(2010) 01 AHC CK 0158

In the Allahabad High Court

Case No : Criminal Miscellaneous Writ Petition No. 16212 of 2008

Brahmaji — APPELLANT

Vs

State of U.P. and others — RESPONDENT

Date of Decision : 29-01-2010

Acts Referred:
Constitution of India, 1950 — Article 226

Citation : (2010) 01 AHC CK 0158

Hon'ble Judges : Amar Saran, J and Shyam Shankar Tiwari, J

Final Decision : Allowed

Judgement

Shyam Shankar Tiwari, J.—We have heard Dr. Ashok Kumar Nigam, Additional Solicitor General of India assisted by Shri Ajay Bhanot and Shri Rishi Kant Singh, Shri V. Tripathi, learned Additional Government Advocate for the State and Shri Suneet Kumar for the intervenor.

The Deputy Drug Controller of India is present today in pursuance of our order dated 8.1.2010.

2. In the affidavit filed by the Deputy Drug Controller of India on behalf of the Government of India, it is mentioned that the Government of India has now issued an amendment Act of 2008 to the Drugs and Cosmetics Act, 1940 (herein after referred to as "the Act'') and the said amendment has been notified in the gazette and the amendment made operational from 10.8.2009. By means of the said amendment, it is pointed out that for the graver offences under section 27(a) of giving adulterated or spurious drugs, which are likely to cause death or grievous hurt, the earlier prescribed imprisonment of not less than five years term, which may extend to life imprisonment and fine not less then 10,000/ has been substituted with an imprisonment of not less than ten years, which may extend to imprisonment for life and fine which is not less than ten lac rupees or three times of the drugs confiscated, whichever is more.

3. The fine realized from the persons is to go to the patient or to his relatives in

cases the patient has died due to use of the adulterated or spurious drug.

The offences under the other provisions have similarly been enhanced.

For the minor offences, under section 32 (b) i.e. for importing of nonprohibited drugs or nondisclosure of the names of the manufacturers or not keeping of documents or nondisclosure of information, which were not punishable by mandatory imprisonment, the said offences have been made compoundable by the Central Government or the State Government or authorised officer before or after the institution of prosecution by payment of fine to the concerned Government, which will not exceed the maximum amount of fine, which could be imposed for the offences so compounded, but a repetition of the offence has been made noncompoundable.

Also the punishments and fines for dealing in adulterated Ayurvedic, Siddha or Unani drug have been enhanced. Under section 36AB (i) the Central Government or the State Government in consultation with the Chief Justice of the High Court are required to designate one or more Courts of Sessions as special courts for trying the offences under the Drugs and Cosmetics Act.

4. It is pointed out that under section 26 A of the Act the Central Government also has the powers of regulating, restricting or prohibiting manufacturing of drugs in public interest if the contents are harmful and carry risk to human and animals or lack the therapeutic value claimed. The Drug Technical Advisory Board (DTAB) renders advice in this matter and so far manufacturing of 78 drug formulation have been prohibited.

5. The Central Drug Control Organization (CDCO) headed by the Drug Controller of India is conducting countrywide surveys for determining the extent of spurious drugs in the market. The states were directed to play a proactive role in assessing the extent of spurious drugs in the 39th meeting of the Drugs Consultative Committee (DCC) and directions were issued for taking action when spurious drugs were found in accordance with the enhanced penalties laid down.

Under the world bank capacity building programme aid has been provided for testing facilities and to establish new drug testing laboratories.

A whistle blower policy has been initiated for giving award to the informers to bring about detection of spurious drugs.

As learned counsel for the intervenor has rightly pointed out that it is not sufficient to enact stringent laws. In the State of UP enhanced laws were issued earlier, but the crucial issue is ensuring that persons dealing in spurious drugs are detected and are speedily tried and given the enhanced punishments prescribed. We therefore would like to get a follow up report from the Central government as to the impact of the stringent measures that have been put in place at the ground level on the next listing.

6. It was pointed out by Shri Suneet Kumar for the intervenor that there is a

considerable shortage of drug staff. Thus in 71 districts in UP, there are only 53 drug inspectors even though there are 400 manufacturing units of drugs and cosmetics and 180 blood banks, which are registered under the Drugs and Cosmetics Act.

It is also pointed out that these inspectors have to deal with approximately 50,000/ retail outlets and 40,000/ wholesale outlets. There is also a very nonuniform distribution of outlets as there are 2000 retail outlets in Ghaziabad and 1200 outlets in Allahabad, wherein in Pilibhit there are only 11 retail outlets. Hence the posting of one or less inspectors per district, irrespective of the number of outlets is irrational Furthermore, in order to avoid appointing pharmacists, whereas ratio of wholesale outlets to retail outlets should be 1/6, but the actual ratio is almost 1:1. These wholesale outlets are usually mangaed by intermediate pass persons and employ no pharmacist. The wholesale outlets are mainly located in rural areas where 3/4th of the population reside and approximately 23% of the population belongs to scheduled castes. The result, it is submitted, is that no proper attention is given to ensure that genuine drugs are given in the rural areas particularly. Also it is pointed out that the posts of Drug Controller and Deputy Drug Controller of UP are vacant for a long time. Three out of seven sanctioned post of drug controllers, six out of eleven senior drug inspectors and 14 posts of sanctioned drug inspectors are short. We would like a comprehensive response from the State government on all these matters and suggestions.

7. Another issue pointed out by the learned counsel was that pursuant to the decision of this Court in D.K. Joshi Vs. State of UP and others, 2001 AWC 757, wherein it was observed that as specialization in pharmacology or pharmacy or pharmaceutical chemistry was needed, hence the Chief Medical Officers were not entitled to function as licensing and controlling authorities under the Act. The appointment of CMOs was thus, held illegal. Also subsequently Government has been appointing pathologists and thereafter professors of the concerned department to be the Drug Controlling Authority even though they lack any practical experience. Consequently there is no proper monitoring and controlling authority. Moreover, the ad hoc appointments of such authority may result in prosecution of accused persons for dealing in spurious drugs being challenged on the score that the appointing authority lacked jurisdiction to function as the controlling authority.

8. It is, therefore, submitted that no conscious and systematic efforts are being made for checking the proliferation of spurious drugs. Let the State give a response on these points made by the intervenor.

Admittedly, there is also very poor infrastructure and there is only a single drug laboratory in UP and a huge pendency of samples which need to be analysed. Undue delay in analysis of samples will only make them unfit for analysis due to passage of time frustrating the very purpose of analysing the drugs with the result that the mischievous dealer in spurious drugs will go scot free.

It is also little disappointing to note that even the raids that was directed by this Court have petered down from 257 raids in November to only 25 raids in December and from 15 FIRs in November, only 3 FIRs were lodged in December, 2009 and only three persons were arrested. This lacklustre effort does no credit to the State Government and suggests that the government is not at all serious in tackling this menace of spurious and adulterated drugs and is indifferent to the lives and health of the large poor population of the State.

9. In this context we are again reiterating our direction in our order dated 14.10.2008, which was reemphasized in our order dated 17.11.08 which has not been complied with for focussed raids and for laying down a comprehensive strategy for tackling the menace of the trade and administration of spurious drugs. The directions are being requoted hereunder, for compliance and detailed response and suggestion about a methodology for putting these suggestions in place on the next date, which would only show the seriousness of the government in these matters. Unless these suggestions are carried out in a missionary spirit, nothing will be achieved:

"7. We suggest that a strategy be devised for serious and focussed intelligence gathering in such matters. Cells need to be created either at the CMO''s level or at the offices of the S.P. or C.O. or local drug inspector or other easily accessible places in each district where the aggrieved persons and care givers of patients may furnish information about suppliers of suspected fake drugs which the patients under their care may have been administered, or about which they have information, and the outlets from where the drugs were purchased. In case the complaint appears credible, there should be swift inspections of such outlets, and samples collected. The complainant may be informed in writing whether action shall be taken on his report or not. In case the local inspector refuses to take action on his complaint, some procedure of approaching an appellate authority should be devised. The public should be informed about the assigned places where they can lodge their complaints by widespread publicity in the press, T.V. and radio. Information about the wholesale supplier and producer of the drug be obtained by interrogation of the person who has sold the suspected spurious drug. Giving of cash memos for sale of any drugs should be made mandatory as required under section 9(1) of the Drugs (Control) Act, 1950 for identifying the seller of the particular drug. The cash memo should mention the manufacturer''s name and batch number. Also a computerized system should be maintained showing the name and address of the manufacturer, the batch number, expiry date of the drug, name of the stockist and the eventual chemist/dispenser, so that information of the entire chain is immediately available. The samples collected should be got tested by the drugs laboratories in a prescribed time frame. In case the sample is found adulterated, then further indepth interrogation of the local dealer be done, for positively identifying the stockist or wholesale supplier and manufacturer of the drug against whom also stringent action must be taken, as we do not want the inspections and raids to be only a one time or sporadic affair. Our intention is to break the back bone of this

nefarious trade by a focussed and targeted intervention in such matters. The dispensing dealer as well as the wholesale stockist should be arrested and effectively prosecuted and the trials be conducted expeditiously. Wide publicity in newspapers and other media be given of such manufacturers and sellers of counterfeit drugs for creating a fear psychosis and for deterring others from engaging in such practices. The public should also be asked to insist on taking duly filled cash memos etc. when purchasing medicines. Responses should also be sought from concerned consumer and other bodies, and the local units of the Indian Medical Association about any information that they may possess regarding the producers or distributors of such spurious, substandard or misbranded drugs, as physicians are the best persons to conclude whether the drug administered is producing the desired results, otherwise the drug could possibly be spurious or adulterated. Another mode for gathering intelligence about spurious drugs would be random inspections. However, rather than blind random inspections and collection of sample from all units selling or manufacturing drugs, which is not humanly or operationally feasible, we think that the random inspections should first focus on unlicensed dealers and manufacturers of drugs, and known areas where such malpractices are extensively reported. We would like a progress report on the implementation of these directions on the next date of listing of this case. "

10. Some indifference was reflected in the reluctance of the Government to release the amount of Rs. 1,14,36,700/ for setting up the computerised system for drug management, which was highlighted in our order dated 22.1.2009 and in the last order by taking a flimsy plea that the budgetary provisions for the new Food and Drugs Department is not sufficient and the sum of money required will get budget approval in the forthcoming budget session.

11. We are pained to note that for less important works, funds are quickly sanctioned, but for a computerisation system, which will ensure that information about taking of samples, wherein the names of the producers, batch numbers, names of the stockists, suppliers etc. in the chain would be mentioned and if any report of fake drug was received, punitive action could immediately be taken against the concerned person there is such laxity. We would therefore like to have the State governments report on speeding up computerisation and release of funds for this purpose on the next listing.

12. We therefore observe that unless the State government pulls up its socks in these matters we may have no option but to summon the Drug Controller or another apex authority on each date of hearing and seek his explanation for this laxity, as we cannot allow any party to play with the lives of our often poor and deprived population.

We, therefore, direct that:

1. That the Central Government and the State Government will both give a clear indication to this Court as to how apart from bringing out amendments to the

law, they plan to take effective action for controlling menace of spurious drugs.

2. The State Government is also directed to ensure within two months all the requisite manpowers and required infrastructure, i.e. creating adequate number of laboratories etc.

3. Both the Central and State Governments are directed to inform this Court as to what strategy they propose to adopt so that focussed raids are conducted and samples taken so that effective measures can be made for identifying the manufacturers or dealers in spurious drugs as has been mentioned earlier in our dated 14.10.2008, which was reemphasized in our order dated 17.11.08 and in the present order italicized above.

4. The State Government is also directed to inform the Court about the time frame in which the computerization system of which the plan has been submitted by the NIC will be operational.

List this case on 5.3.2010 for obtaining responses of the parties concerned and for further orders.

