IN THE HIGH COURT OF HIMACHAL PRADESH, SHIMLA

CWP No.2572 of 2020

Reserved on: 6th August, 2020

Decided on: 14th August, 2020

M/s Digital Vision

.....Petitioner

Versus

State of Himachal Pradesh and others

.....Respondents

Coram

The Hon'ble Mr. Justice Tarlok Singh Chauhan, Judge

The Hon'ble Ms. Justice Jyotsna Rewal Dua, Judge

Whether approved for reporting?[1] Yes.

For the Petitioner: Mr. K.D. Shreedhar, Senior Advocate with Ms. Tanvi Chauhan, Advocate.

For the Respondents: Mr. Ajay Vaidya, Senior Additional Advocate General, for respondents No.1 to 4-State.

Mr. Shashi Shirshoo, Central Govt. Counsel, for respondent No.5.

Jyotsna Rewal Dua, Judge

On the ground that a specific batch of COLDBEST-PC Syrup, one of the drugs manufactured by the petitioner-firm, was found to be adulterated with Diethylene Glycol, the respondent-Department in exercise

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[1] Whether the reporters of Local Papers may be allowed to see the judgment?

of powers conferred by Rule 85(2) of the Drugs and Cosmetics Rules, 1945, on 15.02.2020 issued to the petitioner, a Show Cause Notice-cum-Stop Manufacturing Order of COLDBEST-PC Syrup and all other similar drug compositions, later on observing that provisions of Drugs and Cosmetics Act and Rules framed thereunder were not being adhered to, followed it with another Show Cause Notice-cum-Stop Manufacturing Order issued on 17.02.2020 for all the drugs under its Drugs Manufacturing Licences and finally issued an office order dated 02.03.2020, suspending Drug Manufacturing Licences of the petitioner. Appellate Authority, though did not interfere with these orders, however, already manufactured finished products wherein Propylene Glycol was not used were allowed to be sold after verification by the Department. Aggrieved against these orders and repeated issuance of various show cause notices, instant writ petition has been preferred by the petitioner.

2. Facts:-

2(i). Petitioner-firm was issued following licences on 17.06.2008 to manufacture for sale or for distribution drugs (Tablets, Capsules and Oral liquid dosage forms):-

(a). Drugs other than those specified in Schedule C and C(1) and X, vide Form-25 in terms of Rule 70 of Drugs & Cosmetics Rules (in short 'the Rules').

(b). Drugs specified in Schedule C and C(1) excluding those specified in Schedule X, vide Form-28 in terms of Rule 76 of the Rules.

Both licences were valid till 16.06.2013. Vide retention letter dated 20.12.2018, these licences have been retained upto 16.06.2023.

2(ii). On 10.09.2014, the respondents gave approval to the petitioner to manufacture the drug in question, i.e. COLDBEST-PC Syrup. This is a prescription drug and falls under Schedule G of the Drugs and Cosmetics Act and Rules framed thereunder. The drug is a Fixed Dose Combination (FDC) of Paracetamol, Phenylephrine Hydrochloride and Chlorpheniramine Maleate.

2(iii). For manufacturing COLDBEST-PC Syrup, petitioner claims to be using excipient Propylene Glycol (in short 'PG') for dissolving Paracetamol. Petitioner claims to have purchased the raw material PG of Batch Nos.2085, 2123 and 2116 against invoice dated 16.09.2019, from one M/s Thakur Enterprises of Ambala Cantt, who statedly

claimed that PG under aforesaid batches was manufactured by M/s Manali Petrochemicals at Chennai.

2(iv). After procuring raw material PG, the petitioner-firm, *inter alia,* manufactured 5575 bottles of COLDBEST-PC Syrup, under Batch No.DL5201 in September, 2019. Batch size of this manufactured drug was about 360 litres, wherein about 94.5 kg of PG was statedly used.

2(v). Entire DL5201 batch of COLDBEST-PC Syrup was sold by the petitioner to its distributor M/s Shiva Medical Hall, Ambala Cantt. Haryana, which further sold the drug to various licensed dealers/stockists. According to the petitioner, 3447 bottles out of total stock of 5575 bottles of the drug in question belonging to Batch No.DL5201 have been consumed in eight States of Jammu & Kashmir, Uttar Pradesh, Tamil Nadu, Haryana, Himachal Pradesh, Meghalaya, Andhra Pradesh and Uttarakhand.

2(vi). Vide its letter dated 15.02.2020, the Controller Drugs, Drugs & Food Control Organization, J&K (Jammu) informed State Drugs Controller, Himachal Pradesh about some infant mortalities in Ramnagar area of District Udhampur in the State of Jammu & Kashmir. The letter further conveyed that PGIMER, Chandigarh had given them

to understand that COLDBEST-PC Syrup manufactured by the petitioner-Firm in Batch No.DL5201 was impure as Diethylene Glycol (in short 'DEG') was found in it. Accordingly, request was made to the Drug Controller, Himachal Pradesh to carry out inspection of the petitioner's Unit for evaluating the aspect of impurity as well as for recalling the drug irrespective of batch in larger public interest.

2(vii). Acting on the basis of above communication, the Assistant Drugs Controller-cum-Drugs Licensing Authority, District Sirmour, in exercise of powers under Rule 85(2) of the Drugs & Cosmetics Rules (in short 'the Rules') on 15.02.2020 itself issued to the petitioner a show cause notice-cum-Stop Manufacturing Order of COLDBEST-PC Syrup and all the drugs having similar formula/ composition under generic name or any other brand name. Manufacturing and sale of the drug formulation in question under generic name or any brand name during stop manufacturing period was to be viewed as violation of various provisions of Drugs and Cosmetics Act. On the same day, the Drug Inspector, District Sirmour, collected five samples of COLDBEST-PC Syrup including one sample

under Batch No.DL5201 alongwith one sample of PG from the premises of petitioner.

2(viii). On 17.02.2020, the Drug Inspector, Nahan directed the petitioner to produce certain specified record including stock registers reflecting use of PG. Petitioner vide its communication of even date, expressed its inability to produce the desired record that day and stated that the same can be made available in three days. Observing that record was immediately required by the investigation team specially constituted by the respondents, the Assistant Drugs Controller-cum-Drugs Licensing Authority, Nahan, 'keeping in view the seriousness of the matter in public interest' on 17.02.2020, issued a show cause notice-cum-stop manufacturing order to the petitioner in respect of its Drug Manufacturing Licenses. The show cause notice was issued with respect to not producing the desired record. Manufacturing and sale by the petitioner of any of its drug formulations during stop manufacturing period was to be considered as violation of various provisions of Drugs and Cosmetics Act. This show cause notice/stop manufacturing order was issued in exercise of powers under Rule 85(2) of the Rules.

2(ix). Some record was supplied by the petitioner on 20/22.02.2020. The show cause notices and stop manufacturing orders dated 15.02.2020 and 17.02.2020 were replied by the petitioner. The investigation team under supervision of State Drugs Controller, Himachal Pradesh, submitted its spot/interim report dated 17.02.2020 and after enumerating 20 point observations therein drew following conclusions:-

> *"The investigation team has drawn the samples of 5 batches of Coldbest-PC syrup, including impugned drugs, Propylene Glycol, BN-1A1912057 and all the syrup available in finished good material in which propylene glycol was used have been freezed in Form 15 and samples have been drawn under Section 23 of Drugs and Cosmetics Act 1940 and rules 1945 made thereunder and the documents with respect to the impugned drugs has been seized under from 16 under Section 23 of Drugs and Cosmetics Act 1940 and rules 1945 made thereunder.*
>
> *The State Licensing Authority has issued Stop manufacturing order vide no.HFW-H(Drugs)58/08/Camp-I dated 17-02-2020.*
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> *Also, the detail investigation is required at M/s Thakur Enterprises 180, LalKurti Bazar, Ambala Cantt-133001 and M/s Manali Petrochem Limited, Chennai and to link the supply chain and further wait for report of samples drawn under section 23 of Drugs and Cosmetics Act 1940 and Rules 1945 made thereunder.*
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> *Further, the detail investigation is also required at M/s Digital Vision, 176, Mauza Ogli, Nahan Road, Kala Amb, Tehsil-Nahan, Distt. Sirmour after the reports are received from laboratory of the samples drawn and scrutinization of all records for root cause analysis.*
>
> *Further, the detailed investigation report with root cause analysis will be submitted accordingly."*

On the basis of this report, another show cause notice-cum-stop manufacturing order was issued on

25.02.2020, directing the petitioner to adhere to the earlier issued show cause notice-cum-stop manufacturing order dated 17.02.2020. Petitioner was also asked to respond to 20 observations noticed in the interim report dated 17.02.2020 pointing out various violations/discrepancies at its end. Petitioner responded to letter dated 25.02.2020 vide its communication dated 28.02.2020.

2(x). On 02.03.2020, Government Analyst, Regional Drugs Testing Laboratory (in short 'RDTL'), Chandigarh sent the test/analysis reports of three samples of COLDBEST-PC Syrup Batch No.DL5201, drawn from the States of Jammu & Kashmir and Haryana. In all the three reports, the drug was found to be adulterated with DEG, a poisonous chemical and dangerous to public health. Accordingly, the reports declared the drug as not of standard quality. On the basis of these test reports, respondents issued an office order on 02.03.2020 in exercise of the powers under Rule 85(2) of the Drugs and Cosmetics Rules, suspending the Drugs Manufacturing Licences of the petitioner-firm till further orders. Petitioner was directed neither to manufacture nor to sell any drugs during the suspension period. Also FIR No.21/2020 was

registered on 02.03.2020 at Police Station Kala Amb, District Sirmour, under Section 18(a)(i), 17A & 27(a) of Drugs & Cosmetics Act and Section 308 of Indian Penal Code.

2(xi). Respondent Authorities had collected five samples of COLDBEST-PC Syrup from petitioner's premises on 15.02.2020 alongwith one sample of PG. The analysis reports of these samples were submitted by RDTL, Chandigarh. Following tabulation gives the gist of these reports:-

COLDBEST-PC Syrup

Date of Report	*Batch No.*	*Sample No.*	*Result*
5.3.2020	***B.No.5201***	*NHN/19/94*	***Standard Quality. However, sample was not tested for DEG due to insufficient quantity.***
1.4.2020	*DL 5872*	*NHN/19/95*	*Standard Quality. Tested negative for DEG*
1.4.2020	*DL 2831*	*NHN/19/96*	*Standard Quality. Tested negative for DEG*
1.4.2020	*DL 4302*	*NHN/19/97*	*Standard Quality. Tested negative for DEG*
1.4.2020	*DL 5028*	*NHN/19/98*	*Standard Quality. Tested negative for DEG*

Propylene Glycol

Date of Report	*Batch No.*	*Sample No.*	*Result*
16.3.2020	*BN-1A 1912057*	*NHN/19/99*	*Standard Quality PG*

The PG sample (NHN 19/99) tested by the RDTL, Chandigarh and found to be of standard quality was not supplied by M/s Thakur Enterprises, but was

manufactured in China. Samples No.NHN 19/95, 19/96, 19/97 and 19/98 of COLDBEST-PC Syrup were found to be of standard quality and did not contain DEG. But these samples were not of the batch in question. Sample No.NHN 19/94 drawn from batch in question, i.e. DL5201, though was analyzed to be confirming to standards, but could not be tested for presence of DEG due to insufficient quantity of sample.

2(xii). An appeal was preferred by the petitioner under Rule 85(3) of the Drugs and Cosmetics Rules for setting aside the office order dated 02.03.2020 and show cause notices/stop manufacture/sale orders dated 15.02.2020, 17.02.2020 and 25.02.2020. Learned Appellate Authority held that the action taken by the Assistant Drugs Controller-cum-Licensing Authority, Sirmour at Nahan, was on the basis of gravity of the offence and record/letters/ reports received by him from various agencies from time to time. In absence of (i) final investigation report in FIR No.21/2020 and (ii) final report of Central Drugs Laboratory (in short 'CDL'), Kolkata, the appellate authority-cum-Additional Chief Secretary (Health) to the Government of Himachal Pradesh declined to interfere with

the impugned orders/notices. Petitioner, however, was permitted to sell stocks of 26 drug formulations whose samples collected from petitioner's premises on 17.02.2020 were declared by RDTL, Chandigarh as of standard quality. Additionally, the already manufactured finished products of the petitioner-firm, wherein propylene glycol was not used, were also permitted to be sold after verification by the Department. Feeling aggrieved, instant writ petition has been preferred.

3. Heard learned counsel for the parties and gone through the record. Following broader points need consideration:-

(a). Whether while procuring Propylene Glycol against invoice dated 16.09.2019 and using it in manufacture of its drugs formulations including COLDBEST-PC Syrup, the petitioner complied with standard norms and specifications or not.

(b). Whether various show cause notices, stop manufacture/sale orders, issued to the petitioner from time to time and the order suspending the drugs manufacturing licences of the petitioner are sustainable in law and in the facts and circumstances of the case.

4. Contentions and Discussion for both the above points:-

COLDBEST-PC Syrup:-

4(i). Purchase of raw material PG: Petitioner has placed on record invoice dated 16.09.2019, issued to it by M/s Thakur Enterprises, Ambala Cantt. for purchase of PG under Batch Nos.2085, 2123 and 2116. Petitioner contends that M/s Thakur Enterprises had claimed to be a licensed wholesale dealer of fine chemicals etc. and had further claimed that the PG being supplied to the petitioner was manufactured by M/s Manali Petrochemicals Limited at Chennai. It is also submitted that Certificates of Analysis from Manali Petrochemicals was provided to the petitioner alongwith invoice certifying that the batches so purchased by the petitioner, inter alia, complied with IP specifications.

On behalf of the respondents, it has been submitted that during investigations, it emerged that M/s Thakur Enterprises did not possess valid drugs licence required to stock or exhibit for sale or distribution of PG. Therefore, petitioner-firm in violation of the Act & Rules purchased PG from an unlicensed firm.

No licence of M/s Thakur Enterprises is on record of the case. Even as per the petitioner, it had

purchased PG only on the basis of claims made by M/s Thakur Enterprises without reasonably verifying such claims. Matter is stated to be under investigation.

4(ii). Use of Propylene Glycol (PG):-

4(ii)(a). PG so purchased by the petitioner from a firm, which allegedly did not possess required licence, was used for its drug formulations. According to the petitioner, this raw material procured from M/s Thakur Enterprises was thereafter sent by it (petitioner) for analysis to M/s Shree Sai Test House Private limited, New Delhi. The test result of this laboratory on 20.09.2019 declared the raw material to be of standard quality.

This aspect has been countered on behalf of the State by submitting that petitioner-firm had not maintained the stock register for excipients as per Schedule U and that the petitioner had failed to produce any documented letter/receipt etc. for sending sample of raw material PG to the lab in question. Therefore, this report cannot be relied upon at this stage. The matter is subject of investigation in FIR No.21/2020.

4(ii)(b). Statedly after receipt of analysis report of PG from the lab at New Delhi, the COLDBEST-PC Syrup was

manufactured by the petitioner. Batch No.DL5201 was readied in September, 2019, consisting of 5575 bottles weighing 360 litres, consuming about 94.5 kg of PG. According to the petitioner, post production, its Quality Control Department analyzed the finished product and issued Certificate of Analysis of all the manufactured batches of COLDBEST-PC Syrup including Batch No.DL5201. All the batches were found to be complying with the standard norms and specifications. It has also been urged by the petitioner that Government Analyst, Udhampur, J&K reported on 23.01.2020 that COLDBEST-PC Syrup manufactured by the petitioner under Batch No.DL5201 was of standard quality.

This has been countered by the State by submitting that petitioner-firm had no facility for conducting the test for presence of DEG in its finished drug formulations and had actually not conducted the test for presence of DEG in the drug. The analysis report of petitioner's Quality Control Department indicating compliance of norms relating to Ethylene Glycol and DEG were therefore misleading. It has also been emphasized that in report dated 23.01.2020, the J&K Lab had also not

tested the sample for presence of DEG. Reliance upon these reports by the petitioner is, therefore, misplaced.

4(iii). Sale of COLDBEST-PC Syrup:-

Out of 5575 bottles of COLDBEST-PC Syrup manufactured under Batch No.DL5201, 3447 bottles were consumed in eight States. It appears that some infant mortalities in the State of Jammu & Kashmir were linked with COLDBEST-PC Syrup Batch No.DL5201 manufactured by the petitioner. A team of Doctors from PGI Chandigarh visited Jammu & Kashmir to look into the probable cause of deaths and perhaps made the authorities there to understand that in the COLDBEST-PC Syrup manufactured by the petitioner under Batch No.DL5201, adulterant Diethylene Glycol was found. This fact was brought to the notice of the respondent-Department by their J&K counterparts vide letter dated 15.02.2020, inter alia, requesting for conducting inspection of the unit for ascertaining the aspect of Diethylene Glycol impurity in the drug formulation as well as for recall of the product in question irrespective of its batch, in larger public interest.

4(iv). Action by State Drug Controlling Authorities:-

4(iv)(a). Taking cognizance of the contents of above referred letter of 15.02.2020 to the effect that PGI, Chandigarh has reported presence of DEG in COLDBEST-PC Syrup manufactured by the petitioner under Batch No.DL5201, the Competent Authority of respondent-Department on 15.02.2020 itself, in exercise of the powers conferred under Rule 85(2) of the Rules, issued a show cause notice to the petitioner as to why action be not taken against it for manufacturing COLDBEST-PC Syrup containing Diethylene Glycol and as to why its licence should not be cancelled/ suspended for violating various provisions of Drugs and Cosmetics Act and rules made thereunder. Simultaneously, respondents directed the petitioner to stop manufacturing/sale of COLDBEST-PC Syrup as well as all the drugs having similar formulations/ compositions. Petitioner was also directed to completely recall the said drugs from the market and to ensure its complete withdrawal even upto the consumer level.

4(iv)(b). On 17.02.2020, the respondents issued notice to the petitioner to produce the record mentioned therein. Petitioner in writing expressed its inability to immediately

produce the record. Whereafter on 17.02.2020 itself, another show cause notice was issued to it in exercise of the powers under Rule 85(2) of the Rules by the respondents as to why action be not taken against it for not producing the documents immediately required by the investigating team. Additionally, petitioner was directed to altogether stop manufacturing/sale under its Drug Manufacturing Licences till further orders. Petitioner on 20/22.02.2020 produced some records and on 24.02.2020 submitted its combined reply to the show cause notice dated 15.02.2020 and to show cause notice dated 17.02.2020. The investigation team comprising of six officers also submitted its interim report on 17.02.2020 with 20 observations. Apparently, not satisfied with the reply previously submitted by the petitioner and noticing the observations of the interim report, the respondents issued another show cause notice to the petitioner on 25.02.2020 as to why action be not taken against it for various violations/discrepancies observed in the spot/ interim report including following specific observations at Sr. Nos.5, 6, 7, 9, 10, 18 and 20:-

> *"5. During scrutinization of invoice it was observed that M/s Thakur Enterprises 180, LalKurti Bazar, Ambala Cantt-133001 has mentioned 3 batches:-a. Propylen Glycol, B.No.2085, Mfg*

Date June 2019, Exp date: May 2024, b. Propylen Glycol, B.No.2123, Mfg Date July 2019, Exp Date: June 2024, c. Propylen Glycol, B.No.2116, Mfg Date July 2019, Exp date: June 2024. But the number of Drums has not mentioned.

6. *The firm in AR no.Issuing register has mentioned AR No.1268/19-20 only against invoice no.557 dated 16-09-2019 which was further observed fabricated during investigation for entry of AR No.1268(i)/19-20 for batch no.2123 and 1268 (ii)/19-20 for batch no.2116.*
7. *Again in next entry the firm has mentioned s.no.1268A for Serratiopeptidase, B.no.AF45190267, Mfg Date: 08/19, Exp Date: 07/24, Manufactured by: M/s Anthum which was given AR. No.1268 A/19-20.*
9. *The firm does not have any facility to perform the test for Diethyleneglycol but the firm is mentioned the same in COA generated by the firm.*
10. *The firm has also produce the test report from Shree Sai Test House Pvt. Ltd., New Delhi, but the firm has failed to produce the evidence of sent sample like Postal detail etc. but stated that samples are collected by representative of testing firm.*
18. *The firm has failed to produce utilization data of Xanthane Gum, Propyl Paraben Sodium, Sodium Benzoate etc.*
20. *The firm has also failed to produce the BMR of other batches in which of a. Propylen Glycol, B.No.2085, Mfg Date June 2019, Exp date: May 2024, b. Propylen Glycol, B. No.2123, Mfg Date July 2019, Exp date: June 2024, c. Propylen Glycol, B. No.2116, Mfg Date July 2019, Exp date: June 2024 from M/s Manali Petrochemicals Limited, Chennai. In continuation of which the State Licensing Authority has issued Stop manufacturing order vide no.HFW-H(Drugs)58/08/Camp-I dated 17-02-2020."*

Petitioner was also directed to adhere to the Stop Manufacturing Order issued on 17.02.2020 and was further directed to give point-wise reply to all the 20 point observations of the interim report. Petitioner replied to this notice on 28.02.2020 giving its response to 20 observations of the interim report.

4(iv)(c). On 02.03.2020, the Government Analyst, RDTL, Chandigarh, submitted its analysis reports of three samples

of drug COLDBEST-PC Syrup Batch No.DL5201 drawn from the State of Haryana and Jammu & Kashmir. These analysis reports declared the samples of COLDBEST-PC Syrup produced by the petitioner under Batch No.DL5201 as not of standard quality and adulterant Diethylene Glycol, a poisonous chemical, was detected in these samples. Immediately thereafter, on the basis of the analysis reports of Government Analyst, RDTL, Chandigarh in respect of samples of COLDBEST-PC Syrup Batch No.DL5201 found to be adulterated with Diethylene Glycol and finding the replies of the petitioner to the earlier notices unsatisfactory, the respondents issued office order dated 02.03.2020, suspending the Drugs Manufacturing Licences of the petitioner-firm in public interest till further orders.

4(iv)(d). Five samples of COLDBEST-PC Syrup of different batches including one under Batch No.DL5201 and one sample of PG were collected by the respondents on 15.02.2020 from the premises of the petitioner. Out of the five samples of COLDBEST-PC Syrup, the one under Batch No.DL5201, i.e. NHN-19/94, though was found by RDTL, Chandigarh of standard quality vide its report dated 05.03.2020, yet absence of adulterant DEG in it could not

be ruled out as the sample, being of insufficient quantity, could not be tested for DEG. The other samples of COLDBEST-PC Syrup belonging to other batches were declared as of standard quality and tested negative for presence of DEG.

On 26.02.2020, one sample of COLDBEST-PC Syrup Batch No.DL5201, NHN/19/103 collected in accordance with provision of the Act & Rules from the petitioner's premises from the stock recalled from the market, was sent for test to RDTL, Chandigarh on 27.02.2020. RDTL Chandigarh on 09.03.2020, requested the respondents for providing additional sample to complete the analysis. Since physical stock of drug in question was not available in the premises of the petitioner, therefore, permission was sought by the respondents from learned Chief Judicial Magistrate (CJM), District Sirmour at Nahan for drawing additional quantity of drug from the seized drugs. Permission was accorded by the learned Court vide order dated 11.03.2020. Additional sample so drawn was submitted to RDTL, Chandigarh on 12.03.2020. In continuation to earlier sample drawn on 26.02.2020, RDTL Chandigarh submitted its analysis report on 20.03.2020

declaring the entire sample (NHN/19/103) as not of standard quality and adulterated with DEG.

Whereafter, respondents on 20.03.2020, issued another show cause notice to the petitioner for sale of sub-standard and adulterated drug. Petitioner was also directed to comply with previously issued directions. Petitioner expressed its dissatisfaction with the analysis report. Therefore, on application of respondents, learned CJM, Sirmour on 02.05.2020 ordered for sending sealed portions of samples drawn on 26.02.2020 and 11.03.2020 to the Director, CDL, Kolkata for complete re-test. This order, however, has been stayed in Cr.R. No.146/2020 instituted in this Court by the petitioner itself.

4(iv)(e). In an appeal preferred by the petitioner under Rule 85(3) of the Drugs and Cosmetics Rules, learned Appellate Authority in its order dated 22.06.2020 considering the fact that the final investigation report in FIR No.21/2020 and final report of Director, CDL, Kolkata were yet to come, declined to interfere with the suspension order passed by the Assistant Drugs Controller-cum-Licensing Authority on 02.03.2020. Appellate Authority, however, allowed the petitioner to sell stocks of 26 samples

of different drug formulations collected by Drugs Inspector, Central Drugs Standard Control Organization ('CDSCO' in short), Baddi on 17.02.2020 from the premises of the petitioner and declared by Government Analyst, RDTL Chandigarh to be of standard quality. Additionally, petitioner's already manufactured finished products, where PG was not used were also allowed to be sold.

5. Observations:

What emerges from above discussion is that:-

5(i)(a). Before buying PG from M/s Thakur Enterprises, Ambala Cantt., vide invoice dated 16.09.2019, petitioner did not even reasonably verify the authenticity of supplier's claim of being a licensed wholesale dealer of fine chemicals. According to the respondents, M/s Thakur Enterprises did not even possess a valid drug licence required for stocking or exhibiting for sale or distribution of PG.

5(i)(b). There is justification in the stand of respondents that pending further investigations, the analysis report of Shree Sai Test House Private Limited, New Delhi dated 20.09.2019, in respect to PG, allegedly purchased by the petitioner from M/s Thakur Enterprises on 16.09.2019 and used thereafter in manufacturing various drug

formulations, inter alia, COLDBEST-PC Syrup including Batch No.DL5201, declaring PG to be of standard quality and certifying that sample is compliant of DEG cannot be relied upon as the petitioner has failed to produce documented evidence of having sent the sample to the laboratory at New Delhi.

5(ii). In none of the Analysis Reports placed on record of the case, COLDBEST-PC Syrup manufactured by the petitioner under Batch No.DL5201 was declared of standard quality without presence of adulterant DEG.

5(ii)(a). The Certificate of Analysis dated 23.09.2019 of Quality Control Department of the petitioner in respect to finished product COLDBEST-PC Syrup certified this product to be of standard quality and compliant of Ethylene Glycol and Diethylene Glycol norms. However, admittedly the petitioner-firm does not possess the testing facility for checking its drugs formulations for presence of adulterant DEG. Therefore, analysis reports of petitioner's Quality Control Department with respect to COLDBEST-PC Syrup cannot be relied upon. Same goes for test reports of petitioner's Quality Control Department with respect to analysis of sample of PG. It cannot be said to have been

tested for presence of poisonous adulterant DEG in absence of such testing facility available with the petitioner.

5(ii)(b). Three test reports of RDTL, Chandigarh dated 02.03.2020 in respect of samples of COLDBEST-PC Syrup, Batch No.DL5201, drawn from the State of Haryana and Jammu & Kashmir, had declared the drug as not of standard quality after detecting poisonous chemical DEG therein. According to the respondents, Government Analyst Drug Testing Laboratory, Tamil Nadu, has also provided them their analysis report declaring COLDBEST-PC Syrup Batch No.DL5201 as not of standard quality and found to be adulterated with DEG.

5(ii)(c). The test report of RDTL, Chandigarh dated 05.03.2020 with respect to sample of COLDBEST-PC Syrup, Batch No.DL5201 (NHN-19/94), drawn on 15.02.2020 from the premises of petitioner though declared the drug as of standard quality, but due to insufficient quantity, the sample could not be tested for presence of DEG. The analysis report dated 23.01.2020 of Government Analyst, Udhampur also had not tested the sample of COLDBEST-PC Syrup Batch No.DL5201 for DEG.

5(ii)(d). The test report of RDTL, Chandigarh dated 20.03.2020 regarding sample of COLDBEST-PC Syrup, Batch No.DL5201, collected on 26.02.2020 with additional quantity collected under order dated 11.03.2020 passed by learned CJM, Sirmour, confirmed the sample as not of standard quantity as poisonous adulterant DEG was detected in the sample. Petitioner has contested the result. Therefore, on an application moved by the Drugs Inspector, Nahan under Section 25(4) of the Act, learned CJM, Sirmour at Nahan, on 02.05.2020, ordered for dispatching sealed sample portions of COLDBEST-PC Syrup, Batch No.DL5201, collected on 26.02.2020 and 11.03.2020 (Sample No.NHN/19/103) to the Director, Central Drugs Laboratory (CDL), Kolkata. This order has been stayed on 06.05.2020 in Criminal Revision No.146/2020, instituted by the petitioner. Therefore, the sample could not be sent to CDL, Kolkata for complete re-test.

6(i). Though many of above referred aspects are as yet stated to be pending for further investigation, but, prima facie, at this stage, it can certainly be observed that PG purchased by the petitioner from M/s Thakur Enterprises vide invoice dated 16.09.2019 and thereafter

used in different drug formulations including COLDBEST-PC Syrup irrespective of batch numbers cannot be said to be of standard quality as at present neither there is any proof of the same having been purchased from a duly licensed dealer/stockist nor there is any proof of the same having been tested for presence of commonly tested adulterant DEG before being put to use by the petitioner in its different drug formulations. A specific drug COLDBEST-PC Syrup under Batch No.DL5201, manufactured by the petitioner allegedly using this PG, has been tested positive for poisonous chemical and adulterant DEG in samples drawn from the States of Haryana, Jammu & Kashmir and Himachal Pradesh. Though some of the analysis reports have been disputed by the petitioner and further investigation is still going on, however, at this stage, *prima facie*, it can be observed that COLDBEST-PC Syrup, Batch No.DL5201, cannot be said to be of standard quality.

Considering above aspects, action of the respondents in issuing show cause notice to the petitioner on 15.02.2020 and ordering it initially to stop manufacturing/sale of COLDBEST-PC Syrup/similar drugs

formulations and directing it to recall the drug from the market was justified considering public health and safety.

6(ii). Over a period of time, after receipt of various analysis reports, spot/interim report submitted by the investigating agency, further action of the respondents in issuing separate show cause notices to the petitioner and ordering it to stop manufacture/sale of all drug formulations under its Drugs Manufacturing Licences and thereafter suspending till further orders its Drugs Manufacturing Licences, however, cannot be justified. In issuing such notices, the respondents have exercised power under Rule 85(2) of the Rules, which reads as under:-

> *"85. Cancellation and suspension of licenses- (1).....*
>
> *(2) The Licensing Authority may for such licenses granted or renewed by him, after giving the licensee an opportunity to show cause why such an order should not be passed, by an order in writing stating the reasons therefor, cancel a license issued under this Part OR suspend it for such period as he thinks fit either wholly or in respect of any of the drugs to which it relates [OR direct the licensee to stop manufacture, sale or distribution of the said drugs and [thereupon order the destruction of drugs and] the stocks thereof in the presence of an Inspector], if in his opinion, the licensee has failed to comply with any of the conditions of the license or with any provisions of the Act or rules made thereunder."*

The power conferred under the above extracted rule can be exercised only in accordance with law. Reason were required to be given while directing the petitioner to completely stop manufacture/sale of all its licensed drugs

formulations as well as in suspending its Drugs Manufacturing Licences. Petitioner had submitted replies to various show cause notices issued to it by the respondents. However, a perusal of repeatedly issued show cause notices nowhere reflects due consideration of replies submitted by the petitioner. Hon'ble Apex Court in ***Kranti Associates Private Limited and another Versus Masood Ahmed Khan and others, (2010) 9 SCC 496***, vide para 47, held as under:-

> *"47. Summarising the above discussion, this Court holds:*
> *(a). In India the judicial trend has always been to record reasons, even in administrative decisions, if such decisions affect anyone prejudicially.*
> *(b). A quasi-judicial authority must record reasons in support of its conclusions.*
> *(c). Insistence on recording of reasons is meant to serve the wider principle of justice that justice must not only be done it must also appear to be done as well.*
> *(d). Recording of reasons also operates as a valid restraint on any possible arbitrary exercise of judicial and quasi-judicial or even administrative power.*
> *(e). Reasons reassure that discretion has been exercised by the decision maker on relevant grounds and by disregarding extraneous considerations.*
> *(f). Reasons have virtually become as indispensable a component of a decision-making process as observing principles of natural justice by judicial, quasi-judicial and even by administrative bodies.*
> *(g). Reasons facilitate the process of judicial review by superior Courts.*
> *(h). The ongoing judicial trend in all countries committed to rule of law and constitutional governance is in favour of reasoned decisions based on relevant facts. This is virtually the life blood of judicial decision-making justifying the principle that reason is the soul of justice.*
> *(i). Judicial or even quasi-judicial opinions these days can be as different as the judges and authorities who deliver them. All these decisions serve one common purpose which is to demonstrate by reason that the relevant factors have been*

objectively considered. This is important for sustaining the litigants' faith in the justice delivery system.

(j). Insistence on reason is a requirement for both judicial accountability and transparency.

(k). If a Judge or a quasi-judicial authority is not candid enough about his/her decision-making process then it is impossible to know whether the person deciding is faithful to the doctrine of precedent or to principles of incrementalism.

(l). Reasons in support of decisions must be cogent, clear and succinct. A pretence of reasons or "rubber-stamp reasons" is not to be equated with a valid decision-making process.

(m). It cannot be doubted that transparency is the sine qua non of restraint on abuse of judicial powers. Transparency in decision-making not only makes the judges and decision-makers less prone to errors but also makes them subject to broader scrutiny. (See David Shapiro in Defence of Judicial Candor.

(n). Since the requirement to record reasons emanates from the broad doctrine of fairness in decision-making, the said requirement is now virtually a component of human rights and was considered part of Strasbourg Jurisprudence. See Ruiz Torija v. Spain EHRR, at 562 para 29 and Anya v. University of Oxford, wherein the Court referred to Article 6 of the European Convention of Human Rights which requires,

"adequate and intelligent reasons must be given for judicial decisions".

(o). In all common law jurisdictions judgments play a vital role in setting up precedents for the future. Therefore, for development of law, requirement of giving reasons for the decision is of the essence and is virtually a part of "due process".

In ***Civil Appeal No.9417 of 2019,*** titled ***M/S Daffodills Pharmaceuticals Ltd. & Anr. Versus State of U.P. & Anr.***, decided on December 13, 2019, the Hon'ble Supreme Court observed that if there is one constant lodestar that lights the judicial horizon in this country, it is this: that no one can be inflicted with an adverse order, without being afforded a minimum opportunity of hearing, and prior intimation of such a move. This principle is too

well entrenched in the legal ethos of this country to be ignored.

In the facts and circumstances of the case discussed above and as borne out from the record and as is evident from the show cause notices/orders dated 15.02.2020, 17.02.2020, 25.02.2020, 02.03.2020 and 20.03.2020, the allegation against the petitioner primarily pertained to use of specific PG and presence of adulterant DEG in COLDBEST-PC Syrup therefore, the Stop Manufacture/Sale Order could have been restricted to those drug formulations where PG purchased by the petitioner against invoice dated 16.09.2019 was used or at best in respect of those drugs which involved use of PG. In a blanket manner, without setting forth the reasons required to be enumerated under Rule 85(2) of the Rules, neither the manufacture/sale of other drug formulations could be ordered to be stopped where PG was not used nor in the facts and circumstances of the case, petitioner's Drugs Manufacturing Licences could be suspended altogether by the respondents in exercise of powers under Rule 85(2) of the Rules. Even though there may be cases where a single violation/contravention of the licence may be

so grave so as to justify cancellation/suspension of entire licence after due application of mind by the Competent Authority. But the record of this case does not reflect application of mind by the respondents in ordering suspension of Drugs Manufacturing Licences of the petitioner, forcing it to completely shut down its unit. The power to cancel/suspend a licence has to be exercised with sound discretion in the given facts and circumstances of the case as well as keeping in mind larger public interest, but not mechanically, hastily or arbitrarily.

The only discernible reasons for issuance of the impugned notices/orders relate to the PG procured and used by the petitioner in above described manner and detection of adulterant DEG in one batch of COLDBEST-PC Syrup, i.e. No.DL5201, manufactured by the petitioner. Even though the samples of COLDBEST-PC Syrup manufactured by the petitioner under other batches were not found to be adulterated with DEG, yet considering larger public interest, public health and safety, the action of the respondents in ordering the petitioner to stop manufacture/sale of COLDBEST-PC Syrup as a whole irrespective of its batches cannot be faulted. However,

apparently no reasons have been put forth by the respondents to stop manufacture/sale of all drugs by the petitioner under show cause notice-cum-stop manufacturing/sale order dated 17.02.2020 and thereafter to pass order dated 02.03.2020 for suspending its Drugs Licences altogether till further orders. The replies submitted by the petitioner to the show cause notices were discarded mechanically. Therefore, show cause notice dated 17.02.2020 and its reiteration in the notice dated 25.02.2020 to the extent they order the petitioner to stop manufacture/sale of its all drug formulations and order dated 02.03.2020 suspending drug manufacturing licences of the petitioner and its reiteration in communication dated 20.03.2020 cannot be sustained.

7. Conclusion:-

For the forgoing discussions and observations, we hold and direct that:-

7(i). No interference with show cause notice/stop manufacturing/stop sale order dated 15.02.2020, directing the petitioner to recall as well as to stop manufacture/sale of COLDBEST-PC Syrup is called for.

7(ii). Show Cause Notice-cum-Stop Manufacturing/Sale Order dated 17.02.2020 as well as Show Cause

Notice-cum-Stop Manufacturing/Sale Order dated 25.02.2020 and communication dated 20.03.2020 to the extent they direct the petitioner to altogether stop manufacture/sale under its drugs manufacturing licences are quashed and set aside. Respondents/Competent Authority is directed to examine the entire matter afresh after considering the replies to the notices submitted by the petitioner and thereafter pass appropriate order in accordance with law within a period of four weeks from today. It shall be open for the parties to take recourse to appropriate remedy in accordance with law in case they still feel aggrieved by the order so passed.

7(iii). Office order dated 02.03.2020, suspending drugs manufacturing licences of the petitioner, is quashed and set aside. However, till the time the competent authority takes fresh decision in terms of direction No.7(ii) above**:- (a)** the petitioner shall not manufacture/sell any of its licensed drugs, which involve use of Propylene Glycol and **(b)** petitioner is permitted to continue manufacture/ sale of all other drugs under its drugs manufacturing licenses, where Propylene Glycol is not used, subject to all applicable provisions of applicable Statutes and Rules made thereunder as well as subject to verification in accordance with law by the Competent Authority of respondent department.

7(iv). The order dated 22.06.2020 passed by the learned Appellate Authority-cum-Additional Chief Secretary (Health) is upheld only to the extent it permitted the petitioner to sell already lying stocks in which PG had not been used as well as to sell stocks of 26 samples of drug formulations declared by RDTL, Chandigarh as of standard quality.

With these observations, the writ petition is disposed of alongwith pending miscellaneous application(s), if any.

(Tarlok Singh Chauhan)
Judge

(Jyotsna Rewal Dua)
Judge

August 14, 2020
Mukesh