ORDER SHEET
HIGH COURT OF SINDH AT KARACHI

Suit No.2565 of 2017.
Suit No.2566 of 2017.
Suit No.2567 of 2017.
&
Suit No.2568 of 2017.

Date	**Order with Signature of Judge**

Suit No.2565 of 2017
1. For orders on C.M.A. No.17188/2017.
2. For orders on C.M.A. No.17189/2017.

Suit No.2566 of 2017.
1. For orders on C.M.A. No.17191/2017.
2. For orders on C.M.A. No.17192/2017.

Suit No.2567 of 2017.
1. For orders on C.M.A. No.17194/2017.
2. For orders on C.M.A. No.17195/2017.

Suit No.2568 of 2017.
1. For orders on C.M.A. No.17201/2017.
2. For orders on C.M.A. No.17203/2017.

14.12.2017.

M/s. Abdul Sattar Pirzada, Mamoon N. Chaudhry, Haroon Dugal & Zaheer-ul-Hassan Minhas, Advocates for the Plaintiffs.

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1. Exemption granted subject to all just exceptions.

2. Through these suits, the plaintiffs have challenged the S.R.O. No.470(I)/2017 issued on 14.06.2017 in exercise of powers conferred by Section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with Clause (a) and Clause (t) of Section 7 thereof and Section 43 of the Drugs Act, 1976 (XXXI of 1976), whereby the Drug Regulatory Authority of Pakistan with the approval of the Federal Government was pleased to make amendment in the Drugs (Labeling and Packing) Rules, 1986. In Rule 3A, it is provided that notwithstanding anything contained in rule 3, a machine readable Barcode as per the GSI general specification shall be printed on the label of all drugs manufactured

for domestic market or export or import, at different packaging levels to facilitate identification, tracking and tracing of these products, further niceties are provided in the same rule for GSI Data-Matrix, 2D Barcode type encoding a unique and global product identification code in the format of a GTIN on the primary packaging, whereas the GSI Data-Matrix of a 2D barcode type encoding a unique and global product identification code in the format of a GTIN on the secondary packaging. Learned counsel also referred to Rule 9 which prescribes that these rules will be applicable to the allopathic drugs including biological for human and veterinary use only and shall not apply to alternate medicines, health and OTC non-drug products etc. For the compliance and implementation of these directions 06 months' time was allowed from the date of publication of the Rules in the Official Gazette.

Learned counsel for the plaintiffs argued that main reason for impugning the S.R.O. is insufficient time for implementation of the guidelines provided under the Rules. He has pointed out a representation submitted by the plaintiff No.1 being an Association of the Drug Manufacturers Companies which is available at page-153 of the court file. The Secretary General of Pakistan Pharmaceutical and Manufacturers Association addressed to Chief Regulatory Authority of Pakistan in paragraph-9 of his representation as under:-

> *"Whilst the PPMA appreciates the initiative by the regulatory authority to introduce innovation, it is submitted that the burdensome requirements of SRO 470 have been prematurely implemented in our system and are counterproductive in the present times. The Pharmaceutical Industry in the country is not ready to implement S.R.O. 470 in the manner and form prescribed therein and it is requested as follows:-*
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> a. *In order to save the nation from a catastrophe leading to acute shortage of drugs in the Country as neither imported nor locally manufactured drugs can be sold without complying with the requirements of S.R.O. 470(I)/2017 dated 14.06.2017, the aforesaid SRO, may be withdrawn immediately and the*

issue of introduction of bar coding as an addition to the existing labeling requirements may be put up for consultation with the stakeholders.

b. *In the alternative, it is requested that at least the same amount of time be provided to the Pakistani Pharmaceutical Industry for implementation of bar coding and serialization at all levels of packaging that has been given to the Pharmaceutical Industry in USA, that is, then (10) years."*

Learned counsel further argued that today is the last date of implementation and there is an acute possibility that the DRAP will take some coercive action for non-implementation of the rules. The learned counsel further submits that on each medicine, the lot/batch number including date of manufacturing, expiry and price is already being mentioned for the information of consumer.

Let notice be issued to the defendants. The defendant No.3 is directed to appear in person on the next date, whereas the defendant No.2 shall be served through District Judge, Islamabad as well as courier service. Also issue notice to the learned Additional Attorney General to cause his appearance for the assistance of this court. Since the General Secretary of the Association has pointed out in his representation to DRAP that the rules cannot be implemented in the time frame given to the pharmaceutical industry in the manner and form prescribed in the S.R.O. which will also create catastrophe and lead to acute shortage of drugs in the country as neither imported nor locally manufactured drugs can be sold without complying with the requirements of S.R.O, therefore, till next date of hearing, the defendants shall not take any adverse action against the plaintiffs.

Adjourned to 20.12.2017.

JUDGE