

Office of the West Bengal Clinical Establishment Regulatory Commission

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Case Reference: WBCERC/SOU/220/2024-25, WBCERC/SOU/221/2024-25, WBCERC/SOU/222/2024-25

Present: Justice Ashim Kumar Banerjee (Retired), Chairman

Dr. Sukumar Mukherjee,

Dr. Makhan Lal Saha

Sri. Sutirtha Bhattacharya, IAS (Retd)- Member

Dr. Maitrayee Banerjee – Member

Smt. Madhabi Das.

Mr. Bhaskar Bhattacharyya.....Complainant

- Versus-

Sri Aurobindo Seva Kendra, Manipal broadway&Dumdum
Medical Centre.....Respondent

Heard on: January 22, 2025.

Judgment on: March 05, 2025.

BACKDROP

Mrs. Chabi Bhattacharyya a 65 years old female patient had pain abdomen. She approached Dr. Amitava Chatterjee at Aurobindo Seva Kendra (First CE) on December 08, 2015. Dr. Chatterjee prescribed medicine and suggested few blood tests and X-ray of cervical spine. We are not sure whether such tests were done or not. After about 4 months the patient again visited Dr. Chatterjee on March 8, 2016 when Dr. Chatterjee advised USG of the right sided swelling. We are not sure what happened thereafter as the patient did not come for check up for about 10 months and ultimately approached Dr. Chatterjee on January 03, 2017 when Dr. Chatterjee prescribed blood tests to see vitaminosis-D and X-ray of cervical spine.

There was complete silence for about 6 years.

The patient visited Dr. Chatterjee on May 22, 2023, December 19, 2023, January 12, 2024 and January 20, 2024. All those OPD consultations did not suggest any advance test even after noticing that the patient had constant pain abdomen for about a decade.

The patient became critical and approached the first CE for admission. She was admitted on February 03, 2024 when Dr. Chatterjee was out of station and the patient was admitted under Dr. Tanmoy Chatterjee. The patient was advised to go for CT abdomen that indicated soft tissue mass in the right iliac fossa.

The relevant observation is extracted below:-

“An irregularly marginated patchily enhancing soft tissue mass in the right iliac fossa involving the caecum, terminal ileum & adjacent peritoneum with mild localised collection causing subacute small bowel obstruction. Chronic Inflammatory/ Neo-plastic.”

The patient was referred to Dr. Achintya Das, Surgeon who advised immediate surgery however, according to Dr. Das, it could be a case of lingual hernia. Dr. Das suggested and “*Exploratory Laparatomy*” to be performed on the gastro intestinal tap for hernia repair.

The patient did not agree and got a discharge under DAMA. The patient was readmitted in Manipal Broadway (Second CE) on February 8, 2024 at 2 pm with pain abdomen for almost two weeks

with diagnosis suggested of acute intestinal obstruction (appendicular mass with umbilical hernia).

The patient was admitted under Sujit Choudhary who referred the patient to Dr. Anirban Banerjee surgeon. Dr. Banerjee found a lump at the right lower quadrant with dilated bowel loop suggestive of **"long standing obstruction"**. The patient and the complainant were counselled and explained about the nature of the disease and possibly of advance obstructive type of malignant growth that would require immediate surgical intervention. That time, the patient and the complainant agreed to go for surgery. Surgery was performed on the next day i.e, February 09, 2024. There had been post surgical complication resulting irreversible shock stage acute kidney injury. The patient was too critical. Yet, she was discharged on DAMA and shifted to Dumdum Medical Centre (third CE) which is admittedly a smaller set-up than Manipal Broadway. The patient had a brief stay at third CE. She breathed her last on the day of admission i.e. on February 13, 2024.

COMPLAINT

The complainant, Mr. Bhaskar Bhattacharyya, is the son of Ms. Chabi Bhattacharyya, the ill-fated patient. The biopsy report received on February 17, 2024, confirmed carcinoma.

The relevant extract of the complainant is quoted below:-

1. *"That the deceased Chabi Bhattacharyya used to avail the medical advise and services of Mr. Amitava Chatterjee, doctor and her family physician for regular health checkups.*
2. *That on December 8, 2015, the deceased Chabi Bhattacharyya approached Dr.Amitava Chatterjee on account of experiencing abdominal pain, bloating and discomfort wherein she was prescribed medicines for acid reflux and asked to take some routine tests and tests for certain abdomen related ailments. After having examined the findings to the aforesaid tests, Dr. Chatterjee dismissed the deceased's complaints stating that it is caused due to indigestion.*
3. *Between 2015 to 2023, the deceased visited Dr.Amitava Chatterjee multiple times, however, the complaints of the deceased were*

dismissed every time stating that those are rooted in minor causes such as indigestion or acid reflux. However, on persistence and worsening of the deceased's symptoms, I, the complainant in the instant case, insisted the doctor to opt for medical services rendered by a hospital as the doctor advises for total body check and final diagnosis.

4. Things aggravated when the deceased did not pass stool for 15 consecutive days and suffered severe stomach distention, coupled with symptoms of oliguria, nausea and foul smelling vomitus wherein, upon further insistence of the complainant, she was admitted to Aurobindo Seva Kendra on advise of the family physician, on February 3, 2024, under the supervision of Dr. Tanmay Chatterjee in the said hospital along with the reference of Dr. Amitava Chatterjee, and within some time of admission in the hospital and on medical intervention namely assisted enema, her symptoms of distention were relieved but were not cured completely. Since the deceased's symptoms did not subside, the complainant insisted on Dr. Tanmay Chatterjee for further evaluation and to only discharge only after receiving satisfactory results. Accordingly, several consultants were called up and the consultants



acting in coordination with each other ran a CT scan of the entire abdomen on February 4, 2024, whose finding report dated February 5, 2024, showed a neoplastic growth of soft tissue mass in the deceased's intestines wherein Dr. Achintya Kumar Das, a general surgeon, suggested an exploratory laparotomy to be performed on the deceased's gastrointestinal tract for hernia repair which was the same as the recommendations made by Dr. Tanmoy Chatterjee as seen through the Referral Consultant's advice sheet dated February 4, 2024.

5. In light of these circumstances, the complainant initially wanted to postpone the surgery by a few days owing to the deceased's shaken mental state through a written request dated February 6, 2024. However, the same was not considered with by the said Hospital and the said CE suggested to discharge the patient and to transfer her to a higher medical centre for better management and care as evident from the treatment advice sheet dated February 7, 2024. Subsequently, the complainant was handed a transfer discharge certificate for the deceased dated February 8, 2024.

6. After the sequence of events in the Opposite party hospital, the deceased was admitted to AMRI, Salt Lake (presently and hereinafter referred to as "Manipal Hospitals Broadway") on February 8, 2024 wherein the condition of the deceased deteriorated considerably. However, she was outwardly in good mental and physical health and was hemodynamically stable. At this point, following the completion of several tests under the supervision of gastroenterologist Dr. Sujit Choudhury, who also suggested the surgery of the same GI tract, that is a resection of the colon, which was denied by the complainant, as he wanted to get a second opinion. However, the said doctor assured the complainant that his mother would be under his care even at the time of operation and that he would also be observing the procedure conducted by a doctor Anirban Banerjee, a general surgeon tasked with performing an anastomosis on the deceased which was subsequently done on February 9, 2024 after assurance by the Manipal Hospitals Broadway.

7. That even though the complainant and his mother were skeptical about the said operation, they were assured by the consultant gastroenterologist and the Hospital that the complainant's mother

would be perfectly fine after the said operation. Accordingly, being laymen in the hands of the so-called medical experts, the complainant and his mother conceded to the operation only with the assurance of a better success rate and betterment of physical condition.

But after the said operation, the condition of the deceased deteriorated very fast. Even with all this, the deceased was still conscious and informed the complainant of distension that she was experiencing in her abdomen. Within a few hours, the complainant was informed to arrange blood for his mother because they suspected a ruptured suture and internal blood loss. They initially wanted to perform CT scan over the whole abdomen to reconfirm but at that juncture, the CT scan machine of the hospital was not functional and the complainant was shocked to hear that in a super speciality hospital where CT scan is a basic parameter for imaging diagnostic is non functional and for evaluation at any critical situation the same was not present.

8. I was asked to give a high risk consent and tried to fix liability on me for shifting my mother to some other private diagnostic centre for

the CT Scan and wanted me to sign a risk bond, which no normal human being could expect from any hospital and I also could not consent for the same.

9. At such a turn of events I asked the consultant surgeon about the failing health of my mother and wanted for a second opinion, to which I was given an assurance that she will be fine within a few hours and there is no need of any CT Scan. However, on February 11, 2024 the consultant Dr.Sujit Chaudhary as well as the nursing staff came to me and disclosed about the worsening condition of my mother and told me that they have sent the resected part of the lower GI tract to the lab for a biopsy and further evaluation. At this I was shocked and spellbound and for the first time came to know that the entire operation was conducted without biopsy and/or other clinical evaluation.

10. After a few days, the said biopsy report arrived which clearly speaks about metastasis. Had the complainant or the diseased been informed about metastasis or carcinoma they would have taken a

second opinion from higher centre, specialists in oncology and/ or would have opted for holistic treatment.

Therefore the consent for the said operation was taken with duress and coercion which is evident from the said unprofessional act of obtaining the consent by misleading the patient and the patient party for material benefits.

11. That on February 12th, 2024 the mother of the complainant was shifted to Dum Dum Medical Centre on advise of the consultant surgeon stating there will be better treatment in the instant case, by giving Discharge Against Medical Advice (DAMA) after being lured by the consultant doctor Sujit Chaudhary to take the deceased out of the hospital and get her admitted to a private nursing home for better treatment and care under the supervision of Dr. Anirban Banerjee and for material betterment. Furthermore, the application of the complainant for Bed-Head Ticket from Manipal Hospitals Broadway at Salt lake was not considered. During such a crisis, I blindly trusted Dr Sujit Chowdhury and accordingly discharged my mother and

admitted her to the said nursing home. In the said nursing home, on the contrary there was no proper equipment and a CT Scan machine which was not functioning and as such I having lost my temperament for the first time argued with the doctor and asked for a complete set of Bed-Head Ticket for further evaluation but I was refused.

Within a few hours of the said heated argument, I was informed that my mother was in a comatose state and soon thereafter she passed away leaving me confused and hurt.”

RESPONSE

We asked for response from all the three CE's.

The gist of the response is as under:-

FIRST CE

The patient was under regular treatment of Dr. Chatterjee who is a consultant physician. According to them, they were not sure whether the tests as advised, were done or not.

On January 20, 2024 the patient was reviewed by Dr. Sanjay Basu, the consultant Gastroenterologist who also advised USG abdomen

that was not done or made available for check-up on January 27, 2024. The patient again visited OPD and was seen by Dr. Chatterjee and Dr. Basu. The USG advised were not done at that point of time. There was no history of bleeding per rectum or progressive weight loss. The patient came with acute pain and history of constipation for about 15 days on February 03, 2024. On examination she was noted to have slight abdominal bulge and sluggish peristaltic sound. She was admitted under Dr. Tanmoy Chatterjee. Tests were done. CT abdomen was planned along with surgery referral on February 04, 2024. Dr. Das advised "*Exploratory Laparotomy*" for removing the obstruction due to umbilical hernia. On the next day, i.e, February 4, 2024 Dr. Tanmoy Chatterjee also agreed to such advice of Dr. Das however, the patient and/or the patient family did not give consent for surgery. On February 06, 2024 the patient was discharged on DAMA where the complainant, the son of the patient, categorically stated:

"Considering the consequences and since my mother is not mentally prepared at his point of time for the said operation I am requesting the doctor and the hospital to postpone the operation as there is a fear factor working in the conscious mind of the patient and till date I



request to make stable the patient so that she can go home and prepare herself for further decision."

On February 07, 2024 the CT abdomen report came that clearly suggested probable chronic inflammation/Neoplastic lesion. The patient and her son did not give consent for surgery and ultimately the patient had to be discharged under DAMA despite the CT abdomen report referred to above.

SECOND CE

The patient was admitted on February 8, 2024 at 2 pm at Manipal Broadway under Dr. Sujit Choudhary, who after examination of the patient, referred her to Dr. Anirban Banerjee, Surgeon. Dr. Banerjee, after evaluating the medical records as well as the biopsy report, categorically counselled both the patient and her son, it could be a malignant growth that required immediate surgical intervention. This time, the patient's son agreed and the surgery was done on the next day that resulted in post surgical complication. The doctor advised the patient to shift for CT scan only after intubation and ventilation. Pertinent to note, the second CE had some problem on that day for

which CT scan could not be done on February 12, 2024. It was arranged at another set-up of the second CE just 300 meters away. The complainant did not agree and got the patient discharged under DAMA. The patient was shifted to Dumdum Medical Centre (Third CE) in a gasping state at his own risk. According to the second CE, the patient's son was fully aware of her condition and despite the critical state, insisted her transfer at midnight.

THIRD CE

Dr. Anirban Banerjee, the concerned surgeon, was also attached with the third CE. On his advice, the patient was shifted to the third CE as appears from the response given by them. Dr. Banerjee, himself, gave the response above on behalf of the Dumdum Medical Centre. According to him, the patient and her son were thoroughly counselled and explained about the nature of the disease, high possibility of advanced obstructive type of malignant growth that would require immediate surgical intervention. Initially they were reluctant in taking a decision about the surgery later on consent was given and surgery was done on the very next day that developed complication. She was

shifted to ICU. Patient's blood pressure was not maintained ultimately leading to acute kidney injury. CT scan was planned but the patient could not be transferred to other facility as the condition was not favourable. As the patient condition was not improving her son refused for any sort of aggressive management and requested Dr. Banerjee to shift to some other facility for "**terminal care**."

Hence, Dr. Banerjee arranged her transfer to the third CE in a gasping state. She arrived there at 12.15 am on February 13, 2024. All necessity measures were taken up. The complainant was updated time to time about the poor outcome and ultimately she passed away at 7:22 am on the next day.

We have heard the complainant, an advocate by profession. He was assisted by Dr. Siddharta Goswami, another advocate. We have also heard the representative of the CEs.

Our esteemed members Dr. Sukumar Mukherjee and Dr. M L Saha interacted with the parties in detail. They also evaluated the medical records. They gave their opinion which are extracted below:-

DR. SUKUMAR MUKHERJEE

“Facts: The index patient 65 years with background history of hypertension and diabetes presented with abdominal pain and dyspepsia in 2016 to her family physician locally when USG abdomen was recommended. But it was not done. In 2024 she attended Sri Aurobindo Seva Kendra Emergency Department on 03.02.2024 at 7.40 pm with prolonged constipation of 15 days duration and loss of appetite and got admitted under Dr. Tanmoy Chatterjee, MD. At that time serum sodium was also reduced needing replacement. She was also examined by Dr. Achintya Kumar Das, Consultant surgeon who opined surgical intervention after CECT abdomen. On 07.02.2024 CECT abdomen reported an irregularly marginated partially enhancing soft tissue mass in right iliac fossa involving caecum, terminal ileum and adjacent peritoneum with mild localised collection causing subacute intestinal obstruction. Suggestive of probable Chronic Inflammatory / Neo-plastic lesion.

Since her son Mr. Bhaskar Bhattacharyya was not satisfied with the care at Sri Aurobindo Seva Kendra of her mother she was taken to



AMRI (Manipal Broadway) hospital at Salt Lake.

The patient was admitted at Manipal Hospital Broadway (previous AMRI Salt Lake city) under care of Dr. Sujit Choudhary on February 8, 2024. Exploratory Laparotomy was done on February 9, 2024. Patient during operation developed hypotension (Low BP) for which she was shifted to ICU. Biopsy report was awaited which takes nearly 08 days.

In the mean time this sick patient was shifted against medical advice to Dum Dum Medical centre almost in critical stage of gasping at midnight on 13.02.2024 and Dum Dum Medical Centre accepted her and the patient died there on 13/02/2024 with sepsis and acute kidney injury on the same day.

Comments:

1. There was inordinate delay to do USG abdomen which was advised in 2016 till 2024 and the diagnosis remained uncertain. Subsequently, in 2024 the patient became more symptomatic with increasing constipation and loss of appetite .



2. In February 2024 CECT done at Sri Aurobindo Seva Kendra which reports either chronic inflammatory mass or neoplasm causing subacute intestinal obstruction.

3. Exploratory lapratomy was done at Monipal Hospital Broadway after transfer on February 8, 2024 under General Anaesthesia on February 9, 2024. Biopsy was awaited. She did have low BP all through operation and supported with fluids. Post operatively she developed septic shock and was under care at ICU of Manipal Boardway Hospital.

4. She was sick on critical care and patient's son pretend to take her to Dum Dum Medical Centre with DAMA on specific request. The shift of very sick patient on 12 February, 2024 is unexpected and unwarranted on the part of Manipal Boardway (AMRI) Hospital despite DAMA .

5. Patient died from ongoing septic shock with acute kidney injury leading to death on February 13, 2024 at Dum Dum Medical Centre which is most unfortunate."

DR. M L SAHA

"Mrs Chhabi Bhattacharyya mother of Mr Bhaskar Bhattacharyya (Complainant) was under treatment under Dr Amitava Chatterjee as an OPD patient at EEDF hospital from 2015 to 2023. She visited him several times with different abdominal complaints during this period of time. All the OPD prescriptions are annexed with the complaints. Once on USG revealed gall stone disease. During these visits she had some bowel complaints but Dr Chatterjee never suspected any bowel pathology and has not asked for any investigations related to bowel complaints. Patient bowel complaints were ascribed to indigestion and was treated accordingly.

On 3rd February 2024 patient presented with S/S of acute intestinal obstruction and was admitted at EEDF Hospital under Dr Tanmoy Chatterjee. Patient was treated with IV fluid, Ryles tube aspiration, antibiotics and PPI. Some investigations were done. Patient was relieved to some extent. Patient was referred to Dr Achintya Das, Surgeon. Dr Das diagnosed acute intestinal obstruction due to umbilical hernia and advised for surgery – Laparotomy and repair of



umbilical hernia. The CT scan report recorded in BHT revealed a mass in right colon- neoplastic/inflammatory mass. However patient son declined to give consent for surgery as he felt patient was not mentally prepared for the surgical treatment. The doctors at EEDF insisted for surgery and on 5th and 7th February it was intimated that either they opt for surgery or do LAMA and take the patient to a higher centre for further treatment. On 8th February patient was shifted to Manipal Hospital(AMRI) and was admitted under Dr Sujit Chowdhury. Patient was referred to Dr Anirban Banerjee, surgeon with the opinion of small intestinal obstruction due to ileocecal mass. Seen By Dr Anirban Banerjee on 8.2.24. and advised for TPN, PAC, RTA and other supportive treatment . A decision was taken for urgent surgery. Once again patient son did not give consent for surgery on 8.2.24. After proper consent on 9.2.24. patient was taken up for surgery. Exploratory laparotomy and right hemicolectomy with primary anastomosis was done by Dr Anirban Banerjee. Patient condition deteriorated in postoperative period with abdominal distension and they suspected internal bleeding. On first postoperative day patient was having low urine output and

hypotension and was kept on IV fluid and vasopressor support. Patient was referred to Dr Ranjan Sarkar and TPN was advised. The hemoglobin level dropped to 7.5gm% on 11.2.24. and one unit PRBC transfused on 11.2.24.

On 11.2.24. a CT scan was advised for diagnosis. The CT scan machine at Manipal Hospital was nonfunctional on that day. The CE sought a high risk consent from complainant for transporting the patient to another centre for CT scan. Patient son declined to give that consent for undergoing CT scan in a different centre. Patient condition continue to deteriorate. Dr Sujit Chowdhury asked for a Straight X ray abdomen and if free gas is found planned for Relaparotomy on 12/2/24 at 9,45 am case reviewed by Dr Sujit Chowdhury and noted significant abdominal distension with suspicion of anastomotic leak and asked for review by Dr Anirban Banerjee for opinion regarding the need for laparotomy. On 12.2.24. at 10am Dr Sujit Chowdhury asked for CT scan and instructed to send the patient to another hospital Manipal Salt Lake for CT scan. Reviewed by Dr Anirban Banerjee and instructed to get the CT scan done from another hospital. Then Note at 11am on 12.2.24. revealed

that patient was having gasping breathing and ABG showing acidosis, hypoxia and high lactate. Advised for elective intubation and advised for shifting the patient for CT scan on vasopressor support.

12.2.24. at 9.30pm it is recorded that patient son does not want to sign the risk bond for shifting the patient to another hospital for CT scan.

There is no other note in BHT after the last note at 9.30pm. The circumstances under which the patient was transferred to Dum Dum Medical Centre is not clear from the BHT. The DAMA summary attached as last page issued on 12.2.24. at 11pm mentioned about critical condition of the patient, also written that patient was advised mechanical ventilation during transit, this was refused by the patient party. But no such informed consent is available in BHT.

In a very serious condition the patient was shifted to Dum Dum Medical centre on 12.2.24. and she breathed her last on the next day on 13.2.24. at Dum Dum Medical centre.

Observation and Comments:-

- It appears that there is failure on the part of Dr Amitava Chatterjee to diagnose the clinical condition of Mrs Bhattacharyya when she was attending to him in his OPD and diagnosis could only be made when she presented with S/S of acute intestinal obstruction due to carcinoma colon. Considering this issue is outside the purview of WBCERC.*
- Once she was admitted with acute intestinal obstruction at EEDF she was properly managed conservatively and was seen by surgeon. Although exact diagnosis was not achieved decision was made for exploratory laparotomy on 4.2.2024.*
- Patients son did not give consent for surgery at EEDF, She underwent surgery on 9.2.24. almost 6 days after the onset of acute intestinal obstruction. The timing of surgery is very crucial in such surgery. The postoperative complications that happened in this patient could have been avoided if surgery was done early.*
- At Manipal surgery was done early on second day of admission. The tumor was resectable and a primary anastomosis was done.*

- *The exact cause of deterioration in the postoperative period was not diagnosed as the CT scan was advised but not done.*
- *As the CT machine was out of order at Manipal Broadway, it was the responsibility of the CE to get it done from their other centre. It was not proper to ask for high risk consent to be signed by the patient relative to get the CT scan from their other centre.*
- *The patient condition was worsening since the operation and on 12.2.24 a decision was taken to shift the patient to Dum Dum Medical Centre by the operating surgeon to curtail the cost of treatment.*
- *The referral note says that the patient was gasping at the time of referral on 12.2.24. It was extremely unfortunate to refer such a patient to another centre.*
- *Dum Dum Medical Centre is not a hospital with higher facilities than Manipal Hospital. They should not have accepted such a cortically ill patient from Manipal hospital.*
- *Patient died on 13.2.24. suggesting that patient was moribund at the time of referral.*

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- *A number of factors was the reason for unfortunate outcome of this elderly lady suffering from colon cancer.*
- *Long delay in diagnosis by treating doctor at EEDF, delaying the consent for surgery by 6 days by the son of the patient and unrealistic approach of treating doctors at Manipal Hospital was the reason for her death.”*

OUR VIEW

On a combined appreciation of facts and carefully going through the expert opinion quoted above, we are ad idem on the issue, the ill-fated patient died due to inordinate delay in diagnosing the actual disease. The patient and her son were equally responsible for their lackadaisical approach to the problem.

The patient had pain abdomen. In 2015 she was advised USG of cervical spine, not the abdomen. She came with the same problem after about 4 months and then after 10 months. We are not sure whether the tests prescribed from time to time, were done or not and if so whether those reports were considered by the concerned doctor on follow up check up however, all the prescriptions, (as many as 7 to

8 visits) for a span of 9 years, there was not a single advice for CT abdomen that was for the first time done by Dr. Tanmoy Chatterjee during in-patient treatment and CT abdomen suggested mass that also explained by the surgeon as herein however the concerned surgeon categorically advised "*Exploratory Laparatomy*". The patient did not agree and went back home taking DAMA. The pain persisted. She was admitted in the second CE where the actual disease could be diagnosed by Dr. Banerjee. This time surgery was done on the very next day. It was too late. The patient had post surgical complication. She was shifted to ICU. She was not in a state to be shifted elsewhere that was categorically informed to the complainant.

The patient was shifted to the third CE despite caution being given by the doctor that the patient was in a critically stage and not advisable to be shifted. She was there in the third set up for about 6 hours and breathed her last.

Medical issues are outside our domain. The complainant is free to choose his course of action on the issue.

On a some total of the situation, we do not find any scope to blame any of the three CEs who are complained of before us.

The complaint is disposed of accordingly.

Sd/-

(ASHIM KUMAR BANERJEE)

We agree,

Sd/-

Dr. Sukumar Mukherjee,

Sd/-

Dr. Makhan Lal Saha

Sd/-

Sri. Sutirtha Bhattacharya, IAS (Retd)- Member

Sd/-

Dr. Maitrayee Banerjee – Member

Sd/-

Smt. Madhabi Das.

Authenticated

Secretary
West Bengal Clinical Establishment
Regulatory Commission.