IN THE HIGH COURT OF SINDH, KARACHI

Constitution Petition Nos. D-1276 & 1277 of 2025

Date	Order with signature of Judge

Present: ***Mr. Justice Muhammad Junaid Ghaffar, ACJ***
Mr. Justice Mohammad Abdur Rahman, J

PETITIONER in both Petitions	:	**M/s. Abbott Laboratories Pakistan Limited Through Mr. Abdul Sattar Pirzada alongwith Mr. Muhammad Inzimam Sharif, Advocates.**
RESPONDENT	:	**Federation of Pakistan Through Ms. Mehreen Ibrahim, Assistant Attorney General.**
RESPONDENTS	:	**Drug Regulatory Authority of Pakistan & others Through Mr. Abdullah Nizamani, Advocate.**
Date of Hearing	:	**30.04.2025**
Date of Judgment	:	**18.06.2025**

J U D G M E N T

Muhammad Junaid Ghaffar, ACJ :-- Both these Petitions involve a common issue and were, therefore, heard together and are being decided through this common judgment. Prayer in C.P. No.D-1276 of 2025 read as under: -

> *(a) Declare that the order bearing No. No. F.14-79/2024-AB (M-170) dated 12.03.2025 (the "Impugned Order") passed Respondent No. 5 in respect of the products i.e. Brufen 200mg Tablet 100's, Brufen Suspension 120ml and Thyronorm Tablet 125 mcg 100's (the "Subject Products") is illegal, unlawful, unconstitutional, without jurisdiction, malafide, and of no legal effect;*
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> *(b) Grant any further relief that this Honourable Court deems appropriate; and*
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> *(c) Grant the costs of the Petition.*

2. Learned counsel appearing on behalf of the Petitioners has contended that the impugned orders dated 07.11.2024 passed by the (Division of Costing and Pricing) of The Drug Regulatory Authority of Pakistan ("**DRAP**") and 12.03.2025 passed by its Appellate Board respectively, are unlawful and in violation of the Drug Pricing Policy, 2018. Learned counsel has contended that the petitioner approached DRAP for an annual increase of prices of

various drugs in terms of Drug Pricing Policy, 2018, including the drugs in question, which have always been categorized as lower priced drugs for the past many years. However, the request was declined by DRAP and so also by the Appellate Board by treating the dugs in question as other than lower priced drugs. According to him, as such drugs were treated as a lower priced drugs in the past, including the immediate past year, therefore, now at this point of time the impugned decision, whereby it has been held that the drugs in question are other than lower priced drugs, is not justified and is in violation of the Policy in question. Per learned counsel, Petitioner on yearly basis approaches DRAP for annual adjustment in Minimum Retail Prices (MRPs) of the drugs in question and in terms of Rule 7 of the Drug Pricing Policy, 2018 it is provided that MRPs of essential drugs (excluding lower priced drugs) can be increased from the existing MRPs to 70% increase in Consumer Pirce Index (CPI) (with a cap of 7%), whereas the MRPs of all other products, including lower priced drugs, can be increased up to 10% cap subject to certain conditions. According to him, in the instant case, DRAP was approached for the increases in the MRPs up to 10% in respect of the drugs in question being lower priced drugs, whereas DRAP failed to take any decision and, therefore, in terms of Rule 7(2)(ii) ibid, the revised MRPs ought to have been increased as determined by the Petitioner and, therefore, the impugned orders cannot be sustained. He has further contended that even in terms of Rule 10(2) ibid it is required that threshold limit of lower priced drugs must be increased by equal to CPI every year and that shall be notified by the Ministry of National Health Services, Regulations and Coordination, which in the instant case, has not been done and, therefore, the drugs in question will still remain as lower priced drugs, even if they have crossed the threshold of the price as provided in Rule 10(1) ibid. He has prayed that the orders of the Authority in question be set aside, and the prices determined and calculated by the Petitioner be ordered to be notified pursuant to Rule 7(2)(ii) of the Drug Pricing Policy, 2018.

3. Conversely, learned counsel appearing on behalf of DRAP/ Respondents has opposed these Petitions on the ground that the drugs in question are no more lower priced drugs, as their MRPs are much higher than the maximum threshold provided in Rule 10(1) ibid and, therefore, the prices in question cannot be increased to 10%, but only to 7% if at all, as being drugs other than lower priced drugs. Per learned counsel, such fact is not in dispute that presently last MRPs of the drugs in question are higher than the threshold so prescribed in Rule 10(1) of the Policy in question.

4. Learned Assistant Attorney General appearing on behalf of the Federation of Pakistan has supported the arguments of the Respondents' Counsel.

5. We have heard learned counsel for the parties as well as learned Asst. Attorney General and perused the record. The Petitioner is a registered manufacturer of pharmaceutical products and is engaged in its production, sale, import, marketing and distribution. As per the record placed before us, Petitioner approached DRAP (Director Costing & Pricing) through letter dated 01.07.2024 for annual increase of MRPs in terms of Drug Pricing Policy, 2018 based on CPI for July 2023 to June 2024. This exercise appears to be a routine matter in respect of prices of drugs and their increase related to CPI and is an annual exercise for all types of drugs. The Petitioner pleaded that MRPs of the product in question must be increased based on CPI announced for 2023-2024 by the Pakistan Bureau of Statistic i.e. 23.41% and requested for 7% price increase for essential drugs and 10% price increase for the lower priced drug based on CPI. It further appears that initially no final order was passed on this request, and it is the case of the Petitioner that since the decision was not arrived at within 30 days of such request, the MRPs determined by the Petitioners are deemed to be notified and so determined in terms of the Drug Pricing Policy, 2018. However, subsequently an order was passed

on 07.11.2024, by which the Petitioner felt aggrieved and filed an appeal which also stands dismissed by the Appellate Board.

6. Before proceeding further, it would be advantageous to refer to the relevant Rules of the Drug Pricing Policy, 2018 i.e. Rule 7 and Rule 10, which reads as follows: -

> ***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.*
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> *(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:-*
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> *(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). 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;*
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> *(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;*
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> *(iii) revised price list shall 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;*
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> *(iv) no manufacturer, importer, retailer, hospital, clinic, whole-seller or distributor shall be allowed to affix stickers 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;*
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> *(vi) the revised MRPs shall be printed on the label in the manner prescribed by the Drugs (Labelling 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.*
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> ***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:*
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> *(a) Rs.3.11/- per tablet / capsule / respule / caplet*
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> *(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.*
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> *(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.*

7. In terms of Rule 7 as above, annual increase in MRPs of drugs has been linked with CPI of the immediately preceding financial year and the manufacturers as well as importers can increase their existing MRP's of essential drugs (excluding lower priced drugs) equal to 70% increase in CPI (with a cap of 7%) and MRPs of all other drugs (as well as lower priced drugs) up to increase in CPI (with a cap of 10%) subject to various conditions. Rule 7(2)(ii) further provides that if calculations of revised MRPs are in accordance with this sub-paragraph, 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. The Petitioner's first argument is that since DRAP failed to issue the revised prices within the mandatory period of 30 days, therefore, the prices so determined by the Petitioner shall be deemed to have been duly notified and issued. However, we are unable to agree with such submission; as firstly, Rule 7(2)(ii)

provides that *if calculations of revised MRPs are in accordance with this sub-paragraph*, it is only then, that the later part of the provision can be invoked i.e. if the prices are not notified by the Authority within 30 days such issuance shall be deemed to have been made. It is not that if a manufacturer or importer calculates or determines MRPs on its own without following the clear mandate of the Rules that such self-determined price shall be deemed to have been notified. The prices in question as per the existing Rules were required to be calculated in accordance with Rule 7 and Rule 10 thereof. The Petitioner on its own has categorised the prices of the drugs in question as *"lower priced drugs"*, whereas presently it is not so. Admittedly, at this point of time, after the last increase, the prices of the dugs in question are not falling within the threshold of lower priced dugs as provided in Rule 10 ibid. It appears that with a gradual increase in the price of these drugs on annual basis, they have now crossed the threshold of lower priced drugs and are no more lower priced drugs, notwithstanding the fact that such threshold limit of lower priced drugs has not been increased by equal to CPI by Respondent No.1, as required under Rule 10(2) of the Drug Pricing Policy, 2018. We are told that a representation in that regard is pending; however, for the present purposes and for adjudication of this petition, the said issue is neither before us nor relevant at this moment of time as the sole prayer of the Petitioner is in respect of the orders of DRAP and the Appellate Board. Therefore, till such time any revised notification is issued by Respondent No.1 in terms of Rule 10(2) ibid, the Petitioner on its own cannot assume the role of Respondent No.1 and treat its own increase in the threshold limit of lower priced drugs and thereafter make calculations for its increase to an extent of 10% of the CPI. Accordingly, the calculations made by the Petitioner do not seem to be in conformity with the Drug Pricing Policy, 2018; hence, no question would arise for invoking Rule 7(ii) of the Drug Pricing Policy, 2018 for any deemed issuance of such self-determined revised prices.

8. Secondly, and though not required in view of the above finding, the argument of the learned Counsel that the provisions of Rule 7(ii) ibid are mandatory is also not tenable. Here, as already discussed, the requirement as provided in Rule 7(i) ibid has not been fulfilled as the calculations are not in conformity with Policy in question, and therefore, no occasion has arisen to take shelter under sub-rule (ii) thereof. Per settled law, a provision in a statute is mandatory if the omission to follow it renders the proceedings to which it relates illegal and void, while a provision is directory if its observance is not necessary to the validity of the proceedings[1]. Moreover, to distinguish where the directions of the legislature are imperative and where they are directory, the real question is whether a thing has been ordered by the legislature to be done and what is the consequence, if it is not done and the duty of the Court is to unravel the real intention of the legislature[2]. It can even be the case that a certain portion of a provision, obligating something to be done, is mandatory in nature whilst another part of the same provision, is directory, owing to the guiding legislative intent behind it[3]. In the instant case, though it is provided that an inaction on the part of DRAP in notifying the revised prices per Rule 7(2)(ii) ibid within 30 days of its submission, such issuance shall be deemed to have been made, the exception that calculations of revised MRP's must be in accordance with the Rules and shall also be "correct calculations", by itself shows the intent of the legislature that the said Rule is not mandatory but directory. In each case one must look to the subject matter and consider the importance of the provision disregarded and the relation of that provision to the general object intended to be secured[4]. Here, it may be a case that increase in prices (subject to correct calculations) shall be deemed to be notified, as it is an annual exercise based on CPI; however, when there is an issue like the one in hand, where the question that

[1] The State v Imam Baksh (2018 SCMR 2039)
[2] The State v Imam Baksh (2018 SCMR 2039)
[3] The State v Imam Baksh (2018 SCMR 2039)
[4] The State v Imam Baksh (2018 SCMR 2039)

whether a drug is a lower priced drug or not, for an automatic increase based on CPI, then, the said provision cannot be held to be mandatory. We are bound to follow the Supreme Court and its pronouncements[5] , both of which reiterate that in situations where a statute's provision pertains to the execution of a public duty and imposes inconvenience or injustice on individuals who lack control over those tasked with the duty, without furthering the fundamental objectives intended by lawmakers, such directives are typically viewed as directory. Neglecting these directives may result in penalties, but it does not invalidate actions taken in disregard of them[6]. Therefore, the argument that the prices determined by the present Petitioner are deemed to have been notified in terms of Rule 7(2)(ii) ibid, is misconceived and is hereby repelled.

9. As to merits of the case that whether the Petitioner is entitled for an increase of 10% or 7%, there appears to be no dispute that the last MRPs of the drugs in question are above the threshold as provided in Rule 10(1) of the Drug Pricing Policy, 2018, which states that the drugs whose MRPs are less than the notified threshold shall be deemed to be “other drugs” or lower priced drugs even otherwise falling under the category of essential drugs to encourage their production. The application of this provision on the case of the Petitioner, as of today, excludes the drugs in question from the category of “lower priced drugs”. In that case, for a drug to be categorized as a lower priced drug, the MRPs must be less than the prices notified in Rule 10(1) (a) to (h) ibid. It may be a case that the drugs in question were categorized as lower priced drugs by DRAP in the preceding years, but that was for reason since prices of such drugs, at the relevant time, were less than the threshold provided in Rule 10(1). In that case, there cannot be any dispute as to these drugs being lower priced drugs. However, these lower priced drugs (drugs in hand) by virtue of an annual increase in their

[5] Reference No.1 of 1988 (PLD 1989 SC 75) & The State v Imam Baksh (2018 SCMR 2039)
[6] Judgment dated 28.3.2024 passed by a Division Bench of this Court in HCA No.92 of 2023

MRPs continuously in the preceding years based on CPI, (definitely, at least in the last financial year) to an extent have now crossed the threshold as provided in Rule 10(1) of the Drug Pricing Rules, 2018. To that effect, there is no dispute that insofar as the present year increase is concerned, the prices of the drugs in question are much higher than the threshold provided in Rule 10(1) ibid, and, therefore, they are no more a lower priced drugs in terms of the said Rule. The argument of the Petitioner's Counsel that last year, despite an increase in the MRPs of the drugs in question and their notified prices still being above the maximum threshold as per Rule 10(1) ibid, DRAP had still recognised these drugs as lower priced drugs is concerned, it would suffice to hold that we do not appreciate the same, if at all the case is so. Two wrongs did not make a right is a saluted principle of law and we cannot, even for a moment intent to deviate from it. One alleged illegality did not furnish justification to repeat yet another illegality[7]. In our view, even if such mistake has been committed by DRAP, as contended, it still is not binding on this Court as a precedent. It was against the law and rules in question, therefore, is of no help. Since, as of today, the drugs in question cannot be categorized as lower priced drugs, therefore, the impugned orders/decisions of the forums below appear to be correct and justified and no case for indulgence is made out.

10. Before parting, we may observe that insofar as the implication of an inaction on the part of Respondent No.1, in exercising its statutory duty in terms of Rule 10(2) of the Drug Pricing Policy, 2018, which provides that threshold 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 is concerned, the contention of the Petitioner appears to be justified and must be looked into. Since the said issue is not part of the

[7] Naimatullah Khan v Fed.of Pakistan (2020 SCMR 1499); Hasnat Ahmed Khan v Institution Officer (2010 SCMR 354); Noor Muhammad v The State (PLD 1977 SC 507); The City Schools (Private) Limited v Fed. Of Pakistan (2018 CLC Note 4)

prayer clause, we do not deem it appropriate to pass any final orders in this regard, coupled with the fact that this bench has heard these petitions as a bench other than a Constitutional Bench while exercising limited jurisdiction in terms of Article 199(1)(a)(ii) of the Constitution of the Islamic Republic of Pakistan, 1973. However, the Petitioner is at liberty to agitate the same before Respondent No.1 or any other forum as may be available in law. If Respondent No.1 is approached, the said issue shall be decided by the said Respondent within 60 days from the date of this judgment, in accordance with law.

11. In view of hereinabove facts and circumstances of this case and the admitted position to the effect that as on 01.07.2024 the MRPs of the drugs in question were above the threshold as provided in Rule 10(1) of the Drug Pricing Policy, 2018; hence they cannot be categorized as lower priced drugs. Consequently, thereof, while maintaining the impugned orders, both these Petitions are hereby ***dismissed*** with pending application(s).

Dated: 18.06.2025

ACTING CHIEF JUSTICE

JUDGE

Farhan/PS