ORDER SHEET IN THE HIGH COURT OF SINDH, KARACHI

Suit Nos. 2565, 2566, 2567, 2568, 2601, 2602, 2609, 2607, 2608, 2622, of 2017, 114 (Supplementary List) 143, 199, 222 and 225 of 2018

Date

Order with signature of Judge

Before:-Mr.Justice Muhammad Ali Mazhar

(1) Pakistan Pharmaceutical Manufacturers Association & others

(2) Pakistan Chemist and Druggists Association & others.

(3) M/s.Uniferoze (Pvt.) Ltd. & others.

(4) M/s.ISIS Pharmaceuticals & Chemicals Works & others.

(5) OBS Pakistan (Pvt.) Ltd. & others.

(6) M/s.Eli Lilly Pakistan (Pvt.) Limited.

(7) M/s.Novartis Pharma (Pakistan) Limited.

(8) M/s.ICI Pakistan Limited.

(9) M/s.Cirin Pharmaceutical (Pvt.) Limited.

(10) M/s.Getz Pharma (Pvt.) Limited.

(11) M/s.Martin Dow Ltd. & others.

(12) RG Pharmaecutical Pvt. Limited & others.

(13) Bayer Pakistan (Pvt) Limited & others.

(14) M/s.Akhai Pharmaceutical (Pvt.) Limited

(15) Elko-Organization (Pvt.) Limited......Plaintiffs

Versus

Federation of Pakistan & Others......Defendants

15-03-2018

Mr. Abdul Sattar Pirzada, Mr.Haroon Dugal, Mr. Waheed Alam, Mr. Moiz Ahmed, Advocates for the Plaintiffs Mr.Umer Zad Gul, Deputy Attorney General. Syed Hakim Masood, Federal Drugs Inspector, DRAP, Karachi.

<u>Muhammad Ali Mazhar, J:</u> The aforesaid suits have been

brought by the plaintiffs for entreating declaration that the S.R.O. No.470(I)/2017 dated 14.6.2017 is illegal, unlawful and has no legal effect, and as an alternate prayer further declaration has been sought that the Rule 3A(9(b) inserted aforesaid S.R.O. along with through the condition mentioned at Serial No.4 in Form "A" in respect of A1(240) is illegal, unlawful and liable to be struck down. The above mentioned S.R.O. was issued in exercise of powers conferred by Section 23 of the Drug Regulatory Authority of Pakistan Act, 2012 read with clause (a) and (t) of Section 7 thereof and Section 43 of the Drugs Act, 1976. In fact S.R.O. the Federal Government made through this 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 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-Matric, 2D Barcode type encoding a unique and global product identification code in the format in 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.

2. The aforesaid suits were fixed in the court on different dates, however, as an interim measure it was ordered that the defendants shall not take any adverse action against the plaintiffs. The counsel for the plaintiffs placed on record an order passed by hon'ble Supreme Court of Pakistan on 28.2.2018 in the **Human Rights Case No.2858 of 2006** (In the matter regarding high prices of Drugs etc.), whereby the hon'ble Supreme Court by giving various directions further ordered that all pharmaceutical companies, within a period of three months, shall implement and enforce a barcode not only on the box but also on the wrappers affixed upon the containers/bottles of the pharmaceutical products. For the ease of reference the hon'ble Supreme Court order is reproduced as under :-

<u>"HUMAN RIGHTS CASE NO.2858 OF 2006</u> (In the matter regarding high prices of Drugs etc.)

In the early hours of the day the arguments were heard however in order to explore the possibility of some consensual development in the matter, the committee of the learned counsel appearing for the pharmaceutical companies, Secretary, Ministry of National Health Services, Regulations and Coordination, Chief Executive Officer of learned Deputy Attorney DRAP, the General have submitted a joint statement, which has been made part of the record, with the prayer that "It is respectfully stated that the above road map may be graciously approved by this Court and appropriate orders passed". Keeping in view the above consensual statement, we direct that the matters be resolved by the DRAP as per the said statement and the matter be listed for hearing before this Court after a month's time. We also direct that all the pharmaceutical companies, within a period of three months, shall implement and enforce a bar code not only on the box but also on the wrappers affixed upon the containers/bottles of the pharmaceutical products. Furthermore, any stay order granted by any Court including the High Courts of all the Provinces and Islamabad, would not be an impediment/bar in any manner in the way of the implementation of the above consensual statement."

3. The aforesaid suits specifically germane and have direct nexus to the Rule introducing a provision for readable barcode in view of the amendment made in the Drugs (Labeling and Packaging) Rules, 1986. During

pendency of these suits the hon'ble Supreme Court while taking into consideration various other issues relating to the price of Drugs specifically issued directions to the pharmaceutical companies to implement and enforce barcode within a period of three months with further directions that any stay order granted by any court including the High Courts of all the Provinces and Islamabad, would not be an impediment/bar in any manner in the way of the implementation of the above consensual statement. Some of the learned counsel appearing for the plaintiffs made much emphasis and robustly argued that the consensual statement referred to in the order of the apex court was not related for the implementation of barcode and they insisted that the suits should not be dispose of till such time the hon'ble Supreme Court's finally decide the matter in the human rights case. The order of the apex court reproduced above has made unequivocally clear that the pharmaceutical companies have been directed to implement and enforce the barcode not only on the box but also on the wrappers affixed upon the containers/bottles of the pharmaceutical products within a period of three months, therefore, in view of the clear directions there is no rational to keep above suits pending in this court. Admittedly, the plaintiffs are bound by the directions given by the apex court.

4. As a result of above discussion, the aforementioned suits are disposed of accordingly along with pending applications.

Judge