Other Notifications, Orders etc.

Government of Pakistan

Ministry of National Health Services, Regulations and Coordination

(Drug Regulatory Authority of Pakistan)

NOTIFICATION

Islamabad, the 5th March, 2015

F.No.9-12/2014-DDC(P).- The Drug Regulatory Authority of Pakistan with the approval of its Policy Board and the Federal Government is pleased to establish the following drug pricing mechanism as specified in sub-clause (vii) of clause (c) of section 7 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012). The mechanism is termed as Drug Pricing Policy-2015.

1. Commencement and application.- (1) This Policy shall come into force at once.

(2) This Policy shall be applicable to the allopathic drugs including biologicals, for human use only.

2. Definitions.- (1) In this Policy, unless there is any thing repugnant in the subject or context.-

(i) "Act" means the Drugs Act, 1976 (XXXI of 1976);

(ii) "active pharmaceutical ingredient (API)" means a substance or compound that is intended to be used in the manufacture of a pharmaceutical product as a pharmacologically active compound (ingredient);

(iii) "Authority" means the Drug Regulatory Authority of Pakistan established under section 3 of the DRAP Act, 2012;

(iv) "CPI" means Consumer Price Index published by Pakistan Bureau of Statistics.

(v) "DRAP Act" means the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012);

(vi) "decision" includes an order, determination or direction of the Authority or the Policy Board or the Drug Pricing Committee or any other committee made in accordance with the applicable laws, rules and regulations;

(vii) “distributor” means an authorized distributor of a manufacturer or importer having a valid drug sale license of wholesale or distribution;

(viii) “drug” means a drug registered under section 7 of the Act;

(ix) “Drug Pricing Committee” means the committee constituted under section 10 and sub-section (3) of section 12 of the Act, read with clause (a) of section 7 of the DRAP Act;

(x) “Essential Drug List” means the list of essential drugs published by the Authority and as updated or revised from time to time;

(xi) “fee” means fee prescribed by the Authority or the Policy Board, as the case may be;

(xii) “formulation” means all operations involved in converting a drug into a final pharmaceutical dosage form ready for use as a finished drug including compounding, processing, formulating, filling, packing, finishing, labelling and other like processes;

(xiii) “IMS data” means Information Medical Statistics data or information of pharmaceutical market in Pakistan compiled by Information Medical Statistics, an organization which provides pharmaceutical market information globally;

(xiv) “label” means a display of written, printed or graphic matter upon the immediate container, or the outside container or wrapper of a drug package;

(xv) “landed cost” includes import price converted in Pakistani rupee, freight, custom duty, income tax paid at import stage, insurance, bank charges, clearing charges, civil aviation charges or other import levies, if any;

(xvi) “manufacturing cost” includes API cost, other raw materials cost, packaging material cost, wastages of materials during manufacturing not exceeding 3%, quality control cost, production cost including labor, depreciation on plant and machinery, fuel, energy cost, or such other manufacturing costs allowed under applicable cost accounting standards;

(xvii) “MRP” means the maximum retail price of a drug fixed by the Federal Government under section 12 of the Act;

(xviii) “NCE” means the new chemical entity drug that has not been registered in Pakistan;

(xix) “non-scheduled drugs” include drugs which are not listed in the Schedule appended to this Policy;

(xx) “Originator Brand” means a branded drug containing a new chemical entity through research and development;

(xxi) "Policy Board" means the Policy Board of the Authority constituted under section 9 of the DRAP Act;

(xxii) "pharmacopoeia" means publications named in sub-clause (ii) of clause (z) of Section 3 of the Act;

(xxiii) "retailers discount" means the discount to a licensed pharmacy or chemist or medical store calculated at the rate of fifteen per cent on maximum retail price printed on the pack of the drug, which shall not exceed maximum retail price fixed by the Authority with the approval of the Federal Government;

(xxiv) "trade price" means price after deducting retailer discount from the maximum retail price fixed under section 12 of the Act;

(xxv) "schedule" means a Schedule appended to this Policy at Appendix-I;

(xxvi) "sell" means sell, offer for sale, expose for sale, have in possession for sale and distribution and "to sell", "sold" or "sale" shall be construed accordingly;

(xxvii) "storage" means storage for sale and "to store" or "stored" shall be construed accordingly; and

(xxviii) "wholeseller or distribution" means sale to a person who purchases for the purpose of selling again and includes sale to a retailer or hospital or dispensary, or to medical, educational or research institute.

(2) The terms used but not defined herein shall have the same meaning as are assigned to it by the Act or the DRAP Act.

3. Basis of pricing.- (1) MRPs of drugs shall be fixed and regulated subject to procedures as specified in this policy.

(2) Drugs for human use shall be divided in two categories in terms of pricing in the country:-

i. Drugs listed in the Schedule.

ii. Drugs not listed in the Schedule.

(3) List of drugs in the Schedule may be revised after three years or earlier as deemed appropriate by the Policy Board. If MRP of any drug not listed in the Schedule is increased in violation of the provisions of this Policy by any person, it shall stand included in the Schedule.

(4) If MRP of any generic becomes higher than that of the respective Originator Brand due to any reasons, it shall be mandatory for the manufacturer or importer to reduce the MRP of generic at a level not exceeding the Originator Brand MRP.

(5) No person including a retailer, hospital, clinic, wholeseller or distributor shall sell any drug to any consumer at a price exceeding the MRP printed on the respective pack. In case of

sale of a drug in loose quantity, MRP shall not exceed the pro-rata MRP printed on the respective pack.

4. MRP fixation of NCEs.- (1) MRP fixation of Originator Brand of NCE shall be based on average price of the same brand in India and Bangladesh. If the Originator Brand is available in only one of these countries, MRP shall be fixed at its par after considering the exchange rate parity.

(2) If Originator Brand of NCE has not been marketed in India or Bangladesh its maximum retail price shall be fixed equal to the lowest of the following, namely:-

(i) retail price in developing countries which regulate drug prices;

(ii) whole sale price of in UK Monthly Index of Medical Supplies or British National Formulary or Australian Pharmaceutical Benefits Scheme or New Zealand Pharmaceutical Management Agency;

(iii) MRP calculated on the basis of landed cost plus 35% markup to calculate trade price. Trade price shall be grossed up to provide for 15% retailer margin; and

(iv) demanded MRP.

(3) Prices of new chemical entities in other countries shall be verified from independent sources as under.-

(i) price information available on the official website of the regulatory authority or any authentic evidence to prove the retail price fixed by the regulatory authority of the respective country;

(ii) price information available in UK Monthly Index of Medical Supplies or British National Formulary or Australian Pharmaceutical Benefits Scheme or New Zealand Pharmaceutical Management Agency; and

(iii) if price is not available as above, price of the same brand as certified directly to Division of Costing & Pricing, DRAP by any of the following agencies or organizations.-

(a) Pakistan High Commission or Pakistan Embassy in the respective country;

(b) any of top four global firms of chartered accountants operating in Pakistan through their member firms in the respective countries. The certifying firm of the chartered accountants shall also provide a certificate that the firm does not have any conflict of interest in terms of providing any professional services to the respective pharmaceutical company or firm.

(c) IMS Health. Since IMS maintains information on trade prices globally, it shall certify trade price in the respective country.

(d) a format shall be devised by the DRAP to obtain the certified information on price (inclusive and exclusive of VAT, Sales Tax, Excise duty or any other levy on sale of the drug) under sub-clauses (a), (b) & (c) above.

(4) MRPs of generics of NCEs.-

(i) MRPs of generic substitutes of the NCE shall be fixed @ 30% less than the Originator Brand MRP; and

(ii) if Originator Brand of an NCE is not marketed in Pakistan and a generic substitute is registered for marketing, its MRP shall be fixed at 30% less than the Originator Brand MRP as per provisions of sub-paras (1) & (2) of para 4 and price verified as per provisions of sub-para (3) of para 4.

(iii) if Originator Brand is not registered in Pakistan and its price information is not available as per provisions of sub-paras (1) & (2) of para 4, MRP of a generic substitute registered in Pakistan shall be fixed at average price of top 3 generics in India and Bangladesh each and price verified as per provisions of sub-para (3) of para 4.

(5) NCEs shall be deemed to be listed in the Schedule for four years or till the time of entry of at least three generic / bio-similar brands in the market, whichever is later. After that maximum retail price of the Originator Brand of NCE shall be reduced by 10% per annum for 3 consecutive years (cumulative reduction of 30%) and then NCE shall be considered as non-scheduled, if otherwise the molecule is not included in the Schedule. MRP of any generic shall be at least 15% less than the MRP of Originator Brand so reduced and generics where lower MRPs have been fixed shall not be allowed to increase their MRPs except any increase as expressly allowed under this Policy.

5. MRPs of new strengths or new pack sizes.- (1) MRPs of new strengths of existing strengths of drugs shall be fixed by applying the following formulae.-

(i) Calculation of MRP of lower stregnth (new strength is of half of the existing strength)

MRP = MRP of higher strength - 40%; and

(ii) Calculation of MRP of higher stregnth (new strength is double of the existing strength)

MRP = (MRP of lower strength x100) /60.

(2) MRPs of other strengths shall be calculated proportionately to formula in sub-para (1) above.

(3) MRPs of new pack sizes of existing packs of drugs shall be fixed on the basis of pro-rata of already fixed MRP of the existing pack size of the respective brand. In case the new pack

size is more than 1.5 times of the existing pack size, MRP of new pack size shall be reduced by 2% after calculation of pro-rata MRP. MRP of new pack size shall be reduced by 5% if the new pack size is double of the existing pack size and 8% reduction shall be applied if new pack size is larger than double of the existing pack size.

6. Reduction in MRP of Originator Brand.-(1) MRPs of Originator Brands of drugs listed in Schedule shall be reduced by 10% per annum for 3 consecutive years (cumulative reduction of 30%) of MRPs as fixed by the Federal Government except the following.-

(i) where less than 3 generics are available in the market;

(ii) lower priced Originator Brands as defined in para 11.

(iii) Originator Brand where average retail price (exclusive of VAT, Sales Tax, Excise Duty or any other levy on sale of the drug) of the same brand in India and Bangladesh is higher at the time of reduction. In case, the Originator Brand is available in one of these countries, retail price (exclusive of VAT, Sales Tax, Excise Duty or any other levy on sale of the drug) in that country shall be taken as reference for this purpose.

(iv) where Originator Brand has not been marketed in India or Bangladesh its MRP is not higher than the lowest of the following, namely.-

(a) retail price (exclusive of VAT, Sales Tax, Excise Duty or any other levy on sale of the drug) in developing countries which regulate drug prices;

(b) whole sale price of in UK Monthly Index of Medical Supplies or British National Formulary or Australian Pharmaceutical Benefits Scheme or New Zealand Pharmaceutical Management Agency (exclusive of VAT, Sales Tax, Excise Duty or any other levy on sale of the drug); and

(c) MRP calculated on the basis of method specified in para 10.

(2) If MRP of any Originator Brand has already been reduced by the Federal Government or the manufacturer or importer itself, any such earlier reduction by the Federal Government or the manufacturer or importer itself shall be adjusted while calculating reduction under sub-para (1).

(3) MRP of any generic shall be at least 15% less than the MRP of Originator Brand so reduced under sub-para (1) and generics where lower MRPs have been fixed shall not be allowed to increase their MRPs except any increase as expressly allowed under this Policy.

7. **Freeze on MRPs of drugs.-** Notwithstanding any thing contained in this policy MRPs of all drugs shall be frozen at the approved level of MRPs as on 31st October, 2013 and till 30th June 2016.

8. Annual increase in MRPs of drugs.- Effective 1st July 2016 annual increase shall be linked with CPI of the immediately preceding financial year. Manufacturers and importers may increase their existing MRPs of scheduled drugs upto 50% of CPI (with a cap of 4%), MRPs of non scheduled drugs up to 70% of CPI (with a cap of 6%) and MRPs of lower priced drugs shall

be allowed maximum equal to CPI once in any financial year till MRP/ cap of threshold as specified in para 11 is achieved. Calculation of revised MRP shall be intimated to the Authority (Division of Costing and Pricing) at least 15 days prior to affecting the increase. Non intimation of MRPs shall be construed as non revision of MRPs. The failure to intimate the increase in MRP shall tantamount to nullifying the price increase.

9. MRPs fixation of new entrants.- MRPs of new entrants of the drugs already available in the market which have not been fixed so far by the Drug Pricing Committee of the Authority or Drug Pricing Committee or Price Advisory Committee or Price Recommendatory Committee of the Ministry of Health (defunct) shall be fixed at the time of registration according to the following parameters.-

(i) in case of first generic, uniform MRP shall be fixed at 30% less than the Originator Brand. In case of lower priced drugs, MRP of generics shall be fixed at par with the Originator Brand; and

(ii) in case generic(s) of a drug are already available in the market but MRP of the drug has not been fixed so far by any of the above said committee, uniform MRP shall be fixed on the basis of average MRP of brands of the same drug already available in the market.

10. Hardship cases.- (1) A transparent mechanism shall be devised by the Policy Board to review MRPs of drugs which have become non-viable to market.

(2) Notwithstanding anything contained in this Policy, a manufacturer or importer may apply to the Authority, once in 3 years, after payment of the prescribed fee for a review of MRP of any of its drug whose actual manufacturing cost or import cost justify increase as per method given here under. The application shall be filed on specified format and supported with justification, evidence and reasons to increase the MRP.

(i) **Formulae**

For locally manufactured drugs:
Trade Price = Manufacturing cost + mark-up @ 70%

For imported drugs:
Trade Price = Landed cost + mark-up @ 35%

For imported drugs in finished form and local labelling & cartoning
Trade Price = (Landed cost + packaging cost) + mark-up @ 35%

(ii) MRP shall be calculated by grossing up trade price to provide for retail discount @ 15%.

(iii) Components for mark up are given at Appendix-II.

(iv) Manufacturing cost, landed cost and packaging cost shall be competitive and shall be determined according to the parameters laid down in clauses “v, vi & vii” hereunder;

(v) Price of API shall be determined as under:

(a) average selling price charged by the local manufacturers of API.

(b) in case, API is not manufactured locally, purchase price by the manufacturer of the Originator Brand from a source other than its parent or an associated company or under license arrangements.

(c) if price is not available under (a)&(b), average of purchase prices of top 3-5 generics with cumulative minimum 30% market share in unit terms according to IMS data.

(d) if price is not available under (a), (b) and (c), purchase price of API by the manufacturer of the corresponding Originator Brand not exceeding in India & Bangladesh as certified under procedure given in sub para (3) of para 4.

(vi) Cost & freight (C & F) price of a finished drug for the purpose of calculation of landed cost shall be determined as under:-

(a) C & F price of the Originator Brand in case it imports the drug from a manufacturer or from a source other than its parent or an associated company.

(b) if C & F price is not available under (a), average of C & F prices of top 3-5 generics with cumulative minimum 30% market share in unit terms according to IMS data.

(c) if C & F price information is not available under (a) & (b), C & F price of finished drug of the corresponding Originator Brand not exceeding in India & Bangladesh as certified under procedure given in sub para (3) of para 4.

(vii) C & F price of a drug imported in finished form for local labelling and cartoning shall be determined as explained in clause “vi” of sub-para (2) of this para.

(viii) Packaging cost shall include packaging material cost, wastages of packing materials during packaging not exceeding 3%, direct labor cost or such other direct costs allowed under applicable cost accounting standards;

(3) Policy Board shall constitute a committee to provide guidelines to decide the hardship cases and fix maximum limit for increase in MRPs of intravenous infusions.

(4) Hardship cases of scheduled molecules submitted on specified form and complete in all respect shall be processed on priority and decided on the basis of first come first serve basis but not later than 9 months from the date of notification of this Policy.

(5) Maximum increase on hardship cases (except for orphan drugs, lower priced drugs & intravenous infusions) shall be 8% per annum of the existing approved MRP of the respective

drug. In case of lower priced drugs, increase shall not exceed 25 paisa per tablet / capsule / respule / caplet / patch / 5ml of syrup, suspension and elixir.

(6) After disposal of the existing pending hardship cases, new hardship cases shall be decided within 90 days of submission of the hardship case on the specified form and complete in all respect with the DRAP (Division of Costing and Pricing) in manner as specified by the Policy Board. In case, no response is sent to the applicant of hardship case under provisions of this para within 90 days, the applicant may increase its MRP upto maximum of 8% on the existing approved MRP and inform the DRAP (Division of Costing and Pricing) with evidence that a complete case was submitted with the DRAP (Division of Costing and Pricing) 90 days prior to the increase. No applicant shall exercise this option more than once in 3 years.

11. Lower priced drugs.- (1) The drugs whose MRPs are less than the following threshold shall be deemed to be non-scheduled drugs even otherwise falling under the scheduled category to encourage their production:

(i). Rs.3/- per tablet / capsule / respule / caplet
(ii). Rs.3/- 5ml of syrup /suspension/elixir
(iii). Rs.3/- per patch
(iv). Rs.6/- per sachet
(v). Rs.15/- per injection
(vi). Rs.3/- per 1 gm of cream/ ointment/ gel (non sterile) subject to maximum pack size of 20gm.
(vii). Rs.4/- per 1 gm of cream/ ointment/ gel (sterile) subject to maximum pack size of 20gm.
(viii). Rs.4/- per ml of eye/ ear /nasal drops /nasal spray / inhalation solution (sterile) subject to maximum pack size of 10ml.

(2) Threshold limit of lower priced drugs shall increase by 50% of CPI every year.

12. Encouragement for exports to USA & Europe.- The locally manufactured products approved for export to developed countries like USA, UK, EU countries, Japan, Australia or WHO shall be exempted from price control in local market to encourage manufacturing and export of quality drugs subject to the conditions that FOB price for export is not less than the ex-factory price in the country.

13. Miscellaneous.- (1) MRPs fixed under this Policy for locally manufactured drugs shall also be applicable to imported drugs.

(2) Any manufacturer or importer may voluntarily adjust the MRP downward of its registered drug any time and he may reverse the downward adjustment subject to MRP fixed by the Federal Government. However, he shall intimate such adjustment to the Authority (Division of Costing and Pricing) prior to affecting the change.

(3) Notwithstanding anything contained in this Policy, the Policy Board may include non-scheduled drug in the Schedule or vice versa by stating the reasons thereof.

(4) The Authority and the provincial health authorities shall monitor MRPs of all the drugs to ensure that drugs are not sold in market on MRPs higher than fixed under this Policy.

(5) If MRP of any drug or biological is not covered in the policy then its case shall be presented before the Policy Board which shall regulate the mechanism for the fixation of MRP of such drug or biological.

(6) MRP reduction under paras 4 & 6 of this Policy and notification of increase under hardship cases for the first time shall take place simultaneously not later than nine (09) months from the date of notification of this Policy except for orphan drugs as identified by the Committee on orphan drugs constituted by the Policy Board.

Appendix-I

SCHEDULED DRUGS

The following categories of drugs shall fall in the list of scheduled drugs:

(i) Biologicals, infusions and drugs used for the treatment of Cancer, T.B., Hepatitis, HIV, Thalassamia and Organ Transplant.

(ii) 160 molecules of public health significance from the Essential Drug List (EDL) of Drug Regulatory Authority of Pakistan.

(iii) Top 50 molecules in unit terms as per Information Medical Statistics (IMS).

(iv) New Chemical Entities (NCEs).

The following molecules have been found falling in the above categories of scheduled drugs and all drugs containing a molecule listed in the schedule, either individually or in combination with other non schedule drugs will be deemed to be included in the list of scheduled drugs. Top 50 molecules have been taken from IMS 2Q-2014 data. The list is not exhaustive and is subject to inclusion or exclusion as may be decided by the Policy Board.

S.No.	Molecule	Therapeutic use / Indication
1.	Abacavir	HIV Treatment
2.	Abiciximab	Biologicals / Cancer Treatment
3.	Acetazolamide	Anti-Hypertensive
4.	Acetylcysteine	Endocrine drug
5.	Acetylsalicylic acid	Pain Killer
6.	Actinomycin D	Cancer Treatment
7.	Acyclovir	HIV Treatment
8.	Albendazole	Anti-worms
9.	Alcuronium	Muscle relaxant
10.	Allopurinol	Anti-Gout/Joint pain
11.	Alprazolam	Anti-anxiety

12.	Amifostine	Cancer Treatment
13.	Amikacin	Antibiotic
14.	Amiloride	Anti-Hypertensive
15.	Amino Acid Infusions	Infusion
16.	Aminophylline	Anti-asthma
17.	Amitriptyline	Anti-depressant
18.	Amlodipine	Anti-Hypertensive
19.	Amodiaquine	Anti-malarial
20.	Amoxicillin	Anti-biotic
21.	Amoxicillin + clavulanic acid	Anti-biotic
22.	Amphotericin-B	Anti-biotic
23.	Ampicillin	Anti-biotic
24.	Anastrozole	Cancer Treatment
25.	Anti hepatitis b immunoglobulin	Biological Drug
26.	Anti-D immunoglobulin (human)	Biological Drug
27.	Antitetanus immunoglobulin (human)	Biological Drug
28.	Antivenom immunoglobulin	Biological Drug
29.	Artemether + lumefantrine	Anti-malarial
30.	Artesunate	Anti-malarial
31.	Asparaginase	Cancer Treatment
32.	Atenolol	Anti-Hypertensive
33.	Atorvastatin	Anti-Cholesterol
34.	Atropine	Used in various eye operations
35.	Azathioprine	For organ transplant
36.	Basiliximab	Biologicals / Cancer Treatment
37.	BCG Oncotice	Cancer Treatment
38.	BCG vaccine	Biological Drug
39.	Beclometasone	Steroid
40.	Benzoyl peroxide	Anti-septic /anti-itching
41.	Benzyl benzoate	Anti-scabies
42.	Beractant	Biological
43.	Betamethasone	Steroid
44.	Bevacizumab	Biologicals / Cancer Treatment

45.	Bicalutamide	Cancer Treatment
46.	Bisoprolol	Anti-hypertensive
47.	Bleomycin	Cancer Treatment
48.	Bromazepam	Anti-anxiety
49.	Bupivacaine	Anaesthesia
50.	Busulfan	Cancer Treatment
51.	Calcium folinate	Cancer Treatment
52.	Capecitabine	Cancer Treatment
53.	Capreomycin	Anti-biotic
54.	Carbamazepine	Anti-Epileptic
55.	Carboplatin	Cancer Treatment
56.	Cefazolin	Anti-biotic
57.	Cefixime	Anti-biotic
58.	Cefotaxime	Antibiotic
59.	Ceftazidime	Anti-biotic
60.	Ceftriaxone	Anti-biotic
61.	Cephalexin	Anti-biotic
62.	Cephradine	Anti-biotic
63.	Cetirizine	Anti-allergic
64.	Cetuximab	Cancer Treatment
65.	Chlorambucil	Cancer Treatment
66.	Chloramphenicol	Anti-biotic
67.	Chloroquine	Anti-malarial
68.	Cholera vaccines	Biological Drug
69.	Ciclosporin	For organ transplant
70.	Ciprofloxacin	Anti-biotic
71.	Cisplatin	Cancer Treatment
72.	Clarithromycin	Anti-biotic
73.	Clindamycin	Anti-biotic
74.	Clobetasole	Anti-biotic
75.	Clofazimine	Anti-biotic
76.	Clomifene	Anti-fertility
77.	Clomipramine	Anti-depression
78.	Clotrimazole	Anti-biotic /Antifungal

79.	Cloxacillin	Anti-biotic
80.	Codeine	Used as pain killer
81.	Cyclophosphamide	Cancer Treatment
82.	Cyproterone	Cancer Treatment
83.	Cytarabine	Cancer Treatment
84.	Dacarbazine	Cancer Treatment
85.	Dactinomycin	Cancer Treatment
86.	Dasatinib	Biologicals / Cancer Treatment
87.	Daunorubicin	Cancer Treatment
88.	Deferoxamine	Anti-poisoning
89.	Dexamethasone	Steroid
90.	Diazepam	Anti-anxiety
91.	Diclofenac	Pain Killer
92.	Didanosine	HIV Treatment
93.	Dimercaprol	Anti-poisoning
94.	Dipatheria-tetanus vaccine	Biological Drug
95.	Diphtheria antitoxin	Biological Drug
96.	Diptheria-pertussis tetanus vaccine	Biological Drug
97.	D-methionine	Amino acid
98.	Dobutamine	Anti-Hypertensive
99.	Docetaxel	Cancer Treatment
100.	Domperidone	Anti-vomiting
101.	Dopamine	Anti-Hypertensive
102.	Doxorubicin	Cancer Treatment
103.	Doxycycline	Anti-biotic
104.	Efavirenz	HIV Treatment
105.	Emtricitabine	HIV Treatment
106.	Enalapril	Hypertension
107.	Ephedrine	Used in anaphylactic shock
108.	Epinephrine (adrenaline)	Used in anaphylactic shock to improve breathing, respiration and blood pressure.
109.	Epirubicin	Cancer Treatment
110.	Eptifibatide	Biological

111.	Ergometrine	Anti-migraine
112.	Erlotinib	Biologicals / Cancer Treatment
113.	Erythromycin	Anti-biotic
114.	Erythropoiten (Alfa & Beta)	Biological
115.	Esomeprazole	Anti-Ulcer
116.	Etanecept	Biological
117.	Ethambutol	Treatment of T.B
118.	Ethionamide	Treatment of T.B
119.	Etoposide	Cancer Treatment
120.	Exemastine	Cancer Treatment
121.	Exenatide	Biological
122.	Factor ix complex (coagulation factors, ii, vii, ix, x) concentrate	Biological Drug
123.	Factor viii concentrate	Biological Drug
124.	Famotidine	Anti-Ulcer
125.	Filgrastim	Biologicals
126.	Flu vaccines	Biological Drug
127.	Flubiprofen	Pain killer
128.	Fluconazole	Anti-biotic
129.	Flucytosine	Anti-fungal
130.	Fludarabine	Cancer Treatment
131.	Fluorouracil	Cancer Treatment
132.	Fluoxetine	Anti-Depression
133.	Flutamide	Cancer Treatment
134.	Folic Acid	Vitamin moiety
135.	Folinic acid	Cancer Treatment
136.	Follicle Stimulating Hormone	Hormone
137.	Furosemide	Anti-Hypertensive
138.	Gefitinib	Cancer Treatment
139.	Gemcitabine	Cancer Treatment
140.	Gentamicin	Anti-biotic
141.	Glibenclamide	Anti-Diabetes
142.	Glimepiride	Anti-diabetes
143.	Glucose	Infusion

144.	Goserelin	Cancer Treatment
145.	Griseofulvin	Anti-biotic
146.	Haemophilus Influenzae type b vaccine	Biological Drug
147.	Halothane	Anaesthesia
148.	Heparin sodium	Blood thinning agent
149.	Hepatitis A vaccine	Biological Drug
150.	Hepatitis B vaccine	Biological Drug
151.	Human normal immunoglobulin	Biological Drug
152.	Human Chorionic Gonadotropin Hormone	Hormone
153.	Human Menopausal Gonadotropin Hormone	Hormone
154.	Hydralazine	Anti-Hypertensive
155.	Hydrochlorothiazide	Anti-Hypertensive
156.	Hydrocortisone	Steroid
157.	Ibuprofen	Pain Killer
158.	Idarubicin	Cancer Treatment
159.	Ifosfamide	Cancer Treatment
160.	Imatinib	Cancer Treatment
161.	Imipenem + cilastatin	Anti-biotic
162.	Indinavir	HIV Treatment
163.	Infliximab	Biologicals / Cancer Treatment
164.	Insulin (all types)	Biological Drug
165.	Insulin analogues (all types)	Biological Drug
166.	Interferons (all types)	Hepatitis C treament
167.	Interleukin (all types)	Anti-cancer
168.	Intraperitoneal dialysis solution (of appropriate composition)	Used for dialysis
169.	Ipratropium bromide	Anti-asthma
170.	Irinotecan	Cancer Treatment
171.	Isoniazid	Treatment of T.B
172.	Isosorbide dinitrate	Anti-Hypertensive
173.	Ivermectin	Anti-worms
174.	Kanamycin	Anti-biotic
175.	Ketamine	Anaesthesia
176.	Lactulose	Anti-flatulence

177.	Lamivudine	HIV Treatment
178.	Lapatinib	Biologicals / Cancer Treatment
179.	Letrozole	Cancer Treatment
180.	Leuprorelin	Biologicals / Cancer Treatment
181.	Levamisole	Anti-worms
182.	Levodopa + carbidopa	Anti-parkinsonism
183.	Levofloxacin	Anti-biotic
184.	Levothyroxine	Thyroid drug
185.	Lidocaine	Anaesthesia
186.	Lincomycin	Anti-biotic
187.	Liraglutide	Biological
188.	Lopinavir	HIV Treatment
189.	Loratadine	Anti-allergic
190.	Mannitol	Infusion
191.	Measles vaccine	Biological Drug
192.	Measles-mumps-rubella vaccine	Biological Drug
193.	Mebendazole	Anti-worms
194.	Mecobalamin	Vitamin
195.	Mefenamic acid	Pain killer
196.	Mefloquine	Anti-malarial
197.	Melphalan	Cancer Treatment
198.	Meningococcal vaccine	Biological Drug
199.	Mercaptopurine	Cancer Treatment
200.	Metformin	Anti-Diabetes
201.	Methadone	Pain killer
202.	Methotrexate	Cancer Treatment
203.	Methyldopa	Anti-Hypertensive
204.	Metoclopramide	Anti-vomiting
205.	Metronidazole	Anti-biotic
206.	Mintomycin	Cancer Treatment
207.	Mitozantrone	Cancer Treatment
208.	Montelukast	Anti-asthma
209.	Morphine	Used as analgesic /pain killer drug in severe pain conditions.

210.	Mycophenolate	Cancer Treatment
211.	Nalidixic acid	Anti-biotic
212.	Naloxone	Anti-poisoning
213.	Nelfinavir	HIV Treatment
214.	Neostigmine	Endocrine drug
215.	Nevirapine	HIV Treatment
216.	Niclosamide	Anti-worms
217.	Nifedipine	Anti-Hypertensive
218.	Nilotinib	Biologicals / Cancer Treatment
219.	Nimesulide	Pain Killer
220.	Nitrofurantoin	Anit-infective
221.	Nystatin	Anti-biotic
222.	Octreotide	Cancer Treatment
223.	Ofloxacin	Anti-biotic
224.	Omalizumab	Biologicals / Cancer Treatment
225.	Omeprazole	Anti-ulcer
226.	Oseltamivir	HIV Treatment
227.	Oxaliplatin	Cancer Treatment
228.	Paclitaxel	Cancer Treatment
229.	Papiloma Virus Vaccine	Biological Drug
230.	Paracetamol	Pain Killer
231.	Pazopanib	Biologicals / Cancer Treatment
232.	Pegaptanib	Biologicals / Cancer Treatment
233.	Pemetrexed	Cancer Treatment
234.	Pentavalent vaccines	Biological Drug
235.	Permethrin	Anti-Scabies
236.	Pethidine	Used as analgesic /pain killer drug in severe pain conditions.
237.	Phenobarbital	Anti-epileptic
238.	Phenoxymethylpenicillin	Anti-biotic
239.	Phenytoin	Anti-Epileptic
240.	Phytomenadione	Vitamin-K
241.	Picosulfuric Acid	Anti-constipative
242.	Pilocarpine	Eye diseases

243.	Pirarubicin	Cancer Treatment
244.	Pneumococcal vaccine	Biological Drug
245.	Poliomyelitis vaccine	Biological Drug
246.	Potassium chloride	Infusion
247.	Povidone Iodine	Anti-septic
248.	Primaquine	Anti-malarial
249.	Procainamide	Anaesthesia
250.	Procaine benzylpenicillin	Anti-biotic
251.	Procarbazine	Cancer Treatment
252.	Procyclidine	Endocrine drug
253.	Proguanil	Anti-malarial
254.	Promethazine	Anti-Allergic
255.	Propranolol	Anti-Hypertensive
256.	Propylthiouracil	Cancer Treatment
257.	Pulmonary surfactant of natural origin 80.0mg (corresponding to approx. 74.0 of total phospholipids / Poractant (Curosurf)	Biological
258.	Pyrazinamide	Treatment of T.B
259.	Pyridostigmine	Endocrine drug
260.	Pyrimethamine	Anti-malarial
261.	Quinidine	Anti-malarial
262.	Quinine	Anti-malarial
263.	Rabies immunoglobulin	Biological Drug
264.	Rabies vaccine	Biological Drug
265.	Ranibizumab	Biologicals / Cancer Treatment
266.	Ranitidine	Anti-ulcer
267.	Reteplase	Heart Attack
268.	Ribavirin	Antibiotic/Antiviral
269.	Rifampicin	Treatment of T.B
270.	Risperidone	Anti-Psychotic
271.	Ritonavir	HIV Treatment
272.	Rituximab	Cancer Treatment
273.	Rosuvustatin	Anti-Cholesterol
274.	Rota virus vaccine	Biological Drug

275.	Rubella vaccine	Biological Drug
276.	Salbutamol	Asthma
277.	Salicylic acid	Anti-warts
278.	Saquinavir	HIV Treatment
279.	Silver sulfadiazine	Anti-biotic
280.	Simvastatin	Anti-Cholesterol
281.	Sodium calcium edetate	Anti-poisoning
282.	Sodium chloride	Infusion
283.	Sodium hydrogen carbonate	Infusion
284.	Sodium lactate, compound solution	Infusion
285.	Sodium nitroprusside	Used in cardiology
286.	Sodium stibogluconate (s)	Anti-Lishmeniasis
287.	Sofosbuvir	Anti-Hepatitis C
288.	Somatotropin	Growth Hormone
289.	Sorafenib	Cancer Treatment
290.	Spectinomycin	Anti-biotic
291.	Spironolactone	Anti-Hypertensive
292.	Stavudine	HIV Treatment
293.	Streptokinase	Cardiac enzyme used in the treatment of heat attack.
294.	Streptomycin	Anti-biotic
295.	Sulfadiazine	Anti-biotic
296.	Sulfadoxine + pyrimethamine	Anti-biotic
297.	Sulfamethoxazole + trimethoprim	Anti-biotic
298.	Sulfasalazine	Anti-biotic
299.	Sunitinib	Cancer Treatment
300.	Suxamethonium / Succinylcholine	Endocrine drug
301.	Tamoxifen	Cancer Treatment
302.	Tenofovir Disoproxil Fumarate	HIV Treatment
303.	Terbutaline	Anti-Asthmatic
304.	Testosterone	Male hormone
305.	Tetanus vaccine	Biological Drug
306.	Tetracaine	Anaesthesia
307.	Tetracycline	Anti-biotic

308.	Theophylline	Anti-asthma
309.	Thiopental	Anaesthesia
310.	Timolol	Eye diseases
311.	Tocilizumab	Biologicals / Cancer Treatment
312.	Topotecan	Cancer Treatment
313.	Tranexamic acid	Abnormal hemorrhages
314.	Trastuzumab	Biologicals / Cancer Treatment
315.	Typhoid vaccines	Biological Drug
316.	Valproic acid / Sodium Valproate / Divalproic Acid Sodium	Anti-Epileptic
317.	Vecuronium	Muscle relaxant
318.	Verapamil	Anti-Hypertensive
319.	Vinblastine	Cancer Treatment
320.	Vincristine	Cancer Treatment
321.	Vinorelbine	Cancer Treatment
322.	Yellow Fever Vaccine	Yellow Fever
323.	Zinc sulfate	Zinc Supplement

Appendix-II

COMPONENTS OF MARK UP

S. No	Description	Local	Import
1.	Product development and Stability Studies	03	-
2.	Product Expiry	02	02
3.	Warehouse and cold chain	02	02
4.	Salesmen salaries and travel	10	10
5.	Sales Promotion	03	02
6.	Samples	03	-
7.	General Administration	04	02

8.	Financial Charges	03	02
9.	WPPF* and CRF**	01	-
10.	Income Tax	08	-
11.	Distribution expenses and discount	16	10
12.	Manufacturer profit	15	-
13.	Importer Profit	-	05
	Total	**70%**	**35%**

* Workers Profit Participation Fund

** Central Research Fund.

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Director, Costing and Pricing

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