**GOVERNMENT OF PAKISTAN**
**Ministry of National Health Services, Regulations and Coordination**
**(Drug Regulatory Authority of Pakistan)**

# DRUG PRICING POLICY, 2018

(As amended upto 15th July, 2020)

*Islamabad, the 6th June, 2018*

F.No.9-13/2016-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 read with caluse (a) of sub-section (1) of Section 11 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012). The mechanism is termed as Drug Pricing Policy, 2018.

**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 anything 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;

(iv) "Biosimilar biological drug" means Similar Biotherapeutic Product (SPB) which is similar in terms of quality, safety and efficacy to an already licensed biotherapeutic product:

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

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

(vii) "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;

(viii) "distributor" means an authorized distributor of a manufacturer or importer having a valid drug sale license of wholesale or distribution;

(ix) "drug" means a drug registered under section 7 of the Act read with Section 7 of the DRAP Act;

(x) "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;

(xi) "Essential Drugs and Biologicals" for the purposes of this Policy means the drugs and biologicals included in the list of essential medicines as published by the World Health Organization (WHO) and notified by the Ministry of National Health Services, Regulations and Coordination and as updated or revised from time to time, subject to the following conditions, namely:-

(a) all strengths of a particular dosage form of drug and biological shall be considered as essential, if any of the strength of that dosage form is present in notified WHO Model List of Essential Medicines (MLEM);

(b) Dosage forms mentioned below in each rowshall be considered as interchangeable with each other in the same rowand essentialif any of the strength in one dosage form is present in WHO MLEM;

(i) Tablets and capsules;
(ii) Oral suspension, syrup, solution, emulsion, elixir and other oral liquids;
(iii) Cream, ointment, gel, lotion and paste;
(iv) Eye and ear drops;
(v) Nasal drops and nasal spray;
(vi) Liquid inhaler, dry powder inhaler and rotacap inhaler;
(vii) Intravenous, intramuscular, subcutaneous and other injectable forms; and
(viii) Injection, vial and ampoule and pre-filled syringe and pen cartridge;

(c) if any biological drugs is present in WHO MLEM, it shall be considered as essential irrespective of its source (human, animal, microbial etc.) and process or technology;

(d) for combination formulations of vaccines and biologicals, if all of combo ingredients are individually labelled andcategorized as essential in WHO MLEM, the combination in all strengths shall be considered as essential; and

(e) If primarydrug orbiological present in WHO MLEMis not registered in Pakistan, the alternative(s) mentioned against that particular molecule shall be considered as essential in that dosage form; [1]

(xii) "fee" means fee prescribed by the Authority or the Policy Board, as the case may be;

[1] Subsituted vide SRO 678(I)/2023 dated 9th June, 2023. Before substitution, clause (xi) of sub-paragraph (1) of paragraph 2 read as under: "essential drugs and biologicals" means the drugs and biologicals included in the list of essential medicines as published by the World Health Organization and notified by the Ministry of National Health Services, Regulations and Coordination and as updated or revised from time to time"

(xiii) "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;

(xiv) "Quintilies IMS data" means information of pharmaceutical market in Pakistan compiled by IQVIA, an organization which provides pharmaceutical market information globally;

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

(xvi) "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;

(xvii) "MRP" means the maximum retail price of a drug fixed by the Federal Government under section 12 of the Act read with Section 7 of the DRAP Act;

(xviii) "National Essential Medicine List" means the list of essential drugs and biologicals published by the Authority as updated or revised from time to time in accordance with WHO list of essential medicines;

(xix) "NCE/NBE" means the new chemical entity / new biological entity that has not been registered in the same dosage form, strength and delivery system in Pakistan;

(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) "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;

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

(xxvii) "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 all drugs including biologicals 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 and biological on National Essential Medicines List; and

(ii) All other drugs.

(3) List of drugs and biologicals in National Essential Medicines List may be revised after three years or earlier as deemed appropriate by the Authority in accordance with WHO list of essential medicines.

(4) MRP of a generic shall not, at any time, exceed the MPR of the respective Originator Brand except those cases where the Originator Brand has itself requested for de-registration or it is confirmed from the manufacturer or importer of the Originator Brand that they can no longer ensure the availability of the same due to the non-viability of the product;

(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.

(6) No person including a manufacturer, importer, retailer, hospital, clinic, wholeseller or distributor shall be allowed to affix stickers, overlapping or masking of prices. However, in case of voluntary reduction in MRP, masking of previous MRP and reprinting of reduced MRP through laser inkjet will be permissible, if so requested.

**4. MRP fixation of NCEs and NBEs.—** (1) MRP fixation of Originator Brand of NCE & NBE in a particular dosage form, strength & delivery system shall be based on average price of the same dosage form and strength 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 or NBE has not been marketed in India or Bangladesh, its maximum retail price shall be fixed as under:

(i) Average retail price of a basket of countries, namely; Indonesia, Philippines, Lebanon, Sri Lanka and Malaysia. If the Originator Brand is not available in all these countries, MRP shall be fixed at average retail price of the country(ies) in which Originator Brand is available; or if not available.

(ii) MRP of Originator Brand of NCE / NBE shall be fixed equal to average of the whole sale /procurement price available in the following:

(a) UK Monthly Index of Medical Supplies or British National Formulary (BNF);

(b) Australian Pharmaceutical Benefits Scheme;

(c) New Zealand Pharmaceutical Management Agency;

(d) If whole sale /procurement price is not available in any one or two of the above references, MRP shall be fixed at average of the whole sale /procurement price which is available in the remaining one or two references; or if not available.

(iii) MRP of Originator Brand of NCE / NBE shall be fixed on the basis of trade price in the country of origin and grossed up for 15% retailer margin; or if not available MRP calculated on the basis of formula in paragraph 9 or demanded MRP, whichever is lower.

(3) Prices of new chemical entities in other countries shall be verified from any one of the 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; or

(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; or

(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; or

(b) Any of top four global firms of chartered accountants operating in Pakistan through their member firms in the respective countries.

(c) IQVIA. Since IQVIA 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 or NBEs.—

(i) MRP of generics shall be fixed at 30% less than the MRP of the Originator Brand, however, it may be reduced to 20% in cases wherein compliance in respect of the regulatory requirements is established. This may include the establishment of Research and Development laboratories, submission of stability studies and comparative dissolution studies and the encouragement of cGMP compliance for local manufacturers.MRP so fixed shall be applicable to in respect of an NCE or NBE of all generic substitutes and not a particular brand.

(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 generic substitutes registered in Pakistan shall be fixed at average price in India (ceiling price of the drug fixed by the regulatory authority and if ceiling price is not available, retail price of the highest priced generic) and Bangladesh (retail price of the highest priced generic) and price shall be verified as per provisions of sub-para (3) of para-4.

(iv) if Originator Brand is not registered in Pakistan and price information of Originator Brand and generics is not available in India & Bangladesh; MRP shall be fixed at average retail pirce of the highest priced generics of the basket of countries as listed in paragraph 4 (2)(i).

(5) After expiry of 6 years or till the time of entry of at least 3 generics / biosimilars in the market, whichever is later, maximum retail price of the Originator Brand of NCE / NBE shall be reduced by 10% per annum for 3 consecutive years (cumulative reduction of 30%). MRP of any generic shall be at least 15% less than the MRP of Originator Brand so reduced. However, if the average of the Originator Brand price in India and Bangladesh is lower by between 0% to 30% the price will be revised by that difference.

(6) MRP of specialized dosage forms and existing drug molecules with new delivery systems shall be dealt under the provisions of reference pricing method under this para. However, in case of any clarification which may be required by the Drug Pricing Committee, Registration Board being technical forum for this purpose will give its opinion.

**5. MRPs of new strengths or new pack sizes.**— (1) MRPs of new strengths of already registered drugs shall be fixed by applying the following formulae.—

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

MRP = MRP of higher strength - 40%; and

(ii) Calculation of MRP of higher strength (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 changed or additional pack sizes of existing drugs shall be calculated on pro-rata basis of already fixed MRP of the existing pack size of an oral dosage form or topical preparation or pack size with different number of injections of the respective drug / brand. In case the new pack size is 2 times of the existing pack size, MRP of new pack size, after calculation of pro-rata MRP, shall be reduced by 2% and 4% reduction shall be applied if new pack size is triple or larger of the existing pack size.

(4) Pharmaceutical concern may apply for additional / changed pack size of their existing registered drugs as specified in sub-para (3) above to the DRAP (Division of Costing and Pricing) and a confirmation of filing of application & calculation of MRP in accordance with the Policy will be issued within 60 days of submission of the application. In case of any correction or deficiency, the pharmaceutical concern shall make the correction within 30 days and resubmit the calculations and document. If no intimation or advice is sent to the applicant within 60 days, the applicant may market the additional or changed pack size at MRP calculated in accordance with this Policy.

(5) MRPs of drugs containing combination of already registered drugs will be sum of MRPs of individual drugs and sum total reduced by 5%.

**6. Reduction in MRP of Originator Brand.**— (1) MRPs of Originator Brands of drugs &biologicals listed in National Essential Medicne List 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 10.

(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. If average price of the Originator Brand in India &Bangladesh is lower by between 0% and 30% then MRP will be reduced by that difference and simultaneously will be netted off over the applicable annual increase under this Policy. In case the Originator Brand is available in one of these countries, retail price in that country will 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 basket of countries as listed in para 4(2)(i);

(b) Whole sale price 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) Originator Brands for which bona fide hardship application are under review.

(2) If MRP of any Originator Brand has already been reduced or frozen for 15 or more years by the Federal Government or the manufacturer or importer itself, any such earlier reduction or freeze by the Federal Government or the manufacturer or importer itself shall be adjusted while calculating reduction under sub-para (1). However, annual increase linked with CPI shall not be granted to such Originator Brands from years 2015 to 2019. Thereafter, from July, 2019 these Originator Brands will be entitled to such annual increase.

(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. Annual adjustment in MRPs of drugs.**— (1) Annual increase in MRPs of drugs has been linked with CPI of the immediately preceding financial year.

(2) Manufacturers and importers may increase their existing MRP's of essential drugs/biological (excluding lower priced) equal to 70% increase in CPI (with a cap of 7%) and MRPs of all other drugs/biological and lower priced drugs up to increase in CPI (with a cap of 10%) subject to the following conditions, namely:-[2]

(i) calculations of revised MRPs, duly signed and stamped by the Managing Director or Managing Partner or CEO or any authorized person on his behalf, shall be submitted along with evidence for authenticity of existing MRPs to

[2] Subsituted vide Notification No. F.11-2/2020-DD(P) dated 15th July, 2020. Before substitution, sub-paragraph (2) of paragraph 7 read as under:

*"(2) Effective 1st July 2018, manufacturers and importers may, without prior approval, increase their existing MRPs of essential drugs/biologicals (excluding lower priced) equal to 70% increase in CPI (with a cap of 7%) and MRPs of all other drugs/biologicalsand lower priced drugs up to increase in CPI (with a cap of 10%) subject to the following conditions:*

*(i) Calculations of revised MRPs, duly signed and stamped by the Managing Director or Managing Partner or CEO or any authorized person on his behalf, shall be submitted along with evidence for authenticity of existing MRPs to the Authority (Division of Costing and Pricing) at least 30 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;*

*(ii) Revised price list shall be submitted in hard copy and uploaded on the DRAP's website or as prescribed by the Authority from time to time;*

*(iii) No manufacturer, importer, retailer, hospital, clinic, wholeseller or distributor shall be allowed to affix stickers, overlapping or masking of prices;*

*(iv) The price increase shall not be applicable on the batches manufactured before affecting the increase under this paragraph. No recall of drugs of already marketed batches shall be allowed; and*

*(v) The revised MRPs shall be printed on the label in the manner prescribed by the Drugs (Labeling and Packing) Rules, 1986."*

the Authority (Division of Costing and Pricing). Non intimation of MRPs shall be construed as non-revision of MRPs. The failure to submit the calculations for increase in MRPs shall tantamount to nullifying the price increase;

(ii) if calculations of revised MRPs are in accordance with this sub-praragraph, the Authority shall issue the revised price within 30 days of submission of the correct calculations by the manufacturer or importer provided that where the Authority fails to issue revised price within the mandatory period of 30 days, such issuance shall be deemed to have been made;

(iii) revised price list hsall be submitted in hard copy and upon issuance shall be uploaded on the DRAP's website or as prescribed by the Authority from time to time;

(iv) no manufacturer, importer, retailer, hospital, clinic, whole-seller or distributor shall be allowed to affix sickers overlapping or masking of prices;

(v) the price increase shall not be applicable on the batches manufactured before affecting the increase under this paragraph. No recall of drugs of already marketed batches shall be allowed;

(vi) the revised MRPs shall be printed on the label in the manner prescribed by the Drugs (Labeling and Packing) Rules, 1986; and

(vii) if there are cogent reasons why the MRP of a drug/biological should not be increased or reduced, the Federal Government may, by notification for reasons to be recorded, declare a specific category of drugs/biological to be excluded from application of this sub-paragraph.

**8. MRPs fixation of new entrants.—** (1) MRPs of the generic(s)/biosimilar(s) fixed 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 applicable to new entrants of the same drug. However, the manufacturer or importer may submit calculations of its MRP with DRAP, (Division of Costing & Pricing) to adjust MRP notified on registration letter under sub-rule (4) of rule 29 of the Dugs (Licensing, Registration and Advertising) Rules, 1976 with applicable rate of increase or decrease on the basis of CPI as allowed under Drug Pricing Policy-2015 or this Policy subject to conditions laid down in para 7 of this Policy.

(2) 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) MRP of generic(s)/biosimilar(s) shall be fixed at 30% of the MRP of the Originator, however, it may be reduced to 20% in cases wherein compliance in respect of the regulatory requirements is established. This may include the establishment of Research and Development laboratories, submission of stability studies and comparative dissolution studies and the encouragement of

cGMP compliance for local manufacturers. MRP so fixed shall be applicable to in respect of all generic substitutes and not a particular brand.

(ii) In case generic(s)/biosimilar(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, MRP shall be fixed at the highest MRP of a generic brand of the same drug/biological already available in the market.

(3) If strength of drug(s) in a tablet is equal, same MRP will be fixed for its all coated and un-coated forms.

(4) If strength of drug(s) in a capsule as powder or pellets is equal, same MRP will be fixed for its all hard forms.

(5) If strength of drug(s) in a liquid oral dosage form is equal, same MRP will be fixed for its all liquid dosage forms.

(6) If strength of drug(s) in otic or ophthalmic or nasal dosage form is equal, same MRP will be fixed for its all liquid dosage forms.

(7) If strength of drug(s) in a topical dosage form (gel/cream/ointment/paste/lotion/liquid) is equal, same MRP will be fixed for equal pack sizes in grams/milliliters etc.

(8) If contents of drug(s) in an injection is equal, same MRP will be fixed for its vial or ampoule irrespective of its filling in glass or plastic or Low Density Polyethylene (LDPE) or any other material upto 20ml pack size.

(9) If strength of drug(s) in a tablet or capsule in a modified release form is equal, same MRP will be fixed for its all modified (sustained/extended/delayed/corecoated /prolong /slow) release forms.

(10) If MRP is fixed for base, then same MRP will be considered for the salt as approved by reference regulatory authorities as adopted by the Registration Board.

**9. Hardship cases.**— (1) Hardship case of a drug means a situation in which a manufacturer or importer of a drug is unable to recover its costs and the profit margin as per the formula set out in this Paragraph (which deals with hardship cases).

(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 material 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

**<u>For locally manufactured drugs</u>:**

MRP = (Cost of active materials + excipients + cost of packing materials) x factor as under:

| Category | Factor |
|---|---|
| All oral types of drugs (except antibiotics &birth control pills) and topical preparations | 2.40 |
| All types of oral antibiotics, antiviral, anti-fungal and anti-infective drugs | 2.45 |
| Sustained release tablet /capsule | 2.95 |
| All sterile preparations and birth control pills | 2.95 |
| Dispersible tablets | 3.15 |
| Anti-T.B. drugs[3] | 3.15 |
| All aseptic preparations | 3.55 |
| Steroids and hormones | 3.55 |

**For imported drugs:**

Trade Price = Landed cost + mark-up @ 45% provided that in case of anti-cancer, biologicals, immunosupressants and anti-retroviral drugs, the mark up shall be 40%.

**For imported drugs in finished form and local labelling & cartooning**

Trade Price = (Landed cost + packaging cost) + mark-up @ 45% provided that in case of anti-cancer, biologicals, immunosupressants and anti-retroviral drugs, the mark up shall be 40%.

(ii) In case of imported drugs in finished form and finished import & local packaging, MRP shall be calculated by grossing up trade price to provide for retail discount @ 15%.

(3) Cost of raw and packaging materials and imported finished drugs will be as per actual of applicant. In case of locally produced raw materials, evidence of actual price as per commercial invoice and in case of packaging material, actual price as per sale tax invoice will be submitted along with application. In case of imported raw and packaging materials and finished drug, evidence of value as determined on bill of entry under the Customs Act, 1969 along with commercial invoice and import documents will be submitted.

(4) MRP of an Originator Brand shall not be increased over and above its average retail price (exclusive of VAT, GST, Excise Duty or any other levy on sale of drug) in India and Bangladesh or retail price in any of these countries if available only in one country or if Originator Brand is not available in any of these countries, MRP of Originator Brand shall not be increased over & above its retail price in other reference countries as per mechanism provided in paragraph 4 of this Policy.

(5) All new hardship applications filed after issuance of this Policy shall be decided within 120 days of submission of the hardship case on the specified from and complete in all respect with the DRAP (Division of Costing and Pricing) in manner as specified in this Policy. In case, no response is sent to the applicant of hardship case under provisions of this paragraph within 120 days, the applicant may apply to the Authority for increase of MRP

[3] Inserted vide Notification No. F.9-13/2016-DDC(P) dated 21st January, 2019.

upto maximum of 10% on the existing approved MRP with evidence that a complete case was submitted with the DRAP (Division Cositing and Pricing) provided that the applicant must have sent a reminder to DRAP 30 days before the expiry of the 120 days period. The Authority shall approve and issue the increase of MRP upto maximum of 10% subject to such increase not being more than what has been soughbt in the application, on the existing approved MRP as requested within 7 days of submission of application provded that where the Authority fails to issue the revised price within the mandatory period of 07 days, such issuance shall be deemed to have been made utpo an extent of 10% of MRP or the relief sought, whichever is lower. Further provided that if the matter has been referred by DRAP to the Federal Government within the aforesaid 120 days, the Federal Government shall decide the matter within 60 days of being submitted by the Authority.[4]

(6) The Drug Pricing Committee may consider hardship cases of critically needed drugs on the basis of import prices of raw materials or finished drugs as per Letter of Credit established by the applicant.[5]

**10. Lower priced drugs.—** (1) The drugs whose MRPs are less than the following threshold shall be deemed to be other drugs even otherwise falling under the category of essential drugs to encourage their production:

(a) Rs.3.11/- per tablet / capsule / respule / caplet

(b) Rs.3.11/- 5ml of syrup /suspension/elixir

(c) Rs.3.11/- per patch

(d) Rs.6.21/- per sachet

(e) Rs.15.53/- per injection

(f) Rs.3.11/- per 1 gm of cream/ ointment/ gel (non sterile) subject to maximum pack size of 20gm.

[4] Subsituted vide Notification No. F.11-2/2020-DD(P) dated 15th July, 2020. Before substitution, sub-paragraph (5) of paragraph 9 read as under:

*"(5) All new hardship applications filed after issuance of this Policy shall be decided within 180 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 in this Policy. In case, no response is sent to the applicant of hardship case under provisions of this para within 180 days, the applicant may increase its MRP upto maximum of 10% 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) provided that the applicant must have sent a reminder to DRAP 30 days before the expiry of the 180 days period. Further provided that if the matter has been referred by DRAP to the Federal Government within the aforesaid 180 days and the notification is not issued within a further period of 90 days (i.e. within a period of 270 days from the date of the submission of the hardship application) then the applicant may increase its MRP upto the level recommended by the DPC of DRAP to the Federal Government. For this purpose, DRAP will share the minutes of the relevant meeting with the applicant upon the expiry of 180 days after the submission of the hardship application. No applicant shall exercise this option more than once in 3 years."*

[5] Inserted vide Notification No. F.9-13/2016-DDC(P) dated 21st January, 2019.

(g) Rs.4.14/- per 1 gm of cream/ ointment/ gel (sterile) subject to maximum pack size of 20gm

(h) Rs.4.14/- 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 be increased by equal to CPI every year and notified by the Ministry of National Health Services, Regulations and Coordination.[6]

**11. Encouragement for exports to USA & Europe.—** (1) 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.

(2) This exemption shall stand withdrawn when export to such countries is discontinued for more than 12 months.

**12. 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 effecting the change.

(3) 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.

(4) 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.

(5) The MRPs fixed for any generic substitute will be applicable to, and in respect of, a molecule or combination of molecules of such generic substitutes, and not a particular brand. This will be applicable to all cases of anomalies of MRPs which shall be dealt with and addressed in the aforementioned manner.

(6) MRP of registered brand of a drug will remain same in case of its de-registration from name of its existing registration holder to its registration in the name of new applicant provided that the existing price is within approved maximum retail price of that brand and any pending application as hardship case under this Policy by earlier registration holder shall deemed to be a pending aplication for new registration holder.

(7) DPC will decide all cases in accordance with the provisions of this Policy and on the basis of material & evidence produced before it.

[6] Subsituted vide Notification No. F.11-2/2020-DD(P) dated 15th July, 2020. Before substitution, sub-paragraph (2) of paragraph 10 read as under:

*"(2) Threshold limit of lower priced drugs shall increase by equal to CPI every year."*

(8) The Policy Board may for reasons to be recorded in writing, recommend to the Federal Government that the MRP of a drug or class of drugs may be fixed or reduced or raised in modification of this Policy.

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