IN THE HIGH COURT OF SINDH AT KARACHI

Present:
Mr. Justice Muhammad Shafi Siddiqui, CJ
Mr. Justice Jawad Akbar Sarwana

C.P. No. D-3906 of 2012

Pakistan Pharmaceutical Manufacturers' Association
Versus
Province of Sindh & others

A N D

C.P. No. D-2304 of 2013

Pakistan Chemists & Druggists Association
Versus
Province of Sindh & others

Date of Hearing:	22.08.2024
Petitioner in C.P. No.D-3906 of 2012:	Through Mr. Rashid Mureed Advocate.
Petitioner in C.P. No.D-2304 of 2013:	Not represented.
Respondent No.1:	Through Mr. Saifullah, Addl. Advocate General Sindh.
Respondents No.2&3:	Through Mr. Sajid Ali Memon, Drug Inspector in person.

J U D G M E N T

Muhammad Shafi Siddiqui, CJ.- Through these petitions the petitioners have challenged certain clauses of notification dated 27.04.2010 in terms whereof Government of Sindh, in continuation of earlier notification of 29.09.2007 and in exercise of powers conferred by Section 44 of the Drugs Act, 1976, has amended the Sindh Drugs Rules, 1979.

2. It is the case of the petitioners that impugned notification in terms of clause (ie) of Rule 18 has restricted the sale of the drugs and

controlled substances only to the holder of valid drug license on Form 7-A whereas in terms of clause (if) the same shall be sold to licensed retailer on Form-6 or licensed pharmacy on Form-8 or the one who has a license on Form-9 and specifically excluded the sale of the such drugs and controlled substances from one Form-7 license holder to another Form-7 or Form-7A License Holder. So also introduction of Form 9, pertaining to narcotics and controlled drugs/substances, is claimed to be against the provisions of main statute i.e. Drugs Act, 1976 as the same fall under the ambit of Control of Narcotics Substances Act, 1997.

3. The petitioners further pleaded that the amendments followed by letter dated 20.06.2012 of Provincial Inspector of Drugs Jacobabad & Shikarpur sent to one of the members of the petitioners to provide requisite information in pursuance of Rule 21 of Sindh Drugs Rules 1979 followed by letter dated 25.06.2012 of Provincial Inspector of Drugs, District Sanghar, which, according to the petitioners, is a refusal to issue license. The petitioners thus challenged such amendments as according to them the same are against the main statute and will create obstacles in running their business and the petitioners' members will not be able to manufacture the drugs made from controlled substances.

4. We have heard learned counsel for the petitioner in C.P. No.D-3906 of 2012 as well as learned Assistant Advocate General and perused material available on record. No one appeared on behalf of the petitioner in connected C.P. No.D-2304 of 2013 however since both the petitions are on same set of facts and law hence are being decided through this common judgment.

5. Perusal of record reveals that the petitioners are Pharmaceutical Manufacturers' and Chemist and Drugs Associations and have no locus standi to file the instant petitions as they are not directly aggrieved of any of the actions or inactions on the part of the respondents. Even in

both the petitions the petitioners have annexed the correspondence with the department concerned of one M/s Martin Dow Pharmaceuticals (Pak) Ltd., which appears to be the only aggrieved party, but it has also not come forward to agitate the case before this Court.

6. Another very crucial aspect of the matter is that since the subject controversy there has been much development on the subject as Drug Regulatory Authority of Pakistan Act, 2012 has come into force. Preambles of both the statutes as to the regulation, import, export, manufacture, storage, distribution and sale of drugs/therapeutic is more or less same. Hence for all practical purposes, we are of the view that the petitioners could have the recourse in pursuance of the new enactment. Even otherwise, we are in agreement with the learned Additional Advocate General who during course of his arguments has pointed out that the petitioners' members could not remain idle from the date of filing of these petitions i.e. 03.11.2012 and 24.05.2013 and may have applied for the respective licenses. The inference in such a situation could be drawn that the petitions virtually have become infructuous.

7. Before coming to the merits of the case, we may first observe that when it comes to the policy in respect of the drugs/medicine the most prioritize aspect to be considered is the health of the people and the business aspect could be considered on the same touchstone. The culture of earning money for sale of medicines/drugs is always to have a very strict check and balance. Supreme Court in Criminal Misc. Application 66 of 2006 has also issued certain directions to the effect, amongst others, that the business of medicines, other than in medical stores or pharmacies should be stopped as it had been noted that medicines were also being sold on the grocery shops etc.

8. Keeping in mind the above, the sale of drugs is made licensed-based and restrictive. Chapter III is for sales of Drugs and its clause 12 describes the types of licenses to sell drugs. The license to sell drugs by way of retail sale shall be on Form-6; by way of wholesale it shall be issued to the manufacturer, importer or indenter on Form-7; by way of wholesale as authorized agent of manufacturer, importer or indenter it shall be issued on Form 7-A; license for pharmacy shall be on Form-8 and license to sell narcotics substances shall be on Form-9. Similarly, in terms of newly added Rule 2(bb) "authorized agent" is defined to be a person who is authorized in writing to sell and issue warranty in respect of the drugs. In Rule 13 fees are imposed on different kinds of licenses. In Rule 17 certain pre-conditions for issuance of license have been added which include an area of the premises to be not less than 100 and 200 sq. feet for retail and wholesale and pharmacy respectively etc. Rule 19 provides procedure for cancellation and suspension of the license and appeal against such cancellation or suspension.

9. The impugned insertion in Rule 18 has also put certain additional conditions to regulate the sale or stock of the drugs and the same in no way appear to have an adverse effect on the business and/or sale of the drugs except that a vigorous check and balance is put in. The impugned amendments shall ensure issuance of licenses to only those establishments which have registered pharmacists; sale of drugs shall be under warranty; only registered pharmacist would be able to get drug sale licenses; only authorized agents would deal in the drugs; mushroom growth of medical stores will be avoided; and storage conditions will be maintained properly in the respective institutions

10. It is also noticed that nowadays there is an afflux of spurious and substandard drugs not only in Pakistan but at international level. Globally, every country is the victim of substandard or spurious drugs,

which result in life threatening issues, financial loss of consumer and manufacturer and loss in trust on health system. In this scenario, it is the responsibility of all and not the government alone rather the petitioners being the associations representing the pharmaceutical companies etc. also have a great responsibility on their shoulders; they should approach the authorities under the hierarchy of Drug regulators for a feedback rather directly approaching the Courts. The respondents have attempted to carve out a policy in consultation with all the stakeholders, including the petitioners as well. The same to some extent is evident from the efforts as narrated in their comments but on the part of the petitioners no such attempts appear to have been made. Indeed, this menace of spurious and substandard drugs can efficiently be dealt by effective legislation which was attempted.

11. From the pleadings and the arguments by learned counsel appearing for the petitioners we have not found anything which may infer that any harassment is being caused to the petitioners and/or their members. So also no fundamental right as to trade and business is being infringed due to the impugned amendments as these amendments do not restrict the business of sale of drugs. Rather by regulating the sale and stock of the drugs, a check and balance is put in thereby safeguarding the interest of the poor people/patients. Such amendments will avoid sale of spurious and substandard drugs and will minify the miseries of the people already suffering from certain diseases.

12. Upshot of the above discussion is that the petitions merit no consideration and thus are being dismissed along with pending applications.

13. Above are reasons of our short order dated 22.08.2024.

Dated: **Chief Justice**

Judge