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Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
(Drug Regulatory Authority of Pakistan)

Islamabad, the 7th September, 2017

NOTIFICATION

S.R.O.905(I)/2017. In exercise of the powers conferred by clause (a) of section 7 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with section 12 of the Drugs Act, 1976 (XXXI of 1976), the Drug Regulatory Authority of Pakistan with the approval of the Federal Government is pleased to fix maximum retail prices specified in column (4) of the Table below on which the drugs specified in column (2) thereof, having packing sizes specified in column (3) of that Table, shall be sold, subject to the conditions specified in paragraph 2 of this Notification, namely:-

TABLE

| S. No | Brand Name, composition and company | Pack size | Approved maximum retail price |
|-------|--|----------------|-------------------------------|
| (1) | (2) | (3) | (4) |
| 1. | Ranitidine as HCl Syrup 75 mg/5ml Each 5 ml contains:- Ranitidine as HCl....75 mg (USP Specification) | 60ml | Rs.26.00 |
| 2. | Aciclovir Syrup Each 5 ml contains:- Aciclovir.....200mg (BP Specification) | 60ml | Rs.160.00 |
| 3. | Ondansetron Injection 8mg Each 4 ml ampoule contains:- Ondansetron (as HCl dihydrate)....8mg (USP Specification) | 5x4ml 1x4ml | Rs.2585.00 Rs.517.00 |
| 4. | Clarithromycin 125 mg / 5 ml Dry powder suspension. Each reconstituted 5 ml contains: Clarithromycin (as taste masked granules 27.5 %)... 125 mg (USP Specification) | 60ml | Rs.223.00 |

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| 5. | Clarithromycin 250 mg / 5 ml Dry powder suspension. Each reconstituted 5 ml contains: Clarithromycin (as taste masked granules 27.5 %)... 250 mg (USP Specification) | 60ml | Rs.368.00 |
| 6. | Cefaclor Drops Each ml when reconstituted Contains:- Cefaclor (as monohydrate)...50mg (USP specifications) | 15ml | Rs.80.00 |
| 7. | Pantoprazole Sodium ≡ Pantoprazole Injection Each vial contains:- Pantoprazole Sodium ≡ Pantoprazole.....40mg | 1 vial | Rs.250.00 |
| 8. | Quetiapine Fumarate ≡ Quetiapine Tablets Each film coated tablets contains:- Quetiapine Fumarate ≡ Quetiapine.....400mg | 10's | Rs.750.00 |
| 9. | Polyethylene glycol+ Sodium bicarbonate+ Sodium Chloride+ Potassium Chloride Sachet Each sachet contains:- Polyethylene glycol.....13.125gm Sodium bicarbonate.....178.5mg Sodium Chloride.....350.7mg Potassium Chloride.....46.6mg | 10's | Rs.225.00 |
| 10. | Tetrahydrozoline HCl+ Sodium Cromoglycate 0.5%w/v/4%W/v Eye Drops Each ml contains:- Tetrahydrozoline HCl.....0.5% w/v Sodium Cromoglycate.....4% w/v | 15ml | Rs.116.00 |
| 11. | Amino Acid IV Injection Each 100ml contains:- (Total amino acids.....10.641g) L-Isoleucine.....0.56g L-Leucine HCl.....1.25g L-Lysine HCl.....1.10g L-Methionine.....0.35g L-Phenylalanine.....0.935g L-Threonine.....0.65g L-Tryptophan.....0.13g L-Valine.....0.45g L-Alanine.....0.955g L-Aspartic Acid.....0.38g L-Cysteube HCl (H2O).....0.145g L-Glutamic Acid0.65g L-Histidine HCl (H2O).....0.811g L-Proline.....0.33g L-Serine.....0.22g L-Tyrosine.....0.035g Amino acetic acid.....1.07g (Amino Acids) | 500ml | Rs.317.00 |

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| 12. | Pentavalent Vaccine DTwP-rHepB-Hib Each 0.5 ml contains:- Diphtheria Toxoid 25LF(≥ 30 IU) Tetanus Toxoid 5.5LF(≥ 60 IU) B. pertussis (Whole cell) 161OU(≥ 41 U) r-HBs Ag 12.5mcg Purified capsular polysaccharide 11mcg Tetanus Toxoid (Carrier protein) 20 to 36.7mcg A1+++ (s AIPO ₄) ≤ 1.25 mg Thiomersal BP 0.01% w/v | 0.5ml x 1's | Rs.2589.00 |
| 13. | Amino Acid IV Injection Each 1000ml contains:- (Amino acids (L-form)).....50.0g L-Isoleucine.....3.20g L-Leucine.....2.40g L-Lysine HCl.....2.50g L-Methionine.....3.00g L-Phenylalanine.....4.00g L-Threonine.....2.00g L-Tryptophan.....1.00g L-Valine.....3.20g L-Alanine.....6.00g L-Arginine HCl.....2.66g L-Arginine.....4.00g L-Histidine HCl.H ₂ O.....1.35g L-Proline.....2.00g Glycine (amino acetic acid).....14.0g D-Sorbitol.....100.00g Vitamin C.....400.00mg Inositol.....500mg Nicotinamide.....60.00mg Pyridoxine HCl.....40.00mg Riboflavin sodium Phosphate...2.50mg Water for injectionq.s Electrolytes (mEq/L) Sodium.....35 Potassium.....25 Magnesium.....5 Acetate.....35 Malate.....22 Chloride.....38 (Amino acids, vitamins & sorbitol) | 500ml | Rs.375.00 |
| 14. | Escitalopram as Oxalate 5mg Capsule Each capsule contains:- Escitalopram as Oxalate.....5mg | 14's | Rs.210.00 |
| 15. | Oxytetracycline dehydrate Tablet Each film coated tablet contains:- Oxytetracycline dehydrate equivalent to Oxytetracycline.....250mg | 1000's 1's | Rs.2030.00 Rs.2.03 |
| 16. | Itraconazole Tablet Each tablet contains:- Itraconazole.....100mg | 10's | Rs.690.00 |
| 17. | Ampicillin Sodium eq. to Ampicillin+ Cloxacillin Soium eq. to Cloxacillin Dry 250mg Powder Injection Each vial contains:- Ampicillin Sodium eq. to Ampicillin.....250mg Cloxacillin Soium eq. to Cloxacillin.....250mg | 10's 5's 1's | Rs.230.00 Rs.115.00 Rs.23.00 |

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| 18. | Azithromycin Ophthalmic Solution Each ml contains:- Azithromycin.....10mg | 2.5ml | Rs.133.00 |
| 19. | Amino Acid Tablets Each film coated tablet contains:- Valine Ph.Eur.....135mg L-Mehtonine USP.....90mg Leucine Ph.Eur.....90mg Tyrosine USP.....75mg Phenylalanine Ph.Eur.....70mg Lysine Acetate corresponding to Lysine USP.....65mg Theronine USP.....65mg Isoleucine Ph.Eur.....60mg Histidine Ph.Eur.....45mg Tryptophane USP.....25mg | 100's | Rs.2237.00 |
| 20. | Agomelatine Tablet 25mg Each tablet contains:- Agomelatine.....25mg | 28's 14's 10's | Rs.1960.00 Rs.980.00 Rs.700.00 |
| 21. | Montelukast sodium Sachet Each sachet contains: Montelukast as sodium4mg | 14's 28's | Rs.475.00 Rs.903.00 |
| 22. | Transamin Injection 1gm Each ml contains:- Tranexamic Acid.....100mg | 5 x10ml | Rs.708.00 |
| 23. | Potassium Citrate Tablets Each extended release tablet contains: Potassium Citrate.....1080mg | 100's | Rs.1380.00 |
| 24. | Pregabalin Capsule 300mg Each Capsule contains:- Pregabalin.....300mg | 14's | Rs.672.00 |
| 25. | Clarithromycin 500mg Lyophilized powder for Injection Each vial contains:- Clarithromycin Lactobionate equivalent to Clarithromycin500mg (suitably buffered) | 1's | Rs.160.00 |
| 26. | Glimepiride + Metformin HCl SR 1mg /500mg Tablets Each double layered tablet contains:- Glimepiride.....1mg Metformin HCl500mg (as sustained release) | 30's 20's | Rs.210.00 Rs.140.00 |
| 27. | Glimepiride + Metformin HCl SR 2mg /500mg Tablets Each double layered tablet contains:- Glimepiride.....2mg Metformin Hcl500mg (as sustained release) | 30's 20's | Rs.378.00 Rs.252.00 |
| 28. | Estazolam Tablets 1mg Each tablet contains:- Estazolam.....1mg | 20's | Rs.56.00 |

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| 29. | Methylprednisolone Aceponate Cream Each gram contains:- Methylprednisolone Aceponate0.1% w/w | 5gm 10mg 15gm | Rs.75.00 Rs.142.00 Rs.207.00 |
| 30. | Loratadine 5mg / 5ml Syrup Each 5ml contains: - Loratadine.....5mg | 60ml | Rs.49.00 |
| 31. | Loratadine Oral Solution Each ml contains: - Loratadine.....1mg | 60ml | Rs.49.00 |
| 32. | Ossien Mineral Complex Tablet with Vitamin D Each tablet contains Ossien Mineral Complex 830 mg (Hydroxy Apatite) Corresponding to Calcium177.6mg Phosphorous 82.2mg Residual Mineral Salts24.9mg Collagen224 mg Other Proteins66.1 mg Trace elements Fl,Mg,Zn,Fe,Ni,Cu) Corresponding to approximate.....440 mg of Hydroxyapatite Vitamin D3(Cholecalciferol)....400IU (equivalent to 0.01 mg) | 30's | Rs.225.00 |
| 33. | Etanercept Injection 25mg Each vial contains: Etanercept (Recombinant Human Necrosis Factor (a Receptor II IgG fusion protein) 25mg Lyophilized Powder for injection | 1 vial | Rs.10,500.00 |
| 34. | Amantadine 100mg Capsule Each capsule contains: Amantadine Hydrochloride.....100 mg | 20's | Rs.265.00 |
| 35. | Water for injection Each LDPE Ampoule contains: Water for injection | 20ml | Rs.16.00 |
| 36. | Amino Acid IV Injection Each 1000 ml contains L- Arginine HCl 2.7gm L-Histidine HCl H ₂ O 1.3gm L-Isoleucine 1.8gm L-Leucine 4.1gm L-Lysine HCl 6.2gm L-Methionine 2.4gm L-Phenylalanine 2.9gm L-Threonine 1.8gm L-Tryptophan 0.6gm L-Valine 2.0 gm Glycine (Aminoacetic acid) 3.4gm D. Sorbitol 50gm Water for Injection Q.S Free AA: 2.7% (w/v) E/N 3.1 Total Nitrogen 4.3gm/L Osmolarity 507 mOsm/L | 500ml 1000ml | Rs.230.00 Rs.437.00 |

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| 37. | Hypromellose Eye Drop Each ml contains:- Hypromellose.....3mg | 5ml | Rs.83.00 |
| 38. | Boostrix Vaccine, Each 1 dose (0.5ml) contains:- Diphtheria Toxoid not less than 2 IU Tetanus Toxoid not less than 20 IU <i>Bordetella pertussis</i> antigens: Pertussis Toxoid:8mcg Filamentous Haemagglutinin: 8mcg Pertactin: 2.5mcg <ul style="list-style-type: none"> Imported by GlaxoSmith Kline Pakistan Ltd., Karachi. From Manufacturer: M/s.GlaxoSmithKline Biologicals, Rixensart Belgium. | 1x0.5ml | Rs.1489.00 (Originator Brand) |
| 39. | Shanvac-B 0.5ml Injection Each 0.5ml Paediatric dose contains:- r-DNA Hepatitis –B surface antigen purified.....10mcg (Vaccine). <ul style="list-style-type: none"> Imported by Sanofi-aventis Pakistan Limited, Karachi. Form Shanta Biotech Limited. Survey No.274, Athvelli Village, Medchal, Mandal-501401, Rangareddy, District Andhra Pradesh, India. | 1 dose of 0.5ml | Rs.85.00 |
| 40. | Shanvac-B (rDNA Hepatitis-B Surface Antigen purified. (10 paediatric doses) Paediatric dose of 0.5ml contains:- rDNA Hepatitis-B Surface Antigen purified.....10mcg AlOH gel eq to Al+++.....0.25mg Thiomersal...0.025mg <ul style="list-style-type: none"> Imported by Sanofi Aventis Pakistan Limited, Karachi From Administrative Headquarter: Shantha (A Sanofi Compnay), Vasantha Chambers Fateh Maidan Road,Basheer Bagh Hyderabad AP India. Manufacturing Facility:- Survey No.274, Athvelli Village Medchal Mandal-501401 Rangareddy District, Andhra Pradesh, India. | 5mlx10's (100 doses) | Rs.7,820.00 |
| 41. | Qlaira Tablets (Estradiol valerate / Dienogest) Hormone combination Film coated tablets contains: Estradiol Valerate...2mg Dienogest.....3mg <ul style="list-style-type: none"> a) Imported by Bayer Pakistan (Pvt) Ltd., Karachi b) From Manufacturer M/s Bayer Weimer GmbH und Co. KG Doebereinerstrasse 20 99427 Weimer, Germany. | 28's | Rs.1010.00 (Originator Brand) |

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| 42. | Fluticasone Propionate + Salmeterol Xinafoate Inhaler HFA 50 Each inhaled dose contains:- Fluticasone Propionate.....0.050mg Salmeterol Xinafoate (*)..0.0363mg | Inhaler of 120 mds | Rs.574.00 |
| 43. | Fluticasone Propionate + Salmeterol Xinafoate Inhaler HFA 125 Each inhaled dose contains:- Fluticasone Propionate.....0.125mg Salmeterol Xinafoate (*).....0.0363mg | Inhaler of 120 mds | Rs.637.00 |
| 44. | Fluticasone Propionate + Salmeterol Xinafoate Inhaler HFA 250 Each inhaled dose contains:- Fluticasone Propionate.....0.250mg Salmeterol Xinafoate (*)..0.0363mg | Inhaler of 120 mds | Rs.728.00 |
| 45. | Piperacillin Sodium + Tazobactam sodium Injection Each vial contains:- Piperacillin Sodium equivalent to Piperacillin.....3.0gm Tazobactam sodium equivalent to Tazobactam...0.375gm | 1 vial | Rs.510.00 |
| 46. | Hydroxyethyl Starch 6% Injection. Each 100ml of the solution contains:- Hydroxyethyl Starch 130/0.4....6g Sodium Chloride...0.9g | 500ml | Rs.400.00 |
| 47. | Diatrizoate + Meglumine Injection Each 20ml ampoule contains:- Diatrizoate.....12.64gm Meglumine.....3.20gm | 20ml 5x20ml | Rs.168.00 Rs.773.00 |
| 48. | Gadoteric Acid + Gadolinium Oxide Solution for Injection. Each 100ml contains:- Gadoteric Acid 27.932mg corresponding to Dota.....20.246gm Gadolinium Oxide.....9.062gm | 15ml 10ml 5ml 20ml | Rs.2355.00 Rs.1570.00 Rs.785.00 Rs.2983.00 |
| 49. | Desmopressin Acetate 10mcg Nasal Spray Each actuation contains 10mcg Desmopressin Acetate hydrate 0.600mg corresponds to Desmopressin 0.534mg | 2.5ml (25 sprays) 6ml (60 sprays) | Rs.1516.00 Rs.3,347.00 |
| 50. | Harvoni Tablets Each film coated tablet contains: Ledipasvir.....90mg Sofosbuvir400mg <ul style="list-style-type: none"> • Imported by M/s. Ferozsans Laboratories, Nowshera • Manufactured by M/s Patheon Inc., 2100 Syntex Court, Mississauga, Ontario, L5N 7K9, Canada. • Repacked and batch release by: M/s Gilead Sciences Limited, IDA Business & Technology Park, Carrigtohill, Country Cork, Ireland. • Product License holder: M/s Gilead Sciences Inc., 333 Lakeside Drive, Foster City, CA, 94404, USA. | 28's | Rs.42,000.00 (Originator Brand) |

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| 51. | Esomeprazole Sachet 10mg Each Sachet contains:- Esomeprazole (as Magnesium trihydrate).....10mg as gastro- resistant Granules. | 14's | Rs.78.00 |
| 52. | Esomeprazole Sachet 10mg Each sachet contains:- Esomeprazole Magnesium Trihydrate Enteric Coated pellets 11.5% w/w ≡ Esomeprazole.....10mg | 14's | Rs.78.00 |
| 53. | Omeprazole 20mg Sachet Each sachet contins:- Enteric coated pellets of Omeprazole (22.5%) w/w ≡ Omeprazole20mg | 14's | Rs.150.00 |
| 54. | Iron Protein Succinylate Syrup Each 5ml contains:- Iron Protein Succinylate 800mg eq.to Elemental Iron40mg. Folic Acid2.5mg. | 60ml 120ml | Rs.96.00 Rs.182.00/ |
| 55. | Tramadol 50mg/ml Injection Each ml contains:- Tramadol HCl50mg | 5's 1's 10's 20's 30's 50's | Rs.85.00 Rs.17.00 Rs.162.00 Rs.313.00 Rs.469.00 Rs.782.00 |
| 56. | Phenobarbiton Injection 200mg 1ml Each ml Contains:- Phenobarbital Sodium...200mg (B.P specification) | 200's x 1ml 50's 30's 20's 10's 5's 1's | Rs.1674.00 Rs.419.00 Rs.251.00 Rs.167.00 Rs.84.00 Rs.42.00 Rs.8.37 |
| 57. | Paliperidone XR 6mg Tablet Each extended release tablet contains:- Paliperidone.....6mg | 10's | Rs.1770.00 |
| 58. | Genticyn HC Ear Drops Gentamycin (as sulphate)....0.3% w/v Hydrocortison acetate.....1% w/v | 7.5ml | Rs.28.00 |
| 59. | Sevelamer Carbonate 800mg Tablets Oral Each film coated tabltet contains: Sevelamer Carbonate (anhydrous).....800mg | 30's | Rs.1462.00 |
| 60. | Relvar Ellipta Dry Powder inhaler Each pre-dispensed dose contains: Fluticasone furoate.....100mcg Vilanterol (as trifrenatate).....25mcg <ul style="list-style-type: none"> • Imported by GlaxoSmith Kline Pakistan Ltd., Karachi. • From Manufacturer: M/s.Glaxo Operations UK Limited , Ware UK, | per 30 dose inhaler | Rs.2337.00 (Originator Brand) |

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| 61. | Relvar Ellipta Dry Powder inhaler Each pre-dispensed dose contains: Fluticasone furoate.....200mcg Vilanterol (as trifenate).....25mcg <ul style="list-style-type: none"> • Imported by GlaxoSmith Kline Pakistan Ltd., Karachi. • From Manufacturer: M/s.Glaxo Operations UK Limited , Ware UK, | per 30 dose inhaler | Rs.2727.00 (Originator Brand) |
| 62. | Renvela @ 800mg Tablets Each film coated tablet contains:- Anhydrous Sevelamer Carbonate800mg <ul style="list-style-type: none"> • Imported by Sanofi-aventis Pakistan Limited, Karachi. • Form Genzyme Ireland Ltd., IDA Industrial Park, Waterford, Ireland • Responsible for: Drug Product Manufacturing Labelling Pakaging, Batch Release, Stability, Storage and Distribution. M/s Genzyme Ltd., Haverhill-Suffolk, United Kingdom. | 30's | Rs.2089.00 (Originator Brand) |
| 63. | Tresiba Flextouch 100iu/ml One prefilled insulin pen contains 300 units of Insulin Degludec in 3ml <ul style="list-style-type: none"> • Imported by M/s NovoNordisc (Private) Limited Karachi • Imported from NovoNordisc, Denmark | 5x3ml | Rs.15,000.00 (Originator Brand) |

2. The maximum retail prices (MRPs) shall be subject to the followings conditions, namely:-

- (a) the manufacturers or importers shall have valid drug manufacturing licence or drug sale licence and drug registrations;
- (b) the manufacturers and importers of drugs shall furnish MRPs of drugs to the Division of Costing and Pricing of the Drug Regulatory Authority of Pakistan;
- (c) the MRP shall be printed on the label in the manner prescribed by the Drugs (Labeling and Packing) Rules, 1986; and
- (d) maximum retail prices as mentioned in column (4) of the Table shall not be applicable on drugs whose registrations under sub-rule (4) of rule 29 of the Dugs (Licensing, Registration and Advertising) Rules, 1976 were issued before the issuance of this notification, unless otherwise stated expressly.

[No.F.11-4/2016-DDC (P)]

(Amanullah)
Director Costing & Pricing

The Manager,
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