
(2016) 03 SHI CK 0095
In the High Court Of Himachal Pradesh
Case No : CWPIl No. 16 of 2014

Court on its own motion

APPELLANT

Vs

State of H.P. and Others

RESPONDENT

Date of Decision : 15-03-2016

Acts Referred:

Drugs and Cosmetics Act, 1940 — Section 5, Section 7

Citation : (2016) AIR(HP) 109 : (2016) 2 HimLR 1029 : (2016) ILRHP 258 :
(2016) LatestHLJ(HP) 425

Hon'ble Judges : Mansoor Ahmad Mir, C.J. and Tarlok Singh Chauhan, J.

Bench : Division Bench

Advocate : Satyen Vaidya, Senior Advocate, Amicus Curiae and Vivek Sharma, Advocate, for the Appellant; Shrawan Dogra, Advocate General, Anup Rattan, Romesh Verma, Additional Advocate Generals and J.K. Verma, Deputy Advocate General, for the Respondent

Final Decision : Disposed off

Judgement

Tarlok Singh Chauhan, J.—"As long as greed is stronger than compassion, there will always be suffering".

Rusty Eric.

1. This is precisely what is revealed in the instant case. On 24.11.2014, this Court took notice of a news item published in daily Hindi vernacular Amar Ujjala in its 9th November, 2014 edition, wherein the illegal use of lethal vaccine "Oxytocin" in fruits, vegetables and on milching animals was highlighted.

2. What is Oxytocin has been lucidly explained in the affidavit of respondent No. 1, wherein it is stated that Oxytocin was originally extracted from animal posterior pituitaries and is now chemically synthesized. Its only use is in obstetrics, where it is employed to stimulate uterine contraction to induce or reinforce labour or to promote ejection of breast milk. Oxytocin causes milk ejection by contracting the myoepithelial cells around the mammary alveoli.

Although toxicities are uncommon when the drug is used properly; hypertensive crises, uterine rupture, water retention, and fetal death have been reported. Oxytocin is contraindicated in abnormal fetal presentation, fetal distress and premature births. Oxytocin for human use is available in injections as also by way of nasal solution.

3. Mr. Satyan Vaidya, learned Senior Advocate and Amicus Curiae is at pains to point out that there is rampant and extensive misuse of Oxytocin, not only in the dairy sector, but also in the agriculture and horticulture sector and the State Authorities, as also the Central Authorities entrusted with the task of preventing the misuse of Oxytocin have completely failed to check and curb this menace.

4. In order to buttress his submission, learned Amicus Curiae has relied upon the statistics reflected in the affidavits filed by the official respondents themselves as the basis of his arguments. Apparently, in the last three years, only eleven samples of fruits, four samples of vegetables, eleven samples of non-vegetarian food items and ninety one samples of milk were lifted in the entire State of Himachal Pradesh. Meaning thereby that over the last three years, in all only 117 samples of food articles were lifted, out of which only 65 samples had been analyzed, which means that only one sample per ten days was lifted in the entire State.

5. It is further pointed out by the learned Amicus Curiae that the sole Government Common Testing Laboratory (CTL) Kandaghat, District Solan does not even have the facility for detection of Oxytocin in food samples, as has been admitted by respondent No. 5 in his affidavit and if that be so, then there is no purpose of sending the food articles to CTL Kandaghat and the action of the respondents in doing so is merely an eye wash.

6. It is also pointed out that respondents in their replies have been conspicuously silent about the possibility of the drug Oxytocin being illegally imported in the State of Himachal Pradesh from other parts of the country or even overseas and their assertion that strict vigil and check is being maintained falls flat on the ground as during the last three years, there was only one seizure, wherein 254 injections of Oxytocin (for veterinary use) were seized. This inaction clearly reflects the casual approach of the authorities to such a serious issue.

7. The learned Amicus Curiae has painstakingly placed on record additional material, wherein it is pointed out that the misuse of drug Oxytocin is rampant and wide spread and is being indiscriminately used in most parts of the country on milching animals, vegetables, fruits and non-vegetarian consumable items by unscrupulous people with the motive to earn more profits at the cost of serious consequences on the animals as well as human health. A few of the dangers and hazards, beside many others have been summarized as follows:-

"(a) Its usage predisposes the new born baby to jaundice and reduces the supply of blood to its brain.

(b) Dairy owners use the Oxytocin injection twice a day injecting it into the cow-buffaloes to make the milk flow faster by causing the animal's uterus to start contracting putting the animal in enormous pain.

(c) The drug makes the animal barren within three years and also lowers its life span. The cow-buffalo is inseminated within 24 hours of calving by the dairy owners and then the animal, without any respite, has to undergo the agony and pain of maltreatment with the drug of Oxytocin.

(d) The Oxytocin not only effects the cow/buffalo, it filters into the milk and consequently, has been held responsible for breast and uterine cancers, male impotence, excessive hair on woman and balding for men, early or erratic periods, early development of breasts (in both sexes). Its use is also considered harmful eyes, especially in children. The hormone affects the reproductive ability of woman. Its most common symptoms are exhaustion and loss of energy. Consumption of Oxytocin infected milk by pregnant woman increases risk of hemorrhage. It is also responsible for high spike in tuberculosis cases in humans.

(e) Beef all over India has been found to be extremely toxic with large amount of this drug.

(f) The direct infusion of this drug in vegetables, fruits and other consumables for humans is also widespread making such food items highly infected with Oxytocin."

8. At this stage we may notice that under Section 5 of the Drugs and Cosmetics Act, 1940 (for short the "Act"), the Central Government is required to constitute the Drugs Technical Advisory Board (for short DTAB), whose duty is to advice the Central Government and State Government on technical matters arising out of the administration of the Act and to carry out the other functions assigned to it by the Act.

9. Similarly, under Section 7 of the Act, the Central Government may constitute an advisory committee to be called Drugs Consultative Committee (for short DCC) and its duties is to advise the Central Government, State Government and DTAB on any matter tending to secure uniformity throughout India in the administration of the Act.

10. The respondents in their response have not disputed the misuse of Oxytocin. Rather in the affidavit filed by respondent No. 2, it is clearly pointed out that in the 44th meeting of DCC, held on 20.7.2012, the issue of misuse of Oxytocin injection by dairy owners to extract milk from milch animals and its harmful effects were discussed and the following recommendations were made:-

"The members felt that the misuse of oxytocin is rampant in many of the States and reports of its clandestine manufacture and sale appear now and then in the press. The Drug is available as unlabelled or wrongly labelled packs. Many of the States like UP, Delhi have taken action in seizures of stocks on the basis of intelligence gathered. As the manufacture and sale of these products is through

clandestine channels, it becomes difficult to stop their misuse except through continuous surveillance. After deliberations it was opined that as the bulk drug (oxytocin) is being manufactured in a few States only, the diversion of the bulk drug to the illegal channels could be curtailed to a large extent if it is ensured that the bulk drug is sold to the licensed manufacturer only."

11. The matter was again considered in the 46th DCC meeting held on 12-13 November, 2013 and the following recommendations were made:

"The members felt that the illicit manufacture of Oxytocin injection for the use of extracting milk from milch animals by the dairy owners is a clandestine activity. The manufacture of the drug for dairy owners etc. takes places in the regions where drug control administration is lax and then the drug is transported to other States clandestinely. It is available in unlabelled or wrongly labelled packs. Even though many of the States have taken action on the basis of intelligence gathered through surveillance. However, strong measures are required to restrict the supply of oxytocin injection for veterinary use and also ensured that diversion of the bulk drug to illegal channels is curtailed."

12. In the 65th meeting of DTAB, a statutory body under the Drugs and Cosmetics Act, 1940 (for short the Act of 1940), the issue of continued misuse of Oxytocin injections by the dairy owners for extracting milk from milch animals and its harmful effects on the health of cows and buffaloes as well as on the consumers was again discussed and the silent features of the discussion emerged as under:-

"The drug Oxytocin has medical use for induction and augmentation of labour, to control post partum bleeding and uterine hypo tonicity. The alleged abundant availability and use of the drug in a clandestine way, however, is a matter of great concern for public health. The sale of the Oxytocin injection is regulated under Schedule H of the Rules, which requires the drug to be dispensed on the prescription of a Registered Medical Practitioner only. Further, to avoid its bulk sale, Oxytocin injection is required to be packed in single unit blister pack only."

13. The issue of prohibiting the drug also came up for consideration, but after detailed deliberations the members of DTAB agreed that as the drug has a definite use for therapeutic purposes, it need not to be prohibited. However, the DTAB agreed with the suggestion that the manufacturers of bulk drug should supply active pharmaceutical drug only to the manufacturers licensed for manufacture of formulations and the formulations meant for veterinary use are sold to the veterinary hospitals only. The DTAB further recommended that the State Drug Controllers may be asked to curb the misuse of the drug through increased surveillance and raids conducted on the possible hideouts of clandestine manufacture and sale of this drug and take strict action against the offenders.

14. It was on the basis of the aforesaid recommendations of the DTAB that the Ministry of Health and Family Welfare issued G.S.R. 29(E) dated 17.1.2014,

restricting the manufacture and sale of Oxytocin as under:

"The manufacturers of bulk Oxytocin drug shall supply the active pharmaceutical drug only to the manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug.

The formulations meant for veterinary use shall be sold to the veterinary hospitals only."

15. It was also came in the affidavit of respondent No. 2 that at one time concerns were raised and the Government was requested to have complete ban on circulation/marketing of this drug except in registered hospitals and for this a special meeting of DTAB was convened on 1st April, 2014. The DTAB again deliberated the matter in depth and the members were of the view that the drug is already a prescription drug and can be sold only under the prescription of a Registered Medical Practitioner (RMP). The drug as such had a definite role in the medical field both for humans and animals and the legitimate manufacture and sale of the drugs would not, therefore, be stopped. Moreover, keeping in view the medical emergency in rural or remote areas, the drug could only be obtained from the sale outlets and its sale could not, therefore, be restricted to the registered hospitals.

16. However, even in this meeting, it was acknowledged that there was rampant and wide spread misuse of the drug for the milking purposes and was required to be stopped. The suggestions then mooted and put forth for preventing the misuse of Oxytocin was by way of enhanced surveillance by the regulatory authorities, strict action against the violators, sensitizing the general public by launching campaigns through print and audio visual media and the local police could also book the offenders under Prevention of Cruelty to Animals Act, 1960 and the Drugs and Cosmetics Act, 1940, which do not permit the sale of the drug except under proper prescription.

17. It was further recommended that a new clause be added to the already issued notification stating that the supply of the Oxytocin shall be recorded by the retail chemist at the time of supply giving the name and address of the prescriber, name of the patient and the quantity supplied. Such records would be maintained for three years and shall be open for inspection. This would help in not only maintaining the legitimate supply of the drug but also to curb misuse of the drug through legitimate sale channels.

18. It was pursuant to the aforesaid recommendations that notification G.S.R. 29(E) dated 17.1.2014, restricting the manufacture and sale of Oxytocin was issued and reads thus:-

"The manufacturers of bulk Oxytocin drug shall supply the active pharmaceutical drug only to the manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug."

The formulations meant for veterinary use shall be sold to the veterinary

hospitals only.

The supply of the Oxytocin formulations for human use by the retail chemist shall be recorded at the time of supply giving the name and address of the prescriber, name of the patient and the quantity supplied. Such records shall be maintained for three years and be open for inspection."

19. Further, in order to curb the misuse of Oxytocin, especially by the dairy owners, a notification was issued by the Central Government on 22.10.2014. The relevant portion thereof reads thus:

"Strict regulatory control over the manufacture, sale and distribution of Oxytocin and measures required to be taken to curb the misuse of Oxytocin by dairy owners for milking milch animals. In order to take stringent measures on all cases of misuse of Oxytocin by the State Drug Control Authority in their States/ UT and a constant vigil needs to be kept on the illegal movement of the Oxytocin. Investigate the source of the illegal supply of the Oxytocin sold to dairy owners. The help from the NGOs in the States/UT could be taken to locate the areas where such illegal sale is being done. In this connection, the State Drugs Controllers are requested to provide the details of the manufacturers of bulk and formulations of Oxytocin in their State along with the statistical information on the seizures conducted, quantity seized along with its value persons arrested, prosecutions filed, samples taken, reports of sub-standard quality received during the last three years to the office DCG (I) within 30 days of receipt of this letter."

20. It would be noticed that inspite of various provisions of the Drugs and Cosmetics Act and other statutes in place, this Court cannot be oblivious to the fact that there is large scale manufacture and sale of drugs carried out in clandestine manner and that there is grave misuse of Oxytocin by farmers and dairy owners, which is the matter of great concern. This clandestine activity of manufacture and sale of the drug to the farmers or dairy owners requires constant surveillance and interstate coordination and the violators are required to be dealt with heavy hand. It is not only the health of the animals, especially milch animals, which is matter of concern, but a greater concern lies in the fact that it is this very milk and vegetables which have been injected with Oxytocin to increase its size, that is being consumed by all of us.

21. The above narration of facts do indicate that the respondents have though initiated steps to check and curb the misuse of Oxytocin, but yet the same cannot be termed to be sufficient and therefore, taking into consideration the entirety of the facts and circumstances, we proceed to pass the following directions:-

(i) The respondents shall bring about an efficient Drug Regulatory System both at the Centre and the State for better co-ordination and handling of the entire problem so as to regulate the manufacture, import and distribution, especially, those drugs like Oxytocin. For efficient administration, these authorities are

directed to work with effective co-ordination among themselves, so that there is uniformity of approach amongst different stakeholders.

(ii) The Union of India will establish within three months an Academy for training all drug regulatory officers both from Enforcement and Laboratory set up as decided, in principle, in the 49th meeting of DCC held on 16th October, 2015.

(iii) The State Government shall make available adequate testing facilities of Oxytocin at its Kandaghat Laboratory within a period of three months and the respondent-State shall further ensure that all vacancies and posts in the said Laboratory are made functional by appointing duly qualified personnel(s) within the aforesaid period.

(iv) The State Government will henceforth examine the licences of all the existing manufactures of drugs to ensure that the same have been issued strictly in accordance with the Drugs and Cosmetics Act and Rules.

(v) The State Government through its Drug Controller (under the Drugs and Cosmetics Act) shall place on its website by 10th of each month the details of the licences issued to the various manufacturers alongwith monthly statement of production and sales with complete particulars and details made by the manufacturers. The manufacturers of the drugs shall in turn submit these details in advance so as to reach the Office of the Drug Controller by 7th day of every month.

(vi) The respondent-State shall within three months constitute a Special Task Force in each district, whose duty shall be to ensure that no drug which is either prohibited or regulated is readily available in the open market, save and except, in the manner prescribed.

(vii) The wholesalers and retailers of all prohibited scheduled drugs shall maintain records as required under the law and the same shall be produced for inspection after every quarter before the Officer specially appointed for this purpose by the Drug Controller.

(viii) The State Government will ensure the deployment of sufficient police personnel (atleast four) at all its Inter State Borders so as to ensure that no prohibited or contraband drugs enter into the State and for this purpose it shall be incumbent upon these officials to check all vehicles viz. taxis, private vehicles, official vehicles, public transport vehicles etc.

(ix) Respondent No. 1 is further directed to consider the feasibility of restricting the manufacture of Oxytocin only in public sector companies and also restricting and limiting the manufacture of Oxytocin by companies to whom licenses have already been granted.

(x) The competent authorities under the Food Safety and Standards Act, 2006 are directed to ensure random sampling of milk and vegetables and carry out prosecutions where such products tests positive for Oxytocin.

(xi) The police authorities are directed to book all the offenders under the Prevention of Cruelty to Animals Act, 1960 who are found using Oxytocin, more particularly in milching animals.

(xii) Respondents No. 1 and 2 are directed to sensitize the general public about the misuse and abuse of drugs and its ill effects by launching campaigns through print, audio, video modes etc.

22. With these observations, the petition is disposed of, so also the pending application(s), if any.

Before parting, we place on record our appreciation and gratitude for the valuable assistance rendered by Mr. Satyen Vaidya, Senior Advocate as Amicus Curiae, Mr. Sharwan Dogra, learned Advocate General and Mr. Ashok Sharma, learned Assistant Solicitor General of India to this Court.