March 2008

PHARMACEUTICAL REPRESENTATIVES POLICY

1.0 General Information

In order to minimize disruption to patient care services, to promote fair and equitable purchasing practices, to guard against conflict of interest, and to maintain compliance with the law, the Aga Khan University Hospital, has established the guidelines that Pharmaceutical Sales Representatives must follow when promoting their products in the Aga Khan University Hospital, Nairobi.

2.0 Registration of Pharmaceutical Representatives

This was waived

2.1 All Pharmaceutical Sales Representatives visiting the hospital must first register their visit at the Main Pharmacy Department and get permission from the Pharmacy Department to visit any other areas of the hospital.

2.2 The product to be promoted must have passed the Technical Evaluation Form before the representative will be given permission to proceed with detailing of the product.

2.3 The Pharmaceutical Sales Representatives must wear the Pharmacy and poisons board identification badge, clearly stating the representative's name, designation and company they represent.

2.4 The pharmacy department will provide a permanent identification badge (with an annual renewal fee of KShs 1200), or a temporary identification badge for one-time user KShs150)

2.5 Each representative must sign in with Pharmacy Department, stating their destination, the individuals with whom they have an appointment, and the time of sign-in.

CHARGES – CONSIDER REMOVING

3.0 Pharmaceutical Representatives Visit

3.1 All Pharmaceutical Representatives must wear a Hospital provided identification badge at all times while on the Hospital premises for the purpose of conducting business. The badge must be easily visible.

3.2 Routine pharmaceutical sales visits normally should be during working hours provided work is not disrupted

3.4 The Pharmaceutical Representatives are not permitted to enter the pharmaceutical store areas in MMD.

3.5 Detailing of pharmaceutical products in the clinical areas of the hospital is strictly prohibited.

3.6 The detailing package must include the following:

- 3.6.1 Registration Certificate with PPB (not the applicant letter for registration)
- 3.6.2 Complete product monograph
- 3.6.3 All relevant studies on the product
- 3.6.4 Independent studies on safety and efficacy are to be made available. Comparisons with the innovator product, and if superior, comparisons to a product that is already available should also be included. Bio-equivalence studies to be availed in case of antibiotics
- 3.6.5 Pricing information
- 3.6.6 Sample of the medicine

3.7 The Pharmaceutical Representative is prohibited from rounding with Physicians.

3.8 The Pharmaceutical Representatives will return their badge and sign out at Main Pharmacy Department at the completion of their appointment.

4.0 Pharmaceutical samples and Evaluations

4.1 Free sample of medicines will be received only through the Pharmacy for the purpose of product assessment and may not be used to induce prescribing.

4.2 Product samples are not allowed to be distributed in any areas of the hospital.

4.3 If a physician specifically requests a sample, the product sales representative must deliver the requested sample directly to the physician.

4.4 In a situation that a sample has to administered to a hospitalized patient, the sample must be processed through the Pharmacy Department and an approval obtained from the Pharmacy and Therapeutics Committee

5.0 Price/ Contract Negotiation

5.1 The Pharmacy and Therapeutics Committee will/ may advice MMD-Pharmacy Store on the pricing.

5.2 The actual pricing/ negotiations as per the existing hospital purchase policy.

6.0 Educational sessions/ Product detailing

6.1 Through the office of Chief of Staff, Pharmaceutical representatives can organize an educational session for all Health care workers.

6.2 The meetings should be mediated by a consultant level physician.

6.3 The sessions can be booked through the Chief of Staff Secretary or the CME coordinator, both attached to the Chief of Staff's Office.

6.4 The sessions will be held in the Lecture Theatre every week on Wednesdays and Fridays between 1.00pm-2.00pm.

6.5 The booking will be on first come first served basis, unless extraneous circumstances warrant change. A nominal fee may be charged.

6.6 The Pharmaceutical Representative will have 20 minutes for the presentation and then 20 minutes for question/answer session.
TIMINGS/ VENUE MUST BE FLEXIBLE TO REDUCE OR PREVENT INTERFERENCE

7.0 Appointments to see Pharmacy Manager

7.1 In order for the Pharmacy Manager to book an appointment, the product must have passed the Technical Evaluation form available at the Main pharmacy. Appendix 1

7.2 Appointments to see the Pharmacy Manager can be booked on Tuesday and Thursday mornings through her secretary.

7.3 A slot of twenty minutes will be allocated per company and a maximum of two appointments per company per month.

7.4 The company must present the following documents before a new product will be considered for inclusion in the Pharmacy:

7.4.1 Application for New Drugs Form (available from Pharmacy Department) accompanied by:

i. Registration Certificate must be submitted (not the applicant letter for registration)
ii. Complete product monograph
iii. All relevant studies on the product
iv. Independent studies on safety, efficacy to be made available.
v. Information comparing with innovator product, and if superior to product already available. Bio-equivalence studies to be available in case of antibiotics
vi. Pricing information
vii. Application must be received at least one month before the next Pharmacy and Therapeutics Committee Meeting for Pharmacy Department to assess and prepare a report.
viii. Sample of the drug
ix. The molecule must be FDA/EMEA approved
x. The product must be registered in the country of origin (proof attached) – as per the brand name
xi. The Company must have attained certification from accredited bodies such as MCA, WHO, FDA e.t.c.
xii. No herbal products will be considered

7.4.2 Footnote: In case the quality of the product needs to be assessed, the hospital pharmacy will send samples to an independent laboratory at the supplier's expense

7.5 The new products will finally be evaluated, vetted and approved at the Pharmacy and Therapeutics Committee.

DROP PRODUCT INFO THE DAY BEFORE APPOINTMENT

8.0 Employee Responsibility

Each member of the Aga Khan University Hospital must report violations to this policy to the Pharmacy Manager/ Chief of Staff.

9.0 Gifts, Gratitudes and Entertainment

9.1 AKUH will not knowingly accept anything of value (including gifts, gratitudes or entertainment) offered by a Pharmaceutical Representative to induce or gain acceptance of the medicine.

9.2 Departments may not accept anything of value from potential or current suppliers except promotional or advertising items of nominal value (pens, pads) or food that is given as part of a legitimate educational session.

9.3 Donations to Pharmacy Department or any other Department for the purposes of training of personnel must be made through and approved by the Chief Operating Officer/ Chief of Staff

10.0 Violations

10.1 Pharmaceutical Representatives must refrain from actions that undermine the functions of the hospital formulary or any other policy on medicines.

10.2 Any Pharmaceutical Representative who falsifies any provided information, or violates any Hospital policy or procedure will be issued a first warning in writing. This warning will be sent to the Pharmaceutical Representative's Supervisor.

10.3 A second violation of the terms of this policy or any other Hospital policy or procedure may result in that Pharmaceutical Representative being banned from the Hospital for 30 days.

10.4 A third violation may result in the Pharmaceutical Representative being permanently banned from the hospital.