THE WEST BENGAL CLINICAL ESTABLISHMENT REGULATORY COMMISSION.

Present: Justice Ashim Kumar Roy, Chairperson.

Dr. Sukumar Mukherjee, Member.

Dr. Gopal Krishna Dhali, Member.

Dr. Makhan Lal Saha, Member.

Dr. Madhusudan Banerjee, Member.

COMPLAINT ID: KOL/2017/000207.

Mr. Sankar Chakladar.....Complainant.

-versus-

Medica Superspecialty Hospital & others.....Respondents.

Date of judgment: 11th September, 2018.

J U D G M E N T.

It is the case of the complainant that his wife Sandhya Chakladar, was admitted at Medica Superspecialty Hospital Caring (hereinafter referred to as *"Medica"*) on March 14, 2017 with severe chest pain associated with pain in abdomen (Belly) and was discharged from the hospital on March 17, 2017. Thereafter again on July 18, 2017, she was re-admitted at the said hospital with same complaint, pain in chest and abdomen and discharged on July 21, 2017. The wife of the complainant had chronic kidney disease, gall stone and cardiac problem from long back. In the discharge certificate dated July 21, 2017 the doctor of Medica amongst other prescribed WEPOX 4000 units' injection twice daily and while at home such advice was scrupulously followed and she received WEPX 4000 units' injection twice daily, until on July 27, 2017 another doctor advised to discontinue such injection immediately. The complainant has ascertained WEPOX 4000 units' injection twice daily was an overdose and the maximum dose

must not be more than once or twice a week. The complainant's wife received 9 WEPOX 4000 units' injection at home and after such injection she started suffering from tremendous convulsion and bleeding from mouth. When last injection was given on July 26, 2017, she became disoriented. The complainant immediately on July 27, 2017 rushed to Medica when the attending doctor asked him to stop WEPOX 4000 units' injection twice daily as earlier prescribed. Thereafter again on July 29, 2017, his wife was admitted at Medica in HDU and put on regular dialysis. But she did not recover and finally, on August 4, 2017, she expired after cardiac arrest. After the death of the wife of the complainant, Medica tried to manipulate their mistake relating to the dosage of WEPOX 4000 unit's injection twice daily and corrected the discharge certificate dated July 21, 2017 by interpolation. His wife died due to overdose of injection WEPOX 4000 units twice daily as prescribed by the doctor of the hospital.

2. Immediately upon receipt of the aforesaid complaint, notice was issued against Medica calling upon them to produce the bed head ticket and to deal with the allegations and justify their action.

3. Subsequently, on the first day of hearing the parties were directed to present their respective cases in the form of affidavit. Accordingly, complainant filed his complaint in the form of affidavit and Medica filed its reply also in the form of affidavit and produced the bed head ticket of the service recipient. In addition to that Medica relied on articles published in Medical Website to justify the dose.

4. In its reply, the Medica denied the allegation of negligence and claimed that the same is totally baseless. The allegation of over dose of WEPOX 4000 was vehemently disputed. It was contended that the said medicine neither deteriorated her condition of health nor caused her death. The case of the Medica is as follows,

a) The service recipient Sandhya Chakladar admitted at Medica thrice. First admission was from 14/3/2017 to 17/3/2017 under Dr Dilip Kumar, Cardiologist. Second admission was from 18/7/2017 to 21/7/2017 in Nephrology Department under a team of doctors, Dr Dilip Pahari, Dr N. Roychaudhury and Dr R. N Ghosh, who worked as a team for kidney related

diseases and Dr Dilip Kumar, Cardiologist. For the third time, she was admitted on 29/07/2017 and expired on 14/08/2017.

b) She was first admitted with chief complaints of Left Side Chest Pain associated with shortness of breath from 4 days before admission and was discharged with unstable Angina, Calculous Cholecystitis, Anaemia, Hypertension, Diabetes Mellitus Type- 2 and Chronic Kidney disease. Considering the low Hb level, two units of blood were transfused. On USG of whole abdomen multiple gall stones were found with bilateral small kidney. She was advised laparoscopic cholecystectomy, which was not consented by her relatives.

c) For the second time, she was re-admitted with multiple episodes of coffee ground vomiting, acute pain in abdomen and right sided chest pain with generalized weakness in the background of diabetes mellitus, hypertension, calculous cholecysititis and chronic kidney disease. Before admission patient was fasting due to some religious practice and was not taking food orally. She was insisting for discharge persistently from the day of admission.

ABG showed severe metabolic acidosis. Urine output was also low. She was managed with I.V. fluids, antibiotics and alkali infusion.

UGI Endoscopy was planned in view of coffee ground vomitus and low HB. But patient and relatives did not give consent for same on 18/7/2017 and 19/7/2017 but after repeated counseling regarding the need, they agreed to do it on 20/7/2017. Upper GI Endoscopy revealed Gastric Antral Vascular Extasia (GAVE). Argon Plasma Coagulation (APC) was decided at the time of endoscopy but patient and relative did not agree for same. During the course of treatment the relatives were counseled and all necessary consent was taken. There was resistance/ denial of procedures from the patient's relatives on multiple occasions and the hospital had no option but continued to take care of the patient without the procedures.

Gastro surgeon advised for surgery for gallstone but relatives were not willing for same. Vomiting subsided with PPI, antiemetics etc and urine output also improved (about 1500ml on 19/7/2017). Urine C/S report revealed growth of Kleibsiella Pneumoniae. The patient and relatives were repeatedly requesting for discharge and not interested in continuing the

treatment. On the request of the patient and relatives the consultant had to give discharge on request with advice.

Considering the acute gastritis and need for intravenous injection, she was discharged with Inj. ERTAPENEM 1g intravenously once daily for 5 days to which the urinary pathogen was sensitive. As mentioned earlier APC was advised at the earliest in view of active GAVE and cholecystectomy was scheduled once the infection is controlled.

She was asked to follow up after 5 days and review her condition as well reports including CBC, urea, creatine, Na+, K+. Erythropoitin was prescribed subcutaneously 4000 twice daily till follow up after 5 days to maintain hemoglobin level in the presence of ongoing gastric blood loss and reduced production due to chronic kidney disease. Intravenous iron was also prescribed.

d) On the third occasion, she was admitted under nephrology and referral to Dr. Dilip Kumar, Cardiologist.

She was in HDU and CCU where critical care specialists supervised her and also she was seen by neurologist (Dr Amit Halder), Dr Dilip Kumar (Cardiologist), Gastro-enterologist and Haematologist.

Admitted with complaints of fever with chills, shortness of breath and generalized weakness since around 3 to 4 days. There was a history of single episode of convulsion on 26/7/2017 at around 9 pm.

Clinically, patient was conscious, following commands with features of fluid overload along with bilateral basal crepitation, pedal oedema, pallor and she was intermittently febrile, dyspnoeic (settled on 3L oxygen, SpO2 being 98%) and sinus tachycardia. Work up for fever was done.

Haemoglobin (7.0g/dL) was low as on 29/7/2017 with borderline low normal total WBC count. Hypokalemia and hypocalcemia was seen.

Urea and creatinine were high with low urine output on the day admission. There was an increasing trend in subsequent reports with clinical condition deteriorating further with decreasing urine output CRP was high too.

She was diagnosed as lower respiratory tract infection with sepsis acute on chronic kidney disease, fluid overload, dyselectrolytemia refractory anaemia in the background of Type 2 Diabetes mellitus, hypertension, IHD, GAVE with GI bleeding and calculous cholecystitis.

She was treated with medications like broad spectrum antibiotics, oxygen support, antipyretics, bronchodilators etc., around six PRBC transfusions, haemodialysis and other supportive care like electrolyte correction were done. She developed features of leucopenia with bleeding from multiple sites, features of DIC, coagulopathy and multi organ failure. She received Meropenem, Teicloplanin and Polymixin B at different times. She also received fresh frozen plasma when she developed features of DIC with bleeding from all the sites. She also received haemodialysis as well.

Haematologist and Neurologist opinion taken. CT scan of brain as reviewed by Neuro-Radiologist dated 1/8/2017 showed mild non specific periventricular ischemic changes with no focal parenchymal lesion but no hydrocephalus. EEG was normal.

Impression of Neurologist was sepsis associated with encephalopathy. Haematologist was also of view of sepsis with DIC.

Antibiotics were upgraded with cultures awaited, the condition further deteriorated with high ionotropic support, FFP transfusion, ventilator support, haemodialysis etc.

She suffered cardiac arrest on 4/8/2017 early morning, CPR started according to ACLS protocol but she could not be resuscitated and was declared clinically dead on 4/8/2017 at around 7.05am.

5. In addition, to counter the case of complainant that the advice and prescribing WEPOX (Erythropoitin) 4000 units injection twice daily was not correct, *the Medica* relied on two article "Anemia of chronic disease" authors Stanley L Schrier, MD, Clara Camaschella, MD published in

September,2017 (last updated October 2, 2016) in a medical journals "UPTODATE" and another published in Medscape articles and refer their submissions are as follows,

UPTODATE... Anemia of chronic disease/inflammation by Stanley L Schrier, MD, Clara Camaschella, MD.

Dosage—Although one of the hallmarks of ACD is a reduced erythropoietic response to both endogenous as well as exogenous EPO, high doses of EPO may overcome this hyporesponsiveness. (See 'Pathogenesis' above and "Hematologic manifestations of rheumatoid arthritis" section on Anemia')

Two treatment options are available:

- Standard dosing of EPO is a starting dose of 100 to 150 units/kg subcutaneously three times weekly along with supplemental iron. Responders may show a rise in the hemoglobin concentration of at least 0.5 g/Dl by two to four weeks [103,105]. If there is no elevation in hemoglobin concentration by six to eight weeks, the regimen can be intensified to daily therapy or 300 units/kg three times weekly. It is not worthwhile to continue EPO in patients who do not have a clinically meaningful response by 12 weeks [103]
- An alternative treatment schedule is to employ 30,000 to 40,000 units of EPO given SQ once per week, a single dose that is numerically equivalent to a dose of 140 to 190 units/kg three times per week for a 70 kg person [106,107]. This dose can be increased to 60,000 units if there is no response (ie, hemoglobin rise<1 g/DL) at four weeks.

For ease of use and to minimize inconvenience to the patient, we prefer the latter of these two schedules.

Medscape

Epoetin alfa (Rx).....

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Dosing & Uses.....

Chronic Kidney Disease-Associated Anemia.....

Zidovudine-Related Anemia.....

Chemotherapy-Related Anemia.....

Preparation for surgery with high risk of blood loss.

Reduction of need for allogeneic RBC transfusions in patients with perioperative hemoglobin>10 g/dl but ≤13 g/dl who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery

300 units/kg SC once daily for 15 consecutive days (10 days preceding surgery, day of surgery, 4 days following surgery); alternatively, 600 units/kg SC in 4 doses administered 21, 14 and 7 days before surgery and on day of surgery.

Dosing considerations

Chronic Kidney Disease-Associated Anemia

<1 month:Safety and efficacy not established

>1 month: 50 units/kg IV/SC 3 times weekly initially; if patient on dialysis, IV route recommended

Initiate when hemoglobin level <10 g/DL; if hemoglobin level approaches or exceeds 11 g/dl, reduce or interrupt dose

Dosing Considerations

- Do not increase the dose more frequently than every 4 weeks

- Decrease in dose can occur more frequently; avoid frequent dose adjustments
- If hemoglobin rises rapidly 9eg,>1 g/dl in any 2-weeks period), reduce dose by 25% or more as needed to reduce rapid responses
- In adequate response: If hemoglobin has not increased by>1 g/dl after 4 weeks of therapy, increase dose by 25%; if patient does not respond adequately over 12-week escalation period, further dose increase is unlikely to improve response and may increase risks
- Evaluate iron status before and during treatment, and maintain iron repletion
- When initiating or adjusting therapy, monitor hemoglobin levels at least weekly until they are stable, then monitor at least monthly
- When adjusting therapy, consider rate of hemoglobin rise or decline, responsiveness to ESAs, and hemoglobin variability
- A single hemoglobin excursion may not necessitate dosing change
- Use lowest dose that will maintain hemoglobin level sufficient to reduce need for RBC transfusions
- Evaluate other causes of anemia
- Discontinue if responsiveness does not improve

The Erythropoitin dose prescribed was 4000iu twice daily to be reviewed by CBC after 5 days. She was discharged on July 21, 2017 and reviewed on July 27, 2017 in OPD by Dr. R. N. Ghosh, MD, DM Nephrologist in Medica and work in the same team. Dr. Ghosh stopped the Erythropoitin on July 27, 2017 because she had one episode of convulsion, and she received total of 9 doses i.e. 4000X9= 36000iu of Erythropoitin.

The standard dose prescribed in up to date (updated upto Sept.2017) 100-150iu/kg day thrice in a week. In the intensified therapy of the same standard dose can be given every day. Considering her body weight of around 65Kg the daily intensified dose will be 6500iu/day to 9750iu/day. We prescribed intermediate dose ie. 8000iu per day i.e less than the possible upper limit. In the intermittent intensified dose schedule, the recommended dose being 300iu/Kg three times a week or 19500iu three times a week in her case. The entire up to date

chapter is enclosed here with. The relevant potion enclosed here. Up to date is the most widely read medical journal for reference.

a) Standard dosing of EPO is a starting dose of 100-150 units/kg subcutaneously three times weekly along with supplemental iron. Responders may show a rise in the haemoglobin concentration of at least 0.5g/dL by two to four weeks. If there is no elevation in the haemoglobin concentration by six to eight weeks, the regimen can be intensified to daily therapy or 300U/kg three times weekly.

b) An alternative treatment schedule to employ 30,000 to 40,000 units of EPO given SQ once per week a single dose that is numerically equivalent to a dose of 140 to 190 units/kg three times per week for a 70 kg person. This dose can be increased to 60,000 units if there is no response at four weeks.

If we put Erythropitin dose in Google search engine, it refers to Medscape, widely published medical online journal. As per Medscape we can prescribe 300iu per kg daily for 2 weeks for a quick response. For her the dose will be 19500 iu per day. The Medscape chapter is enclosed for reference.

Preparation for surgery with high risk of blood loss: Reduction of need for allogenic RBC transfusions in patients with perioperative haemoglobin>10g/dL but <13g/dL who are at high risk for perioperative blood loss from elective, non cardiac, nonvascular surgery. 300 units/kg SC once daily for 15 consecutive days (10 days preceding surgery, day of surgery, 4 days following surgery); alternatively, 600 units/kg SC in 4 doses administered 21, 14 and 7 days before surgery and on day of surgery.

Erythropoitin is available not only 2000iu, 3000iu , 4000iu but also 30000iu, and 40000iu per vial in premixed syringes to be given in one shot. For patients with poor response, and for patients where we want a quicker response, we use 30000iu to 40000iu twice/thrice in a week even in a renal failure patients. Hemato-oncologists frequently use much higher dose for quicker response.

According to them, there are multiple reasons for convulsion including advanced kidney failure, treatment with drugs like Etrapenum, and Erythropoitin. However, she had only one episode of seizure and subsequent EEG and CT brain did not reveal any significant abnormalities. She did not have any recurrence of seizure also.

It is, therefore, claimed that this dose of Erythropoitin for only short period caused any significant harm to her and such dose was prescribed for her benefit of gaining health and correction of anaemia in spite of continuing bleeding from GAVE in the stomach. Intravenous iron was planned to be given after 10 days once infection is controlled.

6. Heard the parties at length.

Considered their respective submissions.

Perused the complaint in the form of affidavit, the affidavit-in-reply and the medial literatures relied upon by the Clinical Establishment and the medical file including the Bed Head Ticket of the service recipient.

7. The case of the complainant that while his wife was discharged from Medica Superspecialty on 21st July, 2017, the doctor advised, amongst other medicines wepox (Erythropoitine) 4000 unit injection subcutaneously, twice daily till follow up after five days and after receipt of 9 doses i.e. 4000x9=36000 iu Erythropoitine, since the service recipient started tremendous convulsion and blood vomiting, the complainant rushed to the Medica Superspecialty Hospital i.e. on July 27, 2017 when the doctor at attended the patient at OPD not only advised admission but while advising medicines categorically noted ***"stop wepox"*** but they have taken a specific stand that dosage so prescribed was standard dose and to justify such claim, the Clinical Establishment relied on 2 reviews published in UPTODATE (updated upto Sept. 2017) and another in Medscape.

8. Now without entering into the merits of the case of the complainant and that of the Clinical Establishment and addressing the question whether the dose of wepox 4000 iu twice daily for five days was overdose or not and due to such overdose the service recipient suffered

convulsion and blood vomiting and died or not, we find the allegation of prescribing overdose of a particular medicine is actually directed against the concerned doctor who prescribed such dose and such allegation tends to make out a case of medical negligence by a medical professional. However, on the face of the first proviso to sub-Section (iii) of Section 38 of the West Bengal Clinical Establishment (Registration, Regulation & Transparency) Act, 2017, the scope of adjudicating the issue by the Commission is statutorily restricted.

9. In the result, without proceeding any further on merit, the case stands closed and disposed.

We, however, make it clear that this order will not prevent the petitioner from approaching the concerned State Medical Council for necessary relief in accordance with law.

Sd/-
Justice Ashim Kumar Roy
Chairperson.

Sd/-
Dr. Sukumar Mukherjee, Member.

Sd/-
Dr. Gopal Krishna Dhali, Member.

Sd/-
Dr. Makhan Lal Saha, Member.

Sd/-
Dr. Madhusudan Banerjee, Member.

Authenticated

ARSHAD HASAN WARSI
WBCS (Ex)
Secretary
W. B. C. E. R. C.