# Using Formulary Drugs For Un-approved Indications

**APPLIES TO:** Pharmacy, Medical, and Nursing staff.

### 1.0 PURPOSE

1.1 To provide systematic procedure in dealing with prescribing formulary drugs for un-approved (unlicensed) indication (Unlabeled use of drugs).

1.2 To help detect and prevent diversion of drugs for unauthorized purposes, and assure compliance with applicable laws and internal requirements related to the use of formulary drug for un-approved indications.

### 2.0 DEFINITION

2.1 **Formulary Drug:** Registered medications currently available on hospital drug list.

2.2 **Un-Approved Indication:** The use of a drug product in doses, patient populations, routes of administration, or for indications that are not included in FDA, EMEA, or SFDA-approved product labeling.

### 3.0 RESPONSIBILITY

3.1 **Most Responsible Physician:** Fill a special request Form detailing the use of un-approved drug for investigational purposes.

3.2 **Head of Pharmacy Department:** Defines the duties and responsibilities of the pharmacy staff in checking the un-approved drug indication before referring to P&T Committee.

### 4.0 CROSS REFERENCES POLICY

4.1 N/A.

### 5.0 POLICY

5.1 The Pharmacy Department has an effective and consistent policy on how to dispense a formulary drug for un-approved indication (unlabeled use) in compliance with MOH and the CBAHI Standards.

5.2 Only consultant physicians are allowed to prescribe formulary drugs for un-approved indications.
5.3 The physician’s department head must approve every single case where formulary medication is used for un-approved indication or investigation.
5.4 Every individual case where a formulary medication is used for un-approved indications will be clearly documented on a special request form.

6.0 PROCEDURE

6.1 In case the Most Responsible Physician decides to prescribe a medication that is not licensed for the indication, for certain admitted patients after all therapeutic alternatives have been tried and failed and it is the only hope for the patient, the following steps shall be followed:

6.1.1 The physician shall fill a special request form detailing the use of a formulary drug for un-approved indication (Unlabeled use).
6.1.2 The physician should specify the un-approved indication and provide document(s) that support the rationale for the use of the drug for that indication.
6.1.3 The filled request (Form-B) should be approved and signed by the physician’s department head, and sent to the Department of Pharmacy for reviewing and dispensing.
6.1.4 If the medication is available in the hospital, it will be dispensed to patient as a unit-dose.
6.1.5 In case the drug is not available, the head of the Pharmacy Department will make a request to (MOH) Medical Supply, or inform the physician to make a direct purchase request if it is not available in MOH Medical Supply.
6.1.6 Once the Pharmacy Director receives the requested medication from MOH Medical Supply or by direct purchase, the medication will be sent to the satellite pharmacy where the patient is admitted to be dispensed to patient as a unit-dose while patient is in the hospital.
6.1.7 The physician will be informed as well of the availability of the medication.
6.1.8 If a patient is to be discharged from the hospital, and there is a need to continue treatment at home of the same medication, the patient must be informed of the place where it is available.
6.1.9 All approved requests are kept in a special file at the Main Pharmacy.
6.1.10 The pharmacy department will submit all cases of using formulary medication for un-approved indication or investigation to the P&T Committee for reviewing and monitoring.
7.0 FORMS
   7.1 Form-B (Use Of Formulary Drug For Un-Approved Indication)

8.0 EQUIPMENT
   8.1 N/A.

9.0 REFERENCES
   9.1 CBAHI resource manual.