

ORDER SHEET
HIGH COURT OF SINDH, KARACHI

C.P. No.D-3093 & 3094 of 2019

Date	Order with signature of Judge
-------------	--------------------------------------

Present

Mr. Justice Muhammad Ali Mazhar.
Mr. Justice Yousuf Ali Sayeed.

C.P.No.D-3093 of 2019

M/s. Hakimsons Impex (Private) Limited.....Petitioner

Versus

Federation of Pakistan & others.....Respondents

&

C.P.No.D-3094 of 2019

M/s. Sindh Medical Stores.....Petitioner

Versus

Federation of Pakistan & others.....Respondents

Date of hearing 16.01.2020

Mr. Abdul Sattar Pirzada advocate for the petitioner.
Assistant by M/s. Mamoon N. Chaudhry and Hassan Ansari
advocates.

Mr. Ghulam Mohiuddin, Assistant Attorney General.

Syed Hakim Masood, Federal Drugs Inspector, DRAP,
Karachi.

Muhammad Ali Mazhar, J: The petitioners have sought the declaration that failure of respondents to register the drugs of the petitioner in accordance with Section 7 of the Drugs Act, 1976 is illegal and unlawful. Directions have also been sought against the respondents (DRAP) to immediately register the drugs under the provisions of Drugs Act, 1976. Further directions have been sought to permit the site

inspection of the manufacturing facility of the company by independent inspection.

2. Learned counsel for the petitioner pointed out page 159 in C.P. No.D-3093 of 2019 which was issued by the Deputy Director (Reg-I), Ministry of National Health Services, Regulations and Coordination, DRAP on 30.08.2017 with the subject "Registration of Drugs under Drugs Act, 1976", whereby, Dr. Rafeeq Alam Khan, Professor, Faculty of Pharmacy, University of Karachi/Member Registration Board and Mr. Zafar Minhas, Deputy Director (National Control Laboratory), Islamabad were nominated to arrange inspection of the manufacturer in the exporting country India in accordance with the approved SoP. These two members were nominated for the inspection of the exporting country for the drugs of three companies and at Sr. No. 3, the name of present petitioner is mentioned. Likewise, in C.P. No.D-3094 of 2019, learned counsel pointed out page No. 115 which is also a letter issued by the Deputy Director of the same authority to the petitioner with the subject "Registration of Drugs" and Dr. Qurban Ali, Director General National Veterinary Laboratory, Islamabad/Member Registration Board and Dr. Ghazanfar Ail, Deputy Director, Drug Regulatory Authority of Pakistan, Islamabad were nominated members for inspection of manufacturing process of medicine by M/s. Vins Bioproducts Ltd., Telangana, India. The petitioners were directed to arrange inspection of manufacturing units

through aforesaid approved panel in accordance with the SoP approved by the Federal Government.

3. Learned counsel further argued that though in the case of petitioner in C.P. No.D-3093 of 2019, the members were nominated for inspection vide letter dated 30.08.2017, whereas, in connected C.P. No.d-3094 of 2019 a similar letter was issued on 16.02.2018 but despite lapse of considerable period, no efforts have been made for the inspection and the issue of registration of the drugs applied for registration by both petitioners is pending.

4. In the first round of hearing, Syed Hakim Masood, Federal Drugs Inspector stated that it was the responsibility of the petitioners to contact to the nominated members for visa facilitation and other requirements but they have not initiated any such process so the entire delay cannot be attributed to DRAP.

5. On the contrary, Mr. Abdul Sattar Pirzada advocate stated that there are some visa facilitation issues, therefore, nominated members were not contacted. We had adjourned the matter to be taken up after tea break with the directions to the Federal Drugs Inspector and learned Assistant Attorney General to verify is there any restriction imposed for the visa or not. After tea break, when we took up these matters, learned Assistant Attorney General categorically stated that there is no restriction of visa for India and the Federal Drug Inspector also clearly stated that the petitioners may be

directed to contact nominated members, collect their relevant papers and passports for the grant of visa so that the letters issued for the inspection may be complied with. At this juncture, learned Assistant Attorney General also stated that if the petitioner will have problem for the grant of visa of the nominated members then DRAP will also try to facilitate through foreign office so that the visa may be granted for the purpose of inspection by the nominated members in both the petitions.

6. Today, Mr. Abdul Sattar Pirzada advocate has also filed statement in C.P. No.D-3093 of 2019 along with a letter issued by Section Officer (Admin-I/DRAP), Ministry of National Health Services, Regulations & Coordination, Government of Pakistan on 31.07.2017 with the reference of inspection of manufacturers abroad. Para-3 of this letter is quite relevant which is reproduced as under:-

“3. The Secretary, Ministry of NHS,R&C has further desired that Chief Executive Officer DRAP may bring an item of agenda for consideration of Policy Board to minimize physical inspection of any reliable documentary substitute or consideration is available. What is practiced in neighboring/ regional countries of developed world may also be explored.”

7. The Federal Drug Inspector and the learned Assistant Attorney General submit that in three month's period the DRAP may bring agenda for consideration for Policy Board to minimize physical inspection if any reliable documentary substitute or consideration is found available and what is a

practiced in neighboring/ regional countries of developed world will also be explored.

8. After hearing learned counsel for the petitioners and learned Assistant Attorney General with the assistance of Federal Drugs Inspector, the petitions are disposed of in the following terms:-

(i). The petitioners in both the petitions shall contact the nominated persons pursuant to the letter dated 30.08.2017 issued in connection with C.P. No.D-3093/2019 and the nominated members appointed vide letter dated 26.02.2018 in C.P. No. D-3094 of 2019 for inspection. They will also collect their relevant documents including the passports for the visa facilitation if they are still willing to act on their nomination in view of the above letters.

(ii). Petitioners will apply for visa of the nominated members after fulfilling all required formalities. In case they will have any problem for the visa facilitation then petitioners will intimate in writing to the CEO of the DRAP for the visa facilitation with the consultation of foreign office, Islamabad as already assured by the learned Assistant Attorney General in court.

(iii). Within thirty (30) days, the DRAP will place the Agenda before the Policy Board in pursuance of their letter dated 31.07.2017 issued by Section Officer (Admin-I/DRAP), Ministry of National Health Services,

Regulations & Coordination, Government of Pakistan for consideration of policy board to minimize physical inspection through any reliable documentary substitute for consideration and what is the practice in neighboring/regional countries of developed world

(iv). The Policy Board shall consider the Agenda and make a decision within 45 days. Both petitions are disposed of accordingly along with pending applications.

Office is directed to place copy of this order in connected petition.

JUDGE

JUDGE

Aadil Arab