HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER
MATERNITY AND CHILDREN HOSPITAL

Department:	Pharmaceutical Care Department		
Document:	Multidisciplinary Policy And Procedure (MPP)		
Title:	Off labelled Unlicensed/Unapproved Use of Medication		
Applies To:	Pharmacists and Physicians		
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1. PURPOSE:

1.1 To prevent exposure of patients to drugs that demonstrates lack of safety and clinical benefits
1.2 To outline the process of requesting a medication for unlicensed/unapproved use

2. DEFINITONS:

2.1 Drugs with off-labeled, an unapproved/unlicensed use of a medication may include but is not limited to: Formulary medication that is not approved by Ministry of Healthy (MOH) Pharmacy and Therapeutics Committee (PTC) or reference countries/drug authorities: Saudi Arabia FDA, USA, Canada, UK, and EMA for this particular use (indication, dose, route, duration, or age group).
2.2 Off-labeled, an unapproved/unlicensed use of a medication form: MCH pharmacy approved form that should be completed by a treating consultant and signed by the head of pharmacy before dispensing to patients

3. POLICY:

3.1 All drugs with 0ff-labeled use must have an application form.
- 3.1.1 All forms must be maintained in Pharmacy file for reference.
- 3.1.2 Any use of a medication (formulary or non-formulary) for an unlicensed/unapproved indication, dose, duration, route or age group should be limited to situations where an adequate trial of all approved therapeutic alternatives has failed due to ineffective treatment, adverse reaction or intolerance
- 3.1.3 Consultant physicians can request for an unlicensed/unapproved use of a formulary or non-formulary medication for an individual patient by submitting the Unlicensed/Unapproved Use of Medication Form provided that there is supporting evidence from the literature.
- 3.1.4 The completed Form of Unlicensed/Unapproved Use of Medication has to be reviewed and approved by the Director of Pharmacy
- 3.1.5 Off-labelled medication use must be submitted to the Pharmacy and Therapeutics Committee for evaluation and approval.

4. PROCEDURE:

4.1 Physicians may consider using a medication for unlicensed/unapproved indication, dose, duration, or age group
4.2 Consultant shall complete form of Unlicensed/Unapproved Use of Medication.
4.3 The Head of Pharmacy to revise the form and drug brochures as well as any relevant studies concerning such issue and forwarded to Pharmacy and Therapeutic Committee for approval/disapproval.
4.4 The Head of Pharmacy should report to MOH all approved drugs as per Saudi Ministry of Health regulations
4.5 Pharmacy Dispensing Procedure:

4.5.1 Receive completed physician order or prescriptions sent to the appropriate pharmacy by hand delivery.

4.6 Orders should specify:

4.6.1 Patient name.
4.6.2 Patient medical record number.
4.6.3 A space for the subject height, and weight if applicable.
4.6.4 Drug name and strength, if applicable.
4.6.5 Dosage and the total number to be dispensed.
4.6.6 The instruction, including the route and frequency of administration.
4.6.7 Any additional information necessary to ensure proper dispensing and administration.

5. MATERIALS AND EQUIPMENT:

5.1 Drug Request of Off-Labeled Use Form.

6. RESPONSIBILITIES:

6.1 Consultant physicians
6.2 Head of pharmacy
6.3 Pharmacy Staff

7. APPENDICES:

7.1 N/A

8. REFERENCES:

8.1 Unlicensed/unapproved use of medication policy for MOH

9. APPROVALS:

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