IN THE HIGH COURT OF SINDH AT KARACHI

Present: **Muhammad Ali Mazhar** and **Agha Faisal**, **JJ**.

CP D 4197 of 2019	:	*Sanofi-Aventis Pakistan Limited vs. Federation of Pakistan & Others*
CP D 4215 of 2019	:	*Barrett Hodgson Pakistan (Private) Limited vs. Federation of Pakistan & Others*
CP D 4845 of 2019	:	*Pfizer Pakistan (Private) Limited vs. Federation of Pakistan & Others*
Dates of Hearing	:	23.10.2019, 13.11.2019, 05.12.2019 18.12.2019 & 23.12.2019.
CP D 5612 of 2019	:	*Health (Private) Limited vs. Federation of Pakistan & Others*
CP D 5613 of 2019	:	*Sami Pharmaceuticals (Private) Limited vs. Federation of Pakistan & Others*
CP D 5614 of 2019	:	*Hilton Pharma (Private) Limited vs. Federation of Pakistan & Others*
Date of Hearing	:	23.12.2019.
CP D 4101 of 2019	:	*Martin Dow Marker (Pvt.) Limited vs. Federation of Pakistan & Others*
CP D 4291 of 2019	:	*The Searle Company Limited vs. Federation of Pakistan & Others*
CP D 4328 of 2019	:	*Ambrosia Pharmaceuticals vs. Federation of Pakistan & Others*
CP D 5085 of 2019	:	*Indus Pharma (Private) Limited vs. Federation of Pakistan & Others*
CP D 5086 of 2019	:	*Tabros Pharma (Private) Limited vs. Federation of Pakistan & Others*
CP D 5674 of 2019	:	*Schazoo Pharmaceutical Laboratories (Pvt.) Ltd vs. Federation of Pakistan & Others*
CP D 5902 of 2019	:	*Asif Aziz Akhai vs. Federation of Pakistan & Others*
CP D 7768 of 2019	:	*CCL Pharmaceuticals (Pvt.) Ltd. vs. Federation of Pakistan & Others*
Dates of Hearing	:	23.10.2019, 13.11.2019, 21.11.2019 05.12.2019 & 18.12.2019
For the Petitioners	:	Mr. Raashid K Anwar, Advocate (CP D 4845 of 2019)
		Barrister Umaimah Khan (CP D 4101 of 2019)

Barrister Abdul Sattar Pirzada
(CP D 4197 & 4215 of 2019)
(CP D 5612, 5613 & 5614 of 2019)
(CP D 4291, 4328, 5085 & 5086 of 2019)

Mr. Mamoon N. Chaudhry, Advocate
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Mr. Waheed Alam, Advocate
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Mr. Amanullah
Deputy Director Pricing, DRAP

Date of Announcement : 17.02.2020

JUDGMENT

Agha Faisal, **J**: The present petitions assail respective decisions of the Drug Regulatory Authority of Pakistan, Ministry of National Health Services, Regulations and Coordination ("DRAP") in pursuance whereof the maximum retail prices ("MRP"), of drugs purveyed by the petitioners, were rationalized. The petitions under consideration may be classified into three categories; being petitions challenging the reduction in MRP of originator brands ("Originator Petitions"), petitions challenging the reduction in MRP of generic brands ("Generic Petitions") and petitions challenging the reduction in MRP in respect of hardship cases ("Hardship Petitions"). The thread common to all these matters is the impugned reduction in the MRP of drugs, hence, we shall endeavor to determine these matters by this common judgment.

Factual Background

2. Briefly stated, numerous cases were filed before the Courts to remedy grievances related to the pricing of drugs, pursuant to the *Drug Pricing Policy 2015* ("2015 Policy"). The honorable Supreme

Court, in *Human Rights Case 2858 of 2006* (“HRC”), summoned the record of legal proceedings, pertinent to drug pricing, and strove to resolve the issue itself in the larger public interest. As a consequence of the foregoing and with the consensus of the stakeholders, the Drug Pricing Policy 2018 (“2018 Policy”) was notified. Amplificatory directions in such regard were also issued by the honorable Supreme Court in *HRMA 478 of 2018* (“HRMA”).

Thereafter, the tabulation of MRP by DRAP was challenged before this Court in the *Pfizer case*[1]. This Division bench determined the petitions by *inter alia* directing the petitioners to avail the statutory hierarchy of appeal, in consonance with the orders of the honorable Supreme Court, in the HRC / HRMA. Appeals, being CPLA 1510 of 2019 and CPLA 2545 of 2019, were preferred against the judgment of this Court in the *Pfizer case*, however, the same were reportedly dismissed as withdrawn on 19.12.2019.

The first set of petitions before us (“Originator Petitions[2]”) assail the respective orders of the Appellate Board of DRAP (“Appellate Board”), rendered in appeals, proceeded with and concluded pursuant to the judgment in the *Pfizer case*. The second set of petitions (“Generic Petitions[3]”) assail letters of DRAP, directing them to rationalize drug prices to ensure that the MRP of generics is at least fifteen percent lower than that of corresponding originator brands, as prescribed vide the 2018 Policy. The final set of petitions (“Hardship Petitions[4]”) assail the determination of MRP of respective drugs upon the basic premise that the said process is in dissonance with the orders of the honorable Supreme Court, as enunciated vide the HRC and amplified vide the HRMA. These three sets of petitions shall be determined in seriatim vide this judgment.

Originator brands

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1 *Pfizer Pakistan (Private) Limited vs. Federation of Pakistan & Others* reported as *2019 MLD 1849*.
2 *CP D 4197 of 2019, CP D 4215 of 2019 and CP D 4845 of 2019.*
3 *CP D 5612 of 2019, CP D 5613 of 2019 and CP D 5614 of 2019.*
4 *CP D 4101 of 2019, CP D 4291 of 2019, CP D 4328 of 2019, CP D 5085 of 2019, CP D 5086 of 2019, CP D 5674 of 2019, CP D 5902 of 2019 and CP D 7768 of 2019.*

3. The representative context of these petitions is that the 2015 Policy provided for a mechanism for reduction in the MRP of drugs falling within the category of originator brands. It was prescribed that unless it was possible to determine the price upon consideration of the price for the same drug being marketed in India and Bangladesh, the retail price in all developing countries, which regulate drug price, shall be taken into account. This condition was considered to be too onerous, hence, litigation proliferated in such regard culminating upon the issuance of the 2018 Policy. The difference in the 2018 Policy vis-à-vis 2015 Policy, relevant to pricing of originator brands, is that the reduction in the maximum retail price, where the said brand was not marketed in India and Bangladesh, was to be predicated upon a basket of countries, defined in the 2018 Policy as being Indonesia, Philippines, Lebanon, Sri Lanka and Malaysia and not all developing countries, as envisaged per the earlier 2015 Policy.

4. The petitioners' grievance arose when the respondents determined / reduced the MRP of drugs on the basis of 2015 Policy, post issuance of the 2018 Policy[5]. Numerous petitions were filed before this Court and the same were determined collectively vide the *Pfizer judgment*[6], *inter alia* directing the petitioners to avail the statutory remedy available thereto, in line with the specific orders of the honorable Supreme Court. The petitioners proceeded with the appeals and upon dismissal thereof challenged the respective appellate orders in the first set of petitions before us. The operative constituent of the appellate order, assailed in CP D 4845 of 2019, being representative of the appellate orders assailed in the remaining Originator Petitions, is reproduced herein below:

> "21. It is clear from above that reduction in prices of originator brand of the appellant was justified since it could not prove that MRPs of its originator brand fall under the exceptional clause stipulated in paragraph 6 of 2015 Policy. Accordingly, DPC recommended reduction in MRPs as per law.
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> 22. The Board, after hearing arguments and perusing record of the case, decided to dismiss the appeals being without merit."

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[5] *SRO 1610(I)/2018 dated 31.12.2018*.

[6] *Pfizer Pakistan (Private) Limited vs. Federation of Pakistan & Others* reported as *2019 MLD 1849*.

5. Prior to proceeding with the merits of the petitions under consideration, it is imperative to record that the petitioners, in two of the three petitions under scrutiny, had filed appeals[7] before the honorable Supreme Court against the *Pfizer judgment*. The basic crux of these appeals was exactly as the case presently before us, being whether the MRP was required to be determined per the 2015 Policy or the 2018 Policy. These appeals remained pending throughout the successive dates upon which these petitions were heard and subsequently reserved. The issue of parallel proceedings was identified during the course of writing the judgment and consequently these three petitions were listed for rehearing on 18.12.2019, after notice to the learned counsel. The appeals[8] under reference were subsequently withdrawn by the respective parties and verbal intimation to such effect was provided to this Court on 23.12.2019, when these petitions were reserved once again. While we eschew any commentary upon maintaining undisclosed parallel proceedings before this Court, during the pendency of proceedings seeking the determination of the same question by the same parties before the honorable Supreme Court, it would suffice to observe that by virtue of withdrawal of the appeals the *Pfizer judgment*[9] has attained finality, hence, remains binding upon us.

6. Learned counsel for the petitioners assailed the respective orders of the Appellate Board and argued that they were rendered in erroneous interpretation of the law, for the reason that the said orders were prima facie in violation of the edict of the honorable Supreme Court; in violation of the due process of law; and contrary to DRAP's settled customary practice of applying the policy in vogue to matters pending there before. It was submitted that the orders under challenge were not speaking orders and that they merely reiterated the earlier decision of DRAP and upheld the same without any application of mind or consideration of the grounds agitated there before. It was further argued that while the constraints imposed under the 2018 Policy are being applied to the petitioners yet at the

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[7] *CPLA 1510 of 2019* and *CPLA 2545 of 2019*.
[8] *CPLA 1510 of 2019* and *CPLA 2545 of 2019*.
[9] *Pfizer Pakistan (Private) Limited vs. Federation of Pakistan & Others* reported as *2019 MLD 1849*.

same time the benefit emanating from the same policy is being denied to the petitioners.

7. Mr. Amanullah, Deputy Director (Pricing) DRAP appeared, along with learned Assistant Attorney General, and controverted the arguments advanced on behalf of the petitioners. It was submitted that the orders of the honorable Supreme Court were exclusively with respect to hardship cases, particularized therein, and that admittedly the case of the petitioners did not fall within the said category. It was further argued that if the petitioners were seeking interpretation of the orders of the honorable Supreme Court then it was proper for the said arguments be agitated before the apex Court itself[10]. It was also submitted that the same companies market the same drugs under different brand names in different countries and as such it would be inconceivable to expect the regulatory authority to keep track of the same in each country in order to itself determine the pricing. Reliance in such regard was placed on the *Atco Lab case*[11]. In conclusion it was submitted that the appellate orders have been rendered in accordance with the law, hence, merited no interference herein.

8. We have heard the respective arguments and have also considered the law, precedent and documentation to which our surveillance was solicited. It is an admitted fact that the appellate orders were rendered to maintain that the 2015 Policy was applicable in the respective cases of the petitioners for fixation of the MRP. In this backdrop only issue for us to consider is whether the said approach was in accordance with law.

9. The case before the Appellate Board primarily was the determination whether the MRP, of the drugs of the petitioners, was to be determined pursuant to the 2015 Policy, as had been done, or the 2018 Policy, as argued by the petitioners there before. A bare perusal of the impugned order in CP D 4845 of 2019, being

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[10] In this regard reliance was placed on an order of the honorable Supreme Court dated *18.08.2016* in *Criminal Original Petition 89 of 2011* passed on *Criminal Miscellaneous Application No.1381 of 2016*.

[11] *Atco Lab (Pvt.) Limited vs. Pfizer Limited & Others* reported as *2002 CLD 120*.

representative of the impugned orders in the remaining petitions as well, demonstrates that Appellate Board has upheld the recommendations of the Drug Pricing Committee without any deliberation / discussion upon whether the 2018 Policy should have been applied or otherwise.

10. The law[12] specifies that where an authority is making any order or issuing any direction, under the powers conferred by or under any enactment, then it shall give reasons for making the order or as the case may be for issuing the direction. These precepts are included in the definition of a speaking order, being an order that speaks for itself and manifests that the adjudicating authority has applied its independent mind to the issues and controversy involved in the cause[13]. This requirement is not only applicable to courts but also extended to public functionaries, who are duty bound to decide cases after independent application of mind[14] and their orders are obliged to demonstrate reasoning in the redressal of the grievance seized there before[15].

The orders of the Appellate Board, impugned in the Originator Petitions, merely reproduce the facts leading up to the issue there before in a mechanical manner and uphold the order/s under appeal without any demonstrable reasoning and / or independent application of mind. Such a cursory approach to adjudication of appeals is unmerited; more so in view of the importance and relevance attributed to the Appellate Board by the august Supreme Court in the HRC and HRMA. Therefore, we are constrained to observe that the said orders cannot be considered as speaking orders, hence, not sustainable in law.

11. It is manifest that the petitioners have exhausted the prescribed appellate process, which has *prima facie* failed to adjudicate the real issue there before, being whether it was the 2015

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[12] *Section 24A(2) General Clauses Act 1897*.
[13] *Poly Pack Limited vs. Customs & Central Excise Appellate Tribunal & Others* reported as *2005 PTD 2566*.
[14] *United Woolen Mills Limited Workers Unions vs. United Woolen Mills Limited* reported as *2010 SCMR 1475*; *Fasihudin Khan vs. Govt of Punjab* reported as *2010 SCMR 1778*.
[15] *Secretary Health vs. Dr. Rehana Hameed* reported as *2010 SCMR 511*; *Airport Support Services vs. Airport Manager Karachi* reported as *1998 SCMR 2268*.

Policy or the 2018 Policy that is to govern the determination of MRP of the pertinent therapeutic goods subject matter of the present petitions.

It is reiterated that the manifest difference between the aforesaid policies *inter se*, relevant for the present controversy, is that where a brand was not marketed in India and Bangladesh, whether the determination of MRP was to be predicated upon a basket of countries or in consideration of the prices in all developing countries.

12. The 2015 Policy[16] required that where a brand was not marketed in India and Bangladesh, its MRP could not be higher than the lowest retail price of the said item in all developing countries. This condition, relevant to reduction in the MRP of originator brands, was considered unreasonable and onerous, hence, became the subject of multifarious litigation before the courts. It is imperative to record here that the determination of MRP, subject matter herein, pursuant to the 2015 Policy was a constituent of the litigation referred to supra.

The honorable Supreme Court took notice of this litigation, in the interest of the public, and initiated *suo motu* proceedings in such regard[17]. Under the guidance of the honorable Supreme Court a roadmap was agreed between the stakeholder drug manufacturers and the regulatory body and proceedings were concluded observing *inter alia* that the parties had consensually agreed to a roadmap and therefore there was no reason to interfere with the same on any ground whatsoever. This consensual roadmap culminated in the notification of the 2018 Policy.

The 2018 Policy addressed the grievance with regard to the reduction in the MRP of originator brands and specified that in the instances where a brand was not marketed in India and Bangladesh, the determination of MRP was to be predicated upon a specified

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16 *Paragraph 6 of 2015 Policy*.
17 *In HRC 2858 of 2006*.

basket of similarly placed countries. As a consequence hereof, the respective suits, wherein this issue was under challenge prior to the intervention of the august Supreme Court, were disposed of by the Courts seized thereof.

The petitioners' grievance arose when, after conclusion of the HRC, issuance of the 2018 Policy and withdrawal of the relevant litigation matters, the respondents notified SRO 1610[18] and determined the MRP on the basis of 2015 Policy and not the 2018 Policy.

13. The argument advanced before us on behalf of the respondents was that since the same drugs are marketed under different brand names in different countries, therefore, it would be inconceivable to expect the regulatory authority to keep track of the same in each country in order to itself determine the pricing. Instead all that was required, pursuant to the 2015 Policy, was for the concerned company to provide a certification stipulating that the pertinent price, in all developing countries of the world, is higher than that sought in Pakistan.

Respectfully, we find ourselves unable to subscribe to such reasoning. At the very onset the respondents have expressed their inability to independently determine whether the price sought was lower than that prevalent in all developing countries of the world. The said respondents have also expressed their inability to verify the authenticity of such a certification, if given, as it would require independent inquiry with respect to each drug individually from reportedly One Hundred and Eighty Seven countries. This raises the specter of the effectiveness, and resultantly efficiency, of such a certification as impliedly any entity could conceivably present such a certification, notwithstanding the veracity thereof.

Furthermore, if the said requirement, per the 2015 Policy, was reasonable and justifiable then there would be no occasion to remove the same vide the 2018 Policy, which requires that the

[18] *SRO 1610 of 2018 dated 31.12.2018*.

determination of MRP was to be predicated upon a basket of similarly placed countries, being Indonesia, Philippines, Lebanon, Sri Lanka and Malaysia.

Finally, it is poignant to record that the respondents have been unable to advance any justification as to why the earlier determination, per the 2015 Policy, was maintained, at a point in time when the 2018 Policy was admittedly in force, when in fact there was a consensual roadmap agreed *inter se* under the supervision of the august Supreme Court, culminating in the 2018 Policy, based whereupon the litigation, challenging the very application of the 2015 Policy, was withdrawn.

It is thus our considered view that the approach of the Appellate Board to maintain the application of the 2015 Policy, in the present facts and circumstances, has not been justified before us and it sets the entire exercise piloted by the Supreme Court to naught.

14. In view hereof it is our considered view that the orders of the Appellate Board, impugned in CP D 4197 of 2019, CP D 4215 of 2019 and CP D 4845 of 2019 respectively, cannot be sustained, hence, are set aside. As a consequence hereof, the respondent no. 2 is directed to *de novo* determine the MRP of the therapeutic goods of the petitioners, subject matter herein, in application of the 2018 Policy and submit such a determination for notification by the respondent no. 1, preferably within three months from the date hereof.

It is imperative to observe that till such time as the aforesaid exercise is concluded, and the intended determination concluded and notified, the MRP subsisting, as notified vide SRO 1610[19], shall remain in the field.

Generic brands

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[19] *SRO 1610 of 2018 dated 31.12.2018*.

15. The petitioners in the second genre of petitions, Generic Petitions, contend that, per the 2018 Policy, MRP of generic brands is required to be at least fifteen percent less than the MRP of the relevant originator brands. Notwithstanding the marginalization of the MRP of originator brands, as delineated supra, the petitioners contend that since interim orders are operating in the Originator Petitions, therefore, no reduction in the commensurate generic brands is merited till such time as the Originator Petitions are determined.

16. The petitioners were served a letter dated 19.06.2019, issued by DRAP, whereby they were required to rationalize the respective MRP pursuant to the marginalization in the MRP of corresponding originator brands. The petitioners refused to accede to the directions and a representative reply is reproduced herein below:

> "…. We hereby submit that the price reduction cases of the following originator brands are pending in different courts of law at the moment:
> ……..
> As and when these sub-judiced cases attain finality of decision from their respective courts, we would implement revised prices accordingly on our above mentioned generic brands."

The regulatory authority rejected the aforesaid contention of the petitioners, vide letter dated 07.08.2019, stipulating that orders being referred to were specific to the petitioners that had obtained them, exclusive of the present petitioners, hence, entirely inapplicable in the present facts and circumstances. Aggrieved by the two letters referred to supra the present petitions were preferred.

17. We have heard the respective arguments and considered the documentation placed before us. It is an admitted position that the petitioners have filed no proceedings before any fora of appropriate jurisdiction to challenge the impugned letters, unlike the case of the Originator Petitions. The crux of the petitioners herein is that no reduction of MRP can be enforced thereupon until final decisions were obtained in the corresponding Originator Petitions. In view hereof we do hereby confine our scope herein to determine whether the said approach was in accordance with law.

18. With respect, we find ourselves constrained to observe that the petitioners have been unable to advance any cogent grounds to enable us to sustain the aforesaid argument.

It hardly merits reiteration that each case is decided on its own facts and orders passed therein are specific to the parties thereto, unless the said orders are required to operate *in rem*[20]. In the present facts and circumstances no argument has been placed before us to suggest that any order in the Originator Petitions operates *in rem*.

19. The relevant ad interim orders, rendered in the Originator Petitions, restrained the respondents from taking coercive action against the specific petitioners till the subsequent date of hearing. It is apparent from the mere verbiage of the ad interim orders that they were restricted to the petitioners before the Court, of which admittedly the present petitioners were not a constituent. On the contrary the notification specifying the prices of originator brands continues to hold the field and there is no order, in the Originator Petitions or otherwise to our knowledge, suspending the operation thereof.

20. In view hereof we are respectfully constrained to hold that the reliance of present petitioners, in the Generic Petitions, upon ad interim orders, issued in some other petitions, in order to absolve themselves of their legal obligations is misconceived, hence, these petitions are dismissed.

Hardship cases

21. The facts representative of the Hardship Petitions are that the MRP of drugs was increased by seventy five percent or more on 31.12.2018, vide SRO 1610[21], and then once again ten days later

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[20] *Hameed Akhtar Niazi vs. Secretary Establishment Division Pakistan* reported as *1996 SCMR 1185*; *Federation of Pakistan vs. Qamar Hussain Bhatti* reported as *PLD 2004 Supreme Court 77*; *Dawood Sighar & Others vs. Province of Sindh & Others* reported as *2016 PLC CS 1*.

[21] *SRO 1610 of 2018 dated 31.12.2018*.

vide SRO 34[22]. Thereafter, on 24.05.2019 SRO 577[23] was issued, whereby the successive snowballed rise in such MRP was rationalized to the effect that where the rise was in excess of Seventy Five percent the same was capped at Seventy Five percent; where the rise was between Fifty and Seventy Five Percent, the additional rise of Nine percent was withdrawn. Since SRO 577 rationalized the raise in drug prices, as notified vide SRO 1610 and SRO 34, hence, the present petitions seek for SRO 577 to be set aside and seek the implementation of drug prices as contained in SRO 34.

22. Learned counsel for the petitioners submitted that SRO 577 was against the principles of natural justice, repugnant to Section 24A of the General Clauses Act and even otherwise dissonant with the directions of the honorable Supreme Court, issued in HRC and HRMA respectively. Learned counsel submitted that the reduction in prices was without foundation in law as price fixation, undertaken pursuant to the 2018 Policy, could not arbitrarily be interfered with by the DRAP. Learned counsel submitted that the power to alter the prices of drugs in hardship cases is permissible only once in three years, therefore, the present alteration was ultra vires of the law in itself.

It was argued that the price raises, notified vide SRO 1610[24] and SRO 34[25] had created a vested right in favor of the petitioners and they were justified in obtaining the said prices for their products as the relevant stock had already been placed in market. Learned counsel raised the additional ground that the wrong base prices had been utilized by the respondents in determining the maximum retail price and that the respondents had taken no effort to rectify the situation despite having been appraised of the same. Learned counsel demonstrated from the record that prior to the issuance of SRO 577[26], a petitioner had been in correspondence with DRAP in

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22 *SRO 34 of 2019 dated 10.01.2019.*
23 *SRO 577 of 2019 dated 24.05.2019*.
24 *SRO 1610 of 2018 dated 31.12.2018*.
25 *SRO 34 of 2019 dated 10.01.2019.*
26 *SRO 577 of 2019 dated 24.05.2019*.

order to have its true considerations reflected in the upcoming notification, however, the respondents failed to appreciate the contentions of the petitioners in their proper perspective and reduced the drug prices in a discrepant manner.

23. Mr. Amanullah, Deputy Director (Pricing) DRAP appeared, along with learned Assistant Attorney General, and submitted per the decision in the *Pfizer judgment*[27] the present petitions were misconceived as the petitioners were required to file appeals before the Appellate Board. It was submitted that the successive raise in the MRP of drugs, vide SRO 1610[28] and SRO 34[29], had an unintended snowball effect, hence, the rationalization of MRP was undertaken vide SRO 577. It was argued that the 2018 Policy[30] permitted the policy board of DRAP to raise or reduce prices in modification of the said policy. It was further demonstrated from the preamble of SRO 34 and SRO 577 that the two instruments were issued in exercise of identical powers, therefore, it was implausible for the petitioners to seek enforcement of one such instrument to the derogation of the other[31]. The record[32] was also pointed out to demonstrate that consultation had taken place with the stakeholders prior issuance of SRO 577.

24. We have heard the respective arguments and have also considered the law, precedent and documentation to which our surveillance was solicited. It is an admitted fact that the MRP of drugs was determined vide SRO 1610 and then once again ten days later, without waiting for the three year period to expire, vide SRO 34. While the petitioners seek the benefit of SRO 34[33], the challenge is to SRO 577, which was issued in reliance upon the identical provisions of law as SRO 34. However, the primary question for us to consider is whether this Court is the appropriate forum for determination of the controversy.

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[27] *Pfizer Pakistan (Private) Limited vs. Federation of Pakistan & Others* reported as *2019 MLD 1849*.
[28] *SRO 1610 of 2018 dated 31.12.2018*.
[29] *SRO 34 of 2019 dated 10.01.2019*.
[30] *Paragraph 12(8) of the 2018 Policy.*
[31] *As denoted from the prayer clause of CP D 4101 of 2019*.
[32] *Including the statement dated 21.11.2019*.
[33] *As denoted from the prayer clause of CP D 4101 of 2019*.

25. The starting point of the petitioners' case are the respective orders of the august Supreme Court, being the HRC and the HRMA. The HRC was determined vide the order dated 03.08.2018, wherein it as *inter alia* held as follows:

> "5. It is pertinent to mention here that under the law an appellate forum has been provided. Anybody aggrieved of the decision of DRAP in the above matters may challenge the same before the appellate forum. With consensus of all, we direct that instead of approaching the Courts of ordinary jurisdiction i.e. civil courts or High Courts in original jurisdiction or even before agitating the matters in the constitutional jurisdiction of the High Courts, the aggrieved parties shall avail all remedies available to them under the statute….
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> 8. This matter is disposed of in the above terms. However, in case any of the parties feels aggrieved on account of violation or non-compliance with the above directions, it may move an appropriate application for resurrection of the same."

(Underline added for emphasis.)

26. We had earlier observed, in the *Pfizer judgment*[34], that the honorable Supreme Court had emphasized the predominance of the statutorily prescribed appellate mechanism and had discouraged recourse to the High Courts, and the Courts of ordinary jurisdiction. In addition thereto it was specifically observed that in case any of the parties felt aggrieved on account of violation or noncompliance of the directions, contained in the *HRC order*[35], then it could move an appropriate application for resurrection of the same. Thus, it was apparent from the aforesaid pronouncement that that the dispute resolution mechanism was duly articulated. The *Pfizer judgment*[36] had concluded that the petitioners ought to have availed the alternate remedy available thereto and the said judgment has attained finality as the appeals filed there against[37] stand dismissed as withdrawn (per learned counsel for the petitioners).

27. It is, however, considered appropriate to address one aspect of this case, with regard to availing the alternate remedy provided.

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[34] *Pfizer Pakistan (Private) Limited vs. Federation of Pakistan & Others* reported as *2019 MLD 1849*.
[35] *Order dated 03.08.2018 in the HRC*.
[36] *Pfizer Pakistan (Private) Limited vs. Federation of Pakistan & Others* reported as *2019 MLD 1849*.
[37] *CPLA 1510 of 2019 and CPLA 2545 of 2019.*

Learned counsel had argued that since the statutory fora had no authority to strike down an SRO / notification, therefore, there was no alternate forum to address the petitioners' grievance.

This ground was taken in the *Pfizer judgment* also and had been addressed in view of the categorical directive of the august Supreme Court contained in the *HRC order*[38]. The same ground was agitated before the honorable Supreme Court, as denoted from the appeals[39] filed against the *Pfizer judgment*, however, the said appeals stand dismissed as withdrawn.

Notwithstanding the foregoing we shall endeavor to address this objection on merit as well. The *Rules*[40] specify that any person aggrieved by a decision of the registration board, central licensing board or a licensing authority may prefer an appeal to the Appellate Board. It was argued that since the *Rules* do not contemplate a challenge to a notification, hence, an appeal was not competent. We, respectfully, do not concur with the argument advanced.

28. DRAP is the authority constituted[41] to enforce the Drugs Act 1976 and its functions include the regulation of pricing and mechanism for fixation for prices of therapeutic goods[42]. The general direction, administration and monitoring of the Authority vests in its policy board[43]. In the present facts and circumstances two decisions of the policy board, raising the MRP, of drugs ten days after the last raise, and a subsequent decision to rationalize the MRP of drugs are under scrutiny. These decision, taken by DRAP being the licensing authority, culminated in the issuance of SRO 34[44] and SRO 577[45] respectively.

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38 *Order dated 03.08.2018 in the HRC*.
39 *CPLA 1510 of 2019 and CPLA 2545 of 2019.*
40 *Drugs (Appellate Board) Rules 1976.*
41 *Drug Regulatory Authority of Pakistan Act 2012.*
42 *Section 7(c)(vii) of the Drug Regulatory Authority of Pakistan Act 2012.*
43 *Section 9 of the Drug Regulatory Authority of Pakistan Act 2012.*
44 *SRO 34 of 2019 dated 10.01.2019*.
45 *SRO 577 of 2019 dated 24.05.2019*.

29. While we eschew a deliberation upon how the petitioners seek enforcement of SRO 34, issued pursuant to the same authority[46] as SRO 577, while challenging the exercise of identical powers in the issuance of SRO 577, it is observed that the underlying determination common *inter se* is that of the licensing authority, hence, amenable to appeal before the appellate board. This observation is bolstered by the *HRC order*[47]*,* wherein the august Supreme Court has held that any person aggrieved by the decision of DRAP may challenge the same before the appellate forum. It is imperative to record here that the aforementioned directive was rendered *inter alia* specifically in hardship cases and in proceedings where the present petitioners were party / represented.

30. Therefore, it is our considered view that a direct approach to this Court, by the petitioners in the Hardship Petitions, is contrary to the directives of the honorable Supreme Court, as enunciated vide the *HRC order*.

31. In view of the discussion and reasoning delineated supra, the petitions under scrutiny are determined in seriatim as follows:

a. The Originator Petitions, being CP D 4197 of 2019, CP D 4215 of 2019 and CP D 4845 of 2019 along with all applications pending therein, are hereby determined and disposed of in the following terms:

    i. The orders of the Appellate Board, impugned respectively in the Originator Petitions, being CP D 4197 of 2019, CP D 4215 of 2019 and CP D 4845 of 2019, are hereby set aside.

    ii. The Drug Pricing Committee (DRAP / respondent no. 2) is hereby directed to undertake a *de novo* determination of the MRP of the therapeutic goods of the petitioners in application of the 2018 Policy and

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[46] *Paragraph 12(8) of the 2018 Policy.*
[47] *Order dated 03.08.2018 in the HRC*.

submit such a determination for notification by the respondent no. 1.

It is expected that this process may be completed by the respondents within a period of three months from the date hereof.

iii. In the interim period, until issuance of the notification as aforesaid, the MRP subsisting, as determined vide SRO 1610[48], shall remain in the field.

b. The Generic Petitions, being CP D 5612 of 2019, CP D 5613 of 2019 and CP D 5614 of 2019 along with all applications pending therein, and the Hardship Petitions, being CP D 4101 of 2019, CP D 4291 of 2019, CP D 4328 of 2019, CP D 5085 of 2019, CP D 5086 of 2019, CP D 5674 of 2019, CP D 5902 of 2019 and CP D 7768 of 2019 along with all applications pending therein all applications pending therein, are hereby dismissed.

It is pertinent to record that the petitioners shall remain at liberty to place their grievance/s before the appellate forum, subject to all just exceptions, and any such adjudication shall remain uninfluenced by observations herein contained.

32. The office is instructed to communicate a copy hereof directly to the respondents forthwith.

JUDGE

JUDGE

*Farooq PS/**

[48] *SRO 1610 of 2018 dated 31.12.2018*.