IN THE HIGH COURT OF SINDH
AT KARACHI

C.P No. D-6096 of 2019

Petitioner	:	M/s Eli Lilly Pakistan (Private) Limited, through Mr.
Respondent No.1	:	Federation of Pakistan, through Mr. Kafeel Abbasi, DAG.
Respondent No.2	:	Drug Regulatory Authority of Pakistan, through Mr. Amanullah, Director (Pricing).
Date of hearing	:	26.02.2020.
Present	:	Muhammad Ali Mazhar and Yousuf Ali Sayeed, JJ

JUDGMENT

YOUSUF ALI SAYEED, J. The Petitioner has invoked the jurisdiction of this Court under Article 199 of the Constitution of the Islamic Republic of Pakistan, assailing the Order dated 11.06.2019 (the "**Impugned Order**") made by the Drugs Appellate Board in Appeal No. 14 of 2018 filed by the Petitioner against the fixation of the price of its product under the tradename "Trulicity", an anti-diabetic medication for use by patients suffering from Type-2 diabetes.

2. Learned counsel for the Petitioner submitted that Trulicity was an innovative product, heralding a unique delivery system, and contended with reference to the Drugs Pricing Policy 2018, that Trulicity fell within the parameters of what was defined therein as an "NCE/NBE", being a new chemical entity and new biological entity that had not been registered in the same dosage form, strength and delivery system in Pakistan, and, as such, its maximum retail price ("**MRP**") was to be fixed as per the methodology envisaged under Section 4(1) thereof, which reads as follows:

> "**4**. MRP fixation of NCEs and NBEs – (1) MRP fixation of Originator Brand of NCE and 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".

3. Learned counsel for the Petitioner pointed out that a representation had accordingly been made to the Drugs Regulatory Authority of Pakistan ("**DRAP**") on 05.10.2015 for fixation of the MRP of Trulicity along with supporting material to show that a pack of two (2) vials of 0.5 ml and dosage of 0.75mg dosage each was priced in India at INR 3998.4, and on that basis, after factoring in the rate of currency exchange, a request had been made for an MRP of PKR 19,000/- in relation to pack size of four (4) such vials. However, whilst an MRP of PKR 14,389/- was fixed by the Drugs Pricing Committee (the "**DPC**") for a pack of four (4) vials of that size, each of 1.5mg strength, vide letter No.F-3-47/2014-DDC(BD)(Vol-I)(M-254) dated 06.04.2018 issued by DRAP, the Petitioner was informed that a lesser MRP of PKR 8633/- had been fixed for the same pack size of Trulicity with a strength of 0.75 mg per vial.

4. Per learned counsel Trulicity was an innovative product due to its unique delivery system as opposed to its measure or strength, and submitted that there was no rational basis for a distinction in MRP as between the two strengths. He submitted that the price in India was uniform, irrespective of the dosage, and pointed out that the material before the DPC as to the pricing of the product in India was even otherwise in relation to vials that were 0.75 mg in strength.

5. He submitted that an Appeal had accordingly been preferred against such fixation of MRP before the Appellate Board of DRAP, but was not properly considered and the decision rendered was without due application of mind, in as much as the operative part of the Impugned Order related to an altogether different product, completely unconnected to the Petitioner, reading as follows:-

> "The Price Recommendatory Committee (PRC) had already fixed MRP of the originator brand of the same biological drug @ Rs. 46,000/- per vial which was used as a base price. Accordingly, DPC in its 25th DPC meeting held on 6th December, 2017 recommended MRPs Rs.32,200 per vial for Remsima Powder for concentrate for solution for infusion which is 30% less than originator brand price and the same was notified vide S.R.O 252(I)/2018 dated 21st February 2018 after approval of Federal Government"

6. When confronted with this glaring discrepancy, the learned DAG and Director (Pricing), DRAP, were both unable to offer any explanation and conceded that the reference to "Remsina Powder" had no nexus whatsoever with the case of the Petitioner.

7. That being so, it is apparent under the given circumstances that the Impugned Order suffers from a basic failure of the Appellate Board to consider the case advanced by the Petitioner, hence the same cannot stand and requires reconsideration.

8. It is for these reasons that we had remanded the matter to the Appellate Board for decision afresh vide our short Order dictated in Court on 26.02.2020.

JUDGE

JUDGE

TariqAli/PA