Supplier Representative Protocol

1. **Standard**

This protocol aims to serve as a base for compliance and conformance of all Supplier. Representatives that service the Lenmed Group of hospitals.

2. **Scope**

The scope of this protocol is to ensure that proper control and management of the entry of new products and non – formulary supplier representatives in Lenmed hospitals and facilities are supported.

3. **Definitions**

CRICE: is defined as Company Representative in the Clinical Environment (CRICE).

CRICE is a SAMED initiative administered by Masoom Training Solutions (MTS) and is an e-learning programme. Required to be completed by all company representatives who enter the clinical environment and work in the presence of a patient, whether they enter the theatre setting or other areas of the clinical environment such as wards, ICU (Intensive Care Unit), Cath labs etc. CRICE cards are to be renewed yearly by all representatives.

SANS 1541:2004: Are standards that cover requirements for loan set management principles between manufacturers, suppliers, and healthcare facilities. The main objective of these requirements is to standardize the control and management of loan sets.

NOTE: The SANS document should also supply support in the ongoing quality assurance work regarding the handling of loan sets and anything supplied by company on loan.

Formulary Product: refers to a list of pharmaceutical products, defined as medicines in accordance with the Medicines and Related Substance Act 101 of 1965 as well as surgical consumables and medical devices, which are preferred for use within Lenmed Group of hospitals.

Non-Formulary Product: are pharmaceutical products, surgical consumables and medical devices not preferred by Lenmed and not allowed to be marketed in Lenmed hospitals.

Training: Organized activity aimed at imparting information and/or instructions to improve the recipient's knowledge or to help him/her reach a required level of knowledge or skill.

4. **Guiding Principle**

- To ensure patient privacy and safety
- To control the marketing of products by supplier representatives within our hospitals.
- To limit risk through cost benefit assessment of new products prior to use
- To encourage formulary product compliance
- To develop and sustain good supplier relationships.

5. **Confidentiality**

All information relating to a patient's details and treatment, purchasing and utilization transactions are solely the property of the patients and Lenmed Group, respectively. It is unethical and potentially harmful for the reputation and competitive position of the company to directly or indirectly disclose any information obtained and processed by the Company.

Please take note of the following:

Any file and documentation containing sensitive information is confidential and should be appropriately protected from the public or supplier representatives. Supplier representatives shall only be permitted to access data to the extent that they require access to such data for specific purposes.

Although the list is not exhaustive, supplier representatives must be prevented from obtaining confidential information in the following ways:

- By leaving sensitive files and documentation on an open desk during discussions with supplier representatives.
- By taking photos / videos with smart devices, Exception will only be made if the supplier representative is taking a photo for a doctor's records using the requesting doctors' phone.
- During conversations (including telephonic) between employees in proximity with supplier representatives.
- Allowing supplier representatives access to restricted areas or data storage areas when not required for a permitted purpose.
- Displaying sensitive information/ company strategy on screens or boards in public areas.

Direct / indirect derogatory and inflammatory remarks about any competitors' company, personnel, tender award(s) and or product(s) is prohibited. It is important and compulsory that all permanent and temporary employees are to comply with confidentiality and the Promotion of Personal Information Act No. 4 of 2013 (POPIA).

6. Visits

6.1Appointments

Representatives will only be allowed into hospitals by invitation. Pharmacy personnel, clinical engineers or the theatre managers will contact representatives if support, training or help is needed. Scheduling an appointment will prevent Ad hoc representative visits disturbing the pharmacy, clinical engineer, and hospital staff. By managing the entry of representatives, staff will be able to prevent the marketing of non-formulary items that could jeopardise current formulary agreements. Supplier representatives must obtain permission from the responsible clinical engineer (in relation to medical equipment) and pharmacy personnel (regarding pharmaceutical consumables & medical devices) before scheduling appointments with Lenmed staff or doctors (e.g., tearoom appointments).

Preference will be given to supplier representatives from formulary suppliers. For all products that are not covered by a formulary, permission will be granted at the discretion of the pharmacy manager or clinical engineer. Supplier representatives must be aware that it is a privilege and not a right to conduct business in hospitals/institutions and must always be sensitive to the working pressures and environment of personnel.

6.2Visit Protocol

Supplier representatives should be received in a friendly, courteous, and professional manner.

All supplier representatives are to present their CRICE cards upon entry at the pharmacy. Access will be restricted to the wards, ICU's, theatre and sterile areas and access will be granted following the level of training (Refer to card colour indicators).

GREEN CARD ACCESS: CRICE trained which include Sterile Area entry.

BLUE CARD ACCESS: CRICE trained but excludes Sterile Areas.

WHITE CARD ACCESS: CRICE trained only allowed in GENERAL Areas.

If a supplier representative cannot be seen due to work commitments, they should be notified prior to the scheduled appointment and an alternative appointment should be agreed upon.

If a supplier representative arrives at the pharmacy without an appointment, it is up to the pharmacy manager or the relevant person in charge, to decide whether the representative can be seen or not. If the representative cannot be seen at the time, a future visit can be arranged, if applicable.

6.3Authorisation

Supplier representatives will not be allowed to visit nursing staff in the wards and theatre before permission is obtained from the pharmacy manager or pharmacy manager appointed personnel (for pharmaceutical consumables) and the clinical engineer (Regarding medical equipment).

Supplier representatives will only be allowed in theatre and the wards with written permission from the pharmacy manager/clinical engineer. This permission will take the form of a designated sticker for easy identification and will detail the requesting hospital name and purpose of the visit. Permission granted is valid for allocated timeslots on allocated days only.

Supplier representatives will only be allowed into the hospital for general training and demonstrations of products between the hours 10:00 to 14:00. Other appointments for additional training and assistance required by doctors for theatre procedures may be arranged as per hospital requirements. Doctors requesting any form of assistance from representatives in theatre, will not be restricted to the 10:00 to 14:00 timeslot.

The management of representatives wishing to see anaesthetists will be managed by the hospital management team. A register should be kept of the representative visits.

The following information must be included in the register:

- Date of visit
- Name of supplier
- Name and signature of representative
- Unit/s to be visited
- Reason for visit
- Level of CRICE clearance
- Signature of Pharmacy Manager/Pharmacist/Inventory Manager/ Senior Pharmacy Representative.

If a supplier representative bypasses the pharmacy or clinical engineer, it will be the responsibility of the nursing staff to refer them back to the pharmacy or clinical engineer to obtain the necessary authorisation. Supplier representatives not complying with these protocols will have their visits reviewed and may be denied future access into the units.

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7. Product Management

7.1Pharmaceutical and Surgical products.

Non - formulary products may not be marketed in the hospital to nursing, theatre or pharmacy staff. In case of this occurring, it must be reported to the pharmacy manager immediately.

If the supplier representative would like to introduce a new product or should a unit/s or a Doctor request a new product the first line of call is to approach the pharmacy manager.

If this product category is covered by a formulary, the pharmacy manager must refuse the introduction or detailing of this product. Should the product supply better cost benefits and improved quality/clinical efficacy compared to the formulary product, the requesting doctor/s are to sign off the new product requests before it is sent to the Procurement Department for review.

If the product is not covered by the formulary, the pharmacy manager must make the decision whether to meet with the supplier representative.

If the pharmacy manager is unsure as to whether this product is covered by the formulary or not, they must do a formulary search on the Lenmed Gateway (Under Pharmacy Practice, Applications, Formulary Search) to establish the formulary status of the product. If the pharmacy manager is unable to obtain the required information, they should then contact the Procurement Department by logging a general query on Info Quest.

7.2Medical Equipment

If the supplier representative would like to introduce any medical equipment or if this is requested by the unit or doctor the first line of call is the clinical engineer.

In the event of any equipment being placed within the hospital the company placing such equipment needs to obtain permission from the clinical engineer and complete the standard Lenmed placement agreement.

Demonstration of medical equipment is to be coordinated and arranged through the hospital clinical engineer and to be done according to Lenmed policy and procedure.

7.3Samples

Scheduled Ethical Products (S1-S6)

Act 101 of 1965 prohibits the sampling of medicines. No manufacturer, wholesaler, or its agent shall supply free medicine to any Healthcare Professional. Surgical Products and Unscheduled and S0 Ethical Products Supplier representatives may not distribute samples to pharmacy or nursing staff without the authorization of the pharmacy manager.

The pharmacy manager must refuse samples of a non-formulary product. All product evaluations must be approved by the Procurement Department. In the event of an evaluation, the pharmacy manager will be given a product evaluation form by the respective supply manager reviewing that product.

7.4Product Training

Should nursing staff request to be trained on a specific product, the pharmacy manager (if related to pharmaceutical consumables) and/or the clinical engineer (if medical equipment related) need to be notified. The supplier representative involved will be contacted and the training will be arranged by the pharmacy manager or the clinical engineer respectively, in conjunction with the unit manager and/or clinical nurse specialist.

7.5Product and/or Supplier Assessment (Complaints)

In the event of a product or a supplier service complaint, the pharmacy manager (in cases involving pharmaceutical consumables) and/or the clinical engineer (in cases involving medical equipment) must contact the relevant supplier representative to assist in resolving the problem.

All ongoing product complaints or service issues that are unresolved despite attempts by the pharmacy manager and/or clinical engineer to rectify them, must be recorded on Info Quest. All defective products must be kept for the supplier to investigate as per the protocol set out in Q-learning – (Q-LEARN-PHAR-18-001).

8. Restricted Areas

8.1Pharmacy

No representative may enter the pharmacy or the pharmacy storeroom without permission from the pharmacy manager or responsible pharmacist. If permission is granted the supplier representative, he/she must be accompanied by the pharmacy manager or a pharmacy manager always appointed person.

8.2Wards and ICU

Supplier representatives are not allowed into the wards without permission in accordance with this protocol. If a supplier representative is found promoting products that are in direct competition to the formulary, it must be reported to the Procurement Department. Supplier Representatives not complying with this protocol, caught not wearing an identification sticker or found promoting a product that is in direct competition with that of the formulary product will have their access denied to all Lenmed hospitals for 6 months to a year.

8.3Theatre

No representative is allowed into theatre without permission from the clinical engineer, pharmacy manager or theatre manager. Supplier representatives that are requested to assist in theatre cases will only be granted access if patient consent has been obtained by the doctor for the supplier representative to be present for the procedure. Consent forms must be handed to the theatre staff to be kept on file before entry into theatre. Supplier representatives entering theatre must report to the theatre unit manager (Or the second in charge), present their green CRICE card and comply with the requirements in theatre. The theatre unit manager will arrange for orientation to the theatre. Proof of orientation and CRICE card will be kept on file in the theatre.

Theatre manager / second in charge are to make sure that all supplier representatives entering theatre with loan sets must adhere to the loan set guidelines as outlined in SANS – Hospital Loan Sets: 2014 edition1. Inventory checks on loan equipment and stock must be done on delivery in the presence of the unit responsible person in accordance with the SANS 1541: 2014 edition1 guidelines.

Should a supplier representative wish to demonstrate any surgical products in theatre to either the staff or Doctor, they will need to first obtain permission from the pharmacy manager who will liaise with the theatre manager in this regard. Costs involved with any such demonstration will be for the supplier's account. This stock will be considered to be sample stock unless other arrangements have been made with the pharmacy manager.

All supplier representatives wanting to demo or promote any form of medical equipment, permission must be gained from the clinical engineer before they are allowed into theatre.

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9. Gifts and Sponsorship

Any external training with or without additional cost must be assessed as per the Lenmed Code of Ethics policy. Refreshments may only be provided to staff/doctors during a scheduled training session. The management of gifts must be in line with the Lenmed Code of Ethics.

10. Escalation Process for Non-Compliant Representatives

If representatives do not comply to the rep protocol, the pharmacy manager or clinical engineer must meet with the defaulting representative and try resolve issues one on one. If the event reoccurs, both the representative and them respective product manager is to be called in for a meeting.

If the dispute is unresolved, the pharmacy manager or clinical engineer should refuse the defaulting company representatives' access to the hospital and report the matter to the Procurement Department via Info Quest – General Queries.

Access will only be granted to the transgressing company once the Pharmaceutical Procurement Department is satisfied that similar transgressions will not reoccur in the future.

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