MINUTES OF GRIEVANCE COMMITTEE MEETING FAISALABAD INSTITUTE OF CARDIOLOGY, FAISALABAD

Faisalabad. F.Y.2022-23 was held on 25-10-2022 at 10:00AM in the Office of the Medical Superintendent, Faisalabad Institute of Cardiology, A meeting of Grievance Committee for Re-tender of Drug/Medicine & Sutures, Cath lab items and Cardiac surgical disposable items

DRUG/MEDICINE AND SUTURES

M/s Friends enterprises

| - | 5 3 | |
|---|--|----------------|
| | Ь | Sr. |
| | Grievance against M/S Hope Enterprises | Description |
| | The firm claims that Tab. Sinopril of M/S Hope Enterprises approved by TEC was rejected in FIC from last many years due to Invalid cGMP They do not have sufficient cardiac experience | Firm Grievance |
| | The firm provided valid cGMP They have sufficient cardiac experience in Govt. institutes | GC Observation |
| | Grievance rejected and product Tab. Sinopril of M/S Hope Enterprises Accepted | Decision |

ANGIOGRAPHY/ANGIOPLASTY ITEMS

. M/s Friends enterprises

|) | | | | | | |
|----------|-----------------------------------|-----------------------------------|-------------------------------------|------------|---|-----------|
| Rejected | No experience with this institute | No experience with this institute | USA | MEDAS | PTCA Guide wire work horse soft tip, moderate support, 0.014 and 300 cm | . 6 |
| Remarks | GC Observation | TAC Observations | Manufactured By / Imported By | Brand Name | Item Name | Item # |

| | · 1 | | | | | | | | | | |
|------------------|---------------------------|------------------|------------------------|--------------------|-------------------|-------------------|--------------------|----------------------|-----------------------|-----------------------|-------------------|
| | <u></u> | | | | | | | | | | |
| | | | | | | | | | sterilized (powdered) | strgical gloves | |
| | | | | | | | | | | | |
| | | | | | | | | | China | Hengsheng, | lalicially |
| | • | | | | | • | | | | • | • |
| embassy attested | Free sale certificate not | gloves | powdered/powdered free | mentioned either | registration, not | On Medical Device | Notarized attached | Hengsheng, China not | M/S Tianchang | Agency agreement from | Not user triendly |
| | ω | O | • | 7 | _ | _ | Ť | • | 71 | • | |
| | attached | embassy attested | Free sale certificate | Notarized attached | Hengsheng, China | Tianchang | from M/S | Agency agreement | Reservation | End user | |
| | 2 | | | | Rejected | | | | | | |

| | - | | | 1 | | | | Sr. |
|---------------------------|-----------------------------|-----------------------------|-------------------------------|--------------------------------------|---------------------------|-----------------------------|---------------------------|----------------|
| er ^k | | | | Grievance against M/S Husnain Pharma | | | | Description |
| | • | | | | • | | The | |
| registration in sales tax | Husnain pharma never have | registration | have medical device | surgical gloves no 7.5 never | Approved brand Comfit of | | The firm claims that | Firm Grievance |
| | • | | | | | | • | |
| registration | The firm provided Sales tax | Medical device registration | said product now doesnot have | been expired. Therefore, the | implemented which now has | Extension given by DRAP was | At time of TEC evaluation | GC Observation |
| rejected | pharma | Husnain | no 7.5 of M/S | surgical gloves | product | accepted and | Grievance | Decision |







2. M/s Cardiac Care

| Rejected | End User reservation | Poor Conduction | Italy | Fiab | ECG Chest electrodes | သ |
|----------|----------------------|------------------|-------------------------------------|---------------|----------------------|-----------|
| Remarks | GC Observation | TAC Observations | Manufactured By / Imported By | Brand Name | Item Name | Item # |

CARDIAC SURGERY ITEMS

1. M/s Friends enterprises

| | 12 | Item # |
|---|--|-------------------------------------|
| | Disinfectant for Instrument (DRAP REGISTERED) | Item Name |
| | Reprodis | Brand Name |
| | Medimark UK | Manufactured By / Imported By |
| | On free sale certificate regarding expiry date, SAE does not matched with providing associated documents | TAC Observations |
|) | The firm provided relevant document | GC Observation |
| | Accepted | Remarks |

De My of

M/s Friends enterprises

| | H | Sr. |
|---|---|----------------|
| | Grievance against M/S Husnain Pharma | Description |
| | The firm claims that triacid N (disinfectant for instrument) brand never have medical device registration | Firm Grievance |
| | The firm provided medical device registration | GC Observation |
| - | Grievance rejected and product triacid N (disinfectant for instrument) of M/S Husnain pharma accepted | Decision |

2. M/s Safeway System Pakistan

| : | |
|---|-------------------------------------|
| 23 | Item # |
| Oxygenator membrane with low priming volume FDA/CE approved with custom pack for neonares | Item Name |
| Braile Biomedica | Brand Name |
| Brazil | Manufactured By / Imported By |
| Invalid authority letter attached Medical device registration not attached EC certificate not attached | TAC Observations |
| Invalid authority letter attached Medical device registration not attached EC certificate attached | GC Observation |
| Rejected | Remarks |

M/s Safeway System pakistan

| | | 2 Gr | | 1 Gr | Sr. |
|---|--|---|---|--|----------------|
| | | Grievance against M/S Flowtronix systems | | Grievance against M/S Flowtronix systems | Description |
| | | | | • | |
|) | have up to the mark suction control and having leakage problem | cardiac surgical disposables FY 2022-2023 as the product does not | The firm claims that One way vent was rejected by FIC technical committee | The firm claims that flowtronix does not have Free Sale certificate for isolator with loop Flowtronix and Cardiac care both are offering products from TPRI China. It is crucial to justify who is authorized to sell this product | Firm Grievance |
| | | Refer back to TEC | | The firm provided relevant document Original Authority letter from TPRI to M/S Flowtronix provided | GC Observation |
| | . J. 1888. c same service | Refer back to TEC | | Grievance rejected and product isolator with loop of M/S Flowtronix systems accepted | Decision |

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3. M/s Flowtronix Systems

Mrs. Iqra Munir, Pharmacist, FIC, Faisalabad.

Engr. Sharaz Ali Bio Medical Engineer FIC, Faisalabad.

Dr. Rehan Riaz Assistant Prof. of Cardiology, FIC, Faisalabad.

Dr. Maqbool Ahmed, PMO, FIC, Faisalabad.

Dr. Shahbaz Ahmad Khiliji, Prof. of Cardiac Surgery, FIC, Faisalabad