IN THE HIGH COURT OF SINDH AT KARACHI

CP D - 3590 of 2018

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

M/s. Ankaz Pharmex (Private) Limited
vs.
Ministry of National Health & Others

For the Petitioner:	Mr. Khaleeque Ahmed, Advocate
For the Respondents:	Mr. Muhammad Zahid Khan Assistant Attorney General
	Mr. Manzoor Ali Bozdar Secretary Licensing Board Drug Regulatory Authority Pakistan
	Dr. Shoaib Ahmed Federal Inspector of Drugs Drug Regulatory Authority Pakistan
Date of Hearing:	29.11.2018
Date of Announcement:	24.12.2018

JUDGMENT

Agha Faisal, **J**: The petitioner, being a company engaged in the business of manufacturing and purveying drugs, filed this petition upon being aggrieved by the order of the learned Appellate Board Drug Regulatory Authority of Pakistan dated 28.03.2018 ("**Impugned Order**"), whereby the appeal of the petitioner against the order of Central Licensing Board Drug Regulatory Authority of Pakistan dated 18.10.2017 ("**CLB Order**"), whereby the drug manufacturing license of the petitioner was terminated, was dismissed.

2. Mr. Khaleeque Ahmed, Advocate set forth the case of the petitioner and argued that the Impugned Order was otherwise than in

accordance with the law, hence, was required to be set aside forthwith. The arguments of the learned counsel in such regard are summarized and presented herein below:

i) It was argued that the premises of the petitioner were raided by drug Inspectors and as a consequence of the inquiry conducted in pursuance thereof show cause notice/s were issued to the petitioner. It was further submitted that the said show cause notice was replied by the petitioner, however, without appreciation of the same the license of the petitioner to manufacture drugs was cancelled vide the CLB Order. It was further submitted that the petitioner assailed the CLB Order before the statutorily prescribed appellate authority, however, the contentions of the petitioner were not appreciated in their correct perspective culminating in the dismissal of the appeal vide the Impugned Order.

ii) It was pleaded that the learned Appellate Court erroneously applied wrong standards to the appreciation of the evidence and the same led to erroneous observations and findings being rendered by the said authority. It was further pleaded that the learned Appellate Board has misread the evidence and had drawn conjectural conclusions with regard to the culpability of the petitioner. It was further pleaded that the Impugned Order was rendered in violation of Articles 10-A, 14 and 25 of the Constitution and even otherwise the respondents have acted illegally, arbitrarily and against the principle of the law and equity.

3. Mr. Manzoor Ali Bozdar, Secretary Licensing Board - Drug Regulatory Authority of Pakistan ("**Secretary DRAP**"), responded to the

contentions of the petitioner, for and on behalf of the respondents, and submitted that the petition was a misconceived and merited no indulgence of this Court. The Secretary DRAP supported the Impugned Order in its entirety and submitted that the same was passed in due conformity with all the legal and procedural aspects pertinent thereto. The submissions of the Secretary DRAP are encapsulated and delineated herein below:

i) It was submitted that the petitioner was suspected of making of substandard and spurious drugs from 2014 onwards. It was next submitted that criminal cases are pending against the petitioner, and persons connected therewith, in at least five drug courts across the country. It was also stated that numerous laboratories all over the Pakistan have rendered findings with regard to discrepant quality of drugs being manufactured and sold by the petitioner.

ii) Secretary DRAP argued that the petitioner was manufacturing drugs notwithstanding the fact that the registration awarded to the petitioner in respect thereof had been revoked. It was stated that the petitioner was back-dating labels on the packaging in an attempt to hoodwink the regulatory authority and the general public into assuming that the said batches were manufactured prior to the cancellation of the registration.

iii) It was demonstrated from the record that the petitioner has not been able to controvert any findings maintained there against by two successive fori. It was also stated that the allegation of mala fide, levelled by the learned counsel for the petitioner in the oral

arguments, is lien to the pleadings filed by the petitioner as no such plea has been taken therein. Even otherwise, the said plea was stated to be misconceived as the respondents are merely discharging the duty bestowed upon them by the statute for the protection and wellbeing of the public. It was forcefully argued that permitting the petitioner to perpetuate the production of spurious drugs would only endanger the lives of the general public. Thus, it was argued that the present petition merits immediate dismissal.

4. Mr. M. Zahid Khan, learned Assistant Attorney General adopted the arguments advanced by the Secretary DRAP and supported the Impugned Order in its entirety.

5. We have considered the respective arguments and have reviewed the record arrayed before us. It is observed that concurrent findings of fact have been rendered against the petitioner, vide the CLB Order and the Impugned Order. We are conscious of our jurisdiction and cognizant that the role of this Court is not to sit in appeal upon the Impugned Order, but to consider whether any manifest irregularity or illegality has been committed which would merit interference of this Court in the exercise of its Constitutional jurisdiction.

6. A show cause notice dated 07.12.2015, purportedly being one of several, was presented before us wherein the petitioner was directed to satisfy the grave issues raised therein. We have noted from the reply provided, vide letter dated 14.12.2015, that instead of responding to the serious allegations raised therein the petitioner opted not to address the real issues and sought to sanction such conduct on the grounds that the matter was subject matter of a Constitution petition before this

Court and that ad interim orders have been passed therein. The CLB Order raised grave allegations and on account of the petitioner being unable to dispel the preponderance of the claim there against was constrained to cancel the drug manufacturing license of the petitioner. It may be pertinent to reproduce the contents of the CLB Order herein below:

"I am directed and to inform you that Federal Inspector of Drugs, Karachi along with team inspected your business premises (M/s. Ankaz Pharmex Pvt Ltd Karachi) on 19.04.2014, and identified the non-compliance of GMP, and took the samples for test/analysis. He reported the following recommendations:

I. *"That an extension in the period of seizure and not to dispose off articles may be granted under DRAP Act, 2012.*

II. *Safe custody of all seized articles may also be granted till the fate of the case.*

III. The contents of the case may be kept on the agenda of forth-coming meeting of CLB for cancellation of their DML on larger public interest or permission for prosecution against the firm may be granted for violating the Section 23 (1) (a) (viii) of Drugs Act, 1976."

2. The samples of the drugs were also referred to Federal Government Analyst for test/analysis.

3. It was identified that you were manufacturing the Rumin suspension in back dates whose registration had already been cancelled by Registration Board in its 237th meeting held on 26.02.2013 which was communicated to you vide letter bearing No. 03-16/2012-QC, dated 22.03.2013.

4. That the samples of Rumin 200mg tablets Batch No. 640, Rumin 400mg tablets, Batch No. Nil, Rumin 200mg tables Batch No. nil, Rumin 400mg tablets Batch No.1105, Biprim DS tablets Batch No. 305, Biprim tablets DS Batch No 524 were declared as substandard by the Federal Government Analyst. The firm applied for retesting at Appellate Lab, NIH, Islamabad. The NIH also declared the Rumin 400mg tablets Batch No. 1105, Rumin 200mg tablets Batch No.640, loose pink colored Rumin 400mg tablets Batch No. Nil, loose pink colored Rumin 200mg tablets Batch No. Nil as substandard and Biprim DS tablet Batch No. 305 as misbranded.

5. That after the due process, Registration Board cancelled the registration of said products and referred the case to Central Licensing Board for cancellation of license in its 246th meeting held on 10th – 11th December, 2014.

6. That the Central Licensing Board in its 239th meeting held on 22.01.2015 considered the case and decided to issue the Show Cause Notice for the cancellation of the Drug Manufacturing License under section 41 of Drugs Act, 1976 and also for prosecution of the above named firm and the accused persons in the Drugs Court of Sindh.

7. The personal hearing was given to you and its nominated persons in Central Licensing Board in its 246th meeting held on 22.02.2016.

8. That the Drug Court Lahore directed to suspend the Drug Manufacturing License of M/s. Ankaz Pharmex, Ltd. Karachi till the arrest of accused persons in separate case.

9. That you filed the appeal before the Appellate Board against the decision of registration board but appellate board decided to maintain the decision of registration board in its 146th meeting held on 24.05.2017.

10. After the decision of Appellate Board, the case was again presented before the Licensing Board in its 255th meeting held on 17th – 18th, August, 2017. The Central Licensing Board considered the complete case under the facts and relevant law and decided to.

i. Cancel the DML of M/s. Ankaz Pharmex, (Pvt), Karachi under section 41 of the Drugs Act, 1976 read with rule 12 of the Drugs (Licensing Registering and Advertising) Rules, 1976 due to poor GMP compliance that resulted in manufacturing of substandard drug and also for manufacturing the unregistered drug i.e. Rumin suspension.

ii. The CLB also granted the permission of prosecution to the Federal Inspector of Drugs, Karachi against the firm under Section 23 and 27 of the Drugs Act, 1976 and rules framed thereunder in the court of law.

11. In view of above, the license No. 000247 in favour of M/s. Ankaz Pharmex, Ltd, Pvt, Karachi is cancelled/withdrawn and it is directed that you cannot operate further as manufacturer under the DRAP Act, 2012 and the Drugs Act, 1976."

(Underline added for emphasis.)

7. The CLB Order was assailed by the petitioner before the learned Appellate Board Drug Regulatory Authority of Pakistan and the said proceeding culminated in the dismissal of the appeal, vide the Impugned Order. It is relevant to reproduce the pertinent content of the Impugned Order herein below:

“Proceedings:

The Federal Inspector of Drugs, Karachi along with team inspected premises of the appellant on 19.04.2014 and took samples for test/analysis while identifying non-compliance of GMP. The FID recommended the following:

i. An extension in the period of seizure and not to dispose of articles may be granted under DRAP Act, 2012.

ii. Safe custody of all seized articles may also be granted till the fate of the case.

iii. The contents of the case may be kept on the agenda of forthcoming meeting of CLB for cancellation of their DML in larger public interest or permission for prosecution against the firm may be granted for violating the section 23 (I) (a) (viii) of Drugs Act, 1976.

2. The samples of the drugs were also referred to Federal Government Analyst for test/analysis. It was identified that the appellant was manufacturing the Rumin suspension in back dates whose registration had already been cancelled by Registration Board in its 237th meeting held on 26.02.2013 communicated vide letter No. F.3-16/2012-QC dated 22.03.2013.

3. The samples of Rumin 200mg tablets Batch No 640, Rumin 400 mg tablets, Batch No. Nil, Rumin 200mg tablets Batch No Nil, Rumin 400mg tablets Batch No 1105, Biprim DS tablets Batch No. 305, Biprim tablets DS Batch No 524 were declared as substandard by the Federal Government Analyst. The firm applied for retesting at Appellate Lab, NIH, Islamabad. The NIH also declared the Rumin 400mg tablets Batch No. 1105, Rumin 200mg tablets Batch No.640, loose pink colored Rumin 400mg tablets Batch No. Nil, loos pink colored Rumin 200mg tablets Batch No. Nil as substandard and Biprim DS tablet Batch No. 305 as misbranded.

4. Accordingly, the Drug Registration Board cancelled the registration of aforesaid products and referred the case to Central Licensing Board for cancellation of license in its 246th meeting held on 10th – 11th December, 2014. The Central Licensing Board in its 239th meeting held on 22.01.2015 considered the case and decided to issue the Show Cause Notice for cancellation of the Drug Manufacturing License under section 41 of Drugs Act, 1976 and also for prosecution of the above named firm and the accused persons in the Drugs Court of Sindh. Personal hearing was granted to the appellant and its nominated persons in 246th Central Licensing Board meeting held on 22.02.2016.

5. On appeal filed by the appellant, the Appellate Board upheld the decision of the Registration Board in its 146th meeting held on 24.05.2017. The case was again presented before the Central Licensing Board in its 255th meeting held on

17th – 18th, August, 2017 and after considering the facts on record, it decided to:-

i. Cancel the DML (No.000247) of appellant under section 41 of the Drugs Act, 1976 read with rule 12 of the Drugs (Licensing Registering and Advertising) Rules, 1976 due to poor GMP compliance that resulted in manufacturing of substandard drug and also for manufacturing the unregistered drug i.e. Rumin suspension.

ii. Granted the permission of prosecution to the Federal Inspector of Drugs, Karachi against the appellant under Section 23 and 27 of the Drugs Act, 1976 and rules framed thereunder.

6. The Secretary CLB has informed to the Board that the appellant has informed in the CLB meeting that there is stay order from the Hon'ble Sindh High Court. However, there was not stay by the Court. Further the appellant has not replied the show cause notice given by the CLB. In CLB meeting the appellant has only given verbal statements. Furthermore, the area FID report is also against the appellant that 69 bottles/packs which were openly placed and there was no seal on the bottles. Replying to Boards question, the representative of the firm informed that the recalled products were lying in the warehouse racks along with other products/ materials. The board members observed that even if these were the discarded or recalled products, it should be in locked or sealed area. The appellant admitted that the recalled products were found opened and not placed in a locked or sealed area.

7. The Chairman asked from the appellant that whether there is any SOP for containing the substandard or recalling samples/ products from market, if yes, then will he be able to produce it? The appellant answered in negative and admitted before the Board that there was no SOP developed at that time.

8. The Board observed that the appellant has never replied the show cause notice given by the CLB. The Board also observed that the bottles which were recovered were opened, although it should be sealed and be in a locker and locked and sealed. Further, there is no stay order granted by the Hon'ble Sindh High Court. The firms legal counsel agitated that there was no complaint for his client product as unsafe to the public and thus should not be canceled. The firm representative admitted that they do not have pharmacovigilance system to collect data from market about the safety and efficacy of their product, not he can get the copy of the same to show and prove to the Board, thus the raised argument for their product safety. In addition, Board observed that the appellant has many times given mis-statement in various proceedings of CLB Board and in the court. The Board observed that the firm could not present anything substantial to disprove the objections

> reported against them, nor their track record is satisfactory as appearing from registration and licensing boards proceedings, about their substandard products and it was further reported that they continue manufacturing of product for which the registration was cancelled by the Registration board; hence the instant appeal should be dismissed in the public interest.
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> Decision.
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> 9. The Board, after hearing arguments and perusing record of the case, decided to uphold the decision of the CLB and dismissed the appeal.

8. A perusal of the documentation pertaining to the process by which the drug manufacturing license of the petitioner was suspended demonstrates that an opportunity for being heard was given to the petitioner at each successive stage. It is apparent from the Impugned Order in itself that the arguments of the petitioner was presented before the appellate authority by the same learned counsel as is presently pleading the petition before us. Therefore, it is our view that no infringement of the principles of natural justice is apparent from the record. The petitioner's counsel has been unable to substantiate its allegation that the Impugned Order infringes upon the fundamental rights of the petitioner, as articulated in Articles 10-A, 14 and 25, hence, the said argument is also dispelled.

9. On the contrary there are two concurrent findings against the petitioner, which have not been dispelled by the learned counsel thereof. The case of the petitioner was considered by the relevant authority, at the first instance and subsequently at the appellate stage, and the respective findings were rendered adverse to the petitioner. We have noted that the allegations against the petitioner were that it was manufacturing de-registered drugs by back dating the packaging of the relevant batches; it was manufacturing tablets of numerous drugs,

which were found and declared to be substandard and such findings were maintained even when the respective batches were retested; and in addition to producing substandard drugs the petitioner was also mis-branding such products. These allegations are very serious in nature and affect the public health at large and it is apparent from the record that despite being afforded due opportunity to defend itself the petitioner remained unable to dispel such allegations either in the forum of first instance or before the appellate authority. It is clear that the proliferation of substandard, misbranded and / or wrongly labelled drugs cannot be permitted and under the law it is *inter alia* the responsibility of the Drug Regulatory Authority of Pakistan to ensure that the public at large is protected from such activities. In the present facts and circumstances it appears that the Drug Regulatory Authority of Pakistan has duly exercised its jurisdiction. Learned counsel for the petitioner has been unable to identify any infirmity with regard to the Impugned Order, which would merit interference of this Court in exercise of its Constitutional jurisdiction.

10. In view of the reasoning and rational contained herein above, we are of the considered opinion that no case for interference by this Court has been made out in the exercise of its Constitutional jurisdiction as the present petition is devoid of merit, hence, this petition, along with pending applications, is hereby dismissed with no order as to costs.

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