

**IN THE HIGH COURT OF SINDH
AT KARACHI**

Present : Muhammad Ali Mazhar and
Yousuf Ali Sayeed, JJ

C.P No. D-2717 of 2020

Tabros Pharma (Private) Limited.....Petitioner

Versus

Federation of Pakistan and others.....Respondents

C.P No. D-2718 of 2020

Schzoo Zaka (Private) Limited.....Petitioner

Versus

Federation of Pakistan and others.....Respondents

Abdul Sattar Pirzada, Advocate, along with Mamoon
N. Chaudhry, Advocate, for the Petitioners.

Kafeel Abbasi, DAG, for the Federation, along with
Syed Hakim Masood, FID DRAP

Date of hearing : 19.08.2020.

JUDGMENT

YOUSUF ALI SAYEED, J - The Petitioners, both of which are pharmaceutical concerns, made independent Applications to the Drug Regulatory Authority of Pakistan (“**DRAP**”) for an upward revision of the Maximum Retail Price (“**MRP**”) of their respective products, viz Amygra 60 mg tablets (“**Amygra**”) Neobutinal 200 mg tablets (“**Neobutinal**”) and Rifapin-H Dry Syrup (“**Rifapin**”) (hereinafter collectively referred to as the “**Products**”), which came to be dealt with as hardship cases under Clause 9 of the Drug Pricing Policy 2018 (the “**2018 Policy**”) formulated by DRAP under the Drug Regulatory Authority of Pakistan Act, 2012.

2. As it transpires, the Application in respect of Amygra, manufactured by the Petitioner in CP No. D-2717/20, was made on 22.02.2019, whereas the Application in respect Neobutinal and Rifapin, manufactured by the Petitioner in CP No. D-2718/20, was made on 21.01.2019, following which the Drug Pricing Committee (the “DPC”), at its 37th Meeting held on 7th and 8th February 2019, considered the matter and, as is apparent from the recorded Minutes of that Meeting, recommended the following MRPs of those Products:

Product	Recommended MRP
Amygra	Rs.133/-, 20’s
Neobutinal	Rs.276, 10 x 10’s
Rifapin	Rs.119/-, 50 ml

3. The grievance of the Petitioners is that notwithstanding the recommendation having been made by the DPC, the MRPs of the Products have not been formally notified as yet, albeit that the cases are of hardship, with Clause 9(5) of the 2018 Policy categorically stating as follows:

“(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”

4. In this backdrop, the respective Petitioners have assailed the inaction on the part of the Federal Government following the referral by the DPC of their cases and vide the captioned Petitions have prayed inter alia that the Respondents be directed to notify the MRPs of the Products as well as be restrained from taking any adverse or coercive action against them on the basis of their acting as per Clause 9(5) of the 2018 Policy so as to deal in the Products in accordance with the recommendation made by the DPC.

5. Learned counsel for the Petitioners argued that the timeframe specified in sub-clause (5) with regard to hardship cases had already lapsed in the matters at hand, despite which no approval has been accorded by the Federal Cabinet on the prices fixed by the DPC. It was pointed out that, Orders had previously been made on 22.01.2020 and 26.02.2020 extending interim relief to certain other pharmaceutical concerns that had approached this Court under analogous circumstances vide Constitutional Petition Nos. D-4998 of 2019 and D-1018 of 2020, where the referral made by DRAP on their hardship applications had remained unattended and instead been referred to a Task Force rather than being addressed and notified by the Federal Cabinet – with it being ordered that no coercive action was to be taken if they were to sell the particular products that were the subject of those hardship applications at the prices that had been recommended by the DPC. It was also pointed out that the Order made in Constitutional Petition No. D-4998 of 2019 had then been assailed before the Honourable Supreme Court through Civil Petition No. 1223 of 2020, which was disposed of vide Order dated 29.06.2020 with the direction to the Federal Cabinet to make its decision within a period of four weeks, without the interim arrangement put in place by this Court being disturbed. It was prayed that the Petitions be disposed of with directions being issued similarly.

6. When confronted with Clause 9(5) of the 2018 Policy, the learned D.A.G, as well as Mr. Syed Hakim Masood, FID DRAP, acknowledged that the crux thereof was that if hardship applications were not attended to by DRAP in a timely manner or if after due consideration of an application by DRAP, the Federal Government did not act within the envisaged timeframe so as to notify the prices as per the referral made, then the applicant could increase its MRP up to the level recommended by the DPC of DRAP, provided that such option could be exercise only once in 3 years. Furthermore, they conceded that the specified timeframe had lapsed in the cases of the Petitioners so as to trigger the inbuilt mechanism for increase.

7. Under the given circumstances, in light of the intent and design of Clause 9(5) of the 2018 Policy as well as the Order made by the Honourable Supreme Court on 29.06.2020 in Civil Petition No. 1223 of 2020, we are so minded as to adopt a similar approach and direct the Respondent No.1 to make a final decision in relation to the MRP's of the Products within a period of 30 days from the date of this Order, pending which the Respondents are restrained from taking any coercive action against the Petitioners if they sell the Products at the prices recommended by the DPC. As it would serve no useful purpose to keep the Petitions pending, the same accordingly disposed of on the foregoing terms, along with all pending Miscellaneous Applications.

JUDGE

JUDGE