GUIDELINE ON SUBMITTING REGISTRATION SAMPLE TO NMQAL

Registration Sample of Medicines, Medical Devices and Borderline Products to National Medicines Quality Assurance Laboratory (NMQAL)

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SUBMITTING REGISTRATION SAMPLE TO NMQAL GUIDELINE

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1. INTRODUCTION

As per the NMRA Act No o5 of 2015 main role of the NMQAL is the testing of the quality of medicines, medical devices or borderline products submitted by the Authority including the articles which are submitted with the application for registration.
The guideline is directed primarily at laboratory personnel, although regulatory pharmacist and the local agent/ manufactures need to be aware of the steps involved in sample receipt.
Effective communications between regulatory divisions and the laboratory not only facilitates problem resolution but also prevents unnecessary delays in the analytical process.
Sample receipt activities need to be done in a timely manner to allow the laboratory and NMRA to resolve any problems on quality testing of registration samples.

2. SCOPE

This chapter provides guidance on laboratory samples receiving for registration purposes.

3. PROCEDURES

3.1 Requirement for quality testing

Before the samples are received laboratory should aware the conformity of sample with registration dossier and the requirement of quality testing.

NMQAL may receive the registration samples for quality testing upon following criteria;

I. Request for sample testing to be mentioned in Dossier Evaluation sheet.
II. Samples for analysis should be submitted for the following products at the time of submitting dossiers for registration

- Meropenam for injection
- Erythromycin (all dosage forms)
- Thyroxin (all dosage forms)

Local agent should submit the request for quotation for Quality testing to the Technical unit/NMQAL with following documents.

- The Evaluation sheet / The Acknowledgement of the registration dossier.
- The product label which is attached to the dossier. (Need to be certified by the NMRA)
- The analytical method for in-house specifications. (Need to be certified by the NMRA whether it is the same copy which is attached to the registration dossier)

NMRA should provide any other special instructions regarding the decision taken for samples to the laboratory on case by case basis.

3.2. Review of competency of sample testing

Laboratory should review of competency for sample testing, the types of analyses that are expected for the samples, before receiving the sample.
Request for sample analysis submitted by the local agent should distribute to the sectional heads of the relevant division at NMQAL.
Sectional heads should review the request with the relevant testing monograph and to be send information on tests which can be carried out by the division depending on the availability of

chemicals and reference standard to the Technical unit. (Referred pharmacopeia monograph need to be attached).
Turn over time for this will be two weeks.

3.3. Payment voucher arrangement.
Cost for the quality testing should be finalized based on the number of tests which can be carried out in the laboratory.
Senior Pharmacist at Technical unit should prepare the payment voucher based on the number of tests to be carried out and the fee for analysis

Payment vouchers to be checked by the chief pharmacist/NMQAL and approved by the D/NMQAL, and then handed over to the local agent.
Prior to payment for quality testing, local agent need to discuss with regulatory division on adequacy of number of tests which can be carried out for the product is satisfied or not for the registration.

3.4. Receipt of Sample.
Then Minimum number of the samples required for quality testing to be submitted with the yellow receipt (issued by the Accounts Branch/NMRA) to the Technical Unit/NMQAL.
Laboratory sample receipt occurs when a package containing samples is accepted
Senior Pharmacist at the Technical unit/ NMQAL should receive Samples and distributed to the relevant laboratory divisions.

4. STANDARD OPERATING PROCEDURES

A laboratory should have standard operating procedures (SOPs) for activities related to registration sample receipt and distribution.
Laboratory SOPs should describe sample management system including chain-of-custody procedures giving a comprehensive list of the elements in the program such as signing the appropriate custody forms, storing samples in a secure area.

5. REGISTER LOGS

The laboratory should keep a register (log) of all quotation requests, payment vouchers and payment receipt on registration samples.

6. REFERENCES

- WHO Handbook on laboratory quality management system

7. FEEDBACK

7.1 Staff and customers may provide feedback about this document by emailing info@nmra.gov.lk