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, (10of1955),andsupersessionoftheDrug(PricesControl)Order,1995,exceptas respect to things done or omitted to be done before such supersession, the Central Government hereby makes the following Order, namely:-

1.Shorttitleandcommencement.–(1)ThisOrdermaybecalledtheDrugs(Prices Control) Order, 2013.

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

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

(b)**"activepharmaceuticalingredientsorbulkdrug"**meansanypharmaceutical, chemical,biological or plant productincluding 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**"meansapersoncarryingonthebusinessofpurchaseorsaleofdrugs, whether as a wholesaler or retailer and includes his agent;

(f) "**distributor**"meansapersonengagedintheworkofdistributionofdrugsand 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**"meansamedicineprocessedoutoforcontainingoneormore 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)anymedicineincludedinanybonafideAyurvedic(including Sidha)orUnani (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 orthenameoftheactivepharmaceuticalingredientcontainedintheformulation, without any brand name;

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

(l)"**import**" with its grammaticalvariations andcognateexpressionsmeans 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 annualturnover)ofabrandoragenericversionofamedicineandthesumoftotal 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)**"margintoretailer"**forthepurposesofthisOrdershallmeanapercentageof price to retailer;

(q)**"marketbaseddata"**meansthedataofsalesrelatedtoadrugcollectedor 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 anddutiesasapplicable,atwhichthedrugshallbesoldtotheultimateconsumerand where such price is mentioned on the pack;

(s) **"movingannualturnover"**ina particularmonthmeanscumulativesalesvalue 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) **"NationalListofEssentialMedicines"**meansNationalListofEssential Medicines, 2011 published by the Min lfare as updated or

revisedfromtimetotimeandincludedinthefirstscheduleofthisorderbythe Government through a notification in the Official Gazette;

(u)**"new drug"** for the purposes of this Order shall mean a formulation launched by anexistingmanufacturerofadrugofspecifieddosagesandstrengthsaslistedinthe NationalListofEssentialMedicinesbycombiningthedrugwithanotherdrugeither listed or not listed in the National List of Essential Medicines or a formulationlaunchedbychanging thestrengthordosagesorbothof thesamedrug of specified dosages and strengths as listed in the National List of Essential Medicines.

(v)**"non-scheduledformulation**"meansaformulation,whichisnotincludedin 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 pricelist referredto 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**"meansadealercarryingontheretailbusinessofsaleofdrugsto customers;

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

(zc) "**schedule**"meansa Scheduleappended to this Order;(zd) "**wholesaler**" means a dealerorhisagentorastockistengagedinthesaleofdrugstoaretailer,hospital,

[1]*SubstitutedvideGSR1233(E),w.e.f.08-05-2015* – [*(n)"manufacturer"forthepurpose ofthisOrdermeansanypersonwhomanufactures,importsandmarketsdrugsfor distributionorsaleinthecountry;]*

[2]*SubstitutedvideGSR686(E),w.e,f.09-03-2015* – [*"non-scheduledformulation"meansa formulation,thedosageandstrengthsofwhicharenotspecifiedintheFirstSchedule;]*

dispensary,medical,educationalorresearchinstitutionoranyotheragency;

(ze) **"wholesalepriceindex"**meansannualwholesalepriceindexofallcommoditiesas announced by the Department of Industrial Policy and Promotion, Government of India, from time to time.

(2) All other wordsand expressions used herein and not definedbut 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 orformulations.–TheGovernmentmay,-(i)withaviewtoachieveadequate availabilityandtoregulatethedistributionofdrugs,incaseofemergencyorin circumstances of urgency or in case of non-commercial use in public interest, direct any manufacturerofanyactivepharmaceuticalingredientorbulkdrugorformulationto increase the production and to sell such active pharmaceutical ingredient or bulk drug to suchothermanufacturer(s)offormulationsandtodirectformulatorstosellthe formulations to institutions, hospitals or any agency as the case may be;

(ii)forthepurposeofgivinganydirectionundersub-paragraph(i),callforsuch informationfrommanufacturersofactivepharmaceuticalingredientsorbulkdrugsor formulations,asitmayconsidernecessaryandsuchmanufacturershallfurnishthe required information within such time the Government may fix.

4. Calculation of ceiling price of a scheduled formulation.– (1) The ceiling price of a scheduledformulationofspecifiedstrengthsanddosagesasspecifiedunderthefirst 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 morethan or equal to one percent of the total market turnover on the basis of moving annual turnover ofthat medicine) / (Total number of such brands and genericversions of the medicine having market sharemore thanorequaltoonepercentoftotalmarketturnoveronthebasisofmovingannual 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)= AveragePricetoRetailerforthesamestrengthanddosageofthemedicineas 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 priceofthe new drug available in domesticmarket 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

underthePatents Act1970(39of1970),shallbefixedaspertheprovisionsofsub-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 CommitteeofExperts formed under paragraph 15.(ii) theretailpriceofsuchnewdrugshallbefixedbyaddingsixteenpercentmarginto retailer on the price to retailer as fixed in item (i)

"(3)(i)the retail priceof the new drug shall be arrivedatby reducing fifty per cent. of the pricecalculatedunder sub-paragraph (1)of paragraph4,and if thenew drug is not availableinthedomesticmarket,theretailpriceofthenewdrug shallbefixedasper 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 inthepharmaceuticalmarketdatabase,whicheverislater,theretailpriceforthe 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 thebrandofthemanufacturerhavingthepatentandthemanufacturerholdingthe permission granted by the patentee shall be excluded.";[4]

6.Ceilingpriceof a scheduled formulation in caseof no reduction in pricedue to absenceofcompetition.–(1)wheretheaveragepricetoretailerofascheduled 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)thereareless than fivemanufacturers for thatformulation having one percentor 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 availableinthelistofscheduledformulation,theaveragepricetoretailershallbe calculated as under:

Step1: Firstthe AveragePricetoRetailerof suchscheduledformulationi.e.P(s) shall be calculated as under:

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

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

Pi=%reductioninAveragePricetoRetailerofotherstrengthsanddosageforms (calculatedasinstep1ofsub-paragraph(1)ofparagraph4)inthelistofschedule formulations w.r.t the highest priced formulation taken for calculating the average price to retailer of such strengths and dosage forms.

N=Numberofsuchotherstrengthsordosageformsorbothinthelistofschedule formulations

Step2. Thereafter,theceilingpriceofthescheduledformulationi.e.P(c)shallbe calculated as under:

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

[3]*Insertedvide SO 2165(E) dated 11-05-2023 vide Drugs (Price Control) AmendmentOrder, 2023*

[4]*Insertedvide SO 2165(E) dated 11-05-2023 vide Drugs (Price Control) AmendmentOrder, 2023*

P(s)=AveragePricetoRetailerofthescheduledformulationascalculatedinstep1 hereinabove and**M** = % Margin to retailer and its value=16

(ii)intheeventofotherstrengthsordosageformsofthescheduledformulationisnot availableintheschedulebuttherareotherscheduledformulationsinsamesub-therapeutic category as that of the scheduled formulation, then the Ceiling Price shall be calculated as under:

Step1: Firstthe AveragePricetoRetailerof suchscheduledformulationi.e.P(s) shall be calculated as under:

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

Pm=Priceofhighestpricedformulationtakenforcalculatingtheaveragepriceto retailerofthe formulationunderconsideration..**Pi**=%reductionin AveragePriceto Retailerofotherscheduleformulations(calculatedasinstep1ofsub-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 form

Step2. Thereafter,theceilingpriceofthescheduledformulationi.e.P(c)shallbe calculated as under:

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

P(s)=AveragePricetoRetailerofthescheduledformulationascalculatedinstep1 above and

M = % Margin to retailer and its value=16

Explanation.-wherethescheduledformulationunderconsiderationiscomingunder morethan one sub-therapeutic category,the Average Priceto Retailerof thescheduled formulation shall be calculated after taking into considerationthe percentage reduction inAveragePricetoRetailerofotherscheduleformulationsunderallsuchsub-therapeuticcategoriesandthelowestaveragepricetoretailershallbetakenfor calculating the ceiling price of the scheduled formulation under consideration;

(iii)incasetheotherstrengthsordosageformsofthescheduledformulationarenot 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: Firstthe AveragePricetoRetailerofsuchscheduledformulationi.e.P(s) shall be calculated as under:

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

Pm=Priceofhighestpricedformulationtakenforcalculatingtheaveragepriceto retailerofthe formulationunderconsideration.**Pi**=%reductionin AveragePriceto Retailerofotherscheduleformulations(calculatedasinstep1sub-paragraph(1)of paragraph4)insametherapeuticcategoryasthatofthescheduledformulationunder 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,theceilingpriceofthescheduledformulationi.e.P(c)shallbe 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.-wherethescheduledformulationunderconsiderationiscomingunder morethanonetherapeuticcategory,theAveragePricetoRetailerofthescheduled formulation shall be calculated after taking into considerationthe percentage reduction in AveragePricetoRetailerofotherscheduleformulationsunderallsuchtherapeutic categoriesandthelowestaveragepricetoretailershallbetakenforcalculatingthe ceiling price of the scheduled formulation under consideration.

(2) Notwithstanding anything contained in this paragraph, where the price has been fixed andnotifiedbytheGovernmentundertheDrugs(PricesControl)Order,1995the provisions of sub-paragraph (1) shall not apply.

7. Margin to retailer.–Whilefixingaceiling priceofscheduledformulationsand 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 shallbefixedbythemanufacturersonthebasisofceilingpricenotifiedbythe 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)

(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]

(2) The Governmentmayin thedue course of time come out with other appropriate mechanismofcollectingorobtainingthemarketbaseddatarelatedtodrugsandthe decision of Government with respect to collection or obtaining of data shall be final.

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

(4) Themarketbaseddataforfixingtheretailpriceofnewdrugsavailableinthe 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 toarevisioninthefirstscheduleshallbethedataavailableforthemonthending immediately before six month of notification of revision in the first schedule.

[5] *Substituted vide SO 39(E) dated 03-01-2019 vide Drugs (Price Control) AmendmentOrder, 2019 [9. Reference data andsourceofmarketbaseddataInitially,thesourceofmarketbaseddatashallbethedataavailablewiththe pharmaceuticals market data specializing company – IMS Health (IMS) and if the Government deems necessary, it may validate such data by appropriate survey or evaluation]*

(6) Notwithstandinganythingcontainedinthisorder,thereferencedateforthe 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 thisparagraph,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 saidorder,upto31stMay,2012,shallremaineffectiveforfurtheroneyeari.e.upto 30thMay'2013andthemanufacturersmayrevisethepricesofsuchscheduled formulationsaspertheannualwholesalepriceindexforthepreviouscalendaryear 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) ThepricesofscheduledformulationS,whicharealsospecifiedintheFirst ScheduletotheDrugs(PricesControl)Order,1995,fixedandnotifiedunderthe provisionsofDrugs(PricesControl)Order,1995after31stMay,2012,shallremain effectiveforoneyearfrom thedateofnotificationofsuchpricesunderDrugs(Prices Control) Order,1995 and immediately thereafter the manufacturers may revise the prices aspertheannualwholesalepriceindexforthepreviouscalendaryearannouncedby DepartmentofIndustrialPromotionandPolicyandonthe1stAprilofsucceeding 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) ThepricesofscheduledformulationS,whicharespecifiedintheDrugs(Prices Control)Order,1995butnotspecifiedintheFirstScheduleofthisorder,fixedand notifiedundertheprovisionsofthesaidorder,upto31stMay,2012,shallremain effective for further one year i.e.up to the 30thMay'2013 and thereafterprices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order.

(4) ThepricesofscheduledformulationS,whicharespecifiedintheDrugs(Prices Control)Order,1995butnotspecifiedintheFirstScheduleofthisorder,fixedand notifiedundertheprovisionsofthesaidorder,after31stMay,2012,shallremain effectiveforoneyearfrom thedateofnotificationofsuchpricesandthereafter 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 asper theprovisions in paragraphs 4,5 and6shall beon the dosage basis,(per tablet, percapsuleorinjectioninvolumeaslistedinfirstschedule)andtheceilingpriceor retailpriceofapackshallbereachedbymultiplyingthesamewiththenumberor quantity in the pack as the case may be.

[6] *Insertedvide SO 39(E) dated 03-01-2019 vide Drugs (Price Control) AmendmentOrder, 2019*

(2) In the event of the unit of the dosage for a scheduled formulation not available in the firstschedule,thelowestpacksizeforthatcategoryofmedicine,asspecifiedinthe Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules thereunder, shall be taken as unitdosageforcalculating theceiling priceorretailpriceasthecasemaybe,forthat 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)Notwithstandinganythingcontainedinsub-paragraph(1)and(2),inthecaseof injections or inhalation or any other medicine for which dosage form or strength or both arenotspecifiedintheSchedule-IoftheDrugs(PricesControl)Order,2013,the Governmentmayfixandnotifyseparateceilingpriceorretailpriceforsuch formulations with specified therapeuticrationale,considering thetype of packaging or packsizeordosagecomplianceorcontentinthepacknamelyliquid,gaseousorany otherform,in the unit dosage as thecasemaybe,conforming to Indian Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act,1940 (23of 1940) and the rules made thereunder for the same formulation.

(4) TheGovernmentshallformaCommitteeofExperts,asitmaydeemfit,withina periodoffifteendaysfromth mmendfixingof 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 Pricelist;toorbelowtheceilingpricefixedforthatscheduleformulationbythe Government.

(2)Whereanexistingbrandisre-launchedbyanothermanufacturertheprovisionsof paragraph 13 shall be applicable.

13.Priceofscheduledformulationsfortheexistingmanufacturers.–(1)Allthe 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 ofallsuch formulationsdownwardnotexceeding theceiling price(pluslocaltaxesas applicable):

Provided,thatincaseofscheduledformulationsproducedoravailableinthemarket beforethedate ofnotificationofceiling price,the manufacturersshallensurewithina period of forty-five days of the date of suchnotificationthat themaximum retail price ofsuchscheduledformulationdoesnotexceedtheceilingprice(pluslocaltaxesas applicable).

(2) Alltheexistingmanufacturesofscheduledformulations,sellingthebrandedor generic or both theversions of scheduled formulations at a price lower than the ceiling price(pluslocaltaxesasapplicable)sofixedandnotifiedbytheGovernmentshall maintain their existing maximum retail price.

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

(3) Annual increase in maximum retail price may be carried out as per the increase in thewholesalepriceindexwithrespecttopreviousyearasperthe provisionofsub-paragraphs (2) and (3) of paragraph 16.

Provided that in caseof 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.Fixationofceilingpriceofscheduledformulations.–(1)TheGovernmentshall fixandnotifytheceilingpricesofthescheduledformulationsinaccordancewiththe provisions of the paragraphs 4 and 6, as the case may be, and no manufacturer shall sell thescheduledformulationsatapricehigherthantheceilingprice(pluslocaltaxesas applicable) so fixed and notified by the Government.

(2)Whereanymanufacturersellsascheduledformulationatapricehigherthanthe ceiling price (plus local taxes as applicable) fixed and notified by the Government, such manufacturersshallbeliabletodepositthe overchargedamountalongwithinterest thereon from the date of such overcharging.

15.Fixation of retailpriceof anewdrugfor existingmanufacturersof scheduled formulations.– (1) The Government shall form a Standing Committee of such Experts, asitmaydeemfit,withinsixtydaysofnotificationofthisorderwithaviewto 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 inNationalListofEssentialMedicineslaunchesanewdrug,suchexisting manufacturersshallapplyforpriorpriceapprovalofsuchnewdrugfromthe 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,theGovernmentshall 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 forwardthe same totheStandingCommitteeofExpertswhoshallexaminetheapplicationonthe principlesof"Pharmacoeconomics"andmakerecommendationsofretailpriceofthe new drug to the Government within thirty days of the receipt of application.

(4) TheGovernmentshall,onreceiptofrecommendationundersubparagraph(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) Whereexistingmanufacturerofscheduledformulationfailstoapplyforprior approvalofthepriceofthenewdruginForm-I,suchmanufacturershallbeliableto deposittheoverchargedamountoverandabovesuchpricefixedandnotifiedbythe 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 apricehigherthantheretailprice(pluslocaltaxesasapplicable)fixedbythe Government for such new drug and in case such a manufactureris found to sell such a new drug at a price higher thanthe retail price (plus local taxes as applicable) fixed by theGovernment,suchmanufactureroftheneWdrugshallbeliabletodepositthe overchargedamount along with interest from thedate of overcharge,in addition to the penalty.

16.Revisionofceilingpriceof scheduledformulations.–(1) TheGovernmentshall revisetheceilingpricesofscheduledformulationsaspertheannualwholesaleprice 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) Themanufacturersmayincreasethemaximumretailprice(MRP)ofscheduled formulationsonceinayear,in themonthof April,onthebasisofthewholesaleprice indexwithrespectto previouscalendaryearandnoprior approvaloftheGovernment in this regard shall be required.

(3) Informationabouttherevision,ifcarriedout,shallbeforwardedtothe Governmentineitherelectronicorphysicalforminform-II withinaperiodoffifteen days of such revision and non-submission of information under this sub-paragraph shall beconstruedasnonrevisionofmaximumretailprice(MRP)andtheconcerned manufacturershallbeliabletodeposittheamountchargedoverandabovethepre-revisedmaximumretailprice(MRP),alongwithinterestthereonfromthedateof overcharging.

(4) Incaseofdeclineinwholesalepriceindex,thereshallbeacorresponding reduction in themaximum retail price and in case of scheduled formulations produced oravailableinthemarketbeforethedateofnotificationofrevisedceilingprice,the manufacturersshallensurewithinaperiodofforty-fivedaysofthedateofsuch notificationthatthemaximumretailprice(MRP)ofsuchscheduledformulationdoes not exceed the revised ceiling price (plus local taxes as applicable) and information about therevisionshallbesenttotheGovernmentineitherelectronicorphysicalformin

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 liabletodepositthe amountchargedoverandabovethemaximum retailpricerevised basedondeclineinwholesalepriceindex,alongwithinterestthereonasovercharged amount from the date of overcharging.

17. Amendmentofthelistofscheduledformulation.–(1) A decisiontoamendthe firstschedule,clearlystatingthereasonsthereof,shallbetakenbytheGovernment within sixty days of receipt of communicationfrom the Ministry of Health and Family Welfareandtheamendment(s)orrevision,ifrequired,inthefirstscheduleshallbe notified and thereafter, the ceiling price(s) for the medicine(s) added in the first schedule shall be fixed as per theprovisions of this order within a period ofsixty days from the date of the notification.

(2) The medicines omitted from thefirst scheduleshall fall under the categoryof non-scheduled formulations.

18.Revision of ceilingpriceon thebasisofmovingannualturnover (MAT).–The revision of ceiling prices on the basis of moving annualturnover valueshall be carried out,-

(i) everyfiveyearsfromthedateoffixingtheceilingpriceunderthisOrderfor formulations as specified under the SCHEDULE - I.[8]

(ii) whenthe number of manufacturers of a scheduled formulation,having priceof a scheduledformulationmorethanorequaltoseventyfivepercentoftheceilingprice 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, hasincreasedbytwentyfivepercentormorethanthenumberofmanufacturersas existing on the reference date.

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

"18A.Revisionofceilingpriceofscheduledformulationafterexpiryofpatent 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 priceby fifty per cent., and afterone year, theceilingprice shall be revisedagainasperttheprovisionsofsubparagraph(1)ofparagraph4,basedonthe 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 anincreaseordecreaseintheceilingpriceortheretailprice,asthecasemaybe, irrespective of annual wholesale price index for that year.

20. Monitoringthepricesofnon-scheduledformulations.–(1)TheGovernment shallmonitorthemaximumretailprices(MRP)ofallthedrugs,includingthenon-scheduledformulationsandensurethatnomanufacturerincreasesthemaximum retail price of a drug more than ten percent of maximum retail price during preceding twelve monthsandwheretheincreaseisbeyondten percentofmaximum retailprice,itshall reducethesametothelevelofthepercentofmaximumretailpricefornexttwelve months.

(2)Themanufacturershallbeliabletodeposittheoverchargedamountalongwith 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 monitortheproductionandavailabilityofscheduledformulationsandtheactive pharmaceutical ingredients contained in the scheduled formulation and the manufacturer ofscheduledformulationsandtheactivepharmaceuticalingredientscontainedinthe scheduled formulation shall furnish the information as stated in

Form-III of schedule-II of this Order quarterly.

[8]*Substituted vide SO 3249(E) dated 12-08-2021 vide Drugs (Price Control) Third AmendmentOrder, 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]*Insertedvide SO 2165(E) dated 11-05-2023 vide Drugs (Price Control) AmendmentOrder, 2023*

(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 inForm-IVofschedule-IIofthisorderinthisregardatleastsixmonthspriortothe intendeddate of discontinuationand the Governmentmay,in publicinterest, direct the manufacturer of the scheduled formulation to continue with required level of production orimportforaperiodnotexceedingoneyear,fromtheintendeddateofsuch 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, importerordistributorasthecasemaybe,todeposittheamountwhichhasaccrued undertheprovisionsoftheDrugs(PricesControl)Order,1979onorbeforethe commencementofthisorder,intotheDrugsPricesEqualisationAccountandthe 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 DrugsPrices 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 casemay be, the shortfall between his retention price and the common selling price or, asthecasemaybe,thepooledpriceforthepurposeofincreasingtheproduction,or securing the equitable distribution and availability at fair prices, of drugs; (b)meetingtheexpensesincurredbytheGovernmentindischargingthefunctions under this paragraph; and (c)promotinghighereducationandresearchinPharmaceuticalSciencesand Technology and for the purposes incidental thereto.

23. RecoveryofoverchargedamountunderDrugsPricesControlOrders1987 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 Governmentundertheprovisionsof Drugs(PricesControl)Order,1987andDrugs (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):

Providedthatincaseofscheduledformulationsproducedoravailableinthemarket beforethedate of notificationofceilingprice,the manufacturersshallensurewithina period of forty-five days of the date of the notification that the maximum retail price of suchscheduledformulationdoesnotexceedtheceilingprice(pluslocaltaxesas applicable).

(2) Everymanufacturerofascheduleformulationintendedforsaleshalldisplayin 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, inFormVorForm-VI[10]tothedealers,StateDrugsControllersandtheGovernment 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) Everyretaileranddealershalldisplaythepricelistandthesupplementaryprice 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) Everyretailerandadealershalldisplaythepricelistandthesupplementaryprice list,ifany,asfurnishedbythemanufacturerorimporter,onaconspicuouspartofthe premises where hecarrieson business in amanner so as to beeasily accessible to any person wishing to consult the same.

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

27. Saleof splitquantitiesof formulations.–Nodealershallsellloosequantityof 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 provisionsoftheDrugandCosmeticsAct,1940(23of1940)andtherulesmade thereunder, - (a)nomanufacturerordistributorshallwithholdfrom saleorrefusetosellto adealer 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. Maintenanceofrecordsandproductionthereofforinspection.–Every manufacturershallmaintainrecordsrelatingtothesalesofindividualactive pharmaceuticalingredientsorbulkdrugsmanufacturedorimportedandmarketedby him,asthecasemaybe,andthesalesofformulationsunitsandpacksandalsosuch otherrecordsasmaybedirectedfromtimetotimebytheGovernmentandthe

[10] *Insertedvide SO 2899(E) dated 20-07-2021 vide Drugs (Price Control) AmendmentOrder, 2021*
[11] *Insertedvide SO 2899(E) dated 20-07-2021 vide Drugs (Price Control) AmendmentOrder, 2021*

Governmentshallhavethepowertocallforanyrecordandtoinspectsuch recordsat the premises of the manufacturer.

30. Powerofentry,searchandseizure.–(1) AnyGazettedOfficeroftheCentral GovernmentorofaStateGovernment,asthe casemaybe,authorisedbyageneralor specialorderby the CentralGovernmentorbytheStateGovernment,asthecasemay be,in this behalf may,with a view to securing compliancewith 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 thedrug is found, in respect of which he suspects that any provision of this Order has been, isbeing,orisabout tobe contravened,andthereaftertakeallmeasuresnecessary for securing production of the drug, containers, packages or coverings, so seized, in acourtoflawandfortheirsafecustodypendingsuchproduction;(c)seizeany 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 aperiod of thirty days of thedateof publicationof 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–applicationoftheprovisionsofthisorderincertaincases.-The provisions of this order shall not apply to, -
(i) a manufacturer producing a new drug patentedunder 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 throughindigenousResearchandDevelopmentandpatentedundertheIndianPatent Act,1970(39of1970)(processpatent)for a periodoffiveyearsfrom thedateofthe 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 In

[12]*Substituted vide SO 39(E) dated 03-01-2019 vide Drugs (Price Control) AmendmentOrder, 2019 [(i)a manufacturer producinganewdrugpatentedundertheIndianPatentAct,1970(39of1970)(productpatent)andnotproduced elsewhere,ifdevelopedthroughindigenousResearchandDevelopment,foraperiodoffiveyearsfromthedateof commencement of its commercial production in the country]*

[13]*Insertedvide SO 39(E) dated 03-01-2019 vide Drugs (Price Control) AmendmentOrder, 2019*

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

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

"**SCHEDULE-I**[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]*SubstitutedvideSO701(E)dated10-03-2016videDrugs(PriceControl) 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 % gluco
1.2.2	Lignocaine*	P,S,T	Topical forms 2-5 % Injection 1 % Injection 2 % Injection 5 % with 7.5 % glucos
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 Ag 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 **Neostigmine Management **Acetylsalic*	**Medicine**	**Level of Healthcare**	Tablet 300 mg to 500 mg Effervescent/ Dispersible/ Enteri Tablet 300 mg to 500 mg
			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 Medicin 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 Palliativ*

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

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 for*			
*** 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 li Lyophilized polyvalent -As licer
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 I 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/ Enteri 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 disor*

***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), Medi*
treat Gout and Disease Modifying Agents used in Rheumatoid Disorders Non-opioid Analgesics, Antipyretics andNon-steroidal Anti- i
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, antipy
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 Co*

B. Section 23.2.1.1 - *Medicines used in treatment of Psychiatric Disorders -Medicines used in mood disorders- Medicines used in depressive*

	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 ** Albendazol*	**Medicine**	**Level of Healthcare**	Tablet 50 mg Tablet 100 mg Oral liquid 120 mg/5 mL (p)
			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 m (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) +20
6.2.1.3	Ampicillin	P,S,T	Powder for Injection 500 mg Po Injection 1000 mg
6.2.1.4	Benzathine benzylpenicillin	P,S,T	Powder for Injection 6 lac units Injection 12 lac unitsPowder for lac units
6.2.1.5	Benzylpenicillin	P,S,T	Powder for injection 5 lac units 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 Opportun 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 (as 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 for Syndromic Management of Sexually Transmitted Infections, the management of HIV- Additional Medicines for treatment of HIV Opportunistic 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 (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 (= 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 amoebia other parasitic infections*

6.3 - Antileprosy Medicines

	Medicine	**Level of**	**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			Tablet 400 mg

	Medicine	**Level of Healthcare**	**Dosage form(s) and strength(s)**
**Clofazimine medicines*			
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 **Rifampicin f* ***Amphoteri* *medicines*	**Medicine**	**Level of Healthcare**	a) Amphotericin B (conv Injection 50mg/vial b) Lipid Amphotericin B - Injection 50 mg/vial c) Liposomal Amphotericin B 50 mg/vial
			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)
6.6 - 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 Po 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 /
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 **Acyclovir fo rmulations are also listed in -*	Abacavir	S,T	Tablet 60 mg (p) Tablet 300 mg

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)(Tablet 600 mg (A) + 300 mg (E
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) +Nevirapine (C)	S,T	Tablet 60 mg (A) + 30 mg (B)(p) Tablet 300 mg (A) + 150 mg (B)
6.7.1.10		S,T	Tablet 60 mg (A) + 30 mg (B) + (p) Tablet 300 mg (A) + 150 mg (B) + 200 mg (C)

** Tenofovir D Anti-*

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/ 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 (CM*

****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 - Ot 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 50 mg b)Lipid Amphotericin B- Injection 50 mg c)Liposomal Amphotericin B- In 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			Capsule 150 mg Capsule 300 mg
6.9.3.2	Co-trimoxazole* [Sulphamethoxazole (A) + Trimethoprim (B)]	P,S,T	Tablet 400 mg (A) + 80 mg (B) mg (A) + 160 mg (B)Oral liquid + 40 mg (B)/5 mL (p)

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

**Amphoterici*

medicines

***Clindamyc*

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 (2 + 12.5 mg) (B) 1 Tablet 50 mg (A) + 1 Tablet (5 + 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 chemoprophyla term travellers like military and troops, travelling from low ende 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 Po Injection 1000 mg
7.1.23	Hydroxyurea*	T	Capsule 500 mg
7.1.24	Ifosfamide	T	Powder for Injection 1000 mg P 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 P 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 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 via 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	**Medicine**	T	Capsule 25 mg Capsule 50 mg Capsule 100 mg Oral liquid 100 mg/mL (p) Injection 50 mg/mL
		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

**Prednisolon*

A. Secti

B. Secti
and synthetic

C. Secti

***Azathiopri*
inflammatory

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 depres 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 ofele 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), Medi 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, tec 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 licens are considered as included in NLEM. However, considering the source, process, technology and other relevant aspects, they should b 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 m Tablet 60 m 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	Tablet 50 mg Tablet 100 mg
		P,S,T	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/Disp Enteric coated Tablets 150 mg Conventional/Effervescent/Disp Enteric coated Tablets 325 mg Enteric coated Tablet 75 mgEnte 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, Antipy 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	**Medicine**	P,S,T	Cream 0.05 % Cream 0.1 %
**Clotrimazol*			
A. Secti		**Level of Healthcare**	**Dosage form(s) and strength(s**
B. Secti			
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/r
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 %
	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 Palliativ 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	**Medicine**	S,T	Injection 40mg/mL
Dexamethas* ***A. Secti B. Secti Care - Medic **C.***		**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
18.2.1.2	Levonorgestrel Ormeloxifene (Centchroman) P,S,T	P,S,T	Tablet 0.75 mg Tablet 1.5 mg

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 Levonorgestr
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 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 m
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 availabl such as 12.5,25,50,62.5, 112mcg. Therefore, it was consi give a range of available strengt
Section 19 **Immunologicals** In case of these biologicals, irrespective of variation in source, composition andstrengths, all the products of the same vaccine/ sera/ immun approved by licensing authority are considered as included in NLEM. However, considering the source, process, technology and other rele 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 - AsLi

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 U 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 un 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 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 inst 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 %

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 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	**Medicine**	**Level of Healthcare**	Tablet 0.125 mg Injection 0.2 mg/mL

**Tropicamid*			**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 Pallia*
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 Palliative are- Medicines used in Palliative Car*

	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

23.3 - 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/d Inhalation (MDI/DPI) 200mcg/d Respirator solution for use in ne 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(6 mcg (B) Inhalation (MDI/DPI) 200 mcg(
	Budesonide (A) + Formoterol (B)	P,S,T	+ 6 mcg (B) Inhalation (MDI/DPI) 400 mcg(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/do Respirator solution for use in ne mcg/mL

24.1.5	Montelukast	S,T	Tablet 4 mg Tablet 5 mg (including chewable tablets) Tablet 10 mg
24.1.6 **Hydrocortis* ***A. Secti*** ***B. Secti*** *synthetic sub*	**Medicine**	P,S,T	Tablet 2 mg Tablet 4 mg Oral liquid 2 mg/5 mL Inhalation (MDI/DPI*) 100mcg/ Respirator Solution (Solution for Nebulizer 5 mg/mL
		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 di 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 ele calcium 250 mg) Tablet 1250 mg (equivalent to el 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 dosage form 60000 IU Oral l 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 Chewable Tablet) Oral liquid 100000 IU/mL Inje
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 **Dexamethas* ***A. Secti*** ***B. Secti*** *are- Medicin*	Enoxaparin**	S,T	Injection 40 mg/ 0.4 mL Injection 60 mg/ 0.6 mL
	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 sy 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 a 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 strengthandrouteofadministration,whichdoesnotdemonstratesignificantdifferencein termsofpharmacokinetics/pharmacodynamics/efficacy/safetyoverthedosageform mentioned in the list, should be considered as included. To elaborate, if tablet is included, other oralsoliddosageformsuchascapsuleisconsideredasincluded.However,suchdifferent 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,withoutmentioning the salts.In case, amedicine isavailable inmore than one salt withoutanysignificantdifferenceinpotency/pharmacokinetics/pharmacodynamics/ efficacy-safetyprofileaspects,itindicatesthatthesesaltsaretherapeuticallysimilar. Therefore,all saltsof such medicineswith specified dosage formand strength are considered includedinthisschedule.Incase,wherethedifferentsaltsofamedicinehavesignificant differenceinpotency/pharmacokinetics/pharmacodynamics/efficacy-safetyprofile,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 isomershave been considered as separate entities.Therefore,inclusionofone isomerofamoleculeinthisscheduledoesnot imply inclusion of all other isomers of a molecule.

4. Prodrugs/analogues/derivativesofoneactivemoietyareavailableasdifferent 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 manufacturedfromvarioussources,byusingdifferentprocessesandtechnologies.Insuch 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. Innovationinmedicinemustbeencouraged.Theformulationsdevelopedthrough incrementalinnovationornoveldrugdelivery systemslike lipid/liposomal formulationsetc. shouldbeconsideredasincludedonlyifspecifiedinthelistagainstanymedicine.Such differentformulationsshouldbeconsidereddifferentlyforpurposessuchasprocurement policy, pricing, etc.

7. Forinjectable preparations,the pack size (single and multi-dose packs)hasnotbeen mentioned.Itis suggested that the single and multi-dose pack sizes be considered as separate entities for purposes such asprocurement/pricing etc.".

(1)Forinjectablepreparations,thepacksize(singleandmulti-dosepacks)hasnotbeen 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) AmendmentOrder, 2016*

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. Typeofformulation(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. Anyotherinformationrelevanttoproductanditsprocessofmanufacturing/ packaging/ distribution.

Theinformationfurnishedaboveiscorrectandtruetothebestofmyknowledgeand belief.

Place: Authorized Signatory:

Date: Name:

Designation:

[16] *SubstitutedvideSO2324(E)dated25-05-2023videDrugs(PriceControl)SecondAmendmentOrder,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	Compositio n	Pack Size	GS T	WPI	Price to retailer per	Maximum Retail	Notified	Batch no. and date

	Purchased Formulation										
	Imported Formulation										

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:

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

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

TABLE-B

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

Constraints, if any:

Authorised Signatory:

Name:

Designation:

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

Place:

Date:

he information furnished above is correct and true to the best of my knowledge

thorised Signatory:

me:

Designation:

Mobile:

Email ID:

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:	

egory as per NLEM:
cement of production / import:
discontinuation:
ontinuation of production / import:
lmportduringthelast5yearsincluding
nelast5yearsincludingcurrentyear(in
v drug, as defined under DPCO, 2013,
ation relevant to discontinuation of

Place:

Date

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, asapproved 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.ofall 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,ifany (incl. of all taxes) (Rs.)**	**Maximum Retail Price (incl.ofall 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-Schedul ed formulations:									
	Own Manufactured Formulations									

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

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

[20] *Insertedvide SO 2899(E) dated 20-07-2021 vide Drugs (Price Control)AmendmentOrder, 2021*