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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

Date of decision: 27th February, 2020

+ W.P.(C) 12254/2018 and CM No. 38337/2019

AMIT SAHNI

..... Petitioner

Through: Mr. Anshul Bajaj, Ms. Sonali Tiwary
and Mr. Jasman Singh, Advs.

versus

UNION F INDIA & ANR

..... Respondents

Through: Mr. Ripu Daman Bhardwaj, Central
Govt. Standing Counsel with
Mr. Kushagra Kumar, Adv. for R-1 and 2

CORAM:

HON'BLE THE CHIEF JUSTICE

HON'BLE MR. JUSTICE C.HARI SHANKAR

ORDER

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27.02.2020

D.N. PATEL, CHIEF JUSTICE (ORAL)

W.P.(C) 12254/2018

1. This Public Interest Litigation has been preferred with the following prayers :

“i. Issue a writ in the nature of Mandamus or any other Writ of like nature thereby passing order or directions to thereby directing Respondents for issuing appropriate and

mandatory direction(s) to the respondents, to act upon the representation dated 21-07-2018 made by the Petitioner.

ii. Issue a writ in the nature of Mandamus or any other Writ of like nature thereby passing order or directions to thereby directing Respondents for taking appropriate measures for replacing the existing mechanism of stamping the strip of medicine with other method viz printing etc, so as to avoid or minimize the re-use of expired medicine by stamping afresh with new expiry date after erasing existing manufacturing date/expiry date/price etc.

iii. Pass any other appropriate order or direction as this Hon'ble Court may deem fit and proper in the facts and circumstances of the case.”

2. Having heard learned counsel for both the sides and looking to the facts and circumstances of the case, it appears that as per Rule 96 of Drugs and Cosmetics Rules, 1945 enacted under the Drugs and Cosmetics Act, 1940, there is already a provision for manner of labeling of medicines/drugs.

3. For the ready reference, Rule 96 of the Drugs and Cosmetics Rules, 1945 to be read with Section 33(2)(h) of the Drugs and Cosmetics Act, 1940 read as under :

“33 Power of Central Government to make rules. —

(2) Without prejudice to the generality of the foregoing power, such rules may—

(h) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or

container of any specified drug or class of drugs, and prohibit the sale, stocking or exhibition for sale, or distribution of the said drug or class of drugs after the expiry of a specified period from the date of manufacture or after the expiry of the date of potency;”

“96. Manner of Labelling.—

(1) Subject to the other provisions of these rules, the following particulars shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container of any drug and on every other covering in which the container is packed, namely:—

(i) The name of the drug: 2[(A) For this purpose], 3[the proper name of the drug shall be printed or written in a more conspicuous manner than the trade name, if any which shall be shown immediately after or under the proper name and shall be]—

(a) for drugs included in Schedule F or Schedule F(1), the name given therein;

(b) for drugs included in the Indian Pharmacopoeia or the official Pharmacopoeias and official compendia of drug standards prescribed in rule 124, the name or synonym specified in the respective official pharmacopoeias and official compendia of drug standards followed by the letters ‘L.P.’ or, as the case may be, by the recognised abbreviations of the respective official pharmacopoeia and official compendia of drug standards;

(c) for drugs included in the National Formulary of India, the name or synonym specified therein followed by the letters 'N.F.I.';

(d) for other drugs, the international non-proprietary name, if any, published by the World Health Organisation or where an international non-proprietary name is not published, the name descriptive of the true nature or origin of the substance.

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(ii) A correct statement of the net contents in terms of weight, measure, volume, number of units of contents, number of units of activity, as the case may be, and the weight, measure and volume shall be expressed in Metric system.

(iii) The content of active ingredients— This shall be expressed—

*(a) for oral liquid preparations in terms of the content per single dose, the dose being indicated in 5 millilitres 5[***]: Provided that where the dose is below 5 millilitres the contents of active ingredients may be expressed in terms of one millilitre 6[or fraction thereof]; 7[Provided further that where the single dose is more than 5 millilitre, the content of active ingredients shall be expressed in terms of minimum single dose as approved by the licensing authority,]*

(b) for liquid parenteral preparations ready for administration, in terms of 1 millilitre or percentage by volume or per dose in the case of a single dose container: Provided that if the preparation is contained in an ampoule it will be enough if the composition is shown on the label or

wrapper affixed to any package in which such ampoule is issued for sale;

(c) for drugs in solid form intended for parenteral administration in terms of units or weight per milligramme or gramme;

(d) for tablets, capsules, pills and the like, in terms of the content in each tablet, capsule, pill or other unit, as the case may be;

(e) for other preparations, in terms of percentage by weight or volume or in terms of unitage per gram or millilitre as the case may be: Provided that clause (ii) shall not apply to a pharmacopoeial preparation where the composition of such preparation is specified in the respective pharmacopoeia and to a preparation included in the National Formulary of India;

(iv) 8[The name of the manufacturer and the address of the premises of the manufacturer where the drug has been manufactured:] Provided that if the drug is contained in an ampoule or a similar small container, it shall be enough if only the name of the manufacturer and his principal place of 9[manufacture] is shown.

(v) A distinctive batch number, that is to say, the number by reference to which details of manufacture of the particular batch from which the substance in the container is taken are recorded and are available for inspection, the figure representing the batch number being preceded by the words 'Batch No.' or 'B No.' or 'Batch' or 'Lot No.' or 'Lot'.

Notes.—(1) In the case of drugs manufactured by a

continuous process, like manufacture of magnesium sulphate, pharmaceutical chemicals, etc., the production resulting in one homogeneous mix of the finished products shall be considered as one “Batch”:

(2) In the case of powers, liquid orals, ointments, etc., one “Batch Number” shall be assigned to all the containers filed from one homogeneous bulk.

(3) In the case of tablets, capsules, lozenges, torches, etc. one “Batch Number” shall be assigned to the products manufactured from one homogeneous mix ready for compression or filing.

(4) In case of parental preparations sterilized by steam under pressure, one “Batch Number” shall be assigned to all containers filed from one homogeneous bulk solution and sterilized load.

(5) In the case of containers of parental preparations filed from one homogeneous bulk solution and sterilized in more than one sterilizer load, the “Batch Number” as signed to the containers in the different sterilizer loads shall be same “Batch Number” as is assigned to the homogeneous bulk solution, provided the samples taken from all the sterilizer loads pass the sterility test, and kept separate from one another until the report of the sterility test is available.
Explanation.—For the purpose of chemical and other tests, representative samples from all containers filled from the homogeneous bulk solution should be taken.

(6) In the case of parental and other sterile products filled aseptically a “Batch Number shall be assigned to all containers filled from one homogeneous mix during one filling operation, the filling operation being completed in a period of not more than a day during which no schedule change in the filling assembly is made. When containers are filled from one homogeneous mix, in a number of filling operations, the “Batch Number” assigned to the containers filled in individual filling operations shall be the same “Batch Number” as is assigned to the homogeneous mix, provided the samples taken from all the direction filling operations pass the sterility tests, and are kept separate from one another until the report of the sterility test is available. Explanation.—For the purpose of chemical and other tests, representative samples from all containers filled from the homogeneous mix should be taken.

(7) In the case of medicinal gases produced by a continuous process of operation a week’s production from one tank load shall be considered as a Batch.

(vi) Every drug manufactured in India shall bear on its label the number of the licence under which the drug is manufactured, the figure representing the manufacturing licence number being preceded by the words ‘Manufacturing Licence Number’ or ‘Mfg. Lic. No.’ or ‘M.L.’.

(vii) Drugs specified in Schedule P and their preparations including combinations with other drugs shall bear on their labels the date of manufacture and the date of expiry of

potency, and the period between the date of manufacture and the date of expiry shall not exceed that laid down in the said Schedule 10[under the conditions of storages specified therein. 11[Drugs and their] preparations not included in Schedule P, shall bear on their labels the date of their manufacture and also the date of their expiry which shall not exceed sixty months from the date of manufacture]: Provided that this period may be extended by the licensing authority specified in clause (b) of Rule 21 in respect of any specified drug if satisfactory evidence is produced by the manufacturer to justify such an extension.

(viii) Drugs specified in Schedule C(1) and their preparations including combinations with other drugs shall bear on the labels (a) the date of manufacture, (b) date of expiry of potency fixed by the manufacturer, and (c) where such drugs are imported, also the number of licence under which the drug is imported, preceded by the words 'Import Licence': 12[Provided that drugs in bulk form included in Schedule C(1) which are not ready for use and not included in Schedule P need not bear on the label the date of expiry of potency:] Provided further that no reference shall be made to any other licence number granted by any authority outside India on any label or container or in any covering in which the container is packed or in any other matter or advertisement enclosed therewith.

(ix) Every drug intended for distribution to the medical profession as a free sample shall, while complying with the

labelling provisions under clauses (i) to (viii), further bear on the label of the container the words 'Physician's sample—Not to be sold' which shall be overprinted. 13[(x) If any preparation contains not less than 3 per cent. by volume of alcohol the quantity of alcohol shall be stated in terms of the average percentage by volume of absolute alcohol in the finished products.] 14[(xi) In addition to the other particulars which are required to be printed or written under these rules, the label of innermost container of the following categories of drugs and every other covering in which the container is packed shall bear a conspicuous red vertical line on the left side running throughout the body of the label which should not be less than 1 mm in width and without disturbing the other conditions printed on the label under these rules, namely:— Narcotic analgesics, hypnotics, sedatives, tranquillisers, corticosteroids, hormones, hypoglycemics, antimicrobials, antiepileptics, antidepressants, anticoagulants, anti-Cancer drugs and all other drugs falling under Schedules G, H and X whether covered or not in the above list: Provided that the provisions of this clause shall not apply to—

- (a) preparations intended for animal treatment;*
- (b) preparations intended for external use;*
- (c) ophthalmic preparations and ear drops; and*
- (d) sterile preparations such as sutures, surgical dressings and preparations intended for parenteral use.]*

(2) (i) The particulars to be printed or written on the label of a mechanical contraceptive shall be as specified in Schedule R.

(ii) The following particulars, in addition to those specified under sub-rule (1) shall be either printed or written in indelible ink and shall appear in a conspicuous manner on the label of the innermost container and on every other covering in which the container of a contraceptive, other than a mechanical contraceptive, is packed, namely:—

(a) the date of manufacture;

(b) the date up to which the contraceptive is expected to retain its properties;

(c) the storage conditions necessary for preserving the properties of the contraceptive up to the date indicated in sub-clause (b): Provided that for oral contraceptives it shall be sufficient to display on the label of the container the date of manufacture only.

(3) (i) The particulars prescribed in sub-rule (1) shall be printed or written in indelible ink either on the label borne by a container or vaccine lymph or on a label or wrapper affixed to any package in which the container is issued for sale. The said particulars shall be indelibly marked on the sealed container of surgical ligature or suture or printed or written in indelible ink on a label enclosed therein.

(ii) Nothing in these rules shall be deemed to require the labelling of any transparent cover or of any wrapper, case or

other covering used solely for the purpose of packing, transport or delivery.

(4) Where by any provision of these rules any particulars are required to be displayed on a label on the container such particulars may, instead of being displayed on a label, be etched, painted or otherwise indelibly marked on the container: Provided that, except where otherwise provided in these rules, the name of the drug or any distinctive letters intended to refer to the drug shall not be etched, painted or otherwise indelibly marked on any glass container other than ampoules. Explanation.—For the purpose of this rule, the date of expiry shall be in terms of month and year and it shall mean that the drug is recommended till the last day of the month. The date of expiry shall be preceded by the words ‘Expiry date’.J”

4. In view of the aforesaid provisions, it appears that there are sufficient provisions for manner of labeling of the medicines/drugs. Learned counsel for the petitioner submits that there are several persons who are changing the manufacturing and expiry dates on the medicines/drugs, hence direction may be issued to the respondents that the law may be complied with by them.

5. We are not in agreement with the learned counsel for the petitioner for giving such type of lump sum general directions to the respondents. However, as and when any breach is pointed out to this court with a specific name of the person or of the manufacturer, the action can be initiated. The

breach of law has to be pointed out by the petitioner in an individual writ petition by joining the concerned person as a party/respondent.

6. Hence, we see no reason to entertain this writ petition. However, liberty is reserved with this petitioner to move appropriate proceedings before the appropriate forum for the alleged breach of Rule 96 of Drugs and Cosmetics Rules, 1945 with proper averments, allegations and annexures.

7. With these observations, this writ petition is hereby disposed of.

CM No. 38337/2019

1. In view of the disposal of the writ petition, this application also stands disposed of.

CHIEF JUSTICE

C.HARI SHANKAR, J.

FEBRUARY 27, 2020/kr