IN THE HIGH COURT OF SINDH AT KARACHI

Suit No. 840 of 2019

Plaintiff:	**M/s. Zafa Pharmaceutical Labs (Pvt.) Ltd. Through M/s. Arshad Tayeably & Waqar Ahmed, Advocates.**
Defendants No.1 to 3:	**Federation of Pakistan & others Through Mr. Ishrat Zahid Alvi, Assistant Attorney General alongwith Syed Hakim Masood FID, DRAP, Karachi.**
Defendant No.4:	**M/s. Abbott Laboratories (Pakistan) Ltd. Through Mr. Faisal Siddiqui alongwith Mr. Mohamed Vawda Advocates.**

For hearing of CMA No. 7247/2019.

Dates of hearing:	**18.10.2019, 19.11.2019, 03.02.2020 & 02.03.2020**
Date of Order:	**13.03.2020**

O R D E R

Muhammad Junaid Ghaffar, J. Through this Suit, the Plaintiff has impugned Order dated 26.04.2019 passed by the Drugs Appellate Board **(Appellate Board)**, whereby, the earlier decision taken by the Appellate Board in its 134th meeting held on 17.06.2008 and circulated on 30.6.2008 has been reviewed / modified, through which the Appeal of the Plaintiff against an order of the Registration Board in respect of stoppage of production of the Plaintiff's drug namely **Dirogest [Dydrogesterone (Cis Isomer)]** was allowed.

2. Mr. Arshad Tayeably, Learned Counsel for the Plaintiff at the very outset has contended that the order in question is an ex-parte order, whereas, the adjournment request of the Plaintiff was not acceded to by the Appellate Board; hence, in law, it cannot be sustained; that the Appellate Board had no jurisdiction to review its earlier order at the request of the Registration Board; that there is no authority or power with the Appellate Board to review its orders, whereas, the power of revision under Rule 5 of the Drugs (Appellate Board) Rules, 1976 (**1976 Rules**) is restricted to the extent of the orders passed by the

Subordinate authorities; that the powers and jurisdiction under the 1976 Rules, cannot be exercised beyond the scope of the main Statute, including Section 9 of the Drugs Act, 1976; that the drug in question was duly registered after thorough scrutiny, and in one go the Registration Board vide its decision taken in 211th Meeting held on 30.11.2017 and 1.12.2017 had passed an order for stopping production of the same, which was impugned before the Appellate Board through Appeal No.(s)1849, which was heard on 17.06.2008 in the 134th Sitting of the Appellate Board and the order was passed on 30.06.2008, whereby, the appeal was allowed; that now at the behest of defendant No.4 certain proceedings were initiated before the Registration Board as the drug of similar nature produced by defendant No.4 is too expensive as against the plaintiff's drug; that on this the Registration Board then forwarded the case to the Appellate Board for review / revision of their earlier orders, which according to him is impermissible in law; that all these actions and orders are without lawful authority and jurisdiction; that even setting aside of the same with a remand order would not suffice as this would amount to confer jurisdiction on the Appellate Board which has not been provided under the law; that the drug of the Plaintiff is well reputed and recommended by the Doctors, whereas, the objection regarding the same being of inferior quality or dangerous in nature is misconceived; that the Doctors all along have given favorable views for the said drug; that no opportunity was even otherwise given to the Plaintiff and once the adjournment request was received, it was incumbent upon the Appellate Board to adjourn the matter and grant sufficient hearing and so also providing material confronting the Plaintiff as to the allegations levelled by defendant No.4 and the Registration Board; that the Appellate Board has no power to either review or revise its own orders, which had attained finality as it was never challenged any further; that even otherwise the powers under Rule 5 of the 1976 Rules can only be exercised *suo-motu* and not at the request or application of the Registration Board. He has prayed for confirming the ad-interim injunction till decision of the main Suit, and in support he has relied upon the judgments reported as ***Province of Punjab through District Officer Revenue, Rawalpindi and others v. Muhammad Sarwar*** **(2014 SCMR 1358)**, ***Choudhry Ghulam Rasool through L.Rs v. Mistri Ghulam Rasool*** **(2018 CLC 1099)**, ***Punjab***

Road Transport Corporation v. Punjab Labour Appellate Tribunal, Lahore and others **(1973 SCMR 455)**, ***Liaquat Ali Chugtai v. Federation of Pakistan through Secretary Railways and 6 others*** **(PLD 2013 Lahore 413)** and ***Ishtiaq Ahmed v. Hon'ble Competent Authority*** **(2016 SCMR 943)**.

3. Mr. Faisal Siddiqui, Learned Counsel for Defendant No.4 has contended that after refusing the concession as recorded in order dated 18.10.2019 by this Court for remand of the matter after setting aside the impugned order, the Plaintiff cannot agitate the ground of natural justice and of being condemned unheard; that the Plaintiff was well aware of the proceedings initiated by the Registration Board inasmuch as it was discussed and deferred in the 279th meeting dated 28.02.2018, 281st meeting dated 11.04.2018 and 284th meeting dated 01.08.2018; that all along it was within the knowledge of the Plaintiff that in view of the latest research, the product of the Plaintiff is no more a safe drug; hence, its production has to be stopped in the larger interest of the suffering community; that even before the Appellate Board, the Plaintiff's representative was present and nothing prevented from contesting the matter; that the impugned order is not entirely against the Plaintiff; but it is against the defendant No.4 as well as various other manufacturers of a similar drug as now certain compliance has to be made by all such manufacturers; that even otherwise the decision of the Registration Board of 2007 was only to the extent of stoppage of production and was not in respect of cancellation of the registration, whereas, the order of the Appellate Board dated 30.06.2008 merely allows the appeal with the effect that the Plaintiff can continue with such manufacturing; however, it could not be deemed to be a permission for all times to come; that the Appellate Board has all the powers in the matter and though the Registration Board had referred the matter for review; but the order in question is not an order of review nor a revision strictly; but is in fact an order applicable on all such manufacturers of similar product; that these are general directions for all including the Plaintiff; that there is no order for stopping the production and if that had been the case it could be alleged to be a review or revision, but admittedly it has not been done so; that in terms of Section 3 of the Drugs Act, 1976, all manufacturers are required to act and abide by the safety guidelines issued from time

to time; that as soon as the matter was taken up by the Registration Board, it became open for the Appellate Board to exercise its revisional powers under Rule 5 of the said Rules; that the provisions of Rule 5 (ibid) are analogous to Section 115 of the Civil Procedural Code as well as Section 435 of the Criminal Procedural Code, whereas, the impugned order has been passed by exercising the powers so conferred and it is the gist of the order, which is to be seen and not the title or reference to the very provision; that the question that whether the drug is safe or not, is dependent on the opinion of the experts; hence, all along the Courts have shown reluctance to enter into such aspect, as the opinion of experts cannot be substituted by a Court with its finding. He has relied upon the cases reported as ***Collector, Sahiwal and 2 others v. Mohammad Akhtar*** **(1971 SCMR 681),** ***Zaibtun Textile Mills Ltd. V. Central Board of Revenue and others*** **(PLD 1983 Supreme Court 358)**, ***M/s. E. Merck (India) Ltd. And another v. Union India and another*** **(AIR 2001 Delhi 326)**, ***Vincent Panikurlangara v. Union of India and others*** **(AIR Supreme Court 990)** and an unreported judgment of Delhi High Court in the case of ***Merck Sharp & Dohme Corporation vs Glenmark Pharmaceuticals Ltd.*** **[CS (OS) 586/2013 & CC No.46/2013 & I.A. Nos. 9827/2013, 8048/2014 & 13626/2015].**

4. Mr. Mohamed Vawda, also appearing for Defendant No.4, in response to the query of the Court raised on one of the dates of hearings, has contended that the duration of a Registration of a drug is provided in Rule 27 of the Drugs (Licensing, Registering and Advertising) Rules, 1976, which is a maximum of 5 years, whereas, a Registration Certificate issued to a manufacturer for a drug can be cancelled / revoked under Section 7(11) of the Drugs Act, 1976 after due process as provide therein.

5. Learned Assistant Attorney General appearing on behalf of Drug Regulatory Authority of Pakistan (**DRAP**) has argued that sufficient opportunity was provided to the Plaintiff to appear and plead its case; however, they chose not to do so; hence the objection regarding opportunity of hearing or not is irrelevant; that the issue involved is of public health importance and in such circumstances, no manufacturer can be allowed to continue with the production of a drug against which

complaints have been received by the Registration Board; that the Registration Board under normal circumstances can take steps on its own either to review the registration or even cancel the same; however, in this case, since an order had already been passed by the Appellate Board; therefore, the matter was required to be placed before the said Appellate Board for reviewing its earlier orders; hence, there is no illegality in the impugned order; that Rule-5 of the 1976 Rules empowers the Appellate Board to take notice of such issues and any order could be taken up by the Appellate Board under the said Rule; that the Plaintiff has only been required to follow new and safe standards; hence the order does not prejudice any right of the Plaintiff, and therefore, according to him the application is liable to be dismissed.

6. While exercising his right of rebuttal, learned Counsel for the Plaintiff has referred to Section 9(1) of the Drugs Act, 1976 and has contended that the powers of the Appellate Board emanates from this Statute and any rules beyond the scope of the Statute are void; hence Rule 5 can only be sustained, if it is read in line with the main provision of the Act; that the power is only in respect of revision on its own motion, of a decision of the authorities lower in rank to the Appellate Board, and not of its own orders; that reference to various minutes of meeting is irrelevant as the Plaintiff was never present in these meetings; that the Plaintiff was never informed by the Registration Board regarding its decision taken in 286th meeting for referral of the matter to the Appellate Board; that defendant No.4 wants to monopolize the market inasmuch as the basic ingredient now being asked for to be used in the manufacturing of the drug in question, is only available with and supplied by the parent company of defendant No.4; that there are no allegations against the quality of the drug being manufactured by the Plaintiff except by defendant No.4 and that is for the reason that their drug is too expensive; that the drug in question is valid till its Registration Certificate i.e. 2021 and the Registration Board can always exercise its powers as contemplated in the Act and the Rules at the time of renewal of the Registration Certificate; but not prematurely in the manner as done through the impugned order.

7. I have heard all the learned Counsel as well as the Assistant Attorney General and perused the record. It appears from the pleadings

that the Plaintiff is a manufacturer of pharmaceutical products and is holding registration in respect of the subject drug **"Dirogest"** tablet which is prescribed by specialized doctors and gynecologists to avoid threatened miscarriage and habitual abortion in pregnant women. It further appears that medical compound of this drug is "**Dydrogesterone (Cis Isomer)"**. It is the case of the Plaintiff that presently, apart from the Plaintiff, it is only defendant No.4, who is manufacturing a similar product and is the competitor of the Plaintiff. It is their further case that their drug is much less in price as compared to the one being sold by defendant No.4. It further appears that earlier the Registration Board on a complaint of one of the manufacturers / predecessor in interest of Defendant No.4 to the extent of their competing product namely ***Duphaston*** took a decision in the meeting held on 1.11.2007 and 1.12.2007, whereby, the production of the drug in question was stopped. The relevant minutes of the meeting read as under;

> a. M/s Zafa Pharmaceuticals should stop manufacturing of this product including import of raw material.
>
> b. They should submit evidence from the international studies reference book that the product containing "Trans Isomer" marketed by them has been evaluated and proved similar to the "Cis Isomer" and there is no safety and efficacy concern in addition to the proved indication in the claimed uses. This information would be submitted for the consideration of the Drugs Registration Board for final decision.

The Plaintiff being aggrieved preferred an appeal before the Appellate Board, who after conducting hearing in its 134th Meeting dated 17.6.2008 communicated vide letter dated 30.06.2008 allowed the appeal on the ground that there are no complaints as to the product in question nor there is any evidence that it is less effective or for that matter is harmful since 2008. Thereafter the matter was once again taken up by the Appellate Board and notice dated 17.04.2019 was issued to the Plaintiff in respect of a meeting convened by the Appellate Board on 24.04.2019 on a reference received by the Appellate Board from the Registration Board to review its earlier orders. It appears that the Plaintiff sought adjournment on the ground that it is an old matter and a very short time has been given to respond to the allegations;

however, the adjournment request was turned down and the impugned order was passed. The operative part of the said order reads as follows:

> "12. The Board considered the facts of the case and decided not to adjourn the hearing as requested by M/s Zafa Pharmaceutical Laboratories (Pvt.) Limited, Karachi, being a matter of public health importance. The Board agreed with the scientific opinion / justification and interpretation of the Drugs (Specifications) Rules, 1986 by the Registration Board in its 286th meeting held on 14th – 16th November, 2018. The Board directed the Pharmaceutical Evaluation & Registration Division to ensure that all registered formulation / products and evaluation of *Dydrogesterone* products must comply with the official pharmacopial monograph i.e. USP. The Board further directed the Division of Quality Assurance & Laboratory Testing to allow the import of API for registered products of *Dydrogesterone* as per official monograph *only* and to issue a Circular for information of all concerned."

8. The first and the foremost question is that whether the Appellate Board has any jurisdiction of the nature so exercised by it; and secondly, whether the Plaintiff was afforded any proper opportunity of hearing for defending the case. After briefly hearing the Plaintiff's Counsel, on 18.10.2019 he was directed to seek instructions as to the remand of the matter to the Appellate Board after setting aside the impugned order, and providing opportunity of proper hearing; however, the learned Counsel for the Plaintiff under instructions submitted that the matter be decided on its own merits as it is the case of the Plaintiff that order in question is without jurisdiction as the Appellate Board has no powers of revision.

9. Before proceeding further, to determine as to whether the Appellate Board exercised proper jurisdiction or not, it would be advantageous to refer to Rules (4) & (5) of the 1976 Rules which reads as under: -

> **4. Procedure of Appeal:** (1) Any person aggrieved **by a decision of the Registration Board,** the Central Licensing Board or a licensing authority may, within sixty days of receipt of such decision, submit an appeal to the Appellate Board.
>
> (2) An application for appeal under sub-rule (1) shall be [in triplicate and be] accompanied by a copy of the decision appealed against, and shall contain all material statements and arguments relied on by the appellant.
>
> (3) The Appellate Board shall transmit a copy of the application for appeal referred to in sub-rule (2) to the Registration Board or the Central Licensing Board or the licensing authority against whose decision the appeal has been made. and such Board or authority shall, on demand, produce before the Appellate Board the record of the case leading to the decision.
>
> (4) The Appellate Board shall, after giving the appellant an opportunity of being heard, **pass such orders as it thinks tit and such orders shall be final**.

> **5. Revision.** The Appellate Board may, of its own motion at any time, call for the record of any case for the purpose of satisfying itself as to the correctness, legality or propriety of **such order** and may pass such order in relation thereto as it think. (**Emphasis supplied**)

10. Similarly Section 9 of the Drugs Act, 1976 is also relevant through which the Appellate Board has been constituted and the same reads as under: -

> **9. Appellate Board. –** (1) The Federal Government shall, in accordance with the rules, constitute an Appellate Board for the disposal of appeals preferred by persons **aggrieved by any decision** of the Central Licensing Board or **the Registration Board** or the licensing authority or a Board or Authority to which the powers of the Federal Government under section 12 have been delegated under sub-section (3) of that section **and for revision of any *such decision*** on its own motion.
>
> (2) The Appellate Board shall consist of such representatives of the Federal Government and the Provincial Governments, including a Chairman, as the Federal Government may from time to time appoint.
>
> (3) Subject to sub-section (4), the Chairman and other members of the Appellate Board shall hold office for the prescribed period.
>
> (4) The Chairman or any other member of the Appellate Board may, by writing under his hand addressed to the Federal Government, resign his office or shall vacate his office if the Federal Government, being of opinion that in the public interest it is necessary so to do, so directs.
>
> (5) The members of the Appellate Board shall exercise such powers, including the powers of an Inspector, as may be prescribed.
>
> (6) The Appellate Board may appoint experts for the purposes of detailed study of any specific matter before it.
>
> (7) The Appellate Board shall [with the approval of the Federal Government and by notification in the official Gazette,] make regulations to regulate the conduct of its business.
>
> [(8) The Appellate Board shall meet at least every month and shall decide any appeal preferred to it within sixty days of receipt of appeal unless the Board is prevented from doing so for sufficient cause to be recorded.] (**Emphasis supplied**)

11. Perusal of Rule (4), as above, reflects that any person aggrieved by a decision of the Registration Board, the Central Licensing Board or a licensing authority may, within sixty days of receipt of ***such decision***, file an appeal before the Appellate Board and in terms of Sub-Rule (4) of Rule (4), the Appellate Board shall, after giving the appellant of an opportunity of hearing, pass such orders as it thinks fit and such order ***shall be final***. Rule (5) thereof provides for Revision and reads that the Appellate Board may, on its own motion at any time, call for the record of any case for the purpose of satisfying itself as to the correctness,

legality or propriety of ***such order*** and may pass such order in relation thereto as it thinks fit. On the other hand, Section 9(1) of the Drugs Act, 1976, as above provides that the Federal Government in accordance with the Rules shall constitute an Appellate Board for the disposal of appeals preferred by persons aggrieved by ***any decision*** of the Central Licensing Board or the Registration Board or the Licensing Authority or a Board or Authority to which the powers of Federal Government under Section 12 have been delegated under sub-section (3) of that Section and for revision of ***any such decision*** on its own motion. When the above provision of the Act itself is examined, it reflects that though 1976 Rules of the Appellate Board promulgated pursuant to Section 43 of the Drugs Act, 1976 have been framed in line with Section 9 (ibid); however, while doing so, some confusion has been left out inasmuch as Rule (4) and Rule (5) do not appear to be properly drafted and clearly spelt out. It is not in dispute; nor it could be the case of any of the parties that it is the Act, which shall prevail upon the Rules, which otherwise is a subordinate legislation. In the Act, the Appellate Board has been conferred powers to decide the appeals filed by persons aggrieved by a ***decision*** of the Licensing Board or the Registration Board or other Authorities and so also it has the power of revision of ***any such decision*** on its own motion. Section 9(1) (ibid) is very clear and needs no further interpretation that the powers of the Appellate Board in respect of revision is referring to *any such decision* of the authorities below it i.e. Central Licensing Board or the Registration Board or Licensing Authority etc. It does not confer any power on the Appellate Board for revision of any of its own decisions. Insofar as Rule (5) is concerned, if it is read in juxta-position with the main provisions of Section 9 (ibid), then, one can easily infer that the intention of these Rules is also in line and conformity with the main Statute and any attempt, to read it otherwise, would further complicate the matter. One can say, may be it could have been worded much better; however, when read along with the main Act, which otherwise is to be done on the threshold of settled law that Rules must yield to the Statute and not vice versa, it would appear that Rule (5) in fact, deals with revision by the Appellate Board on its own motion, at any time, by calling the record of any case for the purpose of satisfying itself as to the correctness, legality or propriety of such order and this ***such order*** is apparently the order of the Licensing

Board or the Registration Board as the case may be; and not the order of the Appellate Board itself. This is further supported from the fact that in Rule 4 it has been provided that the orders passed by the Appellate Board shall be final; hence, if an order is to be regarded as final, then any power of revision being vested in the Appellate Board itself in respect of its own orders is meaningless. Therefore, it can be safely held that insofar as Rule 5 of the 1976 Rules is concerned, it refers only to an ***order*** or ***decision*** of the authorities mentioned in s.9(1) of the Drugs Act, 1976, of which the Appellate Board can, and is competent to take notice on its own motion to check the legality and propriety of the same under the powers of revision, and not of its own orders as contended by the Defendants herein. This observation is premised on settled law that the Rules cannot travel beyond the scope of the main Act under which they are framed and all possible effort is to be made so as to read the rules in line with the intention of the legislature as enacted through the Act, whereas, the rule making power cannot be exercised to override the very provision of the Act itself. Here, in this case, the basic law or the Act does not speaks of any revision of the orders of the Appellate Board; hence, Rule 5 ibid, cannot be so construed to confer such powers on the Appellate Board, being impermissible. Any other interpretation of Rule (5), as argued by the learned Counsel for the Defendant No.4 as well as the Assistant Attorney General, would be against the main Statute and it is settled law that any Rules framed under a Statute cannot go beyond the very mandate of the main Statute.

12. The Hon'ble Supreme Court in the case reported as ***Multiline Associates V. Ardeshir Cowasjee and 2 others*** **(PLD 1995 SC 423)** has been pleased to dilate upon this in the following terms;

> "41. Regulations are made by the Authority, which are supposed to be not inconsistent with the provisions of the Ordinance and rules framed thereunder. If there is inconsistency between any provision of the Ordinance and the Regulations, to **that extent, Regulations, being inferior and subordinate** legislation, will yield to the provision of the **Ordinance and the rules framed** thereunder. In the instant case, amendment brought about in section 6 of the said Ordinance, empowering the Government to suspend or cancel no objection certificate and then reprocess it, **shall hold the field for two reasons:** firstly, that provision of Ordinance is substantive law, which has preference over the Regulations which are procedural in nature and made by the Authority which is created under the Ordinance, and secondly, that the amendment in the Ordinance was made after coming into force of the Regulations, hence to the extent of inconsistency, if any, Ordinance shall prevail and not the Regulations. In support of the proposition reference can be made to the case of Hirjin Salt Chemicals (Pak.) Ltd. v. Union Council and others (1982 SCMR 522)."

13. In the case reported ***Hirjina Salt Chemicals (Pak.) Ltd V. Union Council, Gharo and Others*** **(1982 SCMR 522)** the Hon'ble Supreme Court has held as under;

> **17. It is now a well-established principle of interpretation of statute that Rules which are merely subordinate legislation, cannot override or prevail upon the provisions of the parent Statute and whenever there is an in consistency between a Rule and the Statute, the latter must prevail. This, however, envisages that all efforts to reconcile the inconsistency must first be made and the provisions of the parent Statute prevail only if the conflict is incapable of being resolved**. We also do not have any cavil with the proposition that when construing any word used in a Statute which has not been defined therein, it should be understood to have been used in its dictionary meaning or even its ordinary or popularly understood meaning. As a matter of fact, the learned Additional Advocate-General Sind, who appeared for the respondents, also relied on the definition of word 'market' as given in Chamber's Dictionary and the Webster's Dictionary. After going through the meaning of this word as given in the above-mentioned dictionaries, we notice that the same is so wide and extensive that it can be taken to include any place or area where goods of one or more kinds are sold repeatedly, over a short or long period of time. The definition of 'Market' as given in rule 4 is, therefore, covered by the ordinary dictionary meaning of that word. The appellants, counsel also adverted our attention to the definition of the word 'market' as given in Sind Local Government Order, 1979. The Municipal Administration Order, 1960, and the City of Karachi Municipal Corporation Act. No doubt in the definition clause of the above-noted Acts, the word 'market' has been defined more or less in the generally understood meaning of the word, i.e. places where people assemble for the sale or purchase of goods but the learned counsel has overlooked the fact that definitions in those Acts also include "any other place which may be notified as a market by the Rules framed" under these Acts. In other words, said definitions authorize the rule-making authority under those Acts to give to the word `Market' a meaning different to the one given to it by the definition clause itself."

14. Besides this it may also be observed that in terms of s.9 of the Drugs Act, read with the 1976 Rules, the Appellate Board has in fact two jurisdictions. One is in respect of an appeal filed by any party being aggrieved of the order of the Central Licensing Board or the Registration Board or any other Authority as mentioned in Section 9(1) of the Drugs Act, 1976. The second jurisdiction conferred is of revision and that could only be exercised in respect of cases for which no appeals have been preferred; but if the Appellate Board wants on its own motion, it can call for the record of any such case for the purposes of satisfying itself as to the correctness of any decision taken by the Central Licensing Board or the Registration Board etc. There cannot be any other interpretation to the above Rules when they are read in juxta-position with the main Statute i.e. Section 9(1) of the Drugs Act, 1976. To that extent, it appears that the impugned order of the Appellate

Board, whereby, they have reviewed/revised their own decision pursuant to a reference by the Registration Board cannot be sustained. Firstly, it is not a *suo-motu* or an action on its own by the Appellate Board; but has been taken on a reference by the Registration Board. Secondly, it amounts to revision of its own orders, which as discussed hereinabove, is not permissible. Therefore, the impugned order cannot be sustained to the extent of the Plaintiff's case, and at this stage of injunction, pending final adjudication of the main Suit must be suspended; and it is so ordered, but only to the extent of the Plaintiff.

15. However, suspending the order impugned herein does not, in any manner, overrides or can be considered as an impediment for the Registration Board to act in accordance with Section 7(11) of the Drugs Act, 1976, and so also Rule 27 of the Drugs (Licensing, Registering and Adverting) Rules, 1976. It would be advantageous to reproduce both these provisions which reads as under: -

> "7. Registration of drugs. ---
> (1) ……
> (2) ……
> (3) …….
> (4) ……
> (5) ……
> (6) ……
> (7) …….
> (8) ……
> (9)……..
> (10) ……
>
> (11) If the Registration Board, on the basis of information received or an inquiry conducted by it, is of opinion that–
>
> (a) the registration of a drug was procured by fraud or misrepresentation; or
>
> (b) the circumstances in which a drug was registered no longer exist; or
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> (c) there has been a violation of the conditions subject to which a drug was registered; or
>
> (d) it is necessary in the public interest so to do;
>
> the Registration Board may, after affording to the person on whose application the drug was registered an opportunity of showing cause against the action proposed to be taken, cancel or suspend the registration or specify any further conditions to which the registration shall be subject and inform such person and the Provincial Governments accordingly."

Rule 27 of the Drugs (Licensing, Registering and Adverting) Rules, 1976

> "**27. Duration of certificate of registration.** A certificate of registration under this Chapter, [shall unless suspended or cancelled, be in force for a period of five years for the date of [Registration of the drug] and may thereafter be renewed for periods not exceeding five years at a time:

> Provided that if application renewal is made before the expiry of the period of validity of a certificate, the certificate shall continue in force until orders are passed on such application:
>
> [Provided further that in case of an imported drug, the renewal may be granted and a renewal certificate shall be issued, if in the opinion of the Registration Board it is necessary to do so in the public interest.]"

16. Perusal of Section 7 (11), as above, reflects that if the Registration Board, on the basis of information received or any inquiry conducted by it, is of the opinion that the registration of a drug was procured by fraud or misrepresentation; or the circumstances in which a drug was registered no longer exist; or there has been a violation of the conditions subject to which a drug was registered; or it is necessary in the public interest so to do; the Registration Board may, after affording opportunity of showing cause to the person on whose application the drug was registered for the action proposed to be taken including its cancellation, suspension or specifying any further conditions, to which the said registration shall be subject to. Similarly, Rule 27, as above, provides for duration of Certificate of Registration, which shall not exceed a period of 5 years at a time. In these circumstances, I am of the view that if any action has to be initiated by the Registration Board, either on its own or on a complaint received by it in respect of a drug already registered, it could be done under Section 7(11), as above. And this is notwithstanding the fact that earlier any order was passed by the Appellate Board in respect of the same drug. The circumstances so provided in the said Section can always be invoked, at any time including in a situation when it is necessary in the public interest to do so. In fact, the entire case of the defendants including Defendant No.4 is based on this ground alone that it is in public interest to review the earlier orders.

17. In view of hereinabove facts and circumstances of this case, listed application merits consideration as the Plaintiff has made out a prima-facie case and balance of convenience also lies in its favor and if injunction is refused, irreparable loss would be caused to the Plaintiff. Accordingly, the listed application is allowed by suspending the impugned order dated 26.04.2019 to the extent of the Plaintiff till final decision in the Suit. However, this is subject to the observations as

above as to the powers and authority of the Registration Board as contemplated in Section 7(11) of the Drugs Act, 1976.

18. The application stands allowed in the above terms.

Dated: 13.03.2020

J U D G E

Ayaz P.s.