DEPARTMENT OF PHARMACEUTICALS, DRUGS (PRICES CONTROL) ORDER, 2013

REGD. NO. D. "L.-33004/99 Che Gazette of Sftidia 10751 No. 10751 EXTRAORDINARY PART 11—Section 3—Sub-section (ii) PUBLISHED BY AUTHORITY IS, 1935 NEW DELHI, WEDNESDAY, MAY 15, 2013/VAISAKHA 25, 1935 15 2013 1955 (1955 10) 3 gg *UT) 1995 gg 1. 2. 2013 I 1955 (1955 10) e; @ 3iqfä" 1940 (1940 23) (q) iftd" t 1998 2 THE GAZETTE OF INDIA : EXTRAORDINARY [PART IPSEC. 3(Ü)] O (e) "&RGTQ" t t @ "RaqG' ($1) "RÄMR" Ng. (ii) ; (iii) 1940 (1940 23) (51) (Z) "*RZ5R" ; (a) "onuW' (g) "wFfiZ1 (a) Ng "RÄqf71" (UT) 3M' aig Q) 3iAfÄ Aiä (20 "a1•q1N 31i*' G) .31RW' t, 2011 ; -a GINT, . [qq 3(ii)] (IF) t (q) 24 25 3i77f7 (uu) RÄMR" (uE1) R*d' Yr a-Fl ; (ZIV) (2) 1940 (1940 23) a-Fl t (ii) (1) 3@fh I • IO(W) = u)7T) / 4 THE GAZETTE OF INDIA : EXTRAORDINARY [PART IPSEC. 3(ii)] avr 2.' tr(€r) tr(€r) = gq/100), tr(w) = 1 = = 16 (2) (i) 15 (ii) (i) 6. A1) Gai 4 (1) 1 : •tf(w)) /gq*100) }qgt, = q-rå 2. tr(€r) : tf(g9 = 1 = = 16 (ii) 3(ii)] 5 1 : tT(€T) 11. • / ga*100) 2. P(c) -$1 : % = 16 PafiM•Pd ; (iii) t, ati 1 : P(s) : 100)} 2. P(c) : (1+M/100),« M: % = 16 (?) gg 'fi, (3iAfÄ RüU1) 1995 (1) I 6 THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 7. €rq•r- 2012 I 1995 t, 10 10. *UT) 1995 RufVT- (1) *Mä, 1995 2012 t, 30 2013 (2) 1995 t, 1995. 31 qt, 2012 fi-ziaur) 1995, (3) 1995 t, t, 31 2012 t, 30 2013 20 I (4) $rq•ä, 1995 g, t, 31 2012 20 11. A1) 4, 5 6 - 3(ii)] (2) 3iAfÄ 1940 (1940 23) fig wTQ.fi, 12. (niig (2) Aiz 13 I 13. (1) -$1 (Efi (43 a) (3) 16 (2) (3) 3$R, $1 16 (4) 14. - (1) 4 6 7 8 THE GAZETTE OF INDIA : EXTRAORDINARY. [PART IPSEC. 3(ii)] O (5) Rfi•qf7T, 1 (6) (EFT i) 16. Gi - (1) 1 gq€rfh (w tr) 45 a-IR t!) (EF 15 - 2 17. Rg t gg (*ikliFä) ur 18. (g•JNå) 11-7yu•g 3(ii)] (iii) (ii) (iii) $1 2012 Ng I 19. Ätlfvr- frg, -d, 20. (1) (qq3TIRtr) 21. Rq-ill I (2) qti 3T$itr-ll iv $1 3T<fÄ fig 22. 1979 1979 Iqqg 9 10 THE GAZETTE OF INDIA : EXTRAORDINARY [PART IPSEC. 3(ii)] 23. 1979 1995 fiziÄÜT) 1987 1995 24. (1) RIN, (gqm«r) t, (QIT Q7) 3-1fÄm 1 7Tg (3) V 7Tg (4) vrg 25. (3) qgt Rig 26. 27. 28. 1940 (1940 23) @ fig 11-uUz 3(ii)] 29. Rg 11 30. @ fifå e, *ITI I (2) 1973 (1974 2) 100 -a 31. 4, 5 6 $1 32. ati (i) 1976 (1970 39) $1 q-vg, gia 3Rfå (ii) 1970 (1970 39) (#QT 0-äe) 3ßfÄ -a (iii) 1945 fizrq t I FT.«. 31011/17/2012-fikll] [PART [I—SEC. THE GAZETTE OF INDIA : EXTRAORDINARY 12 YT.-T12fiq R.- q.-qåq 3 26), qat, 2011 1.1 3tk Pg., q. Pg., qr., Pg., qr., Pg., qr., Pg., q Pg., 1.2 qr., Pg., 10 / frttéT, 50 / 0.5 an., 1 0.25%, 0.50/0, 0.5% 7.5% 2.5%, 1.2%. 7.5% 1%, 20/0± 1: 200.000 1.3 QI) 3tpqr«tü) qr., Pg., Pg., qr., tg., Pg., 2.1: 0.6 S frd1T. 5 /fhOéT frn0ét 10 / 11-@Trg 3(ii)] 2.4 Pg., pg., Pg., Pg., 2.3 Pg., ur., yr., yr., 2.2 Pg., Pg., Pg., Pg., Pg., Pg., Pg., 50 5 13 325 hl. 50 ht. 200 400 hl. 100 ISO / 125 frt31T. / S frrPä 500 80 Pdöfl., 170 Dlöll. 10 / 10 50 fr@ll./ 50 100 P@lt. 0.5.19@11. 10 500 200 10 1 •PFIT. / 4 taut. 0.5 taut. ./ 5 0.5 PR-ur. 100 tF11. 22.75 / 5 taut., 20 10 taut., 25 taut. 10 5 @tur./ 14 THE GAZETTE OF INDIA : EXTRAORDINARY 4.1: [PART 11 —SEC. 3(ii)] pg., Pg., Pg., pg., Pg., Pg., pg., Pg., Pg., Pg., Pg., yr., Pg., qr., pg., 01m: 6 - 6.1 4.2: ft-au 1 taut./ 100 *.11 500 Prut. 10 Paur./ 250 1031311. 50 hr./ 0.1 30 åöll./ 250 fr@1T./ 0.4 &JIT./ 25 tRét 200 frut./ •Pat-ur. 200 100 frrPét 5 Drut. / 500 [hr. / Pdd&l 30 hr., 60 ht. 200 hr./ 20 *./S 50 100 friQ1. 25 fr@fl./ 50 10nu./ 200 Pdö1T., 500 zoo PFIr./s 100. Paur./ 11-ayg 3(ii)] 6.1.1 Pg., pg., Pg., 6.1.3 qr.jetg•., 6.1.2 Pg., 6.2 6;2.1 qt., Pg., ta., Pg., pg., qr., pg., 6.2.2 Pg., ur., Pg., pg., Vl.j,,-tg., q qt., Itg., */gYQ« *frt .3F:q 400 Pawn. 200 5 4.5 JIT. 750 taut./5 50 kt. 600 125 500 frail. 250 250 {hr., 500 Prut. 125 soo frtur. 6 etzu,12 125 fht.,250 PFII. sob 250 PFII.,I JIT. 250 1 JIT. 125 / 5 250 PFII., 500 250 500 250 fr@ll. 125 fr@ll./ 5 625 taut. • 228.5 fr@1T./5 600 1.2 JIZ. 100, 200 PFII. 250 fr@1T. / 2 100, 250,500 100 SOO fr@1T. aoc PRö1T./100 250 PFIT., 500 taut. 80 + 400 %r., 160 ± 800 ?FJII. 40 +200 /. s 100 •PFIT. 125 S 250 soo Paur. 10 40 200 soo tF11./100 16 THE GAZETTE OF INDIA : EXTRAORDINARY Pg., 6.2.3 rr., Pg., 6.2.4 qr., Pg., 6.3 Pg., Pg., qt., Pg., 6.4 6.4.1 6.4.2 Pg., Pg., Pg., [PART IPSEC. 3(ii)] 100 *./5 100 soo taut. 500 ur. 50 frd1T. 50 frQ1.,100 150 Paur.,300 PFIT. 200 PFIT.,400 Paul., 600 tRØIL., 806 fr@1T. 50 Paut.,100 &JII., 300 100 P'åØ11./5 100 frur.,200 50 / 5 500 1000 PFII. so 150 300 Pdölt., 450 taut. 100 / 5 0.75 JIT., 1 JIT. SO 100 frö11.,200 2% 50 fr@ll., 100 PRJI[., 150 frcJ1[., 200 125 ft-ur., 250 h. soo, ooo 100, ooo 3 200 Paut., 400 250 tnn., soo 400 / 5 250 400 150 taut.+. 200 + 30 than. 150 300 15 30 40 100 fr@1T., 300 Pg., Pg., Pg., tce., Pg., Pg., fiftiöäiti•• 6.5 6.5. T !1., Pg., 6.5.2 tg., Pg., 6.5.3 6.5.3.1 Pg., qr., tz., Pg., Pg., Pg., qt., Pg., q Pg., 6.5.4 4. 17 .30' PFIt. '•.+ 150 300 150 200 tRur. 2005k•.,- 600 fhl. 200 50 / 5 200 tRö1T., 400 250 &JIT. 100 PFII., 400 fr@1T./ 5 206 PFIt. • soo 200 Pdöll., 400 taut. 500 56 200 taut. 100 PFIT.7. so zhl. 150 fr@1T. 40 50 ?FII../ 2.5 PFII., 7.5 taut. 25+71. 300 zoa-ur. 300 taut. / 500 25 tFIT. 150, 300 taut. 250 18 THÉ .GAiETTÉ . pg., YI., Pg., Pg., qr., Pg., 7.2:i 8.1: 8.2: 'l.l+SEC. 3(ii)] 80 ±

400 160± Soo 40 +200 / 5 20b tFIT. 300 — fhl. soo•+ölt. 10 PFIT., -40 50 taut. 29 fhl., SO PFIT., 100 100 tFIT./ 0.5 taut. • 3 15 tFIT. 10 50 SO Paut., 200 tRJIT. 500 taut. 100 PFIT./ 1000 so 100 tFIT. 10 taut., 50 100 100 Paut./ S 250 taut. 250 / 5 200 11-auz 3(ii):] 19 46 8.3: pg., 8. Pg., 5000 2 S fr1ö1T. 50 frtöl[. 100 / frTPét 2.5 SO fr@lt./ 10 30 fr@tT./ 5 50+1711. 10 fr@1T. 1 frfiur./ 150 Pd71T., 4SO fr@ll. soo 20 1 ur./2 200 50 400 5 tRd1T. 20 frdll., 25 PFIT. 60 10 tFIT., 20 fr@1T. 10 4 Puul., 8 2 tRd1T./ fr1téT 2 frtau./5 frT?ét - 100 1.25 tna., 2.5 taut. 100 Paut.+. 10 250 25 100 25 2 20 fi.: 10 - tg., -qt.-; Pg., tä., 10.2: •tg.ö•q tg.,-q 1-1 - .40 qt., Pg., .70 THE GAZEITE OF INDiA.: - .mz•-r•._— _ aar 11.1-•. Pg., Pg., Pg., Pg., tg., 11.2. 1 60 25- 1 frtuT.2 so taut. IO 1000 3Tü/ SOOO 3 / 10 10 40 frd1T., 60 fr@1T. 60/0' 5%, 20 % : 12 - 12.1: qt., Pg., -tg.-;-q tg., q qt., Pg., q Pg., Pg., .1- 12 2: 12.3: -"51iäüt 75 PFIT., 100+31T., 350 30 frur.,. 66 20-taut= 25 Paur.,so taut. ZOFII. tFIT'./ 30 ?Rö1T. 10 taur./ 250 PFIT. 100 P471T./ 40 80 tF11. 2.5 PFIT./ 2.5 fr@1T., SO tFIT., •100' tF11. 2.5 1.25 frn0ä 254 Pöll., 50 250 fröåi. 5 PFIT.,IO Paul. 10 10 tFIT.,20 Pfilt. 50 taur./ '5 12.5, 25 PFII. 22 THE GAZETTE OF INDIA : EXTRAORDINARY 12.4: Pg., Pg., 12.5: qr.,AItg., W. 12.6 Pg., : 13 - 13.1: 13.2: tg., [PART 0.2S 0.25 frTPéT 40- 75 100 350 1000 / friar 5000 ./k 7S0,oöo IS, 00, ooo •soo, ooo Pg., qt., Pg., rt., Pg., q_ 13.3: td:, !1., Pg., q. 13.5: 5 frTö1T. aar 13.4: 20/0 0.5% 0.5% soo / 711. 50k 1% 0.05% [m 11--@TC ur•., Ltg., 14.1. e Pg., Pg., a Pg., Pg., q Pg., Pg., Pg., Pg., tg., Pg., Pg., Pg., Pg., pg., Atg., Pg., Pg., qt.,• Pg., 13.6% 14.2: 9, 14 - 15 15.1.• EüäPaq+ 70: 23 0.1-2% 25 % 5% 1% 40/0 1% 100% gq/aqu 250% 590 PFIT. 60% gq/Eft 280 frtölt. / JIT. 100—250 500—600 fr@ll. / 70% -420 PFIT. / sq/at -292 Pnr./ Yä), • frFZT./ 0.5%, 1% 6% (PART (I—SEC. THE ; 24. (40 •.15.2% 30 % gq/gq Pg., Pg., q tg., Pg., Pg., Pg., Pg., gi.,.: tg.t yr., tg., Pg., 17 - 17.1: : 16 Yr., Pg., Pg., Pg., 17.2: (31W.qq. lid) 34 100 [311t.qt. 20/0 10 fr@ll./ frn0ét 40 25 Prur., SO fr@ll. 10%, 25 fr@1T. 10 PFIT., 20 tFIT., 40 25 PFIT. / 40 20 ft-ur. 10 10 10 taut. S metr./ S. 25 taut. •/ 4 fratr., 8 3(ii)] ; 5.DeuW tg., Pg., Pg., Pg., 17.6: am: 18 • 18.1: Pg., Pg., 17.3: 17.4: 17.5: ö1h0üi 17.6.2 18.2: 18.3: 25 400 fr@ll. 10 10 frur./ 20 fron./ 13.5 LIFT. 2.6 Jlt./ ett. 1.5 Jl[./ 2.9 JIT./em 2001*, 500 100Q Buh, qra-gz (31TåÅt. Vd) 20 /5 0.5 4 fhT./ 100 / 40 ?FIT./ 5 taut., 10 frazt., 20 fröll. 40 25 It qqg 60/13 - 26 THE GAZETTE OF iNDlA : EXTRAORDINARY 3 30: 70 Pg., Pg., Pg., Pg., Pg., Pg., Pg., Pg., Pg., 18.5.2 Pg., 18.3.3: 18.4: 18.5: 18.6 18.7 [PART II—SEC. 3(ii)] 0.03 ± 0.15 trut. 0.035 fran.± 1.0. fhfl. 3 0.01 @tur. 0.05 frtur. 2.5 PFIT., 5 frölt. 40 | 40 / 500 40 fhiöt 100 50 PFIT., 100 fr@ll. 10 frtut. 5 fr@1T. 11-aug 3(ii)] Üdt-st F) Q?mt.å?. ét.qt.eq. 20 - Pg., 18.8 rr., Pg., Pg., Pg., am: 19 19.1: 19.2: Pg., qr., Pg., Ill., Pg., pg., qt.,• Pg., 19.3: 19.3.1.• yr., Pg., IIT., Pg., 19.3.2: Pg., Pg., Pg., Pg., tg., 27 10 50 '100 300 10 250 500 10,000 150 10 / frrPéT 15 frt31T., 0.5 fr@lt./ 60 1 @1ö1T./ 50 fr@ll./ 28 21.1. Pg., 21.3 21.5. Pg., 21.6 THE GAZETTE OF INDIA : EXTRAORDINARY [PART 11—SEC. 3(ii)] Tt., Pg., q qr., Pg., Pg., Pg., tg., 21 - 21.2. ±r/dtag 21.4.• Pg., Pg., tg., 22 - 22.1: 2 PFIt./ 0.4%, 0.3% 0.3% 1% 0.6% 10%, 0.1% 0.5% 250 0.25%, 0.50/0 2%, 40/0 0.25%, 0.5%, 1% 2% 5% 0.125 fr@1T. 3(ii)] pg., Pg., 8.1171: 23 - 24.1 : pg., 24.2: 24.2.1: ur., Pg., q gr., Pg., 24.2.2: 22.2: 24 - 0.2 fr@1T./ 200 PFIT. 10 frrPéT 100 2.5 Prut. 0.5 frtut./ 10 25 50 prur. 100 25 frur./5 fr1téT 25 5 PFII../ 25 frur. 20 25 75 300 PFIT. 200 taut., 500 [PART II—SEC. THE GAZETTE OF INDIA : EXTRAORDINARY 30 Pg., 24.3: qt., Pg., q ur., Pg., q rr., Pg., : 25 - Pg., Pg., YI., •Pg., ur., Pg., Pg., Pg., q qr., Pg., Pg., Pa., 25.1: 26 $üerat 25.2: 26.1: taasz 26.2: 26.3: 0.25 0.5 2 PFII., S tRö11. 20 50 100 frtur., 200 fr@1T. 400 2 4 frtur. 2 t4ur./5 100 / 20 10 frruv. 15 fr@1T./5 30 5% 10%, 15% 50/0+ 0.9% 0.9% 11.2% 2 5 10 11-arg Q3t am: 27 - Pg., Pg., Pg., Pg., Pg., Pg., Pg., pg., ölif&-ett 3-q•qtr-2 Rq-l 31 100 fr@1T., 500 250 fhl[., • 500 fhl. 50 •PFII. 25 5 fhl. 100 fhl. 5000 50000 100000 soooo 0.25 1 f)öll. 100 frrut./ 10 1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 11. 12. 26) (ft : 31TR) : (low/åoow/1Ä.€f.'/ / 10Ä.äl. /5UTq/10UM mf<): fä-g : 32 1. 2. m*io THE GAZETTE OF INDIA : EXTRAORDINARY Rq-2 16 (31fÄ•a) [PART 11 —SEC. 3(ii)] Il•uz 3(ii)] RII-3 (QNT 21 (1) üü) 1. 2. 3. (qqg 60113- 5 34 90 THE GAZETTE OF INDIA : EXTRAORDINARY (1) : argo qg I [PART II—SEC. 3(ii)] 1. 2. 3. 4. 5. 6. 7. 8. 9. 10. 11. 12. 13. 14. 15. RI-4 ftTqf [tRT 2(2) (ft q•lg) : qq-g-a-{q-q . 2013 3(ii)] 35 2(x) ä] 1. 2. ($.8XTl?d) (VO) [PART 11—Spc. 3(ii)] THE GAZETTE OF INDIA : EXTRAORDINARY 36 MINISTRY OF CHEMICALS AND FERTILIZERS (Department of Pharmaceuticals) ORDER New Delhi, the 15th May, 2013 —In exercise of the powers conferred by section 3 of the Essential Commodities Act, 1955, (10 of S.O. 1221(E). 1955), and supersession of the Drug (Prices Control) Order, 1995, except as respect to things done or omitted to be done before such supersession, the Central Government hereby makes the following Order, namely:- — (1) This Order may be called the Drugs (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) "active pharmaceutical ingredients or bulk drug" means any

pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, conforming to standards specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and which is Lfed as such or as an ingredient in any formulation; (c) "brand" means a name, term, design, symbol, trademark or any other feature that identifies one seller's drug as distinct from those of other sellers; (d) "ceiling price" means a price fixed by the Government for Scheduled formulations in accordance with the provisions of this Order; (e) "dealer" means a person carrying on the business of purchase or sale of drugs, whether as wholesaler or retailer and includes his agent; (f) "distributor" means a person engaged in the work of distribution of drugs and includes an agent or a stockist for stocking drugs for sale to a dealer; (g) "existing manufactured' means manufacturer existing on the date of publication of this order in the Official Gazette. (h) "Form" means a form specified in the Second Schedule; (i) "formulation" means a medicine processed out of or containing one or more drugs with or without use of any pharmaceutical aids, for internal or external use for or.in the diagnosis, treatment, mitigation or prevention of disease and, but shall not include any medicine included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines; (ii) any medicine included in the Homeopathic system of medicine; and (iii) any substance to which the provisions of the.Drugs and Cosmetics Act, .1940 (23 of 1940) do not apply; (j) "generic version of a medicine'! means a formulation sold in pharmacopeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name; (k) "Government" means the Central Government; (l) "import" with its grammatical variations and cognate expressions means bringing a drug into lhdia from a place outside India for its sale; (m) "local taxes" means any tax or levy (except excise or import duty included in retail price) paid or payable to the Government or the State Government or any local body under any law for the time being in force by the manufacturer or his agent or dealer; (n) "manufacturer" for the purpose- of this Order means any person who manufactures, imports and markets drugs for distribution or sale in the country; (o) "market share" means the ratio of domestic sales value (on the basis of moving annual turnover) of a brand or a generic version of a medicine and the sum of total domestic sales value of the all brands aod generic versions of that medicine sold in the domestic market having same strength and dosage form; (p) "margin to retailer" for the purposes of this Order shall meari a percentage of price td retailer; (q) "market based data" means the data of sales related to a drug collected or obtained by the Government as deemed fit, from time to time; 3(ii)] 37 (r) "maximum retail price" means the ceiling price or the retail price plus local taxes and duties as applicable, at which the drug shall be sold to the ultimate consumer and where such price is mentioned on the pack; (s) "moving annual turnover" in a pärticular month means cumulative sales.value for twelve months in domestic market, where the sales value of that month is added and the corresponding sales of the same month in the previous year are subtracted; (t) "National List of Essential Medicines" means National List of Essential Medicines, 2011 published by the Ministry of Health and Family Welfare as updated or revised from time to time and included in the first schedule of this order by the Government through a notification in the Official Gazette; (u) "new drug ' for the purposes of this Order shall mean a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the National List of Essential Medicines by combining the dhug with another drug either listed or not listed in the National List .of Essential Medicines or a formulation launched by changing the strength or dosages or both of the same drug of specified dosages and strengths as listed in the National List of Essential Medicines. (v) "non-scheduled formulation" means a formulation, thé dosage and strengths of which are not specified in the First Schedule;- (w) "pharmacoeconomics" means a scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another; (x) "price list" means a price list referred to in paragraphs 24 and 25 and includes a supplementary price list; (y) "price to retailed' means the price of a drug at which it is sold to a retailer which includes duties and does not include local taxes; (z) "retail price" means the price fixed by the Government for a new drug under paragraph 5 ; (za) "retailer" means a dealer carrying on the retail business of sale of drugs to customers; (zb) "scheduled formulation" means any formulation, included in the First Schedule whether referred to by generic versions or brand name; (zc) "schedule" means a Schedule appended to this Order; (zd) "wholesaler" means a dealer or his agent or a stockist engaged in the sale of drugs to a retailer, hospital, dispensary, medical, educational or research institution or any other agency; (ze) "wholesale price Index" means annual wholesale price index of all commodities as announced' by the Department of Industrial Policy and Promotion, Government of India, from time to time. (2) All other words and expressions used herein and

not defined but defined in the Act or the Drugs and Cosmetics Act, 1940 (23 of 1940) shall have the meanings respectively assigned to them in the said Acts. .3. Directions to manufacturers of active pharmaceutical ingredients or bulk drugs or formulations.— The Government may, - (i) with a view to achieve adequate availability and to regulate the distribution of drugs, in case of emergency or in circumstances of urgency or in case of non-commercial use in public interest, direct any manufacturer of any active pharmaceutical ingredient or bulk drug or formulation to increase the production and to sell such active pharmaceutical ingredient or bulk drug to such other manufacturer(s) of formulations and to direct formulators to sell the formulations to institutions, hospitals or any agency as the case may be; (ii) for the purpose of giving any direction under sub-paragraph (i), call for such information from manufacturers of active pharmaceutical ingredients or bulk drugs or formulations, as it may consider necessary and such manufacturer shall furnish the required information within such time the Government may fix

4. Calculatio•n of ceiling price of a scheduled formulation.— (1) The ceiling price of a scheduled formulation of specified strengths and dosages as specified under the first schedule shall be calculated as under: Step 1. 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 alt the brands and generic versions of the medicine having market share more than or equal to one percent of the total market turnover on the basis of moving annual turnover of that medicine) / (Total number of such brands and generic versions of the medicine having market share more than or equal to one percent of total market turnover on the basis of moving annual turnover for that medicine.) Step 2. 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 38 THE GAZETTE OF INDIA : EXTRAORDINARY [PART M—SEC. 3(ii)] P(s) Average Price to Retailer for the same strength and dosage of the medicine as calculated in stepl above.. M = % Margin to retailer and its value =16 (2) The ceiling price calculated as per sub-paragraph (1) and notified by the Government shall be applicable to scheduled imported formulations also

5. Calculation of retail price of a new drug for existing.manufacturers of scheduled formulations.— (1) The retail price of the new drug available in domestic market shall be calculated as provided in sub-paragraph (1) of paragraph 4. (2) (i) the price to retailer of a new drug, not available in domestic market, shall be fixed by the Government on the principles of "Pharmacoeconomics" of the new drug, on the recommendation of a Standing Committee of Experts formed under paragraph 15. (ii) the retail price of such new drug shall be fixed by adding sixteen percent margin to retailer on the price to retailer as fixed in item (i): 6. Ceiling price of a scheduled formulation in case of no reduction in price due to absence of competition.— (1) where the average price-to retailer of a scheduled formulation, arrived at as per the formula specified in sub-paragraph (1) of paragraph 4, has the effect of,- (a) no reduction in average price to retailer with respect to the prices to retailer of the schedule formulation; and (b) there are less than five manufacturers for that formulation having one percent or more market share, the ceiling price shali be calculated as under:- in the event of other strengths or dosage forms of the same scheduled formulation is available in the list of scheduled formulation, the average price to retailer shall be calculated as under: Stepl: First the Average Price to Retailer ofasuch scheduled formulation i.e. P(s) shall be calculated as under: P(s) = Where, P = Price to Retailer of highest priced scheduled formulation under consideration. Pl = % reduction in Average Price to Retailer of other strengths and dosage forms (calculated as in stepl of sub-paragraph (1) of paragraph 4) in the list of schedule formulations w.r.t. the highest priced formulation taken for calculating the average price to retailer of such strengths and dosage forms. N = Number of such other strengths or dosage forms or both in the list of schedule formulations Step 2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under: P(c) = where Pt) = Average Price to Retailer of the scheduled formulation as calculated in step 1 hereinabove and M = % Margin to retailer and its value-16 (ii) in the event of other strengths or dosage forms of the scheduled formulation is not available in the schedule but there are other scheduled formulations in same sub-therapeutic category as that of the scheduled formulation, then the Ceiling Price shall be calculated as under: Stepl: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under: P(s) = Where, - Price of highest priced formulation taken for calculating the average price to retailer of the formulation under consideration.. Pi = % reduction in Average Price to Retailer of other schedule formulations (calculated as in stepl of sub-paragraph (1) of paragraph 4) in same sub-therapeutic category

as that of the scheduled formulation under consideration w.r.t the highest priced formulation taken for calculating the average price to retailer. N = .Number of such other schedule formulations in same sub-therapeutic category as that of the scheduled formulation under consideration. o 3(ii)] Step 2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under: P(c) = where P(s) = Average Price to Retailer of the scheduled formu!ation as calculated in stepl above and M = % Margin to retailer and its value=16 Explanation.- where the scheduled formulation under consideration is coming under more than one sub- therapeutic category, the Average Price to Retailer of the scheduled formulation shall be calculated after taking into consideration the percentage reduction in Average Price to Retailer of other schedule formulations under all such sub-therapeutic categories and the lowest average price to retailer shall be taken for calculating the ceiling•price of the scheduled formulation under consideration; (iii) in case the other strengths or dosage forms of the scheduled formulation are not available in the schedule and there is no sub therapeutic category of the scheduled under consideration, the ceiling price shall be calculated as under: Stepl: First the Average Price to Retailer of such scheduled formulation i.e. P(s) shall be calculated as under: P(s) = Where, P - Price of highest priced formulation taken for calculating the average price to retailer of the formulation under consideration. Pl = % reduction in Average Price to Retailer of other schedule formulations (calculated as in stepl sub-paragraph of •paragraph 4) in same therapeutic category as that of the scheduled formulation under consideration w.r.t the highest priced formulation taken for calculating the average price to retailer. N = Number of such other schedule formulations in same therapeutic category as that of the scheduled formulation under consideration. .Step2. Thereafter, the ceiling price of the scheduled formulation i.e. P(c) shall be calculated as under: P(c) = where P(s) = Average Price to Retailer of the scheduled formulation as calculated in stepl above and M = % Margin to retailer and Explanation.- where the scheduled formulation under consideration is coming under more than one therapeutic category, the Average Price to Retailer of'the scheduled formulation shall be calculated after taking into consideration the percentage reduction in Average Prite to Retailer of other. schedule formulations under all such therapeutic categories and the lowest average price to retailer shall be taken for calculating the ceiling price of the scheduled formulation under consideration. (2) Notwithstanding anything contained in this paragraph, where the price has been fixed and notified by the Government under the Drugs (Prices Control)' Order, 1995 the provisions ofsub-paragraph (1) shall not apply

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

8. Maximum retail price.— (1) The maximum retail price of scheduled formulation's shall be fixed by the manufacturers on the basis of ceiling price notified by the Government plus local taxes wherever applicable, as under: Maximum Retail Price = Ceiling price + Local Taxes as applicable (2) The maximum retail price of a new drug shall be fixed by the manufacturers on the basis of retail price determined by the Government plus local taxes wherever applicable, as under: Maximum Retail Price = Retail Price + Local Taxes as applicable 9. Reference data and source of market based data.— (1) Initially, the source of market based data shall be the data available with the pharmaceuticals market data specializing company — IMS Health (IMS) and if the Government deems necessary, it may validate such d?ta by appropriate survey or evaluation. (2) The Gövernment may in the due course of time come out with other appropriate mechanism of collecting or obtaining the market based data related to drugs and the decision of Government with respect to collection or obtaining of data shall be final. (3) The market based data, for fixing the ceiling price of scheduled formulations for the first time after the notification of this order, shall be the data of May, 2012. THE GAZETTE OF INDIA : EXTRAORDINARY [PART IPSEC. (4) The mar.ket based data for fixing the retatt price of new drugs available in the market, shall be the data available for O the month ending immediately before six months of receipt of application for fixing the price of the new drug. (5) The market based data for fixing the ceiling price of a scheduled formulation due to a revision in the first schedule shall be the data available for the month ending immediately before six month of notification of revision in the first schedule. (6) Notwithstanding anything contained in this order, the reference date for the formulations which are-part of the Drugs (Prices Control) Order, 1995 shall be as per the provisions Of paragraph 10 of this Order

10. Pricing of the formulations covered under Drugs (Prices Control) Order, 1995.— (1) The prices of scheduled formulations, which are also specifiédin the First Schedule to the Drugs (Prices Control)

Order, 1995, fixed and notified under the provisions of the said order, up to 31 st May, 2012, shall remain effective for further one year i;e. up to 30 May, 2013 and the manufacturers may revise the prices of such scheduled formulations as per the annual wholesale price index for the previous calendar year announced by Department of Industrial Promotion and Policy and thereafter the formula as in sub- paragraph (1) of paragraph 4 of this Order shall. be applied for fixing the ceiling pr.ices of such formulations. (2) The prices of scheduled formulations, which are also specified in the First Schedule to the Drugs (Prices Control) Order, 1995, fixed and notified under the provisions of Drugs (Prices Control) Order,1995 after 3ff May, 2012, shall remain effective for one year from the date of notification of such prices under Drugs (Prices Control) Order, 1995 and immediately thereafter the manufacturers may. revise the prices as per the annual wholesale price index for the previous calendar year announced by Department of.lndustrial Promotion and Policy and on the April of sücceeding financial year, the formula as in sub-paragraph (1) of paragraph 4 of this Order shali be applied for fixing the ceiling prices of such schedule formulations. (3) The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 butnot specified in the First Schedule of this order, fixed and notified under the provisions of the said order, up to 315t May, 2012, shall remain effective for further one year i.e. up to the 30thMaV2013 and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Order. (4) The prices of scheduled formulations, which are specified in the Drugs (Prices Control) Order, 1995 but not specified in the First Schedule of this order, fixed and notified under the provisions of the said order, after 31st May, 2012, shall remain effective for one year from the date of notification of such prices and thereafter prices of such formulations shall be regulated as in case of other non-scheduled formulations as stated in paragraph 20 of this Ordér

11. Ceiling price or retail price of a pack.— (1) The average price to retailer calculated as per the provisions in paragraphs 4,'5 and 6 shall be on the dosage basis, (per. tablet, per capsule or injection in volume as listed in first schedule) and the ceiling price or retail price of a pack shall be. reached by multiplying the same •with the number or quantity in the pack as the case may be. (2) In the event of the unit of the dosage for a scheduled formulation not available in the first schedule, the lowest pack size for that category of medicine, as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940)- arid the rules thereunder, •shall be taken •as unit dosage for calculating the Feiling price or retail• price és the case may be, för that scheduled formulation•and this shall be applicable while calculating the per unit price of-even non-scheduled medicines for arriving at the retail price in case of paragraph 5

12. Price of formulationS (branded or generic version) listed in the National List of Essential Medicines, launched by a manufacturer.— (1) A manufacturer, launching a scheduled formulation, shall be free to fix the price of the scheduled formulation equal to or below_the ceiling price fixed for that schedule formulation by the Government. (2).Where an existing brand is' re-launched by another manufacturer the provisions of paragraph 13 shåll be applicable. 13. ' Price of Scheduled formulations for the existing manufacturers.— (1) All the existing rfianufactures of scheduled formulation', 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 Che prices of all such formulations downward not exceeding the ceiling price (plus local taxes •as applicable): Provided; that in case of scheduled formulations produced or available in the market before the date of notification of ceiling price, the manufacturers shall ensure within a period of forty-five days-of the date of such notification that the maximum retail price of such scheduled formulation does not exceed the ceiling price (plus local taxes ås applicable). (2) All the existing manufactures of scheduled formulations, selling the branded or generic or both.the versions of scheduled formulations at a price lower than the ceiling price (plus local taxes as applicable) so fixed and notified by the Government shall maintain their existing maximum retail price. (3) Annual increase in maximum retail -price may be Carried out as per the increase in the wholesale price index with respect to previous year as per the provision of sub-paragraphs (2) and (3) of paragraph 16. 11-arrg 3(ii)] 41 Provided that in case of decline in wholesale price index, a corresponding reduction in the prices shall be made as per the provision of sub-paraéraph (4) of paragraph 16

14. Fixation of ceiling price of scheduled formulations.— (1) The Government shall fix and notify the ceiling prices of the scheduled formulations in accordance with the provisions of the paragraphs 4 and 6, as the case may be, and no manufacturer shall sell the scheduled formulations at a price higher than the

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

15. Fixation of retail price of a new drug for existing manufacturers of scheduled formulations.— (1) The Government shall foim a Standing Committee of such Experts, as it may deem fit, within sixty days of notification of this order with a view to recommend the retail prices of new drugs on the principles of "Pharmacoeconomics". (2) Where an existing manufacturer of a drug with dosages and strengths as specified in National List of Essential Medicines launches a new drug, such existing manufacturers shall apply for prior price approval of such new drug from the Government in

Form-I specified under Schedule-ll of this Order. (3) On receipt of the application under sub-paragraph (2), in the event of the new drug available in domestic market, the Government shall fix the retail price of the new drug in accordance with the provision of sub-paragraph (1) of paragraph 5 and in the event of the new drug not available in domestic market, the Government shall.forward the same to the Standing Committee of Experts who shall examine the application on the principles of "Pharmacoeconomics" and make recommendations of retail price of the new drug to the Government within thirty days of the receipt of application. (4) The Government shall, on receipt of recommendation ünder sub-paragraph (3), within thirty days, fix the retail price of such new drug and such price shall be applicable to such applicant of such new drug.. (5) Where existing manufacturer of scheduled formulation fails to apply for prior approval of the price of the new drug in Form-I, such manufacturer shall be liable to deposit the overcharged amount over and above such price fixed and notified by the Government, if any, along with interest thereon from the date pf launch of the new drug, in addition to the penalty. (6) No existing manufacturer of a scheduled formulation shall sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government for such new drug and in case such a .manufacturer is found to sell such a new drug at a price higher than the retail price (plus local taxes as applicable) fixed by the Government, such manufacturer of the new drug shall be liable to deposit the overcharged amount along with interest fromthe date of overcharge, in addition to the penalty

16. Revision of ceiling price of scheduled formulations.— (1) The Government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding calendar. year on or before ISt April of every year and notify the same on the ISt day ofApril every year. (2) The manufacturers may increase the maximum retail pricelMRP) of scheduled formulations once in a year, in the month of April, on the basis of the wholesale price index with respect to previous calendar year and no prior approval of the Government in this •regard shall be required. (3) Information about the revision, if carried out, shall be forwarded to the Government in either electronic or physical

form in Form-ll within a period of fifteen days of such revision and non-submission of information under this sub- paragraph shall be construed as non revision of•maximum retail price (MRP) and the concerned manufacturer shall be liable .to deposit the amount charged over and above the pre-revised maximum retail piice (MRP), alongwith interest thereon from the date of overcharging. (4) In case of decline in wholesale price inde*, there shall be a corresponding reduction in the maximum retail price and in case of scheduled formulations produced or available in the market before the date of notification of revised ceiling price, the manufacturers shall ensure within a period of forty-five daF of ihe date of such notifiqtjon that the maximum retail price (MRP) of such scheduled formulation does not.exceed the revised ceilihg price (plus local taxes as applicable) and information about the revision shall be sent to the Government in either electronic or in Form-ll within a period of fifteen days of such revision. (5) Non-submission of information under the sub-paragraph (4) shall be construed as non reduction in maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the maximum retail price revised based on decline in wholesale price. index, alongwith interest thereon as overcharged åmount from the date of overcharging. 1998<13-6 THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(ii)] 17. Amendment of the list of scheduled formulation.— (1) A decision to amend the first schedule, clearly stating the reasons thereof, shall be taken by the Government within sixty days of receipt of communication from the Ministry of Health and Family Welfare and the amendment(s) or revision, if required, in the first schedule shall be notified and thereafter, the ceiling price(s) for the medicine(s) added in the first schedule shall be fixed as per the provisions of this order within a period of sixty days from the date of the notification. (2) The medicines omitted from the first schedule shall fall under the category of non-scheduled formulations

18. Revision of ceiling price on the basis of moving annual turnover (MAT).— The revision of ceiling prices on the basis of moving annual turnover value shall be carried out,- (i) as and when the National List of Essential Medicines. is revised by the Ministry of Health and Family Welfare or five years from the date of fixing the ceiling price under this Order whichever is earlier; (ii) when the number of manufacturers of a scheduled formulation, having price of a scheduled formulation more than or equal to seventy five percent of the ceiling price fixed and notified by the Government, has decreased by twenty five percent or more than the number of manufacturers as existing on the reference date; (iii) when the number of manufacturers of a scheduled formulation, having prices of their scheduled formulation equal to or lower than twenty five percent of the ceiling price fixed by the Government, has increased by twenty five percent or more than the number of manufacturers as existing on the reference date. Explanation.- For the purpose of items (ii) and (iii) the "reference date" shall be for first revision of ceiling price May, 2012 and for second or subsequent revision the date of previous revision of the ceiling price

19. Fixation of ceiling price of a drug under certain circumstances.- Notwithstanding anything contained in this order, the Government may, in case of extraordinary 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 prige of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year

20. Monitoring the prices of non-scheduled formulations.— (1) The Government shall monitor the maximum retail prices (MRP) of all the drugs, includifig the non-scheduled formulation: and ensure that no manufacturer increases the maximum retail price of a drug more than ten percent of maximum retail price during preceding twelve months and where the increase is beyond ten percent of maximum retail price, it shall reduce the same to the level of ten percent of maximum retail price for next twelve months. (2) The manufacturer shall be liable to deposit the overcharged amount along with interest thereon from the date of increase inprice in addition to the penalty

21. Monitoring the availability of scheduled formulations.— (1) The Government shall monitor the production and availability of scheduled .formulations and the active pharmaceutical ingredients contained in the- scheduled formulation and the manufacturer of scheduled formulations and the active pharmaceutical ingredients contained in the scheduled formulation shall furnish the information as stated in

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

22. Recovery of dues accrued under the Drugs (Prices Control) Order, 1919 and to deposit the same into the Drugs Prices Equalisation (1) Notwithstanding anything contained in this order, the Government may by notice, require a manufacturer, importer or distributor as the case may be, to deposit the amount which has accrued under the provisions of the Drugs (Prices Control) Order, 1979 on or before the commencement of this order, into the Drugs Prices Équalisation Account and the manufacturer, importer or distributor, as the case may be, shall deposit the said amount into the said account within such time as the Government may specify in the said notice.(2) The existing amount, if any, in the Drugs Prices Equalisation Account on or before the date of commencement of this Order, and the amount deposited under sub-paragraph (1) shall be utilised for;- (a) paying to the manufacturer, importer or distributor, as the case may be, the shortfall between his retention price and the common selling price or, as the case may be, the pooled price for the purpose of increasing the production, or securing the equitable distribution and availability at fair prices, of drugs; (b} meeting the expenses incurred by the Government in discharging the functions under this paragraph; and 11-uoz 43 (c) promoting higher education and research in Pharmaceutical Sciences and Technology and for the purposes incidental thereto

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

24. Carrying into effect the price fixed or revised by the Government, its display and proof thereof.— (1) For all the scheduled formulations having maximum retail price (MRP) higher than ceiling price (plus local taxes as applicable), the manufactures shall revise the maximum retail price (MRP) not exceeding the ceiling p?ice (plus local taxes as applicable): Provided that in case of scheduled formulations produced or available in the market before the date of notificatiön of ceiling price, the manufacturers shall ensure within a period of forty-five days of the date of the notification that the maximum retail price of such scheduled formulation does not exceed the ceiling price (plus local taxes as applicable). (2) Every manufacturer of a schedule formulation intended for sale shall display in indelible print mark, on the label of container of the formulation and the minimum pack thereof offered for retail sale, the maximum retail price of that formulation based on the ceiling price notified _in the Official Gazette or ordered by the Government in this behalf with the words "Maximum Retail Price" preceding it and the words 'inclusive of all taxes' succeeding it. (3) Every manufacturer shall issue a price list and supplementary price list, if required, in

Form V to the dealers, State Drugs Controllers and the Government indicating reference to such price fixation or revision as covered by the order or Gazette notification issued by the Government, from time to time. (4) Every retailer and dealer shall display the price list- and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same

25. Display of prices of non-scheduled formulations and price list thereof.— (1) Every manufacturer of a non-Scheduled formulation intended for sale shall display in indelible print mark, on the label of container of the formulation and the minimum pack thereof offered for retail sale, the maximum retail price of that formulation with the words "Maximum Retail Price" preceding it and the words 'inclusive of all taxes' succeeding it. (2) Every manufacturer shall issue a price list and supplementary price list, if required, of the non-Scheduled formulations in

Form-V to the dealers, State Drugs Controllers and the Government indicating changes, from ti+ne to (3) Every retailer and dealer shall display the price list and the sppplementary price list, if any, as furnished by the manufacturer or importer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same

26. Control of sale prices of formulations.— No person shall sell •any formulation to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whithever is 27. Sale of split quantities of formulations.— No dealer shall sell loose quantity of any formulation at a price which exceeds the pro-rata price of the formulation

28. Manufacturer, distributor or dealer not to refuse sale of drug.— Subject to the provisions of the Drug and Cosmetics Act, 1940 (23 of 1940) and the.rules made thereunder, - (a) no manufacturer or distributor shall withhold from sale or refuse to sell to a dealer any drug without good and sufficient reasons; (b) no dealer shall withhold from sale or refuse to sell any drug available with him to a customer intending to purchase such drug

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

30. Power of entry, search and seizure,—(1) Any Gazetted Officer of the Central Government or of 9'State Government, as the case may be, authorised by a general or special order by the Central Government or by the State Government, as 44 THE GAZETTE OF INDIA : EXTRAORDINARY [PART IPSEC. 3(ii)l the case may be, in this behalf may, with a view to securing compliance with this Order or to satisfy himself that the provision of.this Order have been complied with- (a) enter and search any place; (b) seize any drug, alongwith the containers, packages or coverings in which the drug is found, in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened, and thereafter take all measures necessary for securing production of the drug, containers, packages or coverings, so seized, in a court of law and for their safe custody pending such production; (c) seize any document, such as, cash memo or credit memo books, books of account and records of purchase and sale of the drugs in respect of which he suspects that any provision of this Order has been, is being, or is about to be contravened. (2) The provisions of Code of Criminal Procedure, 1973 (2 of 1974), relating to search and seizure shall, so far as may be, apply to searches and seizures under this Order

31. Power to review.— Any person aggrieved by any notification issued or order made under paragraphs 4, 5 and 6 of this Order, may apply to the Government for a review of the notification or order within a period of thirfy days of the date of publication of the notification in the Official Gazette or the receipt of the order by him, as the case may be, and the Government may make such order dn the application as it may deem proper: Provided that pending a decision by the Government on the application submitted under the above paragraph, no manufacturer shall sell a scheduled formulation or a new drug, as the case may be, at a price exceeding the ceiling price or retail price, as the case may be, fixed by the Government of which a review has been applied for

32. Non—application of the provisions of this order in certain cases.- The provisions of this order shall not apply to, - (i) a manufacturer producing a new drug patented under the Indian Patent Act, 1970 (39 of 1970) (product patent) and not produced elsewhere, if developed through indigenous Research and DeVelopment, for a period of five years from the date of commencement of its commercial production in the country. (ii) a manufacturer producing a new drug in the country by a new process developed through indigenous Research and Development and patented under the Indian Patent Act, 1970 (39 of 1970) (process patent) for a period of five years from the date of the commencement of its commercial production in the country. (iii) a manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India: Provided that the provision of this paragraph shall apply only when a docUment showing approval of such new drugs from Drugs Controller General (India) is produced before the Government. Explanation.- Notwithstanding anything contained in this Order, for the purpose of this paragraph "new drug" shall have the same meaning as is assigned to under rule 122E of the Drugs and Cosmetics Rules, 1945. [File No. 31011/17/2012-PI-II] SHAMBHU KALLOLIKAR, Jt. secy. SCHEDULE-I (See Paragraphs-2(t),2(zb)) Symbols P, S and Ta earin in NLEM 2011 denote essentialit at Prima , Secondar and Tertiar levels respectively. NATIONAL LIST OF ESSENTIAL MEDICINES 201 1 Medicines Ether Halothane with vaporizer Section: 1 — Anesthesia 1.1 General Anesthetics and Oxygen Category Route of Administration Inhalation Inhalation Strengths 11-aug 3(ii)] Isoflurane Ketamine Hydrochloride Nitrous Oxide Oxygen Thiopentone Sodium Sevoflurane pro Ofol Medicines Bupivacaine Hydrochloride Lignocaine Hydrochloride Lignocaine Hydrochloride + Adrenaline EMLA cream 45 P, P, Inhalation Injection Inhalation Inhalation Injection Added Medicines Inhalation ln•ection 1.2 Local Anesthetics Category Route of Administration/ Dosa e

Form Injection Topical Forms, Injection, Spinal Injection 10 mg I m', 50 mg / ml 0.5 g, 1 g powder 1% oil sus ension Strengths 0.25%, 0.5%, 0.5% to be mixed with 7.5% glucose solution 2-5%, 5% +7.5% Glucose Added Medicines Cream 1.3 Preo erative Medication and Sedation for Short Term Procedures Medicines Atro ine Sul hate Diazepam Midazolam Mor hine Sul hate Promethazine Category Route of Administration/ Dosage Form tn•ection Tablets Injection, Syrup, Su osito Injection ln•ection Strengths 0.6m / ml 5 mg 5 mg / ml 2mg/5ml 1 mg / mt 5m / ml 10m Imt 5m 15 mi Section: 2 - Analgesics , Antipyretic3, Nonsteroidal Anti-inflammatory Medicines, Medicines used to treat Gout and Disease Modifying AgentS used in Rheumatoid Disorders 2.1: Non-Opioid Analgesics, Antipyretics and Nonsteroidal Anti-inflammatory Medicines Medicines Acet I Salic lic Category Route of Administration/ Dosa e Form Tablets Strengths 325, 350 m [PART II—SEC. 3(ii)l THE GAZEITE OF INDIA-. EXTRAORDINARY 46 Acid Diclofenac Ibuprofen Paracetamol Medicines Morphine Sulphate Tramadol Fentanyl Allo urinoi Colchicine P, P, P, P, Category Tablets ln•ection Tablets S ru ln•ection S ru Tablets Su osito 2.20 ioid Anal esics Route of Administration/ Dosa e Form ln•ection Tablets Added medicines Injection Injection 2.3 Medicines used to treat Gout Tablets Tablets 50m 25m Iml 200 mg. 400 mg 100m 15ml 150m / mi 125m 15ml 500 m 80m , 170m Strengths 10m Iml 10 mg 50 mg/ml 50m ,100m 50ug/ml 2ml ampoule 100 m 0.5 m 2.4 Disease modi in a ents used in Rheumatoid disorders Azathio rine Methotrexate Sulfasalazine Hydroxychloroquine hos hate Leflunomide Section 3 s,T Tablets Tablets Tablets Added medicines Tablets Tablets 50 m 5m , 7.5m , 10m 500 m 200 mg 10m , 20m tab : — Antiallergics and Medicines used in Anaphylaxis Medicines Adrenaline Bitartrate Chlor heniramine Maleate Dexchlorpheniramine Maleate Dexamethasone Hydrocortisone Sodium Succinate Pheniramine Maleate Prednisolone Promethazine Cetrizine Section: 4 - Medicines Activated Charcoal Medicines Category P, P, P, Route of Administration/ Dosa e Form ln•ection Tablets Syrup Tablets In•ection Injection ln•ection Tablets Tablets Added Medicines Tablets S ru Antidotes and Other Substances used in Poisonings 4.1: Nonspecific Route of Administration/ Category Dosa e Form Oral 4.2: S ecific Cate o Route of Administration/ Strengths 1m / ml 0.5 mg 15 mt 0.5 m 4m Iml 100 mg 22.75m / mi 5 mg, 10 mét 20 m 10m , 25m 5m 15 ml 1 Omg 5m Iml Strengths Stren ths o 11-auz 3(ii)] Atro ine Sul hate Specific Antisnake venom Calcium luconate Desferrioxamine mes late Methylthioninium chloride Meth lene blue Penicillamine Dimerca rol Flumazenil Sodium Nitrite Sodium Thiosul hate Naloxone Pralidoxime Chloride(2- PAM N-acet lc steine Medicines Carbamazepine Diazepam Ma nesium sul hate Phenobarbitone Phenytoin Sodium Sodium Valproate Loraze am Medicines Albendazole Piperazine Medicines 47 PISIT p,SIT Dosa e Form ln•ection Injection Polyvalent Solution/ Lyophilyzed POI valent Serum ln•ection Injection Injection Tablets or Capsules ln•ection in oil ln•ection ln•ection ln•ection ln•ection Injection Added medicines: ln•ection Section: 5 — Anticonvulsants/ Antiepileptics Category ST Route of Administration/ Dosa e Form Tablets Injection ln•ection Tablets Injection S ru Capsules or Tablets Injection Tablets ln•ection Added Medicines ln•ection Section: 6 — Anti-infeclive Medicines 6.1 Anthelminthics 6.1.1 Intestinal Anthelminthics Category Route of Administration/ Dosa e Form Tablets Sus ension Added Medicines Tablets Solution 6.1.2 Antifilarials Category Route of Administration/ Dosa e Form Tabtets Dieth Icarbamazine citrate 6.1.3 Antischlstosomals and Antitrematode Medicines 100m Imi 500 mg 250 m 50m Iml 30m Iml 250m 1 mi 0.4m Iml 25 mg/rnr 200 m Imi 5 ml Strengths 100mg 200mg 100 m 15mr 500m Imi 30 mg, 60 mg 200 mg/mf 20m 15m' SO mg, 100mg 25mg/ml 50 mg/ml 200 mg, 500mg 200 m /5ml 100 m Iml 2m Iml Strengths 400 mg 200m 15 mi 760m 15m' Strengths 50 m Stren ths Medicines Route of Administration/ Cate [PART IPSEC. THE GAZETTE OF INDIA : EXTRAORDINARY 48 Prazi uantel Medicines Amoxicillin Ampicillin Benzathine Benz I enicillin Cefotaxime Ceftazidime Ceftriaxone Cephalexin Cloxacillin Amoxicillin+ClavuIinic acid Cefixime Medicines Amikacin Azithromycin Ciprofloxacin H drochloride Cö-Trimoxazole (Trimethoprim + Sulphamethoxazole) Dox c cline Erythromycin Estolate Gentamicin Metronidazole Nitrofurantoin Sul hadiazine Vancomycin H drochloride Medicines Clofazimine Da sone Rifam icin Medicines Ethambutol Dosa e Form Tablets 6.2 Antibacterials 6.2.1 Beta lactam medicines Category P.S.T Route of Administration/ Dosa e Form Powder for suspension Ca sures Capsules Powder for suspension Injection Injection Injection ln'ection In'ection Syrup Ca sules Capsules Injection Li uid Added Medicines Tablets Powder for suspension ln•ection Tablet 6.2.2 Other antibacterials Category p,StT 6.2.3 Antile Category P,s, T Route of Administration/ Dosa e Form ln•ection Tablets Suspension ln•ection Injection Tablets Tablets Suspension Tablets Syrup Tablets Injection Tablet Injection S ru Tablets Tablets In•ection ros

medicines Route of Administration/ Dosa e Form Ca sules Tablets Ca sules or Tablets e.2.4 AntiWbercuIosi8 medicines Category P,s,T Route of Adminls&ation/ Dosa e Form Tablets 600 m Strengths 125 mg / 5 mi 250m , 500 m 250 mg, 500 mg 125 mg 15 ml 500 mg 6 lacs, 12 lacs units 125 mg, 250 mg 500 m 250m , 1 250m , 1 125 mg / 5 ml 250m , 500 m 250 mg, 500 mg 250 mg 125m 15 mi 625 mg 228.5mg/5ml 600m , 1.2 m 100, 200m Strengths 250m 12 mi 100, 250,500mg 100mg/5ml 500m 200 mg 1100 mi 250m , 500m 80 + 400 mg 160+800 mg 40 + 200 mg / 5 ml 100 m 125 mg 1 5 ml 250m , 500 m IO mg/ml, 40 m Iml 200mg,400m 500mg/100m! 100m 15m! 100 m 500 m 500m , 1 Strengths 50m , 100m 50m , 100m 15 m , 300m Strengths 200m , , 3(ii)] Isoniazid Ofloxacin P razinamide Rifam icin Streptomycin Sul hate Medicines Am hotericin B Clotrimazole Fluconazole Griseofulvin N statin Medicines Acyclovir 6.3 Antifun Category Tablets S ru Tablets S ru Tablets Capsules/Tablets. S ru ln•ection al medicines Route of Administration/ Dosa e Form ln•ection Pessaries Gel Ca sules or Tablets Ca sules or Tablets Tablets Pessaries 6.4 Antiviral medicines 6.4.1 Antiher es medicines Category Route of Administration/ Dosa e Form Tablets Injection Sus ension 6.4.2 Antiretroviral medicines 6.4.2.1. Nucleoside reverse transcri tase inhibitors 49 600m , 800 m 50 mg. 100 mg, 300 mg 100m /5ml 100 mg. 200 mg 50m / 5 ml 500 mg, 750 mg. 1000 mg, 1500 m 50 mg, 150 mg. 300 mg,450 mg 100m /5ml 0.75 , 1 Strengths 50 m 100 mg, 200 mg. 2% 50 mg, 100 mg, 150 mg. 200 m 125m , 250m 500,000 IU 100,000 IU Strengths 200 mg. 400 mg 250 mg. 500 mg 400m 15 mi Strengths 250m , 400 m 150 m 150 mg + 200 m +30m 150 mg + 300 m 15 mg. 30 m , 40 m 100 mg. 300 m 30mg+ 150mg 300mg+ 150mg+ 200m Strengths 200 mg. 600 m 200 mg 50m / 5•ml Strengths 200m , 400 467/3 - Medicines Didanosine Lamivudine Lamivudine + Nevirapine + Stavudine .7. Lamivudine + Zidovudine Stavudine Zidovudine Stavudine+ Lamivudine Zidovudine+ Lamivudine+ Nevira ine 6.4.2.2 None Medicines Efavirenz Nevira ine Medicines Indinavir 7 Category Route of Administration/ Dosa e Form Tablets Tablets Tablets Tablets Ca sules Tablets ADDED MEDICINES Tablets Tablets nucleoside revérse transcri tase inhibitors Category Route of Administration/ Dosage Form Ca sules Capsules Sus ension 6.4;2.3 Protease inhibitors Category Route of Administration/ Dosa e Form Ca sules 50 THE GAZETTE OF INDIA : EXTRAORDINARY Nelfinavir Ritonavir Sa uinavir Ca sules Capsules S ru Ca gules 6.5 Anti rotozoal Medicines 6.5.1 Antiamoebic and Anti iardiasls medicines Medicines Diloxanide Furoate Metronidazole Medicines Am hotericin B Pentamidine Isothionate Sodium Stibo luconate Medicines Artesunate (To be used only in combination with Sulfadoxine +P rimethamine Chloroquine phosphate Prima uine P rimethamine Quinine sulphate Sulfadoxine + P rimethamine Clindam cin Medicines Meflo uine Category Route of Administration! Dosa e Form Tablets Tablets ln•ection 6.6.2 Antileishmaniasis medicines Category Route of Administration/ Dosa e Form In•ection ln•ection ln•ection 6.5.3 Antimalarial Medicines 6.5.3.1 For curative treatment Category p.S,T ST Route of Administration/ Dosa e Form Tablets Tablets • Injection Tablets Tablets Tablets ln•ection Tablets Medicines added SIT Tablet 6.5.3.2 For ro h laxis Route of Administration/ Category Dosa e Form Medicines added s,T Tablet [PART II—SEC. 3(ii)l m 250 m 100 mg, 400m 15ml 200 m Strengths 500 m 200 mg, 400 mg 500m 1100 mi Strengths 50 m 200 m 100m Iml Strengths 50 mg 150 mg base 40 mg/ ml 50m / 5 ml 2.5m 7.5m 25 m 300 mg 300m / ml 500m +25m 150, 300m Strengths 250m base 6.5.4 Anti neumoc stosis and Antitoxo lasmosis medicines Medicines Co-Trimoxazoie (Trimethoprim + Sulphamethoxazole) Pentamidine Isothionate Medicines Acet I Salic lic Acid Dih droer otamine Paracetamol Medicines Propranolol h drochloride Category Route of Administration/ Dosa e Form Tablets Suspension ln•ection Section: 7 —Antimigraine medicines 7.1: For treatment of acute attack Route of Administration/ Category Dosa e Form Tablets Tablets Tablets 7.2: For Pro h laxis Route of Administration/ Category Dosa e Form Tablets Strengths 80 + 400 mg. 160+800 mg 40 + 200 mg 5 ml 200 m Strengths 300 - 350 m 500 m Strengths 10 mg, 40 mg .[qm 11-auz 3(ii)] 51 Section: 8 — Antineoplastic, immunosuppressives and medicines used in palli8tive care 8.1: Immunosu ressive medicines Medicines Azathio rine Cyclosporine Medicines Actinom cin D Al ha Interferon Bleom cin Busul han Cisplatin Cyclophosphamide Cytosine arabinoside Danazol Doxorubicin Etoposide Flutamide 5-Fluorouracil Folinic Acid Gemcitabine h drochldride L-As ara inåse Mel halari Mercaptopurine Methotrexåte Mitom cin-C Paclitaxel Procarbazine Vinblastine sul hate Vincristine Carboplatin Dacarbazine Daunorubicin Ifosfamide Mesna Oxali latin Imatinib Category •C 8.2. Category Route of Administrationl Dosa e Form Tablets Capsules Concentrate for ln•ection otoxic medicines Route of Administration/ Dosa e Form In•ection ln•ection ln•ection • Tablets Injection Tablets Injection Injection Ca sules ln•ection Capsules Injection Tablet ln•ection ln•ection Injection ln•ection Tablet Tablet Injection

Tablet Injection ln•ection In•ection Ca sules Injection ln•ection Added medicines Injection ln•ection ln•ection ln•ection ln•ection ln•ection Tablets Strengths 10 mg, 25 mg, 50m . 100m 100m Imi Strengths 3 million IU 15m 10 mg I vial 50m I vial 50 mg. 200 mg 500 mg 100 mg/viat 500 mg/vial 1000 m [vial 50m , 100m 10m , 50m 100 mg 100 mg/ 5 ml vial 250 m 250m 15 mi 200 mg 5000 KU. 2m , 5m 50 mg 100 mg / ml 10m 30m 15 ml 50 m 150 mg. 450 mg 500 m 20m vial 1 m/2ml vial 200 m 50m vial 100m , 400m 52 THE GAZETTE OF INDIA : EXTRAORDINARY [PART IPSEC. 3(ii)) Chlorambucil Medicines Prednisolone Raloxifene . Tamoxifen Citrate Medicines Morphine Sul hate Ondansetron Fil rastim Allo urinol Medicines Bromocriptine Mes late Levodopa+ Carbidopa Trihexyphenidyl H drochloride Medicines C anocobalamin, Ferrous Sulphate/ Fumrate Folic Acid Iron Dextian P ridoxine Medicines Heparin Sodium Protamine Sul hate Ph tomenadione Warfarin sodium Enoxa arin -Tablets 8.3: Hormones and antihormones Category Route of Administration/ Dosa e Form Tablets Injection Tablets Tablets 8.4: Medicines used in alliative care Category Category Route of Administration/ Dosa e Form Tablets Tablets ln•ection Added Medicines ln•ection Tablets Section: 9 —Antiparkinsonism medicines Route of Administration/ Dosage Form Tablets Tablets Tablets Section: IO —Medicines affecting the blood 10.1: Antianaemia medicines Category Route of Administration/ Dosa e Form In•ection Tablets Oral solution Tablets In•ection Tablets 10.2: Medicines affectin coa ulation Category Route of Administration/ Dosa e Form Injection Injection ln•ection Tablets Added Medicines ln•ection Strengths 5 mg 20 mg. 25 mg (as sodium phosphate or succinate 60 m 10 mg. 20 mg Strengths 4m, 8m 2 mg/ml 1 ml vial 100m Strengths 1.25 mg, 2.5 mg 100 mg+10 mg 250 mg+25 mg 100m +25 m •2 mg Strengths Tablets equivalent to 60.m elemental iron 25mg elemental iron as sul hate Iml 50 in iron/ml 10m Strengths 1000 IU/ml 5000 IU/ mi 10 mg/nil 10m Iml 40m , 60m Section: 11 —Blood products and Plasma substitutes 11.1: Plasma Substitutes 9 [m 3(ii)] Medicines Dextran-40 Dextran-70 Fresh frozen tasma Hydroxyethyl Starch (Hetastarch) pol Medicines Albumin C o reci itate Factor Vill Concentrate Factor IX Complex (Coagulation Factors II,VII, 'X, x Platelet Rich Plasma Medicines Acetyl salicylic acid Diltiazem .Glyceryl Trinitrate Isosorbide 5 Mononitrate/ Dinitrate Metoprolol Clo ido rel Medicines Adenosine Amiodarone Diltiazem Esmolol Lignocaine H drochloride Procainamide H drochloride Vera amil Category Route of Administiation/ Dosa e Form In-ection ln•ection Injection Injection ln•ection 11.2: Plasma fractions fors ecific use Category Route of Administration/ Dosa e Form in•ection •ln•ection Injection Injection Injection Section: 12 —Cardiovascular medicines 12.1: Antian inal medicines Category PSS, T 12.2: Category ST Route of Administrationl Dosa e Form Tablets Tablets Sublingual Tablets In•ection Tablets Tablets ln•ection Added Medicines Tablets Antiarrh hmic medicines Route of Administration/ Dosa e Form ln•ection Tablets Injection Tablets Injection Injection Injection Tablets ln•ection Tablets 53 Strengths 60/0 6% Strengths 20 % Dried Dried Strengths 75nig, 100mg, 350 mg soluble/dis ersible 30m , 60m 5m Iml 20 mg 25 mg; 50 mg 75m Strengths 100 mg, 200 mg 50 mg/ml (3 ml am oule 30 mg, 60 mg 5 mg/ ml O/ 250 mg 100m Iml 40m . 80 m 54 60 THE GAZETTE OF INDIA EXTRAORDINARY ln•ection 12.3: Antih ertensive medicines Medicines AmlQdipine Atenolol Enalapril Maleate Losartan Potassium Meth Ido a Nifedipine Sodium Nitroprusside Hydrochlorthiazide Medicines Digoxin Dobutamine Dopamine H drochloride Medicines Acetyl salicylic acid Heparin Sodium Streptokinase Urokinase Atorvastatin Medicines Miconazole Medicines Ac ciovir Framycetin Sul hate Methylrosanjlinium Chloride Gentian [PART 2.5m Iml Strengths 2.5 mg. 50 mg. 100 m 2.5 mg, 5mg 1.25m Iml 25 mg, 50 m 250 m 5 mg. 10mg 10mg, 20mg 10mg, 20mg 50 mg/ 5 ml 12.5, 25m Strengths 0.25 mg 0.25 mg/ml 0.05m 50m Iml 40 mg / ml Strengths 75mg, 100mg, 350 mg soluble/dis ersible 1000 IU Imi 5000 IUIml 750,000 NJ 500,000 tU/ml It-Jimi 5m , 10m Strengths 2% Strengths 50/0 0.5% 0.5% —SEC. 3(ii)] Category Route of Administration/ Dosa e Form Tablets Tablets Tablets In•ection Tablets Tablets Capsules Tablets Sustained release tablets or ca sules injection Added Medicines Tablets 12.4: Medicines used in heart failure Category 12.5: Category Route of Administration/ Dosa e Form Tablets Injection Elixir ln•ection Injection Antithrombotic medicines Route of Administration/ Dosa e Form Tablets Injection Injection Injection New Cate o -ADDED 12.6 H oli idemic Medicines Tablets Section: 13 —Dérmatological medicines (Topical) 13.1: Antifun al medicines Category 13.2: Category Route of Administration/ Dosa e Form Ointment or Cream Antiinfective medicines Route of Administration/ Dosa e Form Cream Cream Aqueous solution 3(ii)] Violet Neomycin + Bacitracin Povidone Iodine Silver. Sul hadiazine Medicines Betamethasone Di ro ionate Calamine Medicines Zinc Oxide 13.5. Medicines Coal Tar Dithranol GI cerin Salic lic Acid Medicines Benz I benzoate Permethrin Medicines Fluorescein Li

nocaine Tro icamide Medicines Barium Sulphate Calcium I odate Io anoic Acid Meglumine Iothalamate Meglumine lotroxate Pro liodohe Sodium Iothalamate Ointment Solution or Ointment Cream 13.3: Antiinflammato and anti ruritic medicines Category Category p, SIT Route of Administration/ Dosa e Form Cream / Ointment Lotion • Astrin ent Medicines Route of Administration/ Dosa e Form Dustin Powder 55 5 mg + 500 / g 1% Strengths 0.05% Strengths • Medicines affectin skin differentiation and roliferation Category P,s.T Route of Administration/ Dosa e Form Solution Ointment Solution Solution 13.6: Scabicides and Pediculicides Category s,T Route of Administration/ Dosa e Form Lotion Added Medicines Category 14.2: Category Cream Lotion Section: 14 —Diagnostic agents hthalmic medicines 14.1: O Route of Administration/ Dosa e Form E e dro s E edro s Radiocontrast media Route of Administration/ Dosa e Form Suspension ln•ection Tablets Injectiori Solution Oil , sus ension Injection Injection Sodium Meglumine Diatrizoate Medicines Acriflavin+GI cerin Section: IS —Disinfectants and antigeptics 15.1: Antise tics Categbry Route of Admlnlstratlonl Dou e Fom Solution Strengths Strengths Strengths Strengths 100% wiv, 250% w/v 3 500 m 60% w/v (iodine =280m / ml 5-8 g iodine in IOO- 250 mi 500-600m / mi w/v(lodine -420m Iml 60% w/v(lodine conc. —292 mg I ml), 76% w/v(iodine conc. -370m / ml Strengths 56 THE GAZETTE OF INDIA : EXTRAORDINARY [PART LI—SEC. 3(ii)] Benzoin Com ound Cetrimide Chlorhexidine Eth I Alcohol 700/0 Gentian Violet H dro en Peroxide Povidone Iodine Medicines Bleaching Powder Formaldehyde Solution Glutaraldeh de Potassium Perman anate Medicines Furosemide Hydrochlorothiazide Mannitol S ironolactone Medicines Aluminium Hydroxide + MagnesiÜm Hydroxide Ome raiole Ranitidine Panto razole Famotidine Medicines Domperidone Metoclopramide P, P, P, P, P, Category P, ST S,T P, ST Category p, SIT 15.2 Tincture Solution Solution Solution Solution Solution : Disinfectants Route of Administration/ Dosa e Form Powder SolutiOh Solution Crystals for solution Section: 16 —Diuretics Route of Administration/ Dosa e Form Injection Tablets Tablets ln•ection Tablets Section: 17 — Gastrointestinal medicines 17.1: Antacids and other Antiulcer medicines Category P.S.T Category p, SIT Route of Administration/ Dosage Form Tablet Suspension Ca sules ln•ection Added Medicines ln•ection Tablets 17.2: Antiemetics Route of Administration/ Dosa e Form Tablets S ru Tablets ln•ection 20% (conc. for dilution 5% conc. for dilution Strengths Contains not less than 30 % WIW of. available chlorine (as Dilute 34 ml of formaldehyde solution with water to produce 100 m} (As Strengths 40m 50 m 25 m Strengths 10m , 20m , 40m 25m / mi 40 m 20m Strengths 3(ii)] Promethazine Ondansetron Medicines 5-Amino salicylic Acid 5-ASN Medicines Dicyclomine H droéhloride Hyoscine Butyl Bromide Medicines Bisacod ! Is a hula Medicines Oral Rehydration Salts Medicines inc Sulfate Tablets Elixir or Syrup Injection Added Medicines Tablet Syrup Injection 17.3: Antiinflammator Medicines Route of Administration/ Category SIT Dosa e Form Added Medicines Tablets 17.4: Antis asmodic medicines Category Category Route of Administration/ Dosa e Form Tablets in•ection Tablets ln•ection 17.5: Laxatives Route of Administrationl Dosa e Form Tablets, Su osito Granules 47.6: Medicines used in diarrhorea 17.6.1 Oral deh diation salts Category Route of Administration/ Dosa e Form Powder for solution 17.6.2 Antidiarrhoeal medicines Category Route of Administration/ Dosa e Form Medicines added S ru Section: 18 —HecmoneS, other endocrine medicines and contraceptives 18.1: Adrenal hormones and s nthetic substitutes Medicines Dexamethasone Hydrocortisone Sodium Succinate Category Route of Administration/ Dosa e Form Tablets ln•ection Injection 57 10 mg, 25 mg 5 mg / 5•ml 25 mg / ml 4mg, 8 mg 2 mg/ml 2mg/rdl Strengths 400mg Strengths 10 mg 10m / m! 10 mg 20m / ml Strengths Strengths Glucose: 13.5 g/L Sodium chloric)? 2.6 g/L Potassium chloriue: 11.5 g/L Trisodium citrate dihydrate+: 2.9 g/L Powder for dilution in 200m'; 500 mi; 1000m'. (As er '.P) Strengths 20 m /5ml Strengths 0.5mg 4m Iml 100 mg / ml C16//3- 58 Meth I Prednisolone THE GAZETFE OF INDIA : EXTRAORDINARY ln•ection Tablets ens [PART 11 40m mt 5mg, 1 Omg, 20m Strengths 40mg(as undecanoate) 25mg/ml(as propionate) Strengths 0.03 mg +0.15 m 0.035 mg +1.0 mg IUD Strengths Strengths Strengths 0.01mg 0.05m Strengths 2.5 mg. 5m 40 / mi 40 IU / mi 500mg 401U/ml Strengths 1m Imt 100 mi Strengths —SEC. Prednisolone Medicines Testosterone Medicines Ethinylestradiol + Levonor esterol Eth)nytestradiol + Norethisterone Hormone Releasing IUD Medicines IUD containing Co er Medicines Condoms Medicines Ethinylestradiol Medicines Glibenclamide Insulin Injection Soluble Intermediate Acting(Lente/NPH Insulin Metformin Premix Insulin 30:70 in•ection Medicines Gluca on 25% Dextrose Medicines 18.2: Category Andro Route of Administrationl Dosa e Form Capsules Injéction 18.3: Contrace tives 18.3.1: Hormonal Contrace tives Route of Administration/ Category Doga e Form p,SIT Tablets Tablets Levonorgesterol Releasing 18 3 2: .

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Intrauterine devices Route of Administration/ Category Dosa e Form P,s,T 18 3 3. . . • Barrier Methods Route of Administration/ Category Dosa 9 Form 18.4: Estro ens Category Rou' of Administration/ Dosa e Form Tablets 18.5: Medicines used in Diabetes mellitus 18.5.1: Insulins and other Antidiabetic a ents Category P,SIT Route ofAdministration/ Dosa e Form Tablets Injection Injection Tablets Added medicines Injection 18.5.2 Medicines used to treat h o I cemia Category Route of Administration/ Dosa e Form ln•ection Added medicines ln•ection 18.6 Ovulation Inducers Route of Administration/ Category Dosage Form 45) 59 11-awg 3(ii)] Clomiphene citrate Medicines Medroxy Pro esterone Acetate Norethisterone Medicines Carbimazole Levothyroxine Iodine Drugs Tuberculin, Purified Protein derivative Drugs Anti-D immunoglobin (human) Polyvalent Antisnake Venom Antitetanus Human • immunoglobin Diphtheria Antitoxin Rabies immunoglobin ?Drugs B.C.G Vaccine D.P.T Vaccine Hepatitis •B Vaccine Measles Vaccine OralPoliomyelitis vaccine LA Drugs Rabies Vaccine Tetanus Toxoid Tablets 18.7 Pro esto ens Category Route of Administration/ Dosa e Form Tablets Tablets 18.8 Thyroid and antithyroid medicines Category S,T Route of Administration I Dosa e Form Tablets Tablets Solution Section: 19 Immunolo icals 19.1: Dia nostica ents Category Route of Administration/ Dosa e Form Injection 19.2: Sera and immuno lobins Category Route of Administration/ Dosa e Form Injection Injection Injection Injection Injection '".19.'3': Vaccines 19.3.1: For Universal Immunisation Category__ 19.3.2: For S Category Nöute of Administration/ Dosa e Form ln•ectjon I •ection Injection ln•ection Solution ecific Grou of Individuals Route of Administration/ Dog e Form ln•ection ln•ection 100m Strengths 5mg, 10m 5m Strengths 5mg, 10m 100 Strengths 1 TU, 5 TIJ Strengths 300 250 500 IU 10,000 IU ml Strengths Strengths 60 THE GAZETTE OF INDIA EXTRAORDINARY Section: 20 — Muscle Relaxants (Peripherally ecting) and Cholinesterase Inhibitors Drugs Atracurium bes late Neostigmine Pyridostigmine Succinyl choline chloride Vecuronium Medicines Chlorampheni col Ciprofloxacin H drochloride Gentamicin Miconazole Povidone Iodine Sulphaceta mide Sodium Medicines Prednisolone Acetate Prednisolone Sodium Phos hate Medicines Tetracaine Hydrochloride Medicines Acetazolamide Betaxolol H drochloride Pilocarpine Timolol Maleate Medicines Atropine Sul hate Homatro ine Phen le htine Category Route of Administration/ Dosa e Form ln•ection Tablets, ln•ection Tablets, ln•ection Injection Added dru s bn•ection Category PTS. T SIT 21. Category PISIT Category Section: 21 — Ophthalmological Preparations 21 .1: Anti-infective a ents Route of Administration/ Dosage Form Drops/Ointment Drops/Ointment Dro s Dro s Drops Drops 2: Antiinflammaor a ents 21.3: Route of Administration/ Dosage Form Drops Drops Local Anaesthetics Route of Administration/ Dosage Form Drops 21.4: Miotics and Anti lucoma medicines SIT s,T Route of Admin18tratlon/ Dosage Form Tablets Drops Drops Drops 21.5: M driatics Route of Administration/ Dosage Fotm Drops/Ointment Dro s Dro s [PART 11 Strengths 10m 15 mg. 0.5m mi 60 mg. 1m /ml 50 mg/ml 2m Iml Strengths 0.4%, -10/0 0.3% 0.3% 1% 0.6% 100/0200/0 Strengths 0.10); 10/0 Strengths 0.5% Strength8 250 m 0.25%, 0.5% 4% 0.25%, 0.5% Strengths 50/0.. 65b 3(ii)] Medicines Methyl Cellulose Category 21.6: Ophthalmic Surgical Aids Ro'ute of Administration/ Dosage Form Injection - Section: 22 — Oxytocics and Antioxytocics 22.1: Ox tocics Medicines Methyl Ergometrine Mifepristone Oxytocin Miso rostol Medicines Terbutaline Sulphate Nifedi ine Betamethasone Medicines Intraperitoneal Dial sis Solution Medicines Chlorpromazine hydrochloride Halo eridol Olanza ine Medlclnes Amitri line Fluoxetine Category Route of Administration/ Dosage Form Tablets Injection Tablets Injection Added medicines 22.2: Antiox tocics Tablets Category Route of Administration/ Dosa e Form Tablets Injection Added Medicines SIT Strengths Strengths O. 125mg 0.2mg/ml 200mg IOIU/mI 100u Stangths 0.5 mg/ml 10m Tablets ln•ection Category Section: 23 — Peritoneal Dialysis Solution' Route of Administration/ Dosa e Form Section: 24 — Psychotherapeutic Medicinés 24.1: Medicines used in Ps chotic Disorders Category P.S.T Route of Administration/ Dosa e Form Tablets ln•ection ln•ection Added medicines Tablets Strengths 40f approximate com osition Strengths 25 rig, 50mg, 100mg 25mg/5ml 25m Iml 5m Iml 5m , 10m 24.2: Medicines used in mood disorders 24.2.1: Medlclnes used in De resolve disorders p ST Route of Admlnlctratlon/ Strength' Dou e Form Tableta Ca sulu 62 h drochloride Imi ramine Medicines Lithium Carbonate Sodium Valproate Medicines Alprazolam Diazepam THE GAZETTE OF INDIA : EXTRAORDINARY Tablets 24.2,2: Medicines used in Bi Olar disorders [PART 11 25m , 75m Strengths 300 mg 200 mg. 500mg Disorders SEC. 3(ii)] Category Route of Administration/ Dosa e Form Tablets Added Medicines Tablets 24.3: Medicines used for Generalized Anxie and Slee Category Route of Administrationl Dosa e Form Tablets Tablets 24.4: Medicines used for obsessive com ulsive disorders and Medicines Fluoxetine h drochloride Category Route of Administration/

Dosa e Form Added Medicines Capsules Strengths 0.5 m 2 mg, 5m anic attacks Strengths 20 mg Section: 2S — Medicines acting on the respiratory tract 25.1: Antiasthmatic medicines Medicines Beclomethasone Dipropionate Category Route of Administration/ Hydrocortisone sodium succinate Salbutamol sulphate Ipratropium bromide • Medicines Codeine phosphate Dextromethor han Section: 26 — Medicines Rehydration Salts Medicines Glucose Glucose with sodium chloride Added Medicines 25.2: Antitussives Dosa e Form lhhalation Injection Tablets Inhalation Inhalation Category Route of Administration/ Dosa e Form Tablets Tablets Solutions correcting water, electrolyte and acid-base disturbances 26.1: Oral Category 26.2: Category Route of Administration/ Dosa e Form Powder for Solution Strength s 250pg/do se 200mg, 400 m 2mg, 4mg 2mg/5mI IOOpg/do se 20pg/met ered dose Strength s 5ml 30m Strengths As per IP arenteral Route of Administration/ Dosa e Form Injection Injection S&engths 5% isotonic, 10%, 5% + 0.9% 3(ii)] Normal Saline N12 Saline N/5 Saline Potassium Chloride Ri er Lactate Sodium Bicarbonate Medicines Water for ln•ection Medicines Ascorbic Acid Calcium carbonate Multivitamins (As per Schedule V of Drugs and Cosmetics Rules) Nicotinamide P ridoxine Riboflavin Thiamine Vitamin A Vitamin D Er ocalciferol Calcium luconate ln•ection ln•ection tn•ection Injection in•ection Injection 26.3: Miscellaneous Category Route of Administration/ Dosa e Fonn Injection Sectidn: 27 — Vitamins and Minerals Category p..S,T pts. T Route of Administration/ Dosa e Form Tablets Tablets Tablets Tablets Tablets Tablets Tablets Tablets Capsules ln•ection Ca sules Added Medicines SCHEDULE-II FORM Injection 63 0.9% 11.2% Sol. As er IP As per IP Strengths 2 mt, 5mI, 10 ml Strengths 100m , 500m 250 mg, 500 mg 50m 25 m 100 m 5000 IU, 50000 IU, 100000 50000 ll.J/ml 0.25m , 1 m 100mg/ml in 10 ml am oule 2 1. 2. 3. 4. 5. 6. 7. 9.• 10. 11

12. PROFORMA FOR APPLICATION FOR PRICE FIXATION 1 REVISION OF A NEW DRUG FORMULATION RELATED TO NLEM FORMULATION (See paragraphs 2(u),5,7,8,9,15) Name of the formulation: Name and address of the manufacturer/importer : Name of the Marketing Company, if any: Composition as per label claimed and approved by Drug Control Authorities: Drugs Control Authority Permission Number and Date (copy to be enclosed): Date of commencement of production / import: Type of formulation (Tablets/_Capsules/ Syrup/ Injection/ Ointment/ Powder etc.): Size of packs (IO's/ 100's/ 1 m'/ 2 10 ml/ 5 gms/ 10 gms etc.) Therapeutic category/ use of the formulation. The Retail Price claimed for approval Reason for submission of application for price fixation / révision. Any other information relevant to product and its process of manufacturing/ packaging/ distribution. THE GAZETTE OF INDIA EXTRAORDINARY [PART II—SEC. 64 The information fumi8hed above is correct and true to the best of my knowledge and belief. Place: Date: 1

FORM - 11 PROFORMA FOR SUBMISSION OF REVISED-PRICES FOR SCHEDULED FORMULATIONS (See paragraph 16) Name and address of the manufacturer/importer/distributor. Name and address of the marketing company, if any. Sl. No. Name of the Product (Formulation and its dosage forms) Composition Pack WPI of scheduled Size change Price to retailer (incl. of E.D.) (Rs.) formulation/ new drug (3) w.r.t. preced- ing Year (5) Maximum Retail Price (incl. of E.D.-&Taxes) (Rs.) (1) (2) (4) Pre— Revised (6) Revi- sed (7) Pre- Revi- sed (8) Revi- sed (9) Ceiling Price (Notified) (Rs.) (16) Effec- tive Batch No. and date (11) Scheduled Formulations Own Manufactured Formulations Purchased/lmported Formulations Notes:- In case of purchased formulation, name of the manufacturer shall be indicated. The information furnished above is correct and true to the best of my knowledge and belief. Place: Date: Authorised Signatory: Name: Designation: SCHEDULE-II FORM - Ill PROFORMA FOR QUARTERLY RETURN IN RESPECT OF PROQUCTION/IMPORT AND SALE OF NLEM DRUGS 9 [See paragraphs 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 • (2) Quarter 6 Quarter 11 Name of the Bulk Drug/APl used in Scheduled Formulation 11-wg 3(ii)] Name of the Scheduled Composition/Strength Formulation (1) Previous Year IS 5 Previous Year IS 10 TABLE-A Dosage Form (3) Production/lmport Level Current Year 2 Quarter 7 Domestic Sale Current Year 2n Quarter 12 TABLE-B Unit (Kg/ Ltr) (2) Production/lmport Level .Current Year 2n Quarter (6) Domestic Sale Current Year 2n Quarter (11) Quarter 8 Quarter 13 65 Unit(No/kg/Ltr) (4) 4 Quarter (9) 4 Quarter 14 (1) Previous. Year (4). Previous Year (9) Constraints, if any: IS Quarter (5) IS Quarter (10) 3 Quarter (7) 3 Quarter (12) Installed Capacity (3) 4 Quarter (8) 4 Quarter (13) Note: (1) Production outsourced / carried out on job work basis should also be included •The information furnished above iS correct and true to the best of my knowledge and belief. Place: Date: Authorised Signatory: Name: Designation: SCHEDULE-II FORM • PROFORMA FOR SUBMISSION OF THE DETAILS IN RESPECT OF DISCONTINUATION OF THE PRODUCTION ANDI OR IMPORT OF SCHEDULED FORMULATION [See paragraphs 1. Name of thé formulation: 66 2. 3. 4. 5. 6. 7. 8. 9. 50

11. Place: Date: 1

2. GAZEITE OF INDIA : EXTRAORDINARY Name and address of the manufacturer/importer : Name of the Marketing Company, if any: Composition as per label claimed and approved by Drug Control Authorities: Drugs Control Authority Permission Number and Date (copy to be enclosed): Celling Price and date of notification: Existing maximum retail price (MRP) and its effective date: Therapeutic category as per NLEM: Date of commencement of production / import Proposed date of discontinuation: Reasons for discontinuation of production / import: 12. Year-wise Production/lmport during the last 5 years including current year 13. Year-wise sale during the last 5 years including current year [PART IPSEC. 3(ii)l 14. Whether any new drug asdefined under Proviso of Definition of "New Drug" under DPCO, 2013 has been launched or intended to be launched. tf so, the details thereof: 15. Any other information relevant to discontinuation of scheduled formulation: Authorized Signatory: Name: Designation: SCHEDULE-II

FORM -V PROFORMA FOR PRICE LIST [See paragraphs Name and address of the manufacturer / importer / distributor. Name and address of the marketing company, if any. TABLE-A Pack Size (Formulation and its approved by Drug Control Authorities (3) (4) Price to retailer (incl. of E.D.) (Rs.) (5) Maximum Retail Price (incl. of E.D.&Taxes) (Rs.) (6) Scheduled Formulations Own Manufactured Formulations Purchased/lmported Formulations 67 3(ii)] Sl. Nd. Name •of the (Formulation dosage forms) Product and its (1) (2) TABLE-B Composition approved by Drug Control 'Authorities (3) Pack Size (4) Price to retailer (incl. of (5) Maximum Retail Price (incl. of E.D.&Taxes) (Rs.) (6) Non-Scheduled Formulations Own Manufactured Formulations Purchased/lmported Formulations In case of purchased formulation, •name of the manufacturer shall be indicated. Notes:- The information furnished above is correct and true to the best of my khowledge and belief. Place: Date: Authorised Signatory: Name: Designation: Printed by the Manager, Govemment of India Press, Ring Road, Mayapuri, New Delhi-110064 and Published by the Controller of Publications, Delhi-110054.