/ml
8.4.11	Midazolam	T	Injection 1 mg/ml
8.4.12	Morphine	T	Tablet 10 mg Tablet 20 mg SR Tablet 30 mg
8.4.13	Ondansetron	S,T	Tablet 4 mg Tablet 8 mg Oral liquid 2 mg/5 ml Injection 2 mg/ml
8.4.14	Tramadol	T	Capsule 50 mg Capsule 100 mg Injection 50 mg/ml
8.4.15	Zoledronic acid	T	Powder for Injection 4 mg
Section 9-Antiparkinsonism medicines			
	Medicine	Level of Healthcare	Dosage form and strength
9.1	Levodopa (A) + Carbidopa (B)	P,S,T	Tablet 100 mg (A) + 10 mg (B) Tablet 100 mg (A) + 25 mg (B) CR Tablet 100 mg (A) + 25 mg (B) CR Tablet 200 mg (A) + 50 (B) mg Tablet 250 mg (A) + 25 mg (B)
9.2	Trihexyphenidyl	P,S,T	Tablet 2 mg
Section 10- Medicines affecting blood			
10.1- Antianaemia medicines			
	Medicine	Level of Healthcare	Dosage form and strength

10.1.1	Erythropoietin	S,T	Injection 2000 IU/ml Injection 10000 IU/ml
10.1.2	Ferrous salts	P,S,T	Tablet equivalent to 60 mg of elemental iron Oral liquid equivalent to 25 mg of elemental iron/ml
10.1.3	Ferrous salt (A) + Folic acid (B)	P,S,T	Tablet 45mg elemental iron (A) + 400 mcg (B) Tablet 100 mg elemental iron (A) + 500 mcg (B) Oralliqiud 20 mg elemental iron (A) + 100 mcg (B)/ml
10.1.4	Folic acid	P,S,T	Tablet 5 mg
10.1.5	Hydroxocobalamin	P,S,T	Injection 1 mg/ml
10.1.6	Hydroxyurea	P,S,T	Capsule 500 mg
10.1.7	Iron sucrose	S,T	Injection 20 mg/ml
10.2-Medicines affecting coagulation			
	Medicine	Level of Healthcare	Dosage form and strength
10.2.1	Enoxaparin	T	Injection 40 mg/0.4 ml Injection 60 mg/0.6 ml
10.2.2	Heparin	S,T	Injection 1000 IU/ml Injection 5000 IU/ml
10.2.3	Phytomenadione (Vitamin K1)	P,S,T	Tablet 10mg Injection 10 mg/ml
10.2.4	Protamine	S,T	Injection 10 mg/ml

10.2.5	Tranexamic acid	P,S,T	Tablet 500 mg Injection 100 mg/ml
10.2.6	Warfarin	S,T	Tablet 1 mg Tablet 2 mg Tablet 3 mg Tablet 5 mg
Section 11- Blood products and Plasma substitutes			
11.1-Blood and Blood components			
All forms of the following as approved by licensing authority are considered as included in this schedule. However, considering the process, technology and other relevant aspects, they should be considered differently for purposes such as procurement policy, pricing etc.			
11.1.1	Fresh frozen plasma	S,T	As licensed
11.1.2	Platelet rich plasma	S,T	As licensed
11.1.3	Red blood cells	S,T	As licensed
11.1.4	Whole blood	S,T	As licensed
11.2-Plasma substitutes			
	Medicine	Level of Healthcare	Dosage form and strength
11.2.1	Dextran-40	S,T	Injection 10%
11.3-Plasma fractions for specific use			
In case of coagulation factors and other blood products, irrespective of variation in source, all forms of these products as approved by licensing authority are considered as included in as included in this schedule. However, considering the source, process, technology and other relevant aspects, and other relevant aspects, they should be considered differently for purposes such as procurement policy, Procurement policy, pricing etc			
	Medicine	Level of Healthcare	Dosage form and strength
11.3.1	Coagulation factor IX	S,T	Powder for Injection 600 IU
11.3.2	Coagulation factor VIII	S,T	Powder for Injection 250 IU Powder for Injection 500 IU
11.3.3	Cryoprecipitate	S,T	As licensed
Section 12-Cardiovascular medicines			

12.1-Medicines used in angina			
	Medicine	Level of Healthcare	Dosage form and strength
12.1.1	Acetylsalicylic acid	P,S,T	Tablet 75 mg Effervescent/ Dispersible/ Enteric coated Tablet 75 mg Tablet 100 mg Effervescent/ Dispersible/ Enteric coated Tablet 100 mg Tablet 150 mg Effervescent/ Dispersible/ Enteric coated Tablet 150 mg
12.1.2	Clopidogrel	P,S,T	Tablet 75 mg
12.1.3	Diltiazem	P,S,T	Tablet 30 mg Tablet 60 mg SR Tablet 90 mg
		T	Injection 5 mg/ml
12.1.4	Glyceryl trinitrate	P,S,T	Sublingual tablet 0.5 mg
		S,T	Injection 5 mg/ml
12.1.5	Isosorbide- 5-mononitrate	P,S,T	Tablet 10 mg Tablet 20 mg SR Tablet 30 mg SR Tablet 60 mg
12.1.6	Isosorbide dinitrate	P,S,T	Tablet 5 mg Tablet 10 mg
12.1.7	Metoprolol	P,S,T	Tablet 25 mg Tablet 50 mg SR Tablet 25 mg SR Tablet 50 mg
12.2-Antiarrhythmic medicines			
	Medicine	Level of Healthcare	Dosage form and strength
12.2.1	Adenosine	S,T	Injection 3 mg/ml
12.2.2	Amiodarone	S,T	Tablet 100 mg Tablet 200 mg Injection 50 mg/ml
12.2.3	Esmolol	T	Injection 10 mg/ml

12.2.4	Lignocaine	S,T	Injection 2% (Preservative free for IV use)
12.2.5	Verapamil	S,T	Tablet 40 mg Tablet 80 mg Injection 2.5 mg/ml
12.3-Antihypertensive medicines			
	Medicine	Level of Healthcare	Dosage form and strength
12.3.1	Amlodipine	P,S,T	Tablet 2.5 mg Tablet 5 mg Tablet 10 mg
12.3.2	Atenolol	P,S,T	Tablet 50 mg Tablet 100 mg
12.3.3	Enalapril	P,S,T	Tablet 2.5 mg Tablet 5 mg
12.3.4	Hydrochlorothiazide	P,S,T	Tablet 12.5 mg Tablet 25 mg
12.3.5	Labetalol	P,S,T	Injection 5 mg/ml
12.3.6	Methyldopa	P,S,T	Tablet 250 mg Tablet 500 mg
12.3.7	Ramipril	P,S,T	Tablet 2.5 mg Tablet 5 mg
12.3.8	Sodium nitroprusside	T	Injection 10 mg/ml
12.3.9	Telmisartan	P,S,T	Tablet 20 mg Tablet 40 mg Tablet 80 mg
12.4-Medicines used in shock and heart failure			
	Medicine	Level of Healthcare	Dosage form and strength

12.4.1	Digoxin	S,T	Tablet 0.25 mg Oral liquid 0.05 mg/ml Injection 0.25 mg/ml
12.4.2	Dobutamine	S,T	Injection 50 mg/ml
12.4.3	Dopamine	S,T	Injection 40 mg/ml
12.4.4	Noradrenaline	S,T	Injection 2 mg/ml
12.5-Antithrombotic medicine (Cardiovascular/ Cerebrovascular)			
	Medicine	Level of Healthcare	Dosage form and strength
12.5.1	Acetylsalicylic acid	P,S,T	Tablet 75 mg Effervescent/ Dispersible/ Enteric coated Tablet 75 mg Tablet 100 mg Effervescent/ Dispersible/ Enteric coated Tablet 100 mg Tablet 150 mg Effervescent/ Dispersible/ Enteric coated Tablet 150 mg
12.5.2	Alteplase	T	Powder for Injection 20 mg Powder for Injection 50 mg
12.5.3	Heparin	S,T	Injection 1000 IU/ml Injection 5000 IU/ml
12.5.4	Streptokinase	S,T	Injection 750,000 IU Injection 15,00,000 IU
12.6-Hypolipidemic medicines			
	Medicine	Level of Healthcare	Dosage form and strength
12.6.1	Atorvastatin	P,S,T	Tablet 10 mg Tablet 20 mg Tablet 40 mg
Section 13-Medicines used in dementia			
	Medicine	Level of Healthcare	Dosage form and strength
13.1	Donepezil	S,T	Tablet 5 mg Tablet 10 mg
Section 14- Dermatological medicines (Topical)			
14.1- Antifungal medicines			

	Medicine	Level of Healthcare	Dosage form and strength
14.1.1	Clotrimazole	P,S,T	Cream 1%
14.2- Antiinfective medicines			
	Medicine	Level of Healthcare	Dosage form and strength
14.2.1	Framycetin	P,S,T	Cream 0.5%
14.2.2	Fusidic acid	P,S,T	Cream 2%
14.2.3	Methylrosanilinium chloride (Gentian Violet)	P,S,T	Topial preparation 0.25% to 2%
14.2.4	Povidone iodine	P,S,T	Solution 4% to 10%
14.2.5	Silver sulphadiazine	P,S,T	Cream 1%
14.3-Antiinflammatory and antipruritic medicines			
	Medicine	Level of Healthcare	Dosage form and strength
14.3.1	Betamethasone	P,S,T	Cream 0.05% Cream 0.1%
14.3.2	Calamine	P,S,T	Lotion (As per IP)
14.4-Medicines affecting skin differentiation and proliferation			
	Medicine	Level of Healthcare	Dosage form and strength
14.4.1	Benzoyl peroxide	P,S,T	Gel 2.5%
14.4.2	Coal tar	P,S,T	Solution 5%
14.4.3	Podophyllin resin	S,T	Solution 10% to 25%

14.4.4	Salicylic acid	P,S,T	Ointment 6%
14.5-Scabicides and pediculicides			
	Medicine	Level of Healthcare	Dosage form and strength
14.5.1	Permethrin	P,S,T	Lotion 1% Cream 5%
14.6-Miscellaneous			
	Medicine	Level of Healthcare	Dosage form and strength
14.6.1	Glycerin	P,S,T	Oral Liquid
14.6.2	White Petrolatum	P,S,T	Jelly 100%
Section 15 - Diagnostic agents			
15.1-Ophthalmic medicines			
	Medicine	Level of Healthcare	Dosage form and strength
15.1.1	Fluorescein	S,T	Eye drop 1%
15.1.2	Lignocaine	S,T	Eye drop 4%
15.1.3	Tropicamide	S,T	Eye drop 1%
15.2-Radiocontrast media			
	Medicine	Level of Healthcare	Dosage form and strength
15.2.1	Barium sulphate	S,T	Oral liquid 100% w/v Oral liquid 250% w/v
15.2.2	Gadobenate	T	Injection 529 mg/ml
15.2.3	Iohexol	S,T	Injection 140 to 350 mg iodine/ml

15.2.4	Meglumine diatrizoate	S,T	Injection 60% w/v Injection 76% w/v
Section 16- Dialysis solutions			
	Medicine	Level of Healthcare	Dosage form and strength
16.1	Haemodialysis fluid	S,T	As licensed
16.2	Intraperitoneal dialysis solution	S,T	As licensed
Section 17- Disinfectants and antiseptics			
17.1-Antiseptics			
	Medicine	Level of Healthcare	Dosage form and strength
17.1.1	Cetrimide	P,S,T	Solution 20% (Concentrate for dilution)
17.1.2	Chlorhexidine	P,S,T	Solution 5% (Concentrate for dilution)
17.1.3	Ethyl alcohol (Denatured)	P,S,T	Solution 70%
17.1.4	Hydrogen peroxide	P,S,T	Solution 6%
17.1.5	Methylrosaniliniu m chloride (Gentian Violet)	P,S,T	Topial preparation 0.25% to 2%
17.1.6	Povidone iodine	P,S,T	Solution 4% to 10%
17.2-Disinfectants			
	Medicine	Level of Healthcare	Dosage form and strength

17.2.1	Bleaching powder	P,S,T	Containing not less than 30% w/w of available chlorine (as per IP)
17.2.2	Glutaraldehyde	S,T	Solution 2%
17.2.3	Potassium permanganate	P,S,T	Crystals for topical solution
Section 18- Diuretics			
	Medicine	Level of Healthcare	Dosage form and strength
18.1	Furosemide	P,S,T	Tablet 40 mg Oral liquid 10 mg/ml Injection 10 mg/ ml
18.2	Hydrochlorothiazide	P,S,T	Tablet 25 mg Tablet 50 mg
18.3	Mannitol	P,S,T	Injection 10% Injection 20%
18.4	Spironolactone	P,S,T	Tablet 25 mg Tablet 50 mg
Section 19- Ear, nose and throat medicines			
19.1	Budesonide	P,S,T	Nasal Spray 50 mcg/dose Nasal Spray 100 mcg/dose
19.2	Ciprofioxaein	P,S,T	Drops 0.3%
19.3	Clotrimazole	P,S,T	Drops 1%
19.4	Xylometazoline	P,S,T	Nasal drops 0.05% Nasal drops 0.1%
Section 20-Gastrointestinal medicines			
20.1-Antiulcer medicines			

	Medicine	Level of Healthcare	Dosage form and strength
20.1.1	Omeprazole	P,S,T	Capsule 10 mg Capsule 20 mg Capsule 40 mg Powder for oral liquid 20 mg
20.1.2	Pantoprazole	S,T	Injection 40 mg
20.1.3	Ranitidine	P,S,T	Tablet 150 mg Oral liquid 75 mg/5 ml Injection 25 mg/ml
20.1.4	Sucralfate	S,T	Oral liquid 1 g
20.2-Antiemetics			
	Medicine	Level of Healthcare	Dosage form and strength
20.2.1	Domperidone	P,S,T	Tablet 10 mg Oral liquid 1 mg/ml
20.2.2	Metoclopramide	P,S,T	Injection 5 mg/ml
20.2.3	Ondansetron	S,T	Tablet 4 mg Oral liquid 2 mg/5 ml Injection 2 mg/ml
20.3- Anti- inflammatory medicines			
	Medicine	Level of Healthcare	Dosage form and strength
20.3.1	5-aminosalicylic acid	S,T	Tablet 400 mg Suppository 500 mg Retention Enema
20.4-Antispasmodic medicines			
	Medicine	Level of Healthcare	Dosage form and strength
20.4.1	Dicyclomine	P,S,T	Tablet 10 mg Oral Solution 10mg/5ml Injection 10 mg/ml
20.4.2	Hyoscine butylbromide	P,S,T	Tablet 10 mg Injection 20 mg/ml
20.5-Laxatives			

	Medicine	Level of Healthcare	Dosage form and strength
20.5.1	Bisacodyl	P,S,T	Tablet 5 mg Suppository 5 mg
20.5.2	Ispaghula	P,S,T	Granules/ Husk/ Powder
20.5.3	Lactulose	S,T	Oral liquid 10 g/15 ml
20.6-Medicines used in diarrhoea			
	Medicine	Level of Healthcare	Dosage form and strength
20.6.1	Oral rehydration salts	P,S,T	As licensed
20.6.2	Zinc sulphate	P,S,T	Dispersible Tablet 20 mg
20.7-0ther medicines			
20.7.1	Somatostatin	T	Powder for Injection 3 mg
Section 21-Hormones, other endocrine medicines and contraceptives			
21.1-Adrenal hormones and synthetic substitutes			
	Medicine	Level of Healthcare	Dosage form and strength
21.1.1	Dexamethasone	S,T	Tablet 0.5 mg Injection 4 mg/ml
21.1.2	Human chorionic gonadotropin	T	Injection 1000 IU Injection 5000 IV
21.1.3	Hydrocortisone	P,S,T	Tablet 5 mg Tablet 10 mg Injection 100 mg/ml
21.1.4	Methylprednisolone	S,T	Tablet 8 mg Tablet 16 mg Tablet 32 mg Injection 40 mg/ml

21.1.5	Prednisolone	P,S,T	Tablet 5 mg Tablet 10 mg Tablet 20 mg
21.2-Contraceptives			
21.2.1-Hormonal contraceptives			
	Medicine	Level of Healthcare	Dosage form and strength
21.2.1.1	Ethinylestradiol (A) + Levonorgestrel	P,S,T	Tablet 0.03 mg (A) + 0.15 mg (B)
21.2.1.2	Ethinylestradiol (A) + Norethisterone	P,S,T	Tablet 0.035 mg (A) + 1 mg (B)
21.2.2-Intrauterine devices			
	Medicine	Level of Healthcare	Dosage form and strength
21.2.2.1	Hormone releasing IUD	T	Contains 52 mg of Levonorgestrel
21.2.2.2	IUD containing Copper	P,S,T	As licensed
21.2.3-Barrier methods			
	Medicine	Level of Healthcare	Dosage form and strength
21.2.3.1	Condom	P,S,T	As per the standards prescribed in Schedule R of Drugs and Cosmetics rules, 1945
21.3-Estrogens			
	Medicine	Level of Healthcare	Dosage form and strength
21.3.1	Ethinylestradiol	P,S,T	Tablet 0.01 mg Tablet 0.05 mg
21.3.2	Levonorgestrel	P,S,T	Tablet 0.75 mg
21.4- Medicines used in diabetes mellitus			
21.4.1-Insulins and other antidiabetic agents			
	Medicine	Level of Healthcare	Dosage form and strength

21.4.1.1	Glimepiride	P,S,T	Tablet 1 mg Tablet 2 mg
21.4.1.2	Insulin (Soluble)	P,S,T	Injection 40 IU/ml
21.4.1.3	Intermediate Acting (NPH) Insulin	P,S,T	Injection 40 IU/ml
21.4.1.4	Metformin	P,S,T	Tablet 500 mg Tablet 750 mg Tablet 1000 mg (Immediate and controlled release)
21.4.1.5	Premix Insulin 30:70 Injection (Regular: NPH)	P,S,T	Injection 40 IU/ml
21.4.2-Medicines used to treat hypoglycemia			
	Medicine	Level of Healthcare	Dosage form and strength
21.4.2.1	Glucose	P,S,T	Injection 25%
21.5-Ovulation Inducers			
	Medicine	Level of Healthcare	Dosage form and strength
21.5.1	Clomiphene	T	Tablet 50 mg Tablet 100 mg
21.6- Progestogens			
	Medicine	Level of Healthcare	Dosage form and strength
21.6.1	Medroxyprogester oneacetate	P,S,T	Tablet 5 mg Tablet 10 mg
21.6.2	Norethisterone	P,S,T	Tablet 5 mg
21.7- Thyroid and antithyroid medicines			
	Medicine	Level of Healthcare	Dosage form and strength

21.7.1	Carbimazole	P,S,T	Tablet 5 mg Tablet 10 mg
21.7.2	Levothyroxine	P,S,T	Tablet 12.5 mcg to 150 mcg* (Several strengths are available in market such as 12.5, 25, 50, 62.5, 75, 88, 100, 112 mcg. Therefore it was Considered to give a range of available strengths)
Section 22- Immunologicals			
In case of these biologicals, irrespective of variation in source, composition and strengths, all the products of the same vaccine/ sera/ immunoglobulin, as approved by licensing authority are considered as included in this schedule. However, considering the source, process, technology and other relevant aspects, different products of the same biologicals should be considered differently for purposes such as procurement policy, pricing, etc.			
22.1-Diagnostic agents			
	Medicine	Level of Healthcare	
22.1.1	Tuberculin, Purified Protein derivative	P,S,T	
22.2-Sera and immunoglobulins (Liquid/ Lyophilized)			
	Medicine	Level of Healthcare	
22.2.1	Anti-rabies immunoglobulin	P,S,T	
22.2.2	Anti-tetanus immunoglobulin	P,S,T	
22.2.3	Anti-D immunoglobulin	S, T	
22.2.4	Diphtheria antitoxin	P,S,T	
22.2.5	Hepatitis B immunoglobulin	S,T	
22.2.6	Human normal immunoglobulin	T	
22.2.7	Snake venom antiserum a) Soluble/ liquid polyvalent b) Lyophilized polyvalent	P,S,T	

22.3- Vaccines

(a) All the vaccines which are under Universal Immunization Programme of India (UIP) will be deemed included in this schedule. Presently, the UIP has BCG, DPT, OPV, measles, Hepatitis B, Japanese encephalitis & Pentavalent Vaccines.

(b) The new vaccines, which have been approved by National Technical Advisory Group on Immunization NTAGI)and planned to be given under UIP, will be deemed to be included as and when listed in UIP. These vaccines are inactivated polio vaccine (IPV), Measles Rubella (MR) and Rota virus vaccine.

(c) In future, the vaccines which are under consideration, if and when included in UIP, will also be deemed included from the date of inclusion in UIP. These are pneumococcal and HPV vaccines.

22.3.1-For universal immunisation

	Medicine	Level of Healthcare	
22.3.1.1	BCG vaccine	P,S,T	
22.3.1.2	DPT + Hib + Hep B vaccine	P,S,T	
22.3.1.3	DPT vaccine	P,S,T	
22.3.1.4	Hepatitis B vaccine	P,S,T	
22.3.1.5	Japanese encephalitis vaccme	P,S,T	
22.3.1.6	Measles vaccine	P,S,T	
22.3.1.7	Oral poliomyelitis vaccme	P,S,T	
22.3.1.8	Tetanus toxoid	P,S,T	

22.3.2-For Specific Group of Individuals

	Medicine	Level of Healthcare	
22.3.2.1	Rabies vaccine	P,S,T	

Section 23- Muscle relaxants and cholinesterase inhibitors

	Medicine	Level of Healthcare	Dosage form and strength
23.1	Atracurium	S,T	Injection 10 mg/ml

23.2	Baclofen	S,T	Tablet 5 mg Tablet 10 mg Tablet 20 mg
23.3	Neostigmine	S,T	Tablet 15 mg Injection 0.5 mg/ml
23.4	Succinylcholine	S,T	Injection 50 mg/ml
23.5	Vecuronium	S,T	Powder for Injection 4 mg Powder for Injection 10 mg
Section 24- Medicines for neonatal care			
	Medicine	Level of Healthcare	Dosage form and strength
24.1	Alprostadil	T	Injection 0.5 mg/ml
24.2	Caffeine	S,T	Oral liquid 20 mg/ml Injection 20 mg/ml
24.3	Surfactant	S,T	Suspension for intratracheal instillation (As liensed)
Section 25- 0phthalmological Medicines			
25.1- Anti-infective medicine			
	Medicine	Level of Healthcare	Dosage form and strength
25.1.1	Acyclovir	P,S,T	Ointment 3%
25.1.2	Ciprofioxacin	P,S,T	Drops 0.3% Ointment 0.3%
25.1.3	Erythromycin	P,S,T	Ointment 0.5%
25.1.4	Gentamicin	P,S,T	Drops 0.3%
25.1.5	Natamycin	P,S,T	Drops 5%
25.1.6	Povidone iodine	P,S,T	Drops 0.6% Drops 5%

25.2-Antiinflammatory medicine			
	Medicine	Level of Healthcare	Dosage form and strength
25.2.1	Prednisolone	P,S,T	Drops 0.1% Drops 1%
25.3-Local anaesthetics			
	Medicine	Level of Healthcare	Dosage form and strength
25.3.1	Prop arac aine	P,S,T	Drops 0.5%
25.4-Miotics and anti glaucoma medicines			
	Medicine	Level of Healthcare	Dosage form and strength
25.4.1	Acetazolamide	P,S,T	Tablet 250 mg
25.4.2	Pilocarpine	P,S,T	Drops 2% Drops 4%
25.4.3	Timolol	P,S,T	Drops 0.25% Drops 0.5%
25.5-Mydriatics			
	Medicine	Level of Healthcare	Dosage form and strength
25.5.1	Atropine	P,S,T	Drops 1% Ointment 1%
25.5.2	Homatropine	P,S,T	Drops 2%
25.5.3	Phenylephrine	P,S,T	Drops 5% Drops 10%
25.5.4	Tropicamide	P,S,T	Drops 1%
25.6-Ophthalmic surgical aids			
	Medicine	Level of Healthcare	Dosage form and strength

25.6.1	Hydroxypropyl methylcellulose	T	Injection 2%
25.7 -Miscellaneous			
	Medicine	Level of Healthcare	Dosage form and strength
25.7.1	Carboxymethylcell ulose	P,S,T	Drops 0.5% Drops 1%
Section 26-Oxytocics and Antioxytocics			
26.1-Oxytocics and abortifacient			
	Medicine	Level of Healthcare	Dosage form and strength
26.1.1	Dinoprostone	S,T	Tablet 0.5 mg Gel 0.5 mg
26.1.2	Methylergometrine	P,S,T	Tablet 0.125 mg Injection 0.2 mg/ml
26.1.3	Mifepristone	T	Tablet 200 mg
26.1.4	Misoprostol	T	Tablet 100 mcg Tablet 200 mcg
26.1.5	Oxytocin	S,T	Injection 5 IU/ml Injection 10 IU/ml
26.2-Medicines used in pre term labour			
	Medicine	Level of Healthcare	Dosage form and strength
26.2.1	Betamethasone	P,S,T	Injection 4 mg/ml
26.2.2	Nifedipine	S,T	Tablet 10 mg
Section 27-Psychotherapeutic medicines			
27.1-Medicines used in psychotic disorders			
	Medicine	Level of Healthcare	Dosage form and strength
27.1.1	Clozapine	T	Tablet 25 mg Tablet 50 mg Tablet 100 mg

27.1.2	Fluphenazine	S,T	Depot Injection 25 mg/ml
27.1.3	Haloperidol	S,T	Tablet 5 mg Tablet 10 mg Tablet 20 mg Oral liquid 2 mg/ 5ml
27.1.4	Risperidone	P,S,T	Tablet 1 mg Tablet 2 mg Tablet 4 mg Oral liquid 1 mg/ml
27.2-Medicines used in mood disorders			
27.2.1-Medicines used in depressive disorders			
	Medicine	Level of Healthcare	Dosage form and strength
27.2.1.1	Amitriptyline	P,S,T	Tablet 10 mg Tablet 25 mg Tablet 50 mg Tablet 75 mg
27.2.1.2	Escitalopram	S,T	Tablet 5 mg Tablet 10 mg Tablet 20 mg
27.2.1.3	Fluoxetine	P,S,T	Capsule 10 mg Capsule 20 mg Capsule 40 mg Capsule 60 mg
27.2.2-Medicines used in Bipolar disorders			
	Medicine	Level of Healthcare	Dosage form and strength
27.2.2.1	Lithium	S,T	Tablet 300 mg
27.2.2.2	Sodium valproate	P,S,T	Tablet 200 mg Tablet 500 mg
27.3-Medicines used for Generalized Anxiety and Sleep Disorders			
	Medicine	Level of Healthcare	Dosage form and strength
27.3.1	Clonazepam	P,S,T	Tablet 0.25 mg Tablet 0.5 mg Tablet 1 mg
27.3.2	Zolpidem	P,S,T	Tablet 5 mg Tablet 10 mg
27.4-Medicines used for obsessive compulsive disorders and panic attacks			

	Medicine	Level of Healthcare	Dosage form and strength
27.4.1	Clomipramine	S,T	Capsule 10 mg Capsule 25 mg Capsule 75 mg
27.4.2	Fluoxetine	P,S,T	Capsule 10 mg Capsule 20 mg Capsule 40 mg Capsule 60 mg

Section 28-Medicines acting on the respiratory tract			
28.1-Antiasthmatic medicines			
	Medicine	Level of Healthcare	Dosage form and strength
28.1.1	Budesonide	P,S,T	Inhalation (MDI/DPI) 100 mcg/dose Inhalation (MDI/DPI) 200 mcg/dose Respirator solution for use in nebulizer 0.5 mg/ml Respirator solution for use in nebulizer 1 mg/ml
28.1.2	Budesonide (A)+ Formoterol (B)	P,S,T	Inhalation (MDI/DPI) 100 mcg (A) + 6 mcg (B) Inhalation (MDI/DPI) 200 mcg (A) + 6 mcg (B) Inhalation (MDI/DPI) 400 mcg (A) + 6 mcg (B)
28.1.3	Hydrocortisone	P,S,T	Injection 100 mg Injection 200 mg
28.1.4	Ipratropium	P,S,T	Inhalation (MDI/DPI) 20 mcg/dose Respirator solution for use in nebulizer 250 mcg/ml
28.1.5	Salbutamol	P,S,T	Tablet 2 mg Tablet 4 mg Oral liquid 2 mg/5 ml Inhalation (MDI/DPI) 100 mcg/dose Respirator solution for use in nebulizer 5mg/ml
28.1.6	Tiotropium	P,S,T	Inhalation (MDI) 9 mcg/dose Inhalation (DPI) 18 mcg/dose
			MDI- Metered dose inhaler DPI- Dry Powder inhaler

Section 29-Solutions correcting water, electrolyte disturbances and acid-base disturbances			
	Medicine	Level of Healthcare	Dosage form and strength
29.1	Glucose	P,S,T	Injection 5% Injection 10% Injection 25% Injection 50%
	Glucose (A) +		

29.2	Sodium chloride (B)	P,S,T	Injection 5% (A) + 0.9% (B)
29.3	Oral rehydration salts	P,S,T	As licensed
29.4	Potassium chloride	P,S,T	Injection 150 mg/ml Oral liquid 500 mg/5 ml
29.5	Ringer lactate	P,S,T	Injection (as per IP)
29.6	Sodium bicarbonate	P,S,T	Injection (as per IP)
29.7	Sodium chloride	P,S,T	Injection 0.9%
		S,T	Injection 0.45% Injection 3%
29.3- Miscellaneous			
	Medicine	Level of Healthcare	Dosage form and strength
29.3.1	Water for Injection	P,S,T	Injection
Section 30-Vitamins and minerals			
	Medicine	Level of Healthcare	Dosage form and strength
30.1	Ascorbic acid (Vitamin C)	P,S,T	Tablet 100 mg Tablet 500 mg
30.2	Calcium carbonate	P,S,T	Tablet 250 mg Tablet 500 mg
30.3	Calcium gluconate	P,S,T	Injection 100 mg/ml
30.4	Cholecalciferol	P,S,T	Tablet 1000 IU, Tablet 60000 IU Oral liquid 400 IU/ml
30.5	Nicotinamide	P,S,T	Tablet 50 mg
30.6	Pyridoxine	P,S,T	Tablet 10 mg Tablet 50 mg Tablet 100 mg
30.7	Riboflavin	P,S,T	Tablet 5 mg
30.8	Thiamine	P,S,T	Tablet 100 mg Injection 100 mg/ml

30.9	Vitamin A	P,S,T	Capsule 5000 IU Capsule 50000 IU Capsule 100000 IU Oral liquid 100000 IU/ml Injection 50000 IU/ml

Explanation.

(1) Any dosage form of a medicine, other than the dosage form included in this Schedule, but in same strength and route of administration, which does not have significant difference in terms of pharmacokinetics or pharmacodynamics or efficacy-safety profile over the dosage form mentioned in the list shall be considered as included. To elaborate, if a tablet is included, other dosage forms like conventional tablets and capsules are considered as included. However, such different dosage forms should be considered differently for purposes such as procurement policy, pricing, etc. This principle also applies to all other dosage forms e.g. oral liquid dosage forms, injectables, topical dosage forms, etc.

(2) Innovation in medicine must be encouraged. The formulations developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulations, sustained release/controlled release etc. should be considered as included only if specified in the list against any medicine. Such different formulations should be considered differently for purposes such as procurement policy, pricing, etc.

(3) In cases, where vaccines or immunoglobulins or sera are listed in this Schedule, irrespective of variation in source, composition and strength, all the products of the same vaccines or immunoglobulins or sera as approved by the licensing authority are considered included.

(4) In general, medicines have been mentioned with respect to their active moieties, without mentioning the salts and, in cases where there is significant difference between the salts, the medicine finds mention as its specific salt.

(5) In cases where an active moiety is available as different isomers or analogues or derivatives, they are considered as separate entities, and inclusion of one does not imply inclusion of all isomers or analogues or derivatives.

(6) For injectable preparations, the pack size (single and multi-dose packs) has not been mentioned. It is suggested that the single and multi-dose pack sizes be considered as separate entities for purposes such as procurement/ pricing etc.][4]

[4] Substituted vide SO 701(E) dated 10-03-2016 vide Drugs (Price Control) Amendment Order, 2016

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 Formulation										

	s										
	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:

Authorised Signatory:

Name:

Date: **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)	(11)	(10)	(12)	(13)	(14)

TABLE-B

Name of the Bulk Drugs/API used	**Unit/kg/Ltr)**	**Installed Capacity**	**Production/Import Level**	**Domestic Sale**

in Scheduled Formulation												
			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)	(11)	(10)	(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: **Authorised Signatory:**

Date: **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 Stockist (incl. of E.D.) (Rs.)	Price to retailer (incl. of E.D.) (Rs.)	Maximum Retail Price (incl. of E.D.&Taxes) (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
	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 Stockist (incl. of E.D.) (Rs.)	Price to retailer (incl. of E.D.) (Rs.)	Maximum Retail Price (incl. of E.D.&Taxes) (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
	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:

Name:

Designation:

Date: