THE DRUGS (PRICES CONTROL) ORDER, 2013

(Notified by SO 1221 (E) dated 15.05.2013 and as amended up to vide SO2324(E) dated 25-05-2023)

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 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 – I.[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;

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[1] *Substituted vide GSR 1233 (E), w.e.f. 08-05-2015* – [*(n) "manufacturer" for the purpose of this Order means any person who manufactures, imports and markets drugs for distribution or sale in the country;]*

[2] *Substituted vide GSR 686(E), w.e.f. 09-03-2015* – [*"non-scheduled formulation" means a formulation, the dosage and strengths of which are not specified in the First Schedule;]*

(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 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.

Provided that the retail price of a new drug or the new drug that contain molecules or components or ingredients, that have become off-patent or about to become off-patent under the Patents Act 1970 (39 of 1970), shall be fixed as per the provisions of sub-paragraph (3) of this paragraph.[3]

(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)

"(3) (i) the retail price of the new drug shall be arrived at by reducing fifty per cent. of the price calculated under sub-paragraph (1) of paragraph 4, and if the new drug is not available in the domestic market, the retail price of the new drug shall be fixed as per the provisions of sub-paragraph (2) of this paragraph.

(ii) after one year from the date on which the retail price was fixed as per item (i) or the date on which "price to retailer" of atleast one company fixed under item (i) is captured in the pharmaceutical market database, whichever is later, the retail price for the subsequent manufacturers shall be fixed as per sub-paragraph (1) of paragraph 4:

Provided that while fixing the retail price under item (ii), the prices to retailer of the brand of the manufacturer having the patent and the manufacturer holding the permission granted by the patentee shall be excluded.";[4]

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:

$$P(s) = Pm\{1-(Pi1+Pi2+\ldots)/(N*100)\}$$ 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

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[3] *Inserted vide SO 2165(E) dated 11-05-2023 vide Drugs (Price Control) Amendment Order, 2023*

[4] *Inserted vide SO 2165(E) dated 11-05-2023 vide Drugs (Price Control) Amendment Order, 2023*

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 subtherapeutic 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) The source of market based data shall be the data available with the pharmaceutical market data specializing company as decided by the Government and if the Government deems it necessary, it may validate such data by appropriate survey or evaluation."[5]

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[5] *Substituted vide SO 39(E) dated 03-01-2019 vide Drugs (Price Control) Amendment Order, 2019 [9. Reference data and source of market based data 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.

(7) "Notwithstanding anything contained in this paragraph, for fixing or revising the ceiling price for formulations, the Government may, if it is necessary so to do, consider market based data available for any month, as deemed fit."[6]

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.

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[6] *Inserted vide SO 39(E) dated 03-01-2019 vide Drugs (Price Control) Amendment Order, 2019*

(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 nonscheduled 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.[7]

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):

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

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 subparagraph (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) every five years from the date of fixing the ceiling price under this Order for formulations as specified under the SCHEDULE - I.[8]

(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.

"18A. Revision of ceiling price of scheduled formulation after expiry of patent issued under the Patents Act 1970 (39 of 1970). — In the case of scheduled formulation or its molecules or components or ingredients, which are patented under the Patents Act 1970 (39 of 1970), the ceiling price, on expiry of the patent, shall be revised by reducing the present ceiling price by fifty per cent., and after one year, the ceiling price shall be revised again as per the provisions of subparagraph (1) of paragraph 4, based on the market data of the preceding month.".[9]

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

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[8] *Substituted vide SO 3249(E) dated 12-08-2021 vide Drugs (Price Control) Third Amendment Order, 2021 [(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]*

[9] *Inserted vide SO 2165(E) dated 11-05-2023 vide Drugs (Price Control) Amendment Order, 2023*

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 or Form-VI[10] 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 or Form-VI[11] 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.

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[10] *Inserted vide SO 2899(E) dated 20-07-2021 vide Drugs (Price Control) Amendment Order, 2021*

[11] *Inserted vide SO 2899(E) dated 20-07-2021 vide Drugs (Price Control) Amendment Order, 2021*

27. Sale of split quantities of formulations.– No dealer shall sell loose quantity of any formulation at a price which exceeds the prorata 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), for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country.[12]
(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:
(iv) Drugs for treating orphan diseases as decided by the Ministry of Health and Family Welfare, Government of India.[13]

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;

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[12] *Substituted vide SO 39(E) dated 03-01-2019 vide Drugs (Price Control) Amendment Order, 2019 [(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]*

[13] *Inserted vide SO 39(E) dated 03-01-2019 vide Drugs (Price Control) Amendment Order, 2019*

"**SCHEDULE-I**[14]

National List of Essential Medicines (NLEM) 2022

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

(Symbols P,S and T appearing in this Schedule denote essentiality at Primary, Secondary and Tertiary levels respectively)

Section 1

Medicines used in Anaesthesia

1.1- General Anaesthetics and Oxygen

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
1.1.1	Halothane	S,T	Liquid for inhalation
1.1.2	Isoflurane	S,T	Liquid for inhalation
1.1.3	Ketamine	P,S,T	Injection 10 mg/mL Injection 50 mg/mL
1.1.4	Nitrous oxide	P,S,T	As licensed for medical purpose
1.1.5	Oxygen*	P,S,T	As licensed for medical purpose
1.1.6	Propofol	P,S,T	Injection 10 mg/mL
1.1.7	Sevoflurane	S,T	Liquid for inhalation
1.1.8	Thiopentone	P,S,T	Powder for injection 0.5 g Powder for injection 1 g

14 *Substituted vide SO 701(E) dated 10-03-2016 vide Drugs (Price Control) Amendment Order, 2016 and further substituted vide SO 5249 (E) dated 11.11.2022 vide Drugs (price Control) Amendment Order, 2022*

*Oxygen is also listed in **Section 27.5 -** Medicines for COVID-19 management*

1.2-Local Anaesthetics

	Medicine	Level of Healthcare	Dosage form(s) and strength(s)
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 mcg/mL) (B)

1.3- Preoperative Medication and Sedation for Short Term Procedures

	Medicine	Level of Healthcare	Dosage form(s) and strength(s)
1.3.1	Atropine**	P,S,T	Injection 0.6 mg/mL

*Lignocaine formulations are also listed in **Section 10.2.5** cardiovascular medicines- Antiarrhythmic medicines*

***Atropine formulations are also listed in –*

A. ***Section 4.2.1 -*** *Antidotes and Other Substances used in Management ofPoisonings/Envenomation - Specific*

B. ***Section 21.5.1 -*** *Ophthalmological Medicines- Mydriatics*

	Medicine	Level of Healthcare	Dosage form(s) and strength(s)
1.3.2	Glycopyrrolate	S,T	Injection 0.2 mg/mL
1.3.3	Midazolam*	P,S,T	Tablet 7.5 mg Nasal Spray 0.5mg Nasal Spray 1.25 mg Injection 1 mg/mL Injection 5 mg/mL
1.3.4	Morphine**	P,S,T	Injection 10 mg/mL Injection 15 mg/mL

Section 1.4 -Muscle Relaxants and Cholinesterase Inhibitors

	Medicine	Level of Healthcare	Dosage form(s) and strength(s)
1.4.1	Atracurium	S,T	Injection 10 mg/mL

1.4.2	Baclofen	S,T	Tablet 5 mg Tablet 10 mg Tablet 20 mg

**Midazolam formulations are also listed in -*

***A. Section 5.1.7-** Medicines used in Neurological DisordersAnticonvulsants/ Antiepileptics*

***B. Section 7.4.12-** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care*

***Morphine formulations are also listed in -*

***A. Section 2.2.2-** Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Opioid Analgesics*

***B. Section 7.4.13 -** Anti-cancer agents including immunosuppressives, and medicines used in Palliative Care*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
1.4.3	Neostigmine*	S,T	Tablet 15 mg Injection 0.5 mg/mL
1.4.4	Succinylcholine	S,T	Injection 50 mg/mL
1.4.5	Vecuronium	S,T	Powder for injection 4 mg Powder for injection 10 mg

Section 2

Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders

2.1 - Non-opioid Analgesics, Antipyretics and Non-steroidal Anti- inflammatory Drugs

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
2.1.1	Acetylsalicylicacid**	P,S,T	Tablet 300 mg to 500 mg Effervescent/ Dispersible/ Enteric coated Tablet 300 mg to 500 mg

Neostigmine formulations are also listed in **Section 4.2.8 - Antidotes and Other substances used in Management of poisoning/Envenomation - Specific*

***Acetylsalicylic acid formulations are also listed in -*

***A. Section 5.2.1 -** Medicines used in Neurological Disorders Antimigraine medicines*

***B. Section 10.5.1 -** Cardiovascular medicines -Antithrombotic Medicines (Cardiovascular/ Cerebrovascular) - Antiplatelet and Antithrombotic Medicines*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
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 (p)
2.1.4	Mefenamic acid	P,S,T	Tablet 250 mg Oral liquid 100 mg/5 mL (p)
2.1.5	Paracetamol**	P,S,T	Tablet 500 mg Tablet 650 mg Oral liquid 120 mg/5 mL (p) Oral Liquid 125 mg/5 mL (p) Oral Liquid 250 mg/5 mL (p) Injection 150 mg/ mL Suppository 80 mg Suppository 170 mg
2.2-Opioid Analgesics			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
2.2.1	Fentanyl	S,T	Injection 50 mcg/mL
Ibuprofen formulations are also listed in **Section 5.2.2 - Medicines used in Neurological Disorders-Antimigraine Medicines* *** Paracetamol formulations are also listed in -* ***A.** **Section 5.2.3 -** Medicines used in Neurological Disorders-Antimigraine Medicines* ***B.** **Section 27.4 -** Medicines for COVID- 19 Management*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
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(s) and strength(s)**
2.3.1	Allopurinol***	P,S,T	Tablet 100 mg Tablet 300 mg
2.3.2	Colchicine	P,S,T	Tablet 0.5 mg
Morphine formulations are also listed in –* ***A. **Section 1.3.4 -** Medicines used in Anaesthesia - Preoperative medication and sedation for short term procedures* ***B.** **Section 7.4.13 -** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care*			

*** Tramadol formulations are also listed in-*

Section 7.4.15 - *Tramadol formulations are also listed in Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care*

**** Allopurinol formulations are also listed in-*

Section 7.4.1 - *Allopurinol formulations are also listed in Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care*

2.4-Disease Modifying Agents used in Rheumatoid Disorders

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
2.4.1	Azathioprine*	S,T	Tablet 25 mg (p) Tablet 50 mg
2.4.2	Hydroxychloroquine	P,S,T	Tablet 200 mg Tablet 400 mg
2.4.3	Methotrexate**	P,S,T	Tablet 2.5 mg Tablet 5 mg Tablet 10 mg
2.4.4	Sulfasalazine	S,T	Tablet 500 mg

Section 3

Antiallergics and Medicines used in Anaphylaxis

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
3.1	Adrenaline	P,S,T	Injection 1 mg/mL
3.2	Cetirizine	P,S,T	Tablet 10 mg Oral liquid 5 mg/5 mL (p)

** Azathioprine formulations are also listed in **Section 7.3.1 -** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care*

*** Methotrexate formulations are also listed in **Section 7.1.30 -** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
3.3	Dexamethasone*	P,S,T	Tablet 0.5 mg Tablet 2 mg Tablet 4 mg Oral liquid 0.5 mg/5 mL (p) Injection 4 mg/mL
3.4	Hydrocortisone**	P,S,T	Tablet 5 mg Tablet 10 mg Powder for Injection 100 mg Powder for Injection 200 mg

3.5	Pheniramine	P,S,T	Injection 22.75 mg/mL
3.6	Prednisolone***	P,S,T	Tablet 5 mg Tablet 10 mg Tablet 20 mg Oral liquid 5 mg/5 mL (p) Oral liquid 15 mg/5 mL (p)

**Dexamethasone formulations are also listed in -*

A. ***Section 7.4.3 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used inPalliative Care*

B. ***Section 18.1.1 -*** *Hormones, other Endocrine Medicines and Contraceptives - Adrenal Hormones and Synthetic Substitutes*

C. ***Section 27.1 -*** *Medicines for COVID- 19 Management*

*** Hydrocortisone formulations are also listed in* ***Section 18.1.3 -*** *Hormones, other Endocrine Medicines and Contraceptives- Adrenal Hormones and Synthetic Substitutes*

****Prednisolone formulations are also listed in -*

A. ***Section 7.2.4 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used inPalliative Care - Hormones and Anti-Hormones used in cancer therapy*

B. ***Section 18.1.5 -*** *Hormones, other Endocrine Medicines and Contraceptives –Adrenal Hormones and Synthetic Substitutes*

C. ***Section 21.2.1 -*** *Ophthalmological Medicines- Anti-inflammatory Medicine*

Section 4

Antidotes and Other Substances used in Management of Poisonings/Envenomation

4.1-Nonspecific

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
4.1.1	Activated Charcoal	P,S,T	Powder (as licensed)

4.2 Specific

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
4.2.1	Atropine*	P,S,T	Injection 0.6 mg/mL
4.2.2	Calcium gluconate**	P,S,T	Injection 100 mg/mL
4.2.3	D- Penicillamine	P,S,T	Capsule 150 mg (p) Capsule 250 mg
4.2.4	Desferrioxamine	S,T	Powder for injection 500 mg
4.2.5	Methylthioninium chloride (Methylene blue)	S,T	Injection 10 mg/mL

**Atropine formulations are also listed in -*

A. ***Section 1.3.1 -*** *Medicines used in Anaesthesia -Preoperative Medication and Sedation for short term procedures*

B. ***Section 21.5.1 -*** *Ophthalmological Medicines- Mydriatics*

*** Calcium gluconate formulations are also listed in **Section 26.3 -** Vitamins and minerals*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
4.2.6	N-acetylcysteine	P,S,T	Sachet 200 mg Injection 200 mg/mL
4.2.7	Naloxone	P,S,T	Injection 0.4 mg/mL
4.2.8	Neostigmine*	P,S,T	Injection 0.5 mg/mL
4.2.9	Pralidoxime chloride (2-PAM)	P,S,T	Injection 25 mg/mL
4.2.10	Snake venom antiserum**	P,S,T	Soluble/ liquid polyvalent -As licensed Lyophilized polyvalent -As licensed
4.2.11	Sodium nitrite	S,T	Injection 30 mg/mL
4.2.12	Sodium thiosulphate	S,T	Injection 250 mg/mL
*** Neostigmine formulations are also listed in **Section 1.4.3 -** Medicines used in Anaesthesia - Muscle relaxants and cholinesterase inhibitors* *** Snake Venom antiserum is also listed in **Section 19.2.7. -** Immunologicals -Sera and immunoglobulins (Liquid/ Lyophilized)*			
Section 5 **Medicines used in Neurological Disorders**			
Section 5.1-Anticonvulsants/ Antiepileptics			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
5.1.1	Carbamazepine*	P,S,T	Tablet 100 mg Tablet 200 mg Tablet 400 mg Modified Release – Tablet 200 mg Tablet 400 mg Oral liquid 100 mg/5 mL (p)
5.1.2	Clobazam	S,T	Tablet 5 mg Tablet 10 mg
5.1.3	Diazepam**	P,S,T	Oral liquid 2 mg/5 mL (p) Injection 5 mg/mL Suppository 5 mg
5.1.4	Levetiracetam	S,T	Tablet 250 mg Tablet 500 mg Tablet 750 mg Modified Release Tablet 750 mg Oral liquid 100 mg/mL (p)

			Injection 100 mg/mL
5.1.5	Lorazepam	P,S,T	Tablet 1 mg Tablet 2 mg Injection 2 mg/mL Injection 4 mg/mL
Carbamazepine formulations are also listed in **Section 23.2.2.3 Medicines used in treatment of Psychiatric disorder - Medicines used in Bipolar disorders* *** Diazepam formulations are also listed in **Section 7.4.4 -** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care - Medicines used in Palliative Care*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
5.1.6	Magnesium sulphate	S,T	Injection 500 mg/mL
5.1.7	Midazolam*	P,S,T	Tablet 7.5 mg Tablet 15 mg Nasal Spray 0.5 mg/actuation Nasal Spray 1.25 mg/actuation Injection 1 mg/mL Injection 5 mg/mL
5.1.8	Phenobarbitone	P,S,T	Tablet 30 mg Tablet 60 mg Oral liquid 20 mg/5 mL (p)
		S,T	Injection 200 mg/mL
5.1.9	Phenytoin	P,S,T	Tablet 50 mg Tablet 100 mg Tablet 300 mg Modified Release Tablet 300 mg Oral liquid 30 mg/5 mL (p) Oral liquid 125 mg/5 mL (p) Injection 25 mg/mL Injection 50 mg/mL
Midazolam formulations are also listed in –* ***A. **Section 1.3.3 -** Medicines used in Anaesthesia - Preoperative Medication and Sedation for short term procedures* ***B.** **Section 7.4.12 -** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care - Medicines used in Palliative Care*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
			Tablet 200 mg Tablet 300 mg

5.1.10	Sodium Valproate*	P,S,T	Tablet 500 mg Modified Release – Tablet 300 mg Tablet 500 mg Oral liquid 200 mg/5 mL (p)
		S,T	Injection 100 mg/mL
Section 5.2- Antimigraine Medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
5.2.1	Acetylsalicylicacid**	P,S,T	Tablet 300 mg to 500 mg Effervescent/ Dispersible/ Enteric coated Tablet 300 mg to 500 mg

***Sodium Valproate formulations are also listed in-*

***Section 23.2.2.2 -** Medicines used in treatment of Psychiatric Disorders -Medicines used in Bipolar disorders- Medicines used in mood disorders*

****Acetylsalicyclic acid formulations are also listed in -*

A. ***Section 2.1.1 -** Analgesics, Antipyretics, Non-steroidal Anti-inflammatory*

Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Non-Opioid Analgesics, Antipyretics and Non-Steroidal Anti-Inflammatory Drugs

B. ***Section 10.5.1 -** Cardiovascular medicines- Antiplatelet and Antithrombotic Medicines*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
5.2.2	Ibuprofen*	P,S,T	Tablet 200 mg Tablet 400 mg Oral liquid 100 mg/5 mL (p)
5.2.3	Paracetamol**	P,S,T	Tablet 500 mg Tablet 650 mg Oral liquid 120 mg/5mL (p) Oral Liquid 125 mg/5mL (p) Oral Liquid 250 mg/5mL (p)
5.2.4	Sumatriptan	P,S,T	Tablet 25 mg Tablet 50 mg
Section 5.2.1 - For Prophylaxis			
5.2.1.1	Amitriptyline***	P,S,T	Tablet 10 mg Tablet 25 mg Tablet 75 mg

***Ibuprofen formulations are also listed in **Section 2.1.3 -** Analgesics, Antipyretics, Non- steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders Non-opioid Analgesics, Antipyretics andNon-steroidal Anti- inflammatory Drugs*

Paracetamol formulations are also listed in -* ***A. ***Section 2.1.5 -*** *Analgesics, Antipyretics, Non-steroidal Anti-inflammatory* *Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Non-opioid analgesics, antipyretics and nonsteroidal anti- inflammatory medicines* ***B.*** ***Section 27.4 -*** *Medicines for COVID- 19 management* **** Amitriptyline formulations are also listed in -* ***A.*** ***Section 7.4.2 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used inPalliative Care - Medicines used in Palliative Care-* ***B.*** ***Section 23.2.1.1 -*** *Medicines used in treatment of Psychiatric Disorders -Medicines used in mood disorders- Medicines used in depressive disorders*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
5.2.1.2	Flunarizine	P,S,T	Tablet 5 mg Tablet 10 mg
5.2.1.3	Propranolol	P,S,T	Tablet 10 mg Tablet 20 mg Tablet 40 mg
Section 5.3- Antiparkinsonism Medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
5.3.1	Levodopa (A) + Carbidopa (B)	P,S,T	Tablet 100 mg (A) + 10 mg (B) Tablet 100 mg (A) + 25 mg (B) Tablet 250 mg (A) + 25 mg (B) Modified Release – Tablet 100 mg (A) + 25 mg (B) Tablet 200 mg (A) + 50 mg (B)
5.3.2	Trihexyphenidyl	P,S,T	Tablet 2 mg
Section 5.4-Medicines used in Dementia			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
5.4.1	Donepezil	S,T	Tablet 5 mg Tablet 10 mg
Section 6 **Anti-infective Medicines**			
6.1-Anthelminthics			
6.1.1- Intestinal Anthelminthics			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
			Tablet 400 mg

6.1.1.1	Albendazole*	P,S,T	Chewable Tablet 400 mg Oral liquid 200 mg/5 mL (p)
6.1.1.2	Mebendazole	P,S,T	Tablet 100 mg Oral liquid 100 mg/5 mL (p)
6.1.2 Antifilarial			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.1.2.1	Albendazole*	P,S,T	Tablet 400 mg Chewable Tablet 400 mg Oral liquid 200 mg/5 mL (p)
6.1.2.2	Diethylcarbamazine(DEC)	P,S,T	Tablet 50 mg Tablet 100 mg Oral liquid 120 mg/5 mL (p)
** Albendazole formulations are also listed **Section 6.1.1.1 -** in Anti-infective Medicines-Antifilarial*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.1.2.3	Ivermectin	P,S,T	Tablet 6 mg Tablet 12 mg
6.1.3 - Anti-schistosomal and Anti-trematodal Medicine			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
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(s) and strength(s)**
6.2.1.1	Amoxicillin	P,S,T	Capsule 250 mg Capsule 500 mg Oral liquid 125 mg/5 mL (p) Oral liquid 250 mg/5 mL (p) Powder for Injection 250 mg Powder for Injection 500 mg Powder for injection 1000 mg
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 (p) Dry Syrup 125 mg (A) + 31.25 (B)/ 5 mL (p)

		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 1000 mg
6.2.1.4	Benzathine benzylpenicillin	P,S,T	Powder for Injection 6 lac units Powder for Injection 12 lac unitsPowder for injection 24 lac units
6.2.1.5	Benzylpenicillin	P,S,T	Powder for injection 5 lac units Powder for injection 10 lac units
6.2.1.6	Cefadroxil	P,S,T	Tablet 500 mg Tablet 100 mg Oral liquid 125 mg/5 mL (p)
6.2.1.7	Cefazolin	P,S,T	Powder for Injection 500 mg Powder for Injection 1000 mg
6.2.1.8	Cefixime	S,T	Tablet 200 mg Tablet 400 mg Oral liquid 50 mg/5 mL (p) Oral liquid 100 mg/5 mL (p)
6.2.1.9	Cefotaxime*	S,T	Powder for Injection 250 mg Powder for Injection 500 mg Powder for Injection 1000 mg
Cefotaxime formulations are also listed in **Section 6.7.5.2 - Anti-infective Medicines- Antiviral Medicines-Medicines for treating Opportunistic Infections in People living withHIV*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.2.1.10	Ceftazidime	S,T	Powder for Injection 250 mg Powder for Injection 1000 mg
6.2.1.11	Ceftriaxone	S,T	Powder for Injection 250 mg Powder for Injection 500 mg Powder for Injection 1000 mg Powder for Injection 2000 mg
6.2.1.12	Cloxacillin	P,S,T	Capsule 250 mg Capsule 500 mg Oral Liquid 125 mg/5 mL (p) Powder for Injection 250 mg
	Piperacillin (A) +Tazobactam (B)		Powder for Injection 1000 mg (A) + 125 mg (B) Powder for Injection 2000 mg

6.2.1.13		T	(A) + 250 mg (B) Powder for Injection 4000 mg (A) + 500 mg (B)
6.2.1.14	Meropenem	T	Powder for Injection 500 mg (astrihydrate) Powder for Injection 1000 mg (as trihydrate)
6.2.2 - Other Antibacterials			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.2.2.1	Azithromycin*	P,S,T	Tablet 250 mg Tablet 500 mg Oral liquid 200 mg/5 mL (p) Powder for Injection 500 mg
6.2.2.2	Cefuroxime	P,S,T	Tablet 500 mg Oral liquid 125 mg/ 5 mL (p) Injection 1500 mg
Azithromycin formulations are also listed in **Section 6.7.6.1 Anti-infective Medicines - Medicines used in the management of HIV- Additional Medicines for Syndromic Management of Sexually Transmitted Infections*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.2.2.3	Ciprofloxacin*	P,S,T	Tablet 250 mg Tablet 500 mg Oral liquid 250 mg/ 5 mL (p) Injection 200 mg/ 100 mL
6.2.2.4	Clarithromycin**	S,T	Tablet 250 mg Tablet 500 mg Oral liquid 125 mg/5 mL (p)
6.2.2.5	Clindamycin***	P,S,T	Capsule 150 mg Capsule 300 mg Injection 150 mg /mL
6.2.2.6	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 (p)
**** Ciprofloxacin formulations are also listed in -*** ***A. Section 16.2 -** Ear, Nose and Throat Medicines,* ***B. Section 21.1.2 -** Ophthalmological Medicines- Anti-infective Medicines,* *** Clarithromycin formulations are also listed in **Section 6.4.3 -** Anti-infective medicines-Anti-tuberculosis Medicines* ****Clindamycin formulations are also listed in -*			

A. ***Section 6.7.5.3 -*** *Anti-infective Medicines- Antiviral Medicines- Medicines for treating Opportunistic Infections in People living with HIV*

B. ***Section 6.9.3.1 -*** *Anti-infective Medicines- Drugs for amoebiasis and other parasitic infections - Antipneumocystosis and antitoxoplasmosis medicines*

C. ***Section 6.10.1.5 -*** *Anti-infective Medicines- Antimalarial medicines- For curativetreatment*

***** Co-trimoxazole formulations are also listed in* ***Section 6.9.3.2 -*** *Anti-infective Medicines- Medicines for amoebiasis and other parasitic infections -Antipneumocystosis andantitoxoplasmosis medicines*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.2.2.7	Doxycycline*	P,S,T	Capsule 100 mg Dry Syrup 50 mg/5 mL (p) Power for Injection 100 mg
6.2.2.8	Gentamicin	P,S,T	Injection 10 mg/mL Injection 40 mg/mL
6.2.2.9	Metronidazole**	P,S,T	Tablet 200 mg Tablet 400 mg Oral liquid 200 mg/5 mL (p) Injection 500 mg/100 mL
6.2.2.10	Nitrofurantoin	P,S,T	Tablet 100 mg Oral liquid 25 mg/5 mL (p)
6.2.2.11	Phenoxymethyl penicillin	P,S,T	Tablet 250 mg
6.2.2.12	Procaine Benzylpenicillin	P,S,T	Powder for injection 1000 mg (=1 million IU)
6.2.2.13	Vancomycin	S,T	Capsule 125 mg Capsule 250 mg Powder for Injection 250 mg Powder for Injection 500 mg Powder for Injection 1000 mg

Doxycycline formulations are also listed in* ***Section 6.10.2.1 -* *Anti-infective Medicines- Antimalarial medicines- For prophylaxis*

Metronidazole formulations are also listed in* ***Section 6.9.1.1 - *Anti-infective Medicines - Antiprotozoal Medicines - Medicines for amoebiasis and other parasitic infections*

6.3 - Antileprosy Medicines

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.3.1	Clofazimine*	P,S,T	Capsule 50 mg Capsule 100 mg
6.3.2	Dapsone	P,S,T	Tablet 50 mg

			Tablet 100 mg
6.3.3	Rifampicin**	P,S,T	Capsule 150 mg Capsule 300 mg
6.4-Antituberculosis Medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.4.1	Amikacin	S,T	Injection 100 mg/mL Injection 250 mg/mL Injection 500 mg/mL
6.4.2	Bedaquiline	T	Tablet 100 mg
6.4.3	Clarithromycin***	S,T	Tablet 250 mg Tablet 500 mg Tablet 750 mg
Clofazimine formulations are also listed **Section 6.4.5 - Anti-infective Medicines - Anti-tuberculosis medicines* ***Rifampicin formulations are also listed in **Section 6.4.15 -** Anti-infective Medicines - Anti-tubercular medicine* ****Clarithromycin formulations are also listed in **Section 6.2.2.4 -** Anti-infective Medicines-Antibacterials -Other Antibacterials*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.4.4	Clofazimine*	S,T	Capsule 50 mg Capsule 100 mg
6.4.5	Cycloserine	S,T	Capsule 125 mg Capsule 250 mg
6.4.6	Delamanid	T	Tablet 50 mg
6.4.7	Ethambutol	P,S,T	Tablet 200 mg Tablet 400 mg Tablet 600 mg Tablet 800 mg
6.4.8	Ethionamide	S,T	Tablet 125 mg Tablet 250 mg
6.4.9	Isoniazid	P,S,T	Tablet 100 mg Tablet 300 mg Oral Liquid 50 mg/5 mL (p)
6.4.10	Levofloxacin	P,S,T	Tablet 250 mg Tablet 500 mg Tablet 750 mg
			Tablet 300 mg

6.4.11	Linezolid	P,S,T	Tablet 600 mg
6.4.12	Moxifloxacin	P,S,T	Tablet 400 mg
Clofazimine formulations are also listed in **Section 6.3.1 - Anti-infective Medicines - Antileprosy medicines*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.4.13	Para- aminosalicylic acid	S,T	Granules (As licensed)
6.4.14	Pyrazinamide	P,S,T	Tablet 500 mg Tablet 750 mg Tablet 1000 mg Tablet 1500 mg Oral liquid 250 mg/5 mL (p)
6.4.15	Rifampicin*	P,S,T	Capsule 150 mg Capsule 300 mg Capsule 450 mg Capsule 600 mg Oral liquid 100 mg/ 5 mL (p)
6.4.16	Streptomycin	P,S,T	Powder for Injection 750 mg Powder for Injection 1000 mg
6.5 - Antifungal Medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.5.1	Amphotericin B**	S,T	a) Amphotericin B (conventional) - Injection 50mg/vial b) Lipid Amphotericin B - Injection 50 mg/vial c) Liposomal Amphotericin B - Injection 50 mg/vial
Rifampicin formulations are also listed in **Section 6.3.3 - Anti-infective Medicines-Antileprosy medicines* ***Amphotericin B formulations are also listed **Section 6.9.2.1 -** Anti-infective MedicinesAntileishmaniasis medicines*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.5.2	Clotrimazole*	P,S,T	Pessary 100 mg
6.5.3	Fluconazole	P,S,T	Tablet 50 mg Tablet 100 mg Tablet 150 mg Tablet 200 mg Tablet 400 mg Oral liquid 50 mg/ 5 mL (p)

		S,T	Injection 200 mg / 100 mL
6.5.4	Griseofulvin	P,S,T	Tablet 125 mg Tablet 250 mg Tablet 375 mg
6.5.5	Itraconazole	S,T	Capsule 100 mg Capsule 200 mg Oral liquid 10 mg/mL
6.5.6	Mupirocin	P,S,T	Ointment 2%
6.5.7	Nystatin	S,T	Pessary 1 Lac IU Oral Liquid 1 Lac IU/mL (p)
6.5.8	Terbinafine	P,S,T	Cream 1%
Clotrimazole formulations are also listed in –* ***A.* ***Section 6.7.5.4 -*** *Anti-infective Medicines - Antiviral medicines- Medicines for treating Opportunistic Infections in People living with HIV* ***B.*** ***Section 11.1.1 -*** *Dermatological Medicines (Topical)- Antifungal medicines* ***C.*** ***Section 16.3 -*** *Ear, Nose and Throat Medicines*			
6.6 - Antiviral Medicines			
6.6.1 - Antiherpes Medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.6.1.1	Acyclovir*	P,S,T	Tablet 200 mg Tablet 400 mg Tablet 800 mg Powder for Injection 250 mg Powder for Injection 500 mg Oral liquid 400 mg/5 mL (p)
6.6.2 - Anti-cytomegalovirus (CMV) medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.6.2.1	Valganciclovir**	S, T	Tablet 450 mg Powder for oral solution 50mg / mL
6.7- Medicines used in the Management of HIV			
6.7.1 Nucleoside Reverse Transcriptase Inhibitors			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.7.1.1	Abacavir	S,T	Tablet 60 mg (p) Tablet 300 mg
**Acyclovir formulations are also listed in -*			

A. ***Section 6.7.5.1 -*** *Anti-infective Medicines -Medicines used in the management of HIV -Medicines for treating Opportunistic Infections in People living with HIV*

B. ***Section 21.1.1 -*** *Ophthalmological Medicines- Anti-infective medicine*

Valganciclovir formulations are also listed in* ***Section 6.7.5.5 - *Anti-infective Medicines- Antiviral medicines -Medicines for treating Opportunistic Infections in People living with HIV*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.7.1.2	Abacavir (A) + Lamivudine (B)	S,T	Tablet 60 mg (A) + 30 mg (B)(p) Tablet 600 mg (A) + 300 mg (B)
6.7.1.3	Lamivudine	S,T	Tablet 100 mg Tablet 150 mg
6.7.1.4	Tenofovir Disproxil Fumarate (TDF)*	S,T	Tablet 300 mg
6.7.1.5	Tenofovir Disproxil Fumarate (A) + Lamivudine (B)	S,T	Tablet 300 mg (A) + 300 mg (B)
6.7.1.6	Tenofovir Disproxil Fumarate (A) + Lamivudine (B) + Dolutegravir (C)	P,S,T	Tablet 300 mg (A) + 300 mg (B) + 50 mg (C)
6.7.1.7	Tenofovir Disproxil Fumarate (A) + Lamivudine (B) + Efavirenz (C)	S,T	Tablet 300 mg (A) + 300 mg (B) + 600 mg (C)
6.7.1.8	Zidovudine	S,T	Tablet 300 mg Oral liquid 50 mg/5 mL (p)
6.7.1.9	Zidovudine (A) +Lamivudine (B)	S,T	Tablet 60 mg (A) + 30 mg (B)(p) Tablet 300 mg (A) + 150 mg (B)

** Tenofovir Disproxil Fumarate formulations are also listed in* ***Section 6.8.6 -***

Anti-infective Medicines- Medicines used in Hepatitis B and Hepatitis C

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.7.1.10	Zidovudine (A) +Lamivudine (B) +Nevirapine (C)	S,T	Tablet 60 mg (A) + 30 mg (B) +50 mg (C) (p) Tablet 300 mg (A) + 150 mg (B) + 200 mg (C)

6.7.2 Non-nucleoside Reverse Transcriptase Inhibitors

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.7.2.1	Efavirenz	S,T	Tablet 200 mg (p) Tablet 600 mg

6.7.2.2	Nevirapine	P,S,T	Tablet 200 mg Dispersible Tablet 50 mg (p) Oral liquid 50 mg/ 5 mL (p)
6.7.3 Integrase Inhibitors			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.7.3.1	Dolutegravir	S,T	Tablet 50 mg
6.7.3.2	Raltegravir	S,T	Tablet 400 mg
6.7.4 Protease Inhibitors			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.7.4.1	Atazanavir (A) + Ritonavir (B)	S,T	Tablet 300 mg (A) +Tablet 100 mg (B)
6.7.4.2	Darunavir	S,T	Tablet 600 mg
6.7.4.3	Darunavir (A) +Ritonavir (B)	S,T	Tablet 600 mg (A) +Tablet 100 mg (B)
6.7.4.4	Lopinavir (A) +Ritonavir (B)	S,T	Tablet 100 mg (A) + 25 mg (B) Tablet 200 mg (A) + 50 mg (B) Oral Liquid 80 mg (A) +20 mg (B) /mL (p) Capsule/ Sachet (containing pellets/granules) 40 mg (A) + 10 mg (B) (p)
6.7.4.5	Ritonavir	S,T	Tablet 100 mg
6.7.5 Medicines for treating Opportunistic Infections in People living with HIV			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.7.5.1	Acyclovir*	P,S,T	Injection 250 mg
6.7.5.2	Cefotaxime**	P,S,T	Injection 1000 mg
6.7.5.3	Clindamycin***	P,S,T	Tablet 300 mg

***Acyclovir formulations are also listed in -*

A. ***Section 6.6.1.1 -*** *Anti-infective Medicines -Antiviral medicines -Anti-herpes medicines*

B. ***Section 21.1.1 -*** *Ophthalmological Medicines- Anti-infective Medicine*

*** Cefotaxime formulations are also listed in* ***Section 6.2.1.9 -*** *Anti-infective Medicines -Antibacterials-Beta-Lactam medicines*

****Clindamycin formulations are also listed in –*

A. ***Section 6.2.2.5 -*** *Anti-infective Medicines - Antibacterials -Other antibacterials*

B. ***Section 6.9.3.1 -*** *Anti-infective Medicines - Medicines for amoebiasis and other parasiticinfections - Antipneumocystosis and antitoxoplasmosis medicines*

C. ***Section 6.10.1.5 -*** *Anti-infective Medicines - Antimalarial medicines- For curative treatment*

	Medicine	Level of Healthcare	Dosage form(s) and strength(s)
6.7.5.4	Clotrimazole*	P,S,T	Ointment 1 %
6.7.5.5	Valganciclovir**	S,T	Tablet/Capsule 450 mg
6.7.6 Additional Medicines for Syndromic Management of SexuallyTransmitted Infections			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.7.6.1	Azithromycin***	P,S,T	Tablet 1000 mg
Section 6.8 -Medicines used in Hepatitis B and Hepatitis C			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.8.1	Daclatasvir	S,T	Tablet 30 mg Tablet 60 mg
6.8.2	Entecavir	S,T	Tablet 0.5 mg Tablet 1 mg Oral liquid 0.05 mg/mL (p)
****Clotrimazole formulations are also listed in -* ***A.*** ***Section 6.5.2 -*** *Anti-infective Medicines -Antifungal medicines* ***B.*** ***Section 11.1.1 -*** *Dermatological Medicines (Topical)- Antifungal medicines* ***C.*** ***Section 16.3 -*** *Ear, Nose and Throat Medicines* *****Valganciclovir formulations are also listed in* ***Section 6.6.2.1 -*** *Anti-infective Medicines - Antiviral medicines -Anti Cytomegalovirus (CMV) medicines* ******Azithromycin formulations are also listed in* ***Section 6.2.2.1 -*** *Anti-infective Medicines - Other antibacterials*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.8.3	Ribavirin	S,T	Capsule 200 mg
6.8.4	Sofosbuvir	S,T	Tablet 400 mg
6.8.5	Tenofovir Alafenamide Fumarate (TAF)	S,T	Tablet 25 mg
6.8.6	Tenofovir Disproxil Fumarate (TDF)*	S,T	Tablet 300 mg
Section 6.9 -Antiprotozoal Medicines			
6.9.1 - Medicines for Amoebiasis and other Parasitic Infections			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.9.1.1	Metronidazole**	P,S,T	Tablet 200 mg Tablet 400 mg Injection 500 mg/100 mL

			Oral liquid 200 mg/5 mL (p)

** Tenofovir Disproxil Fumarate formulations are also listed in **Section 6.7.1.4 -***

Anti-infective Medicines Medicines used in the management of HIV- Nucleoside reverse transcriptase inhibitors

*** Metronidazole formulations are also listed in **Section 6.2.2.9 -** Anti-infective Medicines -Antibacterials Beta-lactam medicines - Other antibacterials*

6.9.2 - Antileishmaniasis Medicines

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.9.2.1	Amphotericin B*	S,T	a) Amphotericin B (conventional)- Injection 50 mg b) Lipid Amphotericin B- Injection 50 mg c) Liposomal Amphotericin B- Injection 50 mg
6.9.2.2	Miltefosine	P,S,T	Capsule 50 mg
6.9.2.3	Paromomycin	P,S,T	Injection 375 mg/mL

6.9.3 - Antipneumocystosis and Antitoxoplasmosis Medicines

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.9.3.1	Clindamycin**	P,S,T	Capsule 150 mg Capsule 300 mg

Amphotericin B formulations are also listed in **Section 6.5.1 - Anti-infective Medicines- Antifungal medicines*

***Clindamycin formulations are also listed in -*

A. ***Section 6.2.2.5 -*** *Anti-infective Medicines - Antibacterials -Other antibacterials*

B. ***Section 6.7.5.3 -*** *Anti-infective Medicines - Antiviral medicines- Medicines for treating Opportunistic Infections in People living with HIV*

C. ***Section 6.10.1.5 -*** *Anti-infective Medicines- Antimalarial Medicines - For curativetreatment*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.9.3.2	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 (p)

6.10-Antimalarial Medicines

6.10.1 - For curative treatment

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.10.1.1	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)

6.10.1.2	Artesunate	P,S,T	Powder for Injection 60 mg Powder for Injection 120 mg
6.10.1.3	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)
Co-trimoxazole formulations are also listed in **Section 6.2.2.6 - Anti-infective Medicines-Antibacterials - Other antibacterials*			

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.10.1.4	Chloroquine	P,S,T	Tablet 150 mg Oral liquid 50 mg/5 mL
6.10.1.5	Clindamycin*	P,S,T	Capsule 150 mg Capsule 300 mg
6.10.1.6	Primaquine	P,S,T	Tablet 2.5 mg Tablet 7.5 mg Tablet 15 mg
6.10.1.7	Quinine	P,S,T	Tablet 300 mg Injection 300 mg/mL

6.10.2 - For prophylaxis

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
6.10.2.1	Doxycycline**[#]	P,S,T	Capsule 100 mg Oral liquid 50 mg/ 5mL [#]for prophylaxis of *P. vivax*
6.10.2.2	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.

** Clindamycin formulations are also listed in -*

A. ***Section 6.2.2.5 -*** *Anti-infective Medicines - Antibacterials -Other antibacterials*

B. ***Section 6.7.5.3 -*** *Anti-infective Medicines - Antiviral medicines- Medicines for treating Opportunistic Infections in People living with HIV*

C. ***Section 6.9.3.1 -*** *Anti-infective Medicines - Antipneumocystosis and antitoxoplasmosismedicines*

*** Doxycycline formulations are also listed in* ***Section 6.2.2.7 -*** *Anti-infective Medicines-Antibacterials - Other antibacterials*

Section 7

Anti-cancer agents including Immunosuppressives and Medicines used in Palliative Care

7.1 - Antineoplastic medicines

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
7.1.1	5-Fluorouracil	T	Injection 250 mg/ 5 mL
7.1.2	6-Mercaptopurine	T	Tablet 50 mg
7.1.3	Actinomycin D	T	Powder for Injection 0.5 mg
7.1.4	All-trans retinoicacid	T	Capsule 10 mg
7.1.5	Arsenic trioxide	T	Injection 1mg/ mL
7.1.6	Bendamustinehydrochloride	T	Injection 25 mg/ vial Injection 100 mg/vial
7.1.7	Bleomycin	T	Powder for Injection 15 units
7.1.8	Bortezomib	T	Powder for Injection 2 mg
7.1.9	Calcium folinate	T	Tablet 15 mg Injection 3 mg/mL
7.1.10	Capecitabine	T	Tablet 500 mg
7.1.11	Carboplatin	T	Injection 10 mg/mL
7.1.12	Chlorambucil	T	Tablet 2 mg Tablet 5 mg
7.1.13	Cisplatin	T	Injection 1mg/mL
7.1.14	Cyclophosphamide	T	Tablet 50 mg Powder for Injection 500 mg
7.1.15	Cytosine arabinoside	T	Injection 100 mg/vial Injection 500 mg/vial Injection 1000 mg/vial
7.1.16	Dacarbazine	T	Powder for Injection 200 mg Powder for Injection 500 mg
7.1.17	Daunorubicin	T	Injection 5 mg/mL
7.1.18	Docetaxel	T	Powder for Injection 20 mg Powder for Injection 80 mg
7.1.19	Doxorubicin	T	Injection 2 mg/mL
7.1.20	Etoposide	T	Capsule 50 mg

			Injection 20 mg/mL
7.1.21	Gefitinib	T	Tablet 250 mg
7.1.22	Gemcitabine	T	Powder for Injection 200 mg Powder for Injection 1000 mg
7.1.23	Hydroxyurea*	T	Capsule 500 mg
7.1.24	Ifosfamide	T	Powder for Injection 1000 mg Powder for Injection 2000 mg
7.1.25	Imatinib	T	Tablet 100 mg Tablet 400 mg
7.1.26	Irinotecan HCltrihydrate	T	Solution for injection 20 mg/ mL
7.1.27	L-Asparaginase	T	Powder for Injection 5000 KU Powder for Injection 10000 KU
7.1.28	Lenalidomide	T	Capsule 5 mg Capsule 25 mg
7.1.29	Melphalan	T	Tablet 2 mg Tablet 5 mg
7.1.30	Methotrexate**	S,T	Tablet 2.5 mg Tablet 5 mg Tablet 10 mg Injection 50 mg/mL

Hydroxyurea formulations are also listed in **Section 8.1.6 - Medicines affecting Blood - Antianaemia Medicines*

***Methotrexate formulations are also listed in **Section 2.4.3 -** Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Disease Modifying Agents used in Rheumatoid Disorders*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
7.1.31	Oxaliplatin	T	Injection 5 mg/mL in 10 mL vialInjection 5 mg/mL in 20 mL vial
7.1.32	Paclitaxel	T	Injection 30 mg/5 mL Injection 100 mg/16.7 mL
7.1.33	Rituximab	T	Injection 10 mg/mL
7.1.34	Temozolomide	T	Capsule 20 mg Capsule 100 mg Capsule 250 mg
7.1.35	Thalidomide	T	Capsule 50 mg Capsule 100 mg
7.1.36	Trastuzumab	T	Injection 440 mg/50 mL
7.1.37	Vinblastine	T	Injection 1 mg/mL
7.1.38	Vincristine	T	Injection 1 mg/mL

7.2-Hormones and Anti-hormones used in Cancer Therapy			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
7.2.1	Bicalutamide	T	Tablet 50 mg
7.2.2	Letrozole	T	Tablet 2.5 mg
7.2.3	Leuprolide acetate	T	Powder for injection 3.75 mg Powder for injection 11.25 mg Powder for injection 22.5 mg
7.2.4	Prednisolone*	S,T	Tablet 10 mg Tablet 20 mg Tablet 40 mg Oral liquid 5 mg/5 mL (p) Oral liquid 15 mg/5 mL (p) Injection 20 mg/2 mL
7.2.5	Tamoxifen	T	Tablet 10 mg Tablet 20 mg
7.3 - Immunosuppressive Medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
7.3.1	Azathioprine**	T	Tablet 50 mg
7.3.2	Cyclosporine	T	Capsule 25 mg Capsule 50 mg Capsule 100 mg Oral liquid 100 mg/mL (p) Injection 50 mg/mL

**Prednisolone formulations are also listed in -*

A. ***Section 3.6 -*** *Antiallergics and Medicines used in Anaphylaxis*

B. ***Section 18.1.5 -*** *Hormones, other Endocrine Medicines and Contraceptives -Adrenal Hormones and synthetic substitutes*

C. ***Section 21.2.1 -*** *Ophthalmological Medicines - Antiinflammatory Medicine*

Azathioprine formulations are also listed in* ***Section 2.4.1 - *Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Disease Modifying Agents used in Rheumatoid Disorders*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
7.3.3	Mycophenolate mofetil	T	Tablet 250 mg Tablet 500 mg
7.3.4	Tacrolimus	T	Capsule 0.5 mg Capsule 1 mg

			Capsule 2 mg
7.4-Medicines used in Palliative Care			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
7.4.1	Allopurinol*	S,T	Tablet 100 mg
7.4.2	Amitriptyline**	S,T	Tablet 10 mg Tablet 25 mg
7.4.3	Dexamethasone***	S,T	Tablet 0.5 mg Tablet 4 mg Injection 4 mg/mL
Allopurinol formulations are also listed in **Section 2.3.1 - Analgesics, Antipyretics, Non- steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Medicines used to treat Gout* ***Amitriptyline formulations are also listed in **A**. **Section 5.2.5 -** Medicines used inNeurological Disorders - Anti-migraine medicines -* *For prophylaxis* ***B.*** ***Section 23.2.1.1 -*** *Medicines in treatment of Psychiatric Disorders -Medicines used in mood disorders- Medicines used in depressive disorders* ****Dexamethasone formulations are also listed in* ***A.*** ***Section 3.4 -*** *Antiallergics and medicines used in anaphylaxis* ***B.*** ***Section 18.1.1 -*** *Hormones, other Endocrine Medicines and Contraceptives **-** Adrenal hormones and synthetic substitutes* ***C.*** ***Section 27.1 -*** *Medicines for COVID- 19 management*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
7.4.4	Diazepam*	S,T	Tablet 2 mg Tablet 5 mg Injection 5 mg/mL
7.4.5	Filgrastim	T	Injection 300 mcg
7.4.6	Fluoxetine**	S,T	Capsule 20 mg
7.4.7	Haloperidol***	S,T	Tablet 1.5 mg Tablet 5 mg Injection 5 mg/mL
7.4.8	Lactulose****	S,T	Oral liquid 10 g/15 mL
7.4.9	Loperamide	S,T	Tablet 2 mg
Diazepam formulations are also listed **Section 5.1.3 - Medicines used in Neurological Disorders - Anticonvulsants/Antiepileptics* ***Fluoxetine formulations are also listed in* ***A.*** ***Section 23.2.1.3 -*** *Medicines in used in treatment of Psychiatric Disorders - Medicines used in mood disorders - Medicines used in depressive disorders*			

B. ***Section 23.4.2 -*** *Medicines used in treatment of Psychiatric Disorders - Medicines used inobsessive compulsive disorders and panic attacks*

****Haloperidol formulations are also listed in* ***Section 23.1.3 -***

Medicines used in treatment of psychiatric Disorders - Medicines used in psychotic disorders

*****Lactulose formulations are also listed in* ***Section 17.5.3 -***

Gastrointestinal Medicines - Laxatives

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
7.4.10	Metoclopramide*	S,T	Tablet 10 mg Oral liquid 5 mg/5 mL (p) Injection 5 mg/mL
7.4.11	Mesna	T	Injection 100 mg/mL
7.4.12	Midazolam**	S,T	Injection 1 mg/mL
7.4.13	Morphine***	S,T	Tablet 10 mg Modified Release Tablet 30 mg
7.4.14	Ondansetron****	S,T	Tablet 4 mg Tablet 8 mg Oral liquid 2 mg/5 mL (p) Injection 2 mg/mL

Metoclopramide formulations are also listed in ***Section 17.2.2 -***

Gastrointestinal Medicines Antiemetics

***Midazolam formulations are also listed in -*

A. ***Section 1.3.3 -*** *Medicines used in Anaesthesia - Preoperative medication and sedation for short term procedures*

B. ***Section 5.1.7 -*** *Medicines used in Neurological Disorders -Anticonvulsants/Antiepileptics*

****Morphine formulations are also listed in -*

A. ***Section 1.3.4 -*** *Medicines used in Anaesthesia - Preoperative medication and sedation for short term procedures*

B. ***Section 2.2.2 -*** *Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Opioid Analgesics*

*****Ondansetron formulations are also listed* ***Section 17.2.3 -*** *Gastrointestinal Medicines - anti-ulcer medicines*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
7.4.15	Tramadol*	S,T	Capsule 50 mg Capsule 100 mg Injection 50 mg/mL
7.4.16	Zoledronic acid	T	Powder for Injection 4 mg

Section 8 Medicines affecting Blood			
8.1- Antianaemia Medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
8.1.1	Erythropoietin	S,T	Injection 2000 IU/mL Injection 10000 IU/mL
8.1.2	Ferrous salts (a) Iron Dextran (b) Iron sorbitol citrate complex	P,S,T	Tablet equivalent to 60 mg ofelemental iron Injection 50 mg/mL Injection 50 mg/mL
8.1.3	Ferrous Salt (A)+ Folic acid (B)	P,S,T	Tablet 45 mg elemental iron (A) + 400 mcg (B) Tablet 100 mg elemental iron (A) + 500 mcg (B) Oral liquid 20 mg elemental iron (A) + 100 mcg/mL (B) (p)
***Tramadol formulations are also listed in **Section 2.2.3 -** Analgesics, Antipyretics, Non- steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and disease Modifying agents used in Rheumatoid Disorders- Opioid Analgesics*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
8.1.4	Folic Acid	P,S,T	Tablet 1 mg Tablet 5 mg
8.1.5	Hydroxocobalamin	P,S,T	Injection 1 mg/mL
8.1.6	Hydroxyurea*	S,T	Capsule 500 mg
8.1.7	Iron sucrose	S,T	Injection 20 mg/mL
8.2 - Medicines affecting Coagulation			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
8.2.1	Enoxaparin**	S,T	Injection 40 mg/ 0.4 mL Injection 60 mg/ 0.6 mL
8.2.2	Heparin***	S,T	Injection 1000 IU/mL Injection 5000 IU/mL
8.2.3	Phytomenadione(Vitamin K_1)	P,S,T	Tablet 10 mg Injection 10 mg/mL
8.2.4	Protamine Sulphate	S,T	Injection 10 mg/mL
8.2.5	Tranexamic acid	P,S,T	Tablet 500 mg Injection 100 mg/mL

** Hydroxyurea formulations are also listed in **Section 7.1.26 -** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care- Antineoplastic medicines*

*** Enoxaparin formulations are also listed in*

A. ***Section 10.5.4 -*** *Cardiovascular Medicines - Antiplatelet and Antithrombotic Medicines*

B. ***Section 27.2 -*** *Medicines for COVID- 19 management*

**** Heparin formulations are also listed in **Section 10.5.5 -** Cardiovascular Medicines -Antiplatelet and Antithrombotic Medicines*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
8.2.6	Warfarin	S,T	Tablet 1 mg Tablet 2 mg Tablet 3 mg Tablet 5 mg

Section 9

Blood products and Plasma substitutes

9.1 - Blood and Blood components

All forms of the following as approved by licensing authority are considered as included in NLEM. However, considering the process, technology and other relevant aspects, they should be considered differently for purposes such as procurement policy, pricing etc.

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
9.1.1	Fresh frozen plasma	S,T	As licensed
9.1.2	Platelet rich plasma/ Platelet concentrates	S,T	As licensed
9.1.3	Red blood cells/Packed RBCs	S,T	As licensed
9.1.4	Whole blood	S,T	As licensed

9.2 - Plasma substitutes

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
9.2.1	Dextran-40	S,T	Injection 10 %

9.3 - 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 NLEM. However, considering the source, process, technology and other relevant aspects, they should be considered differently for purposes such as procurement policy, pricing etc.

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
9.3.1	Coagulation factorIX	S,T	Powder for Injection 600 IU
9.3.2	Coagulation factorVIII	S,T	Powder for Injection 250 IU Powder for Injection 500 IU

9.3.3	Cryoprecipitate	S,T	As licensed
Section 10 **Cardiovascular Medicines**			
10.1-Medicines used in Angina			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
10.1.1	Diltiazem	P,S,T	Tablet 30 mg Tablet 60 mg Modified Release Tablet 180 mg
		S, T	Injection 5 mg/mL
		P,S,T	Sublingual Tablet 0.5 mg
10.1.2	Glyceryl trinitrate	S,T	Injection 5 mg/mL
10.1.3	Isosorbide dinitrate	P,S,T	Tablet 5 mg Tablet 10 mg
10.1.4	Metoprolol	P,S,T	Tablet 25 mg Tablet 50 mg Tablet 100 mg Modified Release Tablet 100 mg
		S,T	Injection 1 mg/mL
10.2 - Antiarrhythmic medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
10.2.1	Adenosine	S,T	Injection 3 mg/mL
10.2.2	Amiodarone	S,T	Tablet 100 mg Tablet 200 mg Injection 50 mg/mL
10.2.3	Digoxin*	S,T	Tablet 0.25 mg Oral liquid 0.05 mg/mL Injection 0.25 mg/mL
10.2.4	Esmolol	S,T	Injection 10 mg/mL
10.2.5	Lignocaine**	S,T	Injection 2%
10.2.6	Verapamil	S,T	Tablet 40 mg Tablet 80 mg Injection 2.5 mg/ mL
10.3 - Antihypertensive Medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
10.3.1	Amlodipine	P,S,T	Tablet 2.5 mg Tablet 5 mg Tablet 10 mg

*Digoxin formulations are also listed in **Section 10.4.1 -** Cardiovascular Medicines **-**

Medicines used in Shock and Heart Failure

***Lignocaine formulations are also listed in **Section 1.2.2 -** Medicines used in Anaesthesia - Local Anaesthetics*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
10.3.2	Enalapril	P,S,T	Tablet 2.5 mg Tablet 5 mg
10.3.3	Hydrochlorothiazide*	P,S,T	Tablet 12.5 mg Tablet 25 mg
10.3.4	Labetalol	P,S,T P,S,T	Tablet 50 mg Tablet 100 mg Injection 5 mg/mL
10.3.5	Ramipril	P,S,T	Tablet 2.5 mg Tablet 5 mg
10.3.6	Sodium nitroprusside	S, T	Injection 10 mg/mL
10.3.7	Telmisartan	P,S,T	Tablet 20 mg Tablet 40 mg Tablet 80 mg

10.4 - Medicines used in Shock and Heart failure

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
10.4.1	Digoxin**	S,T	Tablet 0.25 mg Oral liquid 0.05 mg/mL Injection 0.25 mg/mL

*Hydrochlorothiazide formulations are also listed in **Section 15.2** - Diuretics*

***Digoxin formulations are also listed in **Section 10.2.3 -** Cardiovascular Medicines - Antiarrhythmic medicines*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
10.4.2	Dobutamine	S,T	Injection 50 mg/mL
10.4.3	Dopamine	S,T	Injection 40 mg/mL
10.4.4	Noradrenaline	S,T	Injection 2 mg/mL
10.4.5	Spironolactone*	P,S,T	Tablet 25 mg Tablet 50 mg

10.5- Antiplatelet and Antithrombotic Medicines

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
10.5.1	Acetylsalicylic acid**	P,S,T	Conventional/Effervescent/Dispersible/ Enteric coated Tablets 150 mg Conventional/Effervescent/Dispersible/ Enteric coated Tablets 325 mg Enteric coated Tablet 75 mgEntericcoated Tablet 100 mg

Spironolactone formulations are also listed in* ***Section 15.4 -* *Diuretics*

***Acetylsalicyclic acid formulations are also listed in -*

A. ***Section 2.1.1 -*** *Analgesics, Antipyretics, Non-steroidal Anti-inflammatory Drugs (NSAIDs), Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders - Non-opioid Analgesics, Antipyretics and Non-steroidal Anti-inflammatory Drugs*

B. ***Section 5.2.1 -*** *Medicines used in Neurological Disorders- Antimigraine medicines*

10.5.2	Clopidogrel	P,S,T	Tablet 75 mg Tablet 150 mg
10.5.3	Dabigatran	S, T	Tablet 110 mg Tablet 150 mg
10.5.4	Enoxaparin*	S,T	Injection 40 mg/ 0.4 mL Injection 60 mg/ 0.6 mL
10.5.5	Heparin**	S,T	Injection 1000 IU/mL Injection 5000 IU/mL
10.5.6	Streptokinase	S,T	Injection 750,000 IU Injection 15,00,000 IU
10.5.7	Tenecteplase	S,T	Injection 30 mg/vial Injection 40 mg/vial

10.6 - Hypolipidemic Medicines

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
10.6.1	Atorvastatin	P,S,T	Tablet 10 mg Tablet 20 mg Tablet 40 mg Tablet 80 mg

**Enoxaparin formulations are also listed in -*

A. ***Section 8.2.1 -*** *Medicines affecting Blood - Medicines affecting coagulation*

B. ***Section 27.2 -*** *Medicines for COVID- 19 management*

Heparin formulations are also listed in* ***Section 8.2.2 - *Medicines affecting Blood -Medicines affecting coagulation*

Section 11

Dermatological Medicines (Topical)

11.1 - Antifungal Medicines

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
11.1.1	Clotrimazole*	P,S,T	Cream 1 % Lotion 1 %

11.2 - Antibacterial Medicines

	Medicine	Level of Healthcare	Dosage form(s) and strength(s)
11.2.1	Framycetin	P,S,T	Cream 1 %
11.2.2	Fusidic acid	P,S,T	Cream 2 %
11.2.3	Silver sulphadiazine	P,S,T	Cream 1 %
11.3-Antiinflammatory and Antipruritic Medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
11.3.1	Betamethasone valerate	P,S,T	Cream 0.05 % Cream 0.1 %
Clotrimazole formulations are also listed in - ***A. Section 6.5.2 -*** *Anti-infective Medicines -Antifungal medicines* ***B. Section 6.7.5.4 -*** *Anti-infective Medicines - Antiviral medicines- Medicines used in themanagement of HIV* ***C. Section 16.3 -*** *Ear, Nose and Throat Medicines*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
11.3.2	Calamine	P,S,T	Lotion (As per IP)
11.4 - Keratolytic agents			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
11.4.1	Benzoyl peroxide	P,S,T	Gel 2.5 % - 5 %
11.4.2	Coal tar (A) + Salicylic Acid (B)	P,S,T	Solution 1 % (A) + 3 % (B)
11.4.3	Podophyllin resin	S,T	Solution 20 %
11.4.4	Salicylic acid	P,S,T	Ointment 3-6 %
11.5 - Scabicides and Pediculicides			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
11.5.1	Permethrin	P,S,T	Lotion 1 % Cream 5 %
11.6 Miscellaneous			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
11.6.1	Glycerin/glycerol (as mentioned in IP)	P,S,T	Topical
Section 12 **Diagnostic agents**			
12.1 - Ophthalmic Medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
12.1.1	Fluorescein	S,T	Ophthalmic Strips
12.1.2	Proparacaine*	S,T	Eye Drops 0.5%

12.1.3	Tropicamide**	S,T	Eye drop 1 %
12.2 - Radiocontrast Media			
12.2.1	Barium sulphate	S,T	Oral Liquid 95% w/v
12.2.2	Gadobenate dimeglumine	T	Injection 529 mg/mL
12.2.3	Iohexol	S,T	Injection 140 to 350 mg iodine/mL
12.2.4	Meglumine diatrizoate	S,T	Injection 60 % w/v Injection 76 % w/v
***** *Proparacaine formulations are also listed in* ***Section 21.3.1 -*** *Ophthalmological Medicines- Local Anaesthetics*			
****** *Tropicamide formulations are also listed in* ***Section 21.5.4 -*** *Ophthalmological Medicines - Mydriatics*			
Section 13 **Dialysis components (Haemodialysis and Peritoneal Dialysis)**			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
13.1	Haemodialysis fluid	S,T	As licensed
13.2	Peritoneal dialysis solution	S,T	As licensed
Section 14 **Antiseptics and Disinfectants**			
14.1 Antiseptics			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
14.1.1	Chlorhexidine	P,S,T	Solution 5% (Concentrate)
14.1.2	Ethyl alcohol(Denatured)	P,S,T	Solution 70%
14.1.3	Hydrogen peroxide	P,S,T	Solution 6 %
14.1.4	Methylrosaniliniumchloride (Gentian Violet)	P,S,T	Topical preparation 0.25% to 2%
14.1.5	Povidone iodine*	P,S,T	Solution 4 % to 10 %
Povidone Iodine formulations are also listed in* ***Section 21.1.5 -* *Ophthalmological Medicines - Anti-infective medicine*			
14.2 Disinfectants			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
14.2.1	Glutaraldehyde	S,T	As Licensed
14.2.2	Potassium permanganate	P,S,T	Crystals for topical solution
Section 15 **Diuretics**			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
15.1	Furosemide	P,S,T	Tablet 40 mg Oral liquid 10 mg/mL

			Injection 10 mg/ mL
15.2	Hydrochlorothiazide *	P,S,T	Tablet 25 mg Tablet 50 mg
15.3	Mannitol	P,S,T	Injection 10 % Injection 20 %
15.4	Spironolactone**	P,S,T	Tablet 25 mg Tablet 50 mg

** Hydrochlorothiazide formulations are also listed in **Section 10.3.3** - Antihypertensive Medicines*

***Spironolactone formulations are also listed in **Section 10.4.5 -** Cardiovascular Medicines - Medicines used in shock and heart failure*

Section 16

Ear, Nose and Throat Medicines

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
16.1	Budesonide*	P,S,T	Nasal Spray 50 mcg/dose Nasal Spray 100 mcg/dose
16.2	Ciprofloxacin**	P,S,T	Drops 0.3 %
16.3	Clotrimazole***	P,S,T	Drops 1 %
16.4	Xylometazoline	P,S,T	Nasal drops 0.05 % Nasal drops 0.1 %

Budesonide formulations are also listed in **Section 24.1 - Medicines acting on the respiratory tract - Antiasthmatic Medicines*

***Ciprofloxacin formulations are also listed in*

A. ***Section 6.2.2.3 -** Anti-infective Medicines- Antibacterials -Other Antibacterials*

B. ***Section 21.1.2 -** Ophthalmological Medicines- Anti-infective Medicines*

****Clotrimazole formulations are also listed in -*

A. ***Section 6.5.2 -** Anti-infective Medicines -Antifungal medicines*

B. ***Section 6.7.5.4 -** Anti-infective Medicines - Antiviral medicines- Medicines used in themanagement of HIV*

C. ***Section 11.1.1 -** Dermatological Medicines (Topical) -Antifungal medicines*

Section 17

Gastrointestinal Medicines

17.1 - Antiulcer Medicines

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
17.1.1	Omeprazole	P,S,T	Capsule 10 mg Capsule 20 mg Capsule 40 mg Powder for oral liquid 20 mg

17.1.2	Pantoprazole	S,T	Injection 40 mg
17.2 Antiemetics			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
17.2.1	Domperidone	P,S,T	Tablet 10 mg Oral Liquid 1 mg/mL
17.2.2	Metoclopramide*	P,S,T	Tablet 10 mg Injection 5 mg/mL
17.2.3	Ondansetron*	S,T	Tablet 4 mg Oral Liquid 2 mg/5 mL (p) Injection 2 mg/ mL
Metoclopramide formulations are also listed in **Section 7.4.10 - Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care - Medicines used in Palliative Care* **Ondansetron formulations are also listed in **Section 7.4.14 -** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care - Medicines used in Palliative Care*			
17.3 Anti-inflammatory medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
17.3.1	5-aminosalicylic acid (Mesalazine/ Mesalaine)	S, T	Tablet 400 mg Suppository 500 mg Retention Enema
17.4 Antispasmodic medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
17.4.1	Dicyclomine	P,S,T	Tablet 10 mg Oral Solution 10 mg/5mL Injection 10 mg/ mL
17.4.2	Hyoscine butyl bromide	P,S,T	Tablet 100 mg Injection 20 mg/ mL
17.5 Laxatives			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
17.5.1	Bisacodyl	P,S,T	Tablet 5 mg Suppository 5 mg
17.5.2	Ispaghula	P,S,T	Granules/ Husk/ Powder
17.5.3	Lactulose*	S,T	Oral Liquid 10 g/15 mL

17.6 Medicines used in diarrhea

	Medicine	Level of Healthcare	Dosage form(s) and strength(s)
17.6.1	Oral rehydrationsalts**	P,S,T	As licensed
17.6.2	Zinc Sulphate	P,S,T	Dispersible Tablet 20 mg

17.7 Other medicines

	Medicine	Level of Healthcare	Dosage form(s) and strength(s)
17.7.1	Somatostatin	T	Powder for Injection 3 mg

Lactulose formulations are also listed in **Section 7.4.8 - Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care - Medicines used in PalliativeCare*

***Oral rehydration salts formulations are also listed in **Section 25.3 -** Solutions correcting water, electrolyte disturbances and acid-base disturbances*

Section 18

Hormones, other Endocrine Medicines and Contraceptives

18.1-Adrenal Hormones and Synthetic substitutes

	Medicine	Level of Healthcare	Dosage form(s) and strength(s)
18.1.1	Dexamethasone*	S,T	Tablet 0.5 mg Injection 4 mg/mL
18.1.2	Fludrocortisone	S,T	Tablet 0.1 mg
18.1.3	Hydrocortisone**	P,S,T	Tablet 5 mg Tablet 10 mg Tablet 20 mg Powder for Injection 100 mg
18.1.4	Methylprednisolone ***	S,T	Injection 40mg/mL

**Dexamethasone formulations are also listed in –*

A. ***Section 3.4 -*** *Antiallergics and Medicines used in Anaphylaxis*

B. ***Section 7.4.3 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used inPalliative Care - Medicines used in Palliative Care*

C. ***Section 27.1 -*** *Medicines for COVID- 19 Management*

*** Hydrocortisone formulations are also listed in **Section 3.5 -** Antiallergics and Medicines used in Anaphylaxis*

**** Methylprednisolone formulations are also listed in **section 27.3-***

Medicines for COVID - 19 management

	Medicine	Level of Healthcare	Dosage form(s) and strength(s)
			Tablet 5 mg Tablet 10 mg

18.1.5	Prednisolone*	P,S,T	Tablet 20 mg Oral liquid 5 mg/5 mL (p) Oral liquid 15 mg/5 mL (p)
18.2 Contraceptives			
18.2.1 - Hormonal Contraceptives			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
18.2.1.1	Ethinylestradiol (A)+ Levonorgestrel (B)	P,S,T	Tablet 0.03 mg (A) +Tablet 0.15 mg (B)
18.2.1.2	Levonorgestrel	P,S,T	Tablet 0.75 mg Tablet 1.5 mg
18.2.1.3	Ormeloxifene (Centchroman)	P,S,T	Tablet 30 mg
Prednisolone formulations are also listed in -* ***A. Section 3.7 -* *Antiallergics and Medicines used in Anaphylaxis* ***B. Section 7.2.4 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used inPalliative Care Hormones and anti- hormones used in cancer therapy* ***C. Section 21.2.1 -*** *Ophthalmological Medicines – Anti-inflammatory medicine*			
18.2.2 - Intrauterine Devices			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
18.2.2.1	Hormone releasingIUD	T	Contains 52 mg of Levonorgestrel
18.2.2.2	IUD containing Copper	P,S,T	As licensed
18.2.3 - Barrier methods			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
18.2.3.1	Condom	P,S,T	As Licensed-as per the standards of Drugs Rules, 1945
18.3 - Medicines used in Diabetes Mellitus			
18.3.1 - Insulins and other Antidiabetic agents			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
18.3.1.1	Glimepiride	P,S,T	Tablet 1 mg Tablet 2 mg
18.3.1.2	Insulin (Soluble)	P,S,T	Injection 40 IU/mL
18.3.1.3	Insulin Intermediate Acting (NPH)	P,S,T	Injection 40 IU/mL
18.3.1.4	Insulin Glargine	P,S,T	Injection 100 IU/mL
18.3.1.5	Insulin Premix Injection 30:70 (Regular : NPH)	P,S,T	Injection 40 IU/mL

18.3.1.6	Metformin	P,S,T	Tablet 500 mg Tablet 1000 mg Modified release Tablet 1000 mg
18.3.1.7	Teneligliptin	P,S,T	Tablet 20 mg
18.3.2 - Medicines used to treat Hypoglycemia			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
18.3.2.1	Glucose*	P,S,T	Injection 25 %
18.4-Ovulation Inducers			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
18.4.1	Clomiphene citrate	T	Tablet 50 mg Tablet 100 mg
18.4.2	Human chorionic gonadotropin	S,T	Injection 2000 IU Injection 5000 IU Injection 10000 IU
Glucose formulations are also listed in **Section 25.1 - Solutions correcting water, electrolytedisturbances and acid-base disturbances*			
18.5-Progestogens			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
18.5.1	Medroxyprogesteroneacetate	P,S,T	Tablet 5 mg Tablet 10 mg Injection 150 mg/ mL
18.5.2	Norethisterone	P,S,T	Tablet 5 mg
18.6-Thyroid and Antithyroid Medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
18.6.1	Carbimazole	P,S,T	Tablet 5 mg Tablet 10 mg Tablet 20 mg
18.6.2	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, 112mcg. Therefore, it was considered to give a range of available strengths)
Section 19 **Immunologicals**			
In case of these biologicals, irrespective of variation in source, composition andstrengths, all the products of the same vaccine/ sera/ immunoglobulin, as approved by licensing authority are considered as included in NLEM. However, considering the source, process, technology and other relevant aspects, different products of the same biological should be considered differently for purposes such as procurement policy, pricing etc.			

19.1-Diagnostic agents			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
19.1.1	Tuberculin, Purified Protein derivative	P,S,T	As Licensed
19.2-Sera and Immunoglobulins (Liquid/ Lyophilized)			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
19.2.1	Anti-rabies immunoglobulin	P,S,T	As Licensed
19.2.2	Anti-tetanus immunoglobulin	P,S,T	As Licensed
19.2.3	Anti-D immunoglobulin	S,T	As Licensed
19.2.4	Diphtheria antitoxin	P,S,T	As Licensed
19.2.5	Hepatitis B immunoglobulin	S,T	As Licensed
19.2.6	Human normal immunoglobulin	T	As Licensed
19.2.7	Snake VenomAntiserum*	P,S,T	a) Soluble/ liquid polyvalent - As Licensed b) Lyophilized polyvalent - AsLicensed
Snake Venom antiserum also listed in **Section 4.2.12 - Antidotes and Other Substances used in Management of Poisonings/Envenomation - Specific*			
19.3-Vaccines			
a) All the vaccines which are under Universal Immunization Program of India (UIP) will be deemed included in NLEM. Presently, the UIP has BCG, DPT, OPV, measles, Hepatitis B, Japanese encephalitis, Pentavalent Vaccines and Rota virus vaccine.			
b) The 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 inactivatedpolio vaccine (IPV) and Measles Rubella (MR).			
c) In future, the vaccines which are under consideration, if and when included inUIP, will also be deemed included from the date of inclusion in UIP. These are pneumococcal and HPV vaccines.			
For Universal Immunization			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
19.3.1	BCG vaccine	P,S,T	As licensed
19.3.2	DPT+ Hib+ HepB vaccine	P,S,T	As licensed
19.3.3	DPT vaccine	P,S,T	As licensed
19.3.4	Hepatitis B vaccine	P,S,T	As licensed
19.3.5	Japanese encephalitis vaccine	P,S,T	As licensed

19.3.6	Measles vaccine	P,S,T	As licensed
19.3.7	Oral poliomyelitisvaccine	P,S,T	As licensed
19.3.8	Rotavirus vaccine	P,S,T	As licensed
19.3.9	Tetanus toxoid	P,S,T	As licensed
19.4 - For Specific Group of Individuals			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
19.4.1	Rabies vaccine	P,S,T	As licensed
Section 20 **Medicines for Neonatal Care**			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
20.1	Alprostadil	S,T	Injection 0.5 mg/mL
20.2	Caffeine	S,T	Oral liquid 20 mg/mL Injection 20 mg/mL
20.3	Surfactant	S,T	Suspension for intratracheal instillation (As licensed)
Section 21 **Ophthalmological Medicines**			
21.1-Anti-infective Medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
21.1.1	Acyclovir*	P,S,T	Ointment 3%
21.1.2	Ciprofloxacin**	P,S,T	Drops 0.3% Ointment 0.3%
21.1.3	Natamycin	P,S,T	Drops 5 %
21.1.4	Povidone iodine***	P,S,T	Drops 5 %
21.2-Antiinflammatory Medicine			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
21.2.1	Prednisolone****	P,S,T	Drops 1 %
Acyclovir formulations are also listed in -* ***A.* *Anti-infective Medicines -Antiviral medicines -Anti-herpes medicines* ***Section 6.6.1.1*** ***B.*** *Anti-infective Medicines -Medicines used in the management of HIV -Medicines for treating*			

Opportunistic Infections in People living with HIV ***Section 6.7.5.1***

***Ciprofloxacin formulations are also listed in -*

A. ***Section 6.2.2.3 -*** *Anti-infective Medicines- Antibacterials - Other Antibacterials*

B. ***Section 16.2*** *Ear, Nose and Throat Medicines*

****Povidone Iodine Also listed in* ***Section 14.1.5 -*** *Antiseptics and Disinfectants- Antiseptics*

*****Prednisolone formulations are also listed in –*

A. ***Section 3.7 -*** *Antiallergics and Medicines used in Anaphylaxis*

B. ***Section 7.2.4 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative Care - Hormones and anti-hormones used in cancer therapy*

C. ***Section 18.1.5 -*** *Hormones, other Endocrine Medicines and Contraceptives- Adrenal Hormones and synthetic substitutes*

21.3- Local Anaesthetic

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
21.3.1	Proparacaine*	P,S,T	Drops 0.5 %

21.4-Miotics and Antiglaucoma Medicines

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
21.4.1	Acetazolamide	P,S,T	Tablet 250 mg
21.4.2	Latanoprost	P,S,T	Drops 0.005 %
21.4.3	Pilocarpine	P,S,T	Drops 2 % Drops 4 %
21.4.4	Timolol	P,S,T	Drops 0.25 % Drops 0.5 %

21.5-Mydriatics

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
21.5.1	Atropine**	P,S,T	Drops 1% Ointment 1%

Proparacaine formulations are also listed in listed in* ***Section 12.1.2 -*

Diagnostic agents- Ophthalmic Medicines

***Atropine formulations are also listed in –*

A. ***Section 1.3.1 -*** *Medicines used in Anaesthesia -Preoperative medication and sedation forshort term procedures*

B. ***Section 4.2.1 -*** *Antidotes and Other substances used in Management ofpoisoning/Envenomation - specific*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**

21.5.2	Homatropine	P,S,T	Drops 2%
21.5.3	Phenylephrine	P,S,T	Drops 5 % Drops 10 %
21.5.4	Tropicamide*	P,S,T	Drops 1 %
21.6-Miscellaneous			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
21.6.1	Carboxymethylcellulose	P,S,T	Drops 0.5% Drops 1%
21.6.2	Hydroxypropyl methylcellulose	T	Injection 2%
Section 22 **Oxytocics and Antioxytocics**			
22.1 - Oxytocics and Abortifacient			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
22.1.1	Dinoprostone	S,T	Tablet 0.5 mg Gel 0.5 mg
22.1.2	Methylergometrine	P,S,T	Tablet 0.125 mg Injection 0.2 mg/mL
Tropicamide formulations are also listed in **Section 12.1.3 - Diagnostic agents - OphthalmicMedicines*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
22.1.3	Mifepristone	P,S,T	Tablet 200 mg
22.1.4	Misoprostol	P,S,T	Tablet 100 mcg Tablet 200 mcg
22.1.5	Oxytocin	P,S,T	Injection 5 IU/mL Injection 10 IU/mL
22.2 - Medicines used in Preterm Labour			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
22.2.1	Betamethasone	P,S,T	Injection 4 mg/mL

22.2.2	Nifedipine	S,T	Tablet 10 mg
Section 23 **Medicines used in treatment of Psychiatric Disorders**			
23.1 - Medicines used in Psychotic Disorders			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
23.1.1	Clozapine	T	Tablet 25 mg Tablet 50 mg Tablet 100 mg
23.1.2	Fluphenazine	P,S,T	Injection 25 mg/mL
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
23.1.3	Haloperidol*	S,T	Tablet 2 mg Tablet 5 mg Tablet 10 mg Tablet 20 mg Oral liquid 2 mg/5 mL Injection 5 mg/mL
23.1.4	Risperidone	P,S,T	Tablet 1 mg Tablet 2 mg Tablet 4 mg Oral liquid 1 mg/mL Injection (Long acting) 25 mg Injection (Long acting) 37.5 mg
23.2 - Medicines used in Mood Disorders			
23.2.1 - Medicines used in Depressive Disorders			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
23.2.1.1	Amitriptyline**	P,S,T	Tablet 10 mg Tablet 25 mg Tablet 50 mg Tablet 75 mg
Haloperidol formulations are also listed in **Section 7.4.7 - Anti-cancer agents including Immunosuppressives, and Medicines used in Palliative are- Medicines used in Palliative Care* ***Amitriptyline formulations are also listed in -* ***A.** **Section 5.2.5 -** Medicines used in Neurological Disorders - Anti-migraine medicines- For prophylaxis* ***B.** **Section 7.4.2 -** Anti-cancer agents including Immunosuppressives, and Medicines used in Palliativeare- Medicines used in Palliative Care*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
23.2.1.2	Escitalopram	P,S,T	Tablet 5 mg Tablet 10 mg Tablet 20 mg
			Capsule 10 mg

23.2.1.3	Fluoxetine*	P,S,T	Capsule 20 mg Capsule 40 mg Capsule 60 mg
23.2.2 - Medicines used in Bipolar Disorders			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
23.2.2.1	Lithium	S,T	Tablet 300 mg
23.2.2.2	Sodium valproate**	P,S,T	Tablet 200 mg Tablet 300 mg Tablet 500 mg Modified Release – Tablet 300 mg Tablet 500 mg
23.2.2.3	Carbamazepine***	P,S,T	Tablet 100 mg Tablet 200 mg Tablet 400 mg Modified Release – Tablet 200 mg Tablet 400 mg Oral liquid 100 mg/5 mL (p)
Fluoxetine formulations are also listed in - ***A. Section 7.4.6 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used inPalliative are- Medicines used in Palliative Care* ***B. Section 7.4.6 -*** *Medicines used in treatment of psychiatric Disorders - Medicines used inobsessive compulsive disorders and panic attacks* *** Sodium Valproate formulations are also listed in **Section 5.1.10 -** Medicines used in Neurological Disorders -Anticonvulsants / antiepileptics* ****Carbamazepine formulations are also listed in **Section 5.1.1 -** Medicines used in Neurological Disorders- Anticonvulsants / antiepileptics*			
23.3 - Medicines used in Generalized Anxiety and Sleep Disorders			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
23.3.1	Clonazepam	P,S,T	Tablet 0.25 mg Tablet 0.5 mg Tablet 1 mg
23.3.2	Zolpidem	P,S,T	Tablet 5 mg Tablet 10 mg
23.4 - Medicines used in Obsessive Compulsive Disorders and Panic attacks			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**

23.4.1	Clomipramine	P,S,T	Capsule 10 mg Capsule 25 mg Capsule 75 mg
23.4.2	Fluoxetine*	S,T	Capsule 10 mg Capsule 20 mg Capsule 40 mg Capsule 60 mg
Fluoxetine formulations are also listed in –* ***A. Section 7.4.6 -* *Anti-cancer agents including Immunosuppressives, and Medicines used inPalliative are- Medicines used in Palliative Care* ***B. Section 23.2.1.3*** *Medicines used in treatment of Psychiatric Disorders - Medicines used in mood disorders - Medicines used in depressive disorders*			
23.5 Medicines used in Disorders due to Psychoactive substance abuse			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
23.5.1	Buprenorphine	P,S,T	Tablet (Sub-lingual) 0.4 mg
23.5.2	Buprenorphine (A) + Naloxone (B)	P,S,T	Tablet (Sub-lingual) 0.4 mg (A) + 0.1 mg (B) Tablet (Sub-lingual) 2 mg (A) + 0.5 mg (B)
23.5.3	Nicotine (for nicotine replacement therapy)	P,S,T	Oral Dosage forms 2 mg Oral Dosage forms 4 mg
Section 24 **Medicines acting on the Respiratory tract**			
24.1 - Antiasthmatic Medicines			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
24.1.1	Budesonide*	P,S,T	Inhalation (MDI/DPI) 100mcg/dose Inhalation (MDI/DPI) 200mcg/dose Respirator solution for use in nebulizer 0.5 mg/mL Respirator solution for use in nebulizer 1 mg/mL
Budesonide formulations are also listed in* ***Section 16.1 -* *Ear, Nose and Throat Medicines*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
24.1.2			Inhalation (MDI/DPI) 100 mcg(A) + 6 mcg (B) Inhalation (MDI/DPI) 200 mcg(A)

	Budesonide (A) + Formoterol (B)	P,S,T	+ 6 mcg (B) Inhalation (MDI/DPI) 400 mcg(A) + 6 mcg (B)
24.1.3	Hydrocortisone*	P,S,T	Powder for Injection 100 mg Powder for Injection 200 mg
24.1.4	Ipratropium	P,S,T	Inhalation (MDI/DPI) 20mcg/dose Respirator solution for use in nebulizer 250 mcg/mL
24.1.5	Montelukast	S,T	Tablet 4 mg Tablet 5 mg (including chewable tablets) Tablet 10 mg
24.1.6	Salbutamol	P,S,T	Tablet 2 mg Tablet 4 mg Oral liquid 2 mg/5 mL Inhalation (MDI/DPI*) 100mcg/dose Respirator Solution (Solution for Nebulizer 5 mg/mL)

**Hydrocortisone formulations are also listed in -*

A. ***Section 3.5 -*** *Antiallergics and Medicines used in Anaphylaxis*

B. ***Section 18.1.3 -*** *Hormones, other Endocrine Medicines and Contraceptives-Adrenal hormones and synthetic substitutes*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
24.1.7	Tiotropium	P,S,T	Inhalation (MDI) 9 mcg/dose Inhalation (DPI) 18 mcg/dose

MDI- Metered Dose Inhaler

DPI- Dry Powder Inhaler

Section 25

Solutions correcting Water, Electrolyte disturbances and Acid-base disturbances

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
25.1.1	Glucose*	P,S,T	Injection 5 % Injection 10 % Injection 25 % Injection 50 %
25.1.2	Glucose(A) + Sodium chloride (B)	P,S,T	Injection 5% (A) + 0.9 % (B)
25.1.3	Oral rehydrationsalts**	P,S,T	As licensed
25.1.4	Potassium chloride	P,S,T	Oral liquid 500 mg/5 mL

		S,T	Injection 150 mg/mL
Glucose formulations are also listed in **Section 18.4.2.1 - Hormones, other Endocrine Medicines and Contraceptives - Medicines used in diabetes mellitus - Medicines used to treathypoglycemia* ***Oral rehydration salts are also listed in **Section 17.6.1 -** Gastrointestinal Medicines -Medicines used in diarrhea*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
25.1.5	Ringer lactate	P,S,T	Injection (as per IP)
25.1.6	Sodium bicarbonate	P,S,T	Injection (as per IP)
25.1.7	Sodium chloride	P,S,T	Injection 0.9%
		S,T	Injection 3%
25.2-Miscellaneous			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
25.2.1	Water for Injection	P,S,T	Injection
Section 26 **Vitamins and Minerals**			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
26.1	Ascorbic acid(Vitamin C)	P,S,T	Tablet 100 mg Tablet 500 mg
26.2	Calcium carbonate	P,S,T	Tablet 625 mg (equivalent to elemental calcium 250 mg) Tablet 1250 mg (equivalent to elemental calcium 500 mg)
26.3	Calcium gluconate*	P,S,T	Injection 100 mg/mL
26.4	Cholecalciferol	P,S,T	Solid oral dosage form 1000 IU Solid oral dosage form 60000 IU Oral liquid 400 IU/mL
Calcium Gluconate formulations are also listed in **Section 4.2.2 - Antidotes and Othersubstances used in poisoning/Envenomation -Specific*			
	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
26.5	Pyridoxine	P,S,T	Tablet 10 mg Tablet 50 mg Tablet 100 mg
26.6	Riboflavin	P,S,T	Tablet 10 mg
26.7	Thiamine	P,S,T	Tablet 100 mg Injection 100 mg/mL
			Capsule/Tablet 50000 IU (including Chewable Tablet) Oral liquid 100000 IU/mL Injection 50000

26.8	Vitamin A	P,S,T	IU/mL
Section 27 **Medicines for COVID-19 management**			
27.1	Dexamethasone*	P,S,T	Tablet 0.5 mg Tablet 2 mg Tablet 4 mg Oral liquid 0.5 mg/5 mL (p) Injection 4 mg/mL
27.2	Enoxaparin**	S,T	Injection 40 mg/ 0.4 mL Injection 60 mg/ 0.6 mL

**Dexamethasone is also listed in -*

A. ***Section 3.4 -*** *Antiallergics and Medicines used in Anaphylaxis*

B. ***Section 7.4.3 -*** *Anti-cancer agents including Immunosuppressives, and Medicines used inPalliative are- Medicines used in Palliative Care*

C. ***Section 18.1.1 -*** *Hormones, other Endocrine Medicines and Contraceptives - Adrenal hormones and synthetic substitutes*

***Enoxaparin is also listed in -*

A. ***Section 8.2.1 -*** *Medicines affecting Blood - Medicines affecting coagulation*

B. ***Section 10.5.4 -*** *Cardiovascular medicines - Antiplatelet and Antithrombotic Medicines*

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
27.3	Methylprednisolone[*]	S,T	Injection 40 mg/mL
27.4	Paracetamol**	P,S,T	Tablet 500 mg Tablet 650 mg Oral liquid 120 mg/5 mL (p) Oral Liquid 125 mg/5 mL (p) Oral Liquid 250 mg/5 mL (p)
27.5	Oxygen***	P,S,T	As licensed for medical purpose

Methylprednisolone is also listed in* ***Section 18.1.4 -* *Hormones, other Endocrine medicines and Contraceptives- Adrenal Hormones and synthetic substitutes*

***Paracetamol is also listed in*

A. ***Section 2.1.5 -*** *Analgesics, antipyretics, non-steroidal anti-inflammatory medicines, medicines used to treat Gout and disease Modifying agents used in Rheumatoid Disorders- Non-opioid analgesics, antipyretics and nonsteroidal anti-inflammatory medicines*

B. ***Section 5.2.3 -*** *Medicines used in Neurological Disorders-Antimigraine medicines*

**** Oxygen is also listed in Medicines used in* ***Section 1.1.5 -*** *Anaesthesia- General Anaesthetics and Oxygen*

Section 28 **Coronary Stents**	
28.1	Bare Metal Stents (BMS)
28.2	Drug Eluting Stents (DES) which include metallic DES and Bioresorbable Vascular Scaffold (BVS)/ Biodegradable stents
Section 29 **Medicines for animal use**	
29.1	Foot and Mouth Disease (Trivalent) Oil adjuvant vaccine
29.2	Brucella Abortus (S19 strain) Vaccine, Live Freeze Dried

All modified release formulations of same strength such as sustained release, controlled release,extended release, prolonged release etc. are included.

Explanation.

1. Any dosage form of a medicine other than that included in this schedule, but in same strength and route of administration, which does not demonstrate significant difference in terms of pharmacokinetics/ pharmacodynamics/ efficacy / safety over the dosage form mentioned in the list, should be considered as included. To elaborate, if tablet is included, other oral solid dosage form such as capsule is considered as included. However, such different dosage forms should be considered differently for purposes of 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. In general, medicines have been mentioned in this schedule M in terms of their active moieties, without mentioning the salts. In case, a medicine is available in more than one salt without any significant difference in potency / pharmacokinetics / pharmacodynamics / efficacy-safety profile aspects, it indicates that these salts are therapeutically similar. Therefore, all salts of such medicines with specified dosage formand strength are considered included in this schedule. In case, where the different salts of a medicine have significant difference in potency / pharmacokinetics / pharmacodynamics / efficacy-safety profile, the medicine has been mentioned in this schedule with respect to its specific salt.

3. Different isomers of a molecule may differ with respect to potency / pharmacodynamics / safety- efficacy profile. Such different isomers have been considered as separate entities. Therefore, inclusion of one isomer of a molecule in this schedule does not imply inclusion of all other isomers of a molecule.

4. Prodrugs / analogues / derivatives of one active moiety are available as different medicines. They may differ with respect to potency / pharmacokinetics / pharmacodynamics / safety-efficacy profile.Inclusion of one form of such medicines in the schedule will not imply inclusion of other forms.

5. Vaccines, sera and immunoglobulins are complex biological products, which may be manufacturedfrom various sources, by using different processes and technologies. In such cases, irrespective of variation in source, composition, or strengths, all the products of the same vaccine/ sera/ immunoglobulin, as approved by licensing authority are considered as included in this schedule.

6. Innovation in medicine must be encouraged. The formulations developed through incremental innovation or novel drug delivery systems like lipid/liposomal formulations 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.

7. For injectable preparations, the pack size (single and multi-dose packs) has not been mentioned. Itis suggested that the single and multi-dose pack sizes be considered as separate entities for purposes such asprocurement/pricing etc.".

(1) 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.][15]

[15] *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 (in rupees per unit, excluding taxes). [16]

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:

Date: Name:

Designation:

[16] *Substituted vide SO 2324(E) dated 25-05-2023 vide Drugs (Price Control) Second Amendment Order, 2023 [10.The Retail Price claimed for approval]*

SCHEDULE-II

"FORM – II[17]

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, as approved by Drug Control Authorities**	**Pack Size**	**GST rate in %**	**WPI change w.r.t. preceding year in %**	**Price to retailer per pack (excluding taxes) (Rs.)**		**Maximum Retail Price (incl. of all taxes) (Rs.)**		**Notified Ceiling Price (in Rs., excluding taxes)**	**Batch no. and date from which price revision is effective**
						Pre revised	**Revised**	**Pre revised**	**Revised**		
(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**(7)**	**(8)**	**(9)**	**(10)**	**(11)**	**(12)**
	Scheduled formulations:										
	Own Manufactured Formulations										

[17] *Substituted vide SO 2324(E) dated 25-05-2023 vide Drugs (Price Control) Second Amendment Order, 2023*

	Purchased Formulations										
	Imported Formulations										

Notes:- In case of purchased/ imported 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:
Mobile:
Email id:";

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 Schedule d Formulati on												
			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[18]

"FORM – IV

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

(See paragraph 21(2))

Sl.	Particulars	Description
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	Ceiling Price (in Rs. per unit, excluding taxes) and date of notification:	
7	Applicable GST rate (in %)	
8	Pack size	
9	Existing maximum retail price (MRP) of pack including all taxes and its effective date:	

[18] *Substituted vide SO 2324(E) dated 25-05-2023 vide Drugs (Price Control) Second Amendment Order, 2023*

10	Therapeutic category as per NLEM:	
11	Date of commencement of production / import:	
12	Intended date of discontinuation:	
13	Reasons for discontinuation of production / import:	
14	Year-wise Production/ Import during the last 5 years including current year (in quantity of packs)	
15	Year-wise sale during the last 5 years including current year (in quantity of packs)	
16	Whether any new drug, as defined under DPCO, 2013, has been launched or intended to be launched. If so, the details thereof:	
17	Any other information relevant to discontinuation of scheduled formulation:	

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

Place:

Date

Authorised Signatory:

Name:

Designation:

Mobile:

Email ID:

SCHEDULE II

"FORM – V PROFORMA FOR PRICE LIST [19]

(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, as approved by Drug Control Authorities**	**Pack Size**	**GST rate (in %)**	**Price to Distributor (excluding taxes) (Rs.)**	**Price to retailer (excluding taxes (Rs.)**	**Prerevised Maximum Retail Price, if any (incl. of all taxes) (Rs.)**	**Maximum Retail Price (incl. of all taxes) (Rs.)**	**Batch no. and date from which price revision is effective**	**Production capacity**
(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**(7)**	**(8)**	**(9)**	**(10)**	**(11)**
	Scheduled formulations:									
	Own Manufactured Formulations									
	Purchased Formulations									
	Imported Formulations									

Table B

Sl. No.	**Name of the Product (Formulation and its dosage forms)**	**Composition, as approved by Drug Control Authorities**	**Pack Size**	**GST rate**	**Price to Distributor (excluding taxes) (Rs.)**	**Price to retailer (excluding taxes (Rs.)**	**Prerevised Maximum Retail Price, if any (incl. of all taxes) (Rs.)**	**Maximum Retail Price (incl. of all taxes) (Rs.)**	**Batch no. and date from which price revision is effective**	**Production capacity**
(1)	**(2)**	**(3)**	**(4)**	**(5)**	**(6)**	**(7)**	**(8)**	**(9)**	**(10)**	**(11)**
	Non-Scheduled formulations:									

[19] *Substituted vide SO 2324(E) dated 25-05-2023 vide Drugs (Price Control) Second Amendment Order, 2023*

	Own Manufactured Formulations									
	Purchased Formulations									
	Imported Formulations									

Notes:- In case of purchased/ imported 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:

Mobile:

Email ID:

SCHEDULE-II

Form VI[20]

Proforma for Price List for Medical Devices

[See paragraphs 24(3) & 25(2)]

Name of the Company:

Name of the Authorized Signatory:

Address of the Company:

Contact Details:

E-mail Id:

Category-Manufacturer/Importer

(Amount in Rupee)

Sl. No.	Medical Device Registration No. issued by CDSCO	Medical Device Category as per the list issued by CDSCO	Product Name/Specification as per DCGI approval/Generic Name	Product Code (if any)	Brand Name	Minimal Unit of Sale/ Retail Pack Size	Price to Distributor/Stockist Hospital (excluding applicable taxes)	Price to Retailers (excluding applicable taxes)	Applicable GST %	Revised Maximum Retail Prices	Effective Batch No. and Date	Previous Maximum Retail Prices	Remarks
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)	(12)	(13)	(14)

Date:
Place:

Signature:
Name:
Designation with office seal:
Mobile:
Email id:

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20 *Inserted vide SO 2899(E) dated 20-07-2021 vide Drugs (Price Control) Amendment Order, 2021*