IN THE HIGH COURT OF SINDH AT KARACHI

Present:
Mr. Justice Omar Sial
Mr. Justice Shamsuddin Abbasi

Criminal Appeal No.467 of 2024
Criminal Appeal No.468 of 2024

Appellants	:	M/s. Roche Pakistan Limited and others through M/s. Rashid Mureed and Abdul Sami Advocates
The State	:	Through Mr. Muhammad Javed Khalid Rana, Deputy Attorney General along with Dr. Awais Ahmed, Deputy Director, DRAP, Karachi
Date of hearing:		28.08.2026
Date of Judgment:		27.10.2026

JUDGMENT

Omar Sial, J.: The Provincial Inspector of Drugs, accompanied by witness Qazi Shabbir Ahmed, inspected the premises of Roche Pakistan Limited, located on the 1st Floor, Plot No. 37-B, Block-6, P.E.C.H.S., Karachi. They found that the premises were not open to the public. Upon entering, the Inspectors observed that the complete address of the premises and the license number were not painted outside. Furthermore, no separate area—nor any locker, almirah, cupboard, or drawer—was reserved or established to store poisonous substances specified under Schedule B and prevent access by unauthorized or unconcerned persons. Following further inquiry, Invoice No. 8190238291, dated 08-01-2019, and Invoice No. 8190238353 were produced. These invoices showed the sale of Schedule B drugs, namely Avastin 100mg (Batch No. B7237B11) and Ristova 100 mg (Batch No. H0266B01), to Shaukat Khanum Memorial

Hospital, Karachi, and to Liaquat National Hospital, Karachi, without a Form-9 license.

2. A complaint against the company, its proprietor, pharmacist, and warrantor was registered on 22.04.2022. The complaint was registered under sections 23(1)(a)(c)(f) and (x) as well as under section 23(1)(i)(ii), punishable under sections 27(4), 30(1)(b) and 34 of the Drugs Act, 1976 and Rules 2, 14, 18 and 21 of the Sindh Drugs Rules, 1979.

3. On 30.05.2024, the Drug Court of Sindh at Karachi ruled that the two drugs, i.e., Avastin and Ristova, were used in chemotherapy and thus fell under Schedule B of the Drugs Act. Roche Pakistan did not have the Form 9 license required for Schedule B drugs; therefore, the company, its proprietor, pharmacist, and warrantor were fined Rs. 50,000 each. The company paid the fine under protest, and it filed this appeal against the order dated 30.05.2024.

4. I have heard the learned counsel for the company and the individuals who have been fined. I have also heard the learned Deputy Attorney General. My observations and findings are as follows.

5. As mentioned above, the Drug Court has held that both the drugs, i.e., Avastin and Ristova, were biological, but as they fell within Schedule B of the Sindh Drugs Rules, 1979 ("**the Rules**"), a Form 9 license should have been obtained.

6. According to section 2(g) of the Rules, Schedule B is to contain narcotics. Section 12 of the Rules provides that a Form 9 license is required to sell narcotic drugs. In essence, a company that wishes to sell the drugs listed in Schedule B must possess a Form 9 license.

7. A little research shows clearly that Avastin and Ristova are not written or classified as narcotics anywhere in medical

literature or regulatory law. This is probably because they belong to an entirely different class of medicine. The drugs listed under Schedule B in Pakistan include opiates and opioids, barbiturates and sedatives, and other controlled stimulants or psychoactives. The medicines in question are none of them. Schedule B, however, has the following entry:

> "*Chemotherapeutic agents for treatment of neoplastic diseases, microbial diseases, excluding single ingredients containing sulpha drugs. prepared as for tuberculosis and narrow spectrum antibiotics.*"

8. Expert evaluation was required; however, it appears abundantly clear to me that the above is a misclassification in Schedule B. The Drug Court had observed that although both medicines were biological, they still fell in Schedule B because they were "*chemotherapeutic agents*". The Drug Court did not address the misclassification issue. As this Court lacked the requisite knowledge of drugs and chemicals, it issued notice to the Drug Regulatory Authority of Pakistan to depute a senior officer to assist. The Drug Regulatory Authority of Pakistan resolved this controversy. Dr. Awais Ahmed, Deputy Director, DRAP, responded to a court summons and, on 25.08.2026, appeared in Court to assist. Dr. Ahmed categorically and in no uncertain terms stated that both medicines, Avistan and Ristova, were not "*chemotherapeutic agents*" nor were they narcotics or psychotropic substances. After his appearance, the learned Deputy Attorney General filed a letter from Mr. Muneeb Ahmed Cheema, Deputy Director (BE&R), Ministry of Health Services, Regulations & Co-ordination, Drug Regulatory Authority of Pakistan, Government of Pakistan. The letter dated 27.08.2026 categorically stated that neither medicine is a "*chemotherapeutic agent*". In the same letter, the classification of Avistan is given as "Antineoplastic agent, monoclonal antibodies and antibody drug conjugates ATC Code: L01FA01"

while that of Ristova is "Antineoplastic agent, monoclonal antibodies ATC Code: L01FD01.

9. Before concluding the judgment, I wish to put on record my appreciation for the assistance rendered to me by the Drug Regulatory Authority of Pakistan and the learned counsel Mr. Rashid Mureed.

10. Given the above, both the appeals are allowed. The impugned orders of 30.05.2024 are set aside. The money the company deposited as a fine should be returned to it within two weeks of the date of this judgment.

JUDGE

JUDGE