

## Case Report

# Non-Information of Side Effects and Precautions of Drugs: Deficiency in Service

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### Abstract

Non information of important side effects of drugs may amount to deficiency in service on the part of the doctor. It is a case in which a doctor prescribed an antidiabetic drug to a patient who was alcoholic and diabetic without proper diagnosis and side effects of hypoglycaemia was not informed and precautions of antidiabetic drug that it should be taken before food was also not informed. In a case before District Forum no negligence was found, but in appeal SCDRC reverses the order of District Forum and pronounced well reasoned judgment and ordered for compensation for non discharge of duty by the doctor and declared it as deficiency in Service, which was confirmed by the NCDRC in appeal by the treating doctor. Deceased was father of a doctor who fought his own case on behalf of his mother, complainant in this case. This case will create awareness among doctors for taking informed consent in such case implied oral consent and help in preventing future litigations of such nature.

**Key Words:** Diabetic, Alcoholic, Antidiabetic Drug, Side Effects, Precautions, Death, Deficiency in Service, Damages, Compensation

### Introduction:

This case related to non information of serious side effect of antidiabetic drug, manner of administration i.e. taken before food and avoiding alcohol during treatment. NCDRC considered it as duty of doctor and this conduct on the part of doctor amounts to deficiency in service under the Consumer Protection Act.

NCDRC observed that the following questions required considerations in a revision petition [1] were:

- (a) Whether a medical practitioner before prescribing a drug, which has side effects, should be careful or not in informing the patient about its side effects such as hypoglycaemia etc.?
- (b) Whether, a doctor should give treatment for diabetes to a person who is alcoholic, straightway on the basis of urine test report.
- (c) Without confirming by proper pathological test that the patient is diabetes and thereafter without informing the patient that the medicine should be taken before food and alcohol should be avoided?

In NCDRC view, it was the duty of the doctor, before prescribing diabetic drug, to inform the patient about the side effects of a drug, particularly to an alcoholic person and he should be informed that alcohol may increase sugar level and that diabetic drug should be taken before food.

NCDRC further opined that it is not done and it will be a deficiency in service.

### Questions for Consideration before the NCDRC:

- Why the D-1 wanted to test the urine of Late P-1 when he was brought in with the complaint of chronic cough and cold?
- Whether the D-1 was right in coming to the conclusion that the patient was having diabetes on the basis of urine test conducted by him?

Following Abbreviations were used to protect identity of all stake holders: D: Doctor [D-1, D-2, D-3, D-4] H: Hospital: H [H-1, H2], P: Patient (P-1, P2, P-3 etc.) I: Insurance Company

### Background of the Case:

This Revision Petition arises from the order dt.1.7.2002 passed by the State Consumer Disputes Redressal Commission, Goa, in Appeal No.76 of 2000, reversing the order dt.22.2.2000 of the District Forum, Panaji in Complaint No.310 of 1993.

### Brief Facts of the Case:

The P-2 filed a petition before the District Forum stating that her husband Pralhad

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Korgaonkar, aged about 45 years was taken to the D-1 at village Aldona on 23.2.1993, as he was having chronic cough and cold.

D-1 gave some medicines and asked him to come back on 26<sup>th</sup> February, 1993 with a sample of urine for test.

Accordingly on 26.2.93, P-1, presented himself before the D-1 with the urine sample. The D-1 who tested the urine mentioned that the urine sample showed sugar, which is indicative of diabetes and prescribed one tablet of 5 mg. of Euglucon per day for five days.

The P-2 stated that after taking Euglucon tablet, for 3 days, P-1, in the early morning hours of 3.3.1993 at about 2.00 A.M., began sweating very much and had convulsions and became unconscious. He had to be rushed to H-1 at Mapusa at 4.00 A.M., on 3<sup>rd</sup> March, 1993. At the H-1, soon after admission, P-1 went into coma for about 4 days and thereafter recovered consciousness, but remained in the hospital for 40 days and was discharged on 10<sup>th</sup> April, 1993.

P-1 was advised to take the treatment at home. P-1 was again admitted in the H-1 on 22.5.1993 for a few days. However, on 5.8.1993, P-1 passed away.

### **Alleged Negligence:**

The P-2 alleged that the D-1 prescribed the tablet Euglucon a specific drug for diabetes without ascertaining properly whether the patient was in fact suffering from diabetes.

### **Evidence:**

Medical literature was produced to show that Euglucon is a very sensitive drug and needs to be administered with care and the dosage is to be regulated carefully depending on the level of blood sugar.

It was alleged that P-1 went into coma due to hypoglycaemia and that subsequent treatment in the H-1 did not really help him to recover and **that his death is directly attributable to rash administration of Euglucon tablets by the D-1.**

### **Observations of the District Forum/SCDR:**

The District forum which heard the matter dismissed the complaint on the ground that no negligence has been proved. In Appeal, however, the decision was reversed holding that;

- a. In the first instance the D-1 did not even ascertain whether the patient was suffering from diabetes at all;
- b. Without so ascertaining, a specific and very sensitive anti-diabetic drug, dosage of which

has to be regulated with care, has been administered;

- c. The tablets were prescribed in a routine manner without advising the patient who is an alcoholic that he should not consume alcohol and that the drug should be taken only after the food;
- d. That the patient developed Coma because of the adverse effect of Euglucon.

### **Appeal before NCDRC:**

The present appeal is filed by the D-1 against the said order.

### **Arguments of D-1:**

NCDRC heard both the parties and carefully perused the evidence on record. The arguments of the P-3 i.e., D-2 was:

- a. That testing of urine sugar is one of the first steps used by general practitioners like him in detecting diabetes;
- b. That sugar in the urine indicates that the patient had diabetes;
- c. That the dosage of Euglucon prescribed was the minimum;
- d. That no evidence has been produced as to when and how the deceased consumed the tablets of Euglucon;
- e. That there is no evidence produced to link the development of Coma on 3.3.1993 with the prescription of Euglucon given on 26<sup>th</sup> Feb 1993;
- f. That the P-1 in fact never came back to the D-1 after taking prescription on 26.2.1993;
- g. That no medical record of the H-1 was produced to show as to what had transpired in the hospital;
- h. That one of the random blood tests at the H-1 on 3.3.1993 showed that blood sugar as 185 mg confirms that the P-1 was a diabetic;
- i. That the test which took-place in August-1993 can be of no stretch of imagination be said to have been caused by consumption of three Euglucon tablets of 5 mg each in February, 1993;
- j. That the decision of the District Forum was correct; and urged that the order of the State Commission should be set aside.

### **P-3 Defence Argument:**

**The P-3 argued the case for the P-2.** He submitted;

- i. That for testing whether a person is diabetic or not, testing urine for the same is not a definite test to establish diabetes;
- ii. That the urine test can be positive for sugar under various other conditions including alcoholism;

- iii. That the D-1, knew that P-1 was an alcoholic and urine test can be false positive;
- iv. That P-1 was not suffering from any serious disease other than chronic cough and cold when P-1 went to the doctor;
- v. That there was no reason for P-1 to go into a Coma soon within 4 to 5 days after seeing the D-1;
- vi. That the development of Coma can only be attributed to the consumption of tablets prescribed by the D-1.

**Medical [Hospital] Records:**

It was also argued that while unfortunately no record of the H-1, could be produced because they were inadvertently destroyed or misplaced by the H-1 authorities, evidence of the D-2, D-3, D-4 who also submitted themselves to cross-examination was very much on record and it can be relied upon.

**Observations of the NCDRC:**

NCDRC heard both the parties at length and after careful consideration of evidence on record NCDRC was of the opinion that the D-1 was **totally negligent in discharge of his duties and that there is a clear deficiency in service** provided by him for **the following reasons:**

**Why the petitioner doctor (opposite party) wanted to test the urine of late Korgaonkar when he was brought in with the complaint of chronic cough and cold?**

The first question that arises is as to why the D-1 wanted to test the urine of P-1 when P-1 was brought in with the complaint of chronic cough and cold. The D-1 himself answered this by saying that P-1 was smelling alcohol and was in a drunken state and D-1 had suspected P-1 to be an alcoholic. D-1 argued that this is what prompted D-1 to ask the P-1 to bring his urine for test after four days for possible diabetes.

**Medical Evidence:**

The medical literature produced on record shows that Euglucon is a drug belonging to "Sulfonyl Ureas". This is a specific anti-diabetic drug, which is required to be administered after testing blood sugar levels.

As a matter of fact, when diet, exercise and weight reduction do not lower the blood sugar, then the patient is put on drug therapy, with drugs like Euglucon and even then the dosage needs to be adjusted periodically depending on the blood sugar levels.

The literature further shows that "Severe Hypoglycaemia" (lowering blood sugar levels) can be induced by Sulfonyl Ureas. These drugs

increase release of insulin. Therefore, these drugs like Euglucon are required to be administered immediately after intake of food.

Literature further shows that intolerance of alcohol may occur in patient treated with Sulfonyl Ureas. Therefore the patients are strictly advised to avoid alcohol while taking the drug.

NCDRC find that none of the precautions were given to the P-1 and the D-1 merely prescribed Euglucon 5 Mg. for five days.

**Secondly**, the record of admission of the patient to the H-1 on 3.3.1993 clearly shows that P-1 was admitted at 4.00 A.M. on complaint of convulsions. The P-1's relatives P-2, P-3 told the D-2, that the P-1 was not talking since 2.00 A.M., that P-1 had convulsions and frothing at the mouth, and that P-1 had a similar convulsions at 8.00 P.M. on the previous night.

P-2, P3 told the D-2 that the P-1 had taken one tablet of 5 mg. Euglucon for the previous 4 days. D-2 confirmed these facts in his cross-examination, and stated that his diagnosis was that of Hypoglycaemia (fall in blood sugar level) due to consumption of Euglucon, with chronic bronchitis. D-2 stated that he had taken a blood sample to find out random blood sugar level, and thereafter administered 2 ampoules of 24% glucose to restore the blood sugar level.

This record at the time of admission in the H-1 is a **contemporaneous record** and has to be relied upon.

It was clear from the above that in the very first instance when the P-1 was brought to the H-1 in a comatose condition, the D-2 felt that it was a case of Hypoglycaemia resulting from the administration of 4 tablets of Euglucon over the past 4 days. This tentative diagnosis has been confirmed by the very first blood sugar test taken on 3.3.1993 soon after admission of the P-1 in the H-1, which showed the Random blood sugar at less than 50 mg. It was clear that the culprit was Euglucon administered to a non-diabetic patient.

**Whether the opposite party was right in coming to the conclusion that the patient was having diabetes on the basis of urine test conducted by him?**

The third issue to be considered is whether the D-1 was right in coming to the conclusion that the P-1 was having diabetes on the basis of urine test conducted by D-1.

**Observations of the SCDRC:**

The State Commission in its speaking order quoted extensively from medical literature to show that the D-1 was wrong to come to such conclusion.

### Literature Referred:

Literature referred [2] stated as follows:

"The presence of Glycosuria never establishes the diagnosis, and blood sugar determination must be made to confirm or eliminate the diagnosis of diabetes. Renal and alimentary Glycosuria must be differentiated from diabetic Glycosuria as discussed later.

Other Meliturias and non sugar reducing substances in urine which may give **false positive reactions for glucose** also must be considered." [2]

In another textbook [3], it is stated:

"Glycosuria.... the **most serious disadvantage** in the use of urine test diagnostically arises from individual variations in renal threshold, so that on the one hand some undoubtedly diabetic people have a **negative urine test for glucose due to raised renal threshold**, and on the other those with a **low renal threshold give a false positive test**. In order to distinguish cases of this type from patients with mild diabetes, **suitable tests of carbohydrate tolerance is required.**" [3]

### NCDRC Observations:

A perusal of the above authorities on the subject show a **unanimity of opinion that blood sugar estimation and glucose tolerance test are mandatory before confirming diagnosis.**

Further, the D-1 himself in his affidavit-in-reply has admitted, "The patient was suffering from chronic alcoholism and all types of complications." He further admitted in his cross examination that, "sometimes the urine shows positive sugar test even though there is no sugar. However, it is in certain cases like pregnancy and chronic alcoholism etc."

Both the statements clearly show that the D-1 [opposite party] was aware that the patient being alcoholic, urine test could show a false positive. The D-1 clearly ignored standard medical practice and was further negligent in discharge of his duty to the patient.

**Whether administration of the prescribed dosage of Euglucon can cause the damage that the patient suffered in this case?**

The last issue to be considered was whether administration of the prescribed dosage of Euglucon can cause the damage that the patient suffered in this case.

D-3, who attended to the patient in the H-1 has stated in her **examination in chief**; "at the time of discharge of the P-1 he had behaved abnormalities due to prior irreversible,  
3. "Principle and Practice of Medicine", 15<sup>th</sup> Edition, 1987, on page 467.

neurological damage suffered by the P-1 following drug induced hypoglycaemic coma";

In **cross**; "I say that one tablet of Euglucon per day given to a normal person can cause hypoglycaemia causing lack of supply of glucose to the brain resulting in irreversible damage to the brain. This can also occur in patients taking normal diet".

Similarly, D-4 at the H-1 issued a certificate dt.25.8.1993 stating that P-1 was diagnosed as a case of "chronic alcoholism with drug induced Euglucon hypoglycaemic coma with irreversible neurological damage".

This opinion remained unshaken and rebutted in cross-examination. The deposition of the D3, D4 [two doctors] as well as the initial diagnosis of Hypoglycaemia by D-2, discloses a unanimous opinion that the P-1's hypoglycaemic coma was induced by the drug Euglucon.

In view of the findings **NCDRC fully endorsed the well-reasoned order of the State Commission** and dismissed the revision petition. There shall be no order as to costs.

### Compensation Awarded:

The opposite party was directed to pay the complainant an amount of Rs.109000/- along with interest at 18% and he was also to bear a cost of Rs.5000/-. [1]

### Recommendations:

- To avoid such situations in future, doctor should inform in writing important, life threatening adverse effects, side effects, precautions to be taken by the patient and or their relatives in their language.
- Standard protocols for common diseases like diabetes; hypertension etc. should be followed in making diagnosis, investigations and prescribing treatment.
- Specific instructions regarding drug interactions, avoiding of alcohol intake and dietary instructions as per the need of the case.

Above all recommendations may be considered as a part of informed consent needed for decision making on the part of patient and or their relatives as the case may be.

### References:

1. M.B. Shah, J., President, Rajyalakshmi Rao, Member, P.D. Shenoy, Member. Dr.V.K.Ghodekar vs. Smt. Sumitra Pralhad Korgaonkar, Revision Petition No. 1727 of 2002 (From the order dated 1.7.2002 in F.A.No.76/2000 of the State Commission, Goa), date of judgment: 22.05.2008, Available at: <http://ncdrc.nic.in/RP172702.html>
2. Dr. Stephen Fajan and Dr. Robert Williams, MD, Professor of Medicine, University of Washington, in their book "Methods and Criteria for Diagnosis of Diabetes Mellitus".