Health Authority – Abu Dhabi		هـيئـــة الصحة أبوظبي
Division/Department/Section: PHP/PHM Subject: Generic Drugs Policy		Reference Number: PHP/PHM/P0003/09
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1 Purpose

1.1 The Health Authority – Abu Dhabi (HAAD) supports the use, within the healthcare system in the Emirate of Abu Dhabi, of medication that provides the optimum therapeutic benefit to patients in the most cost-effective manner.

1.2 Generic drugs can be as effective as their brand-name alternatives, but at a lesser cost. They therefore allow patients' access to appropriate medications at the best possible price.

1.3 The purpose of this Policy is to ensure that generic drugs will be prescribed and dispensed wherever it is appropriate to do so.

2 Scope

2.1 This Policy applies to –

- Pharmacists
- all other Healthcare Professionals who have the authority to prescribe drugs (Physicians)
- Healthcare Providers in whose facilities such Pharmacists or Physicians are employed.

2.2 This Policy provides that –

- Physicians must (subject to certain exceptions) prescribe Drugs by their generic names.
- Pharmacists must not engage in the therapeutic substitution of drugs.
- Physicians must use a standard prescription form to prescribe drugs and Pharmacists must take certain steps before dispensing them.

3 The Duties on Physicians

Duty to use the standard form

3.1 Any Physician who prescribes medication for a patient must –

(a) Do so by completing the standard form of prescription at Appendix A, and

(b) complete all sections of the standard form in a legible manner, and sign and stamp the form before issuing it to the patient,

except where the medication being prescribed is a controlled drug, in which case the standard form need not be used.

Duty to use Generic Names

3.2 Any Physician who prescribes medication for a patient must refer to the medication in the prescription by its Generic Name unless one of the exceptions set out below applies.

Exceptions to the Duty to use Generic Names

3.3 A Physician who prescribes medication for a patient may choose not to prescribe the medication by reference to its Generic Name where that medication is -

(a) a drug registered with the Federal Ministry of Health as an 'over-the-counter' drug or 'general sale product',
(b) a dietary supplement or food supplement,
(c) a herbal or homeopathic remedy,
(d) a vaccine or insulin preparation, or
(e) a drug listed at the relevant time in Part I and part II of Annex B.

3.4 A Physician who prescribes medication for a patient may also choose not to prescribe the medication by reference to its Generic Name where to do so would place that patient's health at risk because the patient -

(a) has a documented history of an allergic or other adverse reaction to a particular Generic Drug, or

(b) has previously suffered unsuccessful therapeutic control with a Generic Drug.

3.5 Where a Physician prescribes a Brand-name Drug on one of the grounds permitted by paragraph 3.4, he or she

(a) must also place the phrase 'Do Not Substitute' or the initials 'DNS' next to the name of the item being prescribed,
(b) must document the reasons for prescribing a Brand-name Drug in the patient record, and
(c) must be able to give the reasons for prescribing a Brand-name Drug if requested to do so by HAAD.

4 The Duties on Pharmacists

Prohibition of therapeutic substitution

4.1 A Pharmacist must not dispense a Therapeutic Substitute for a prescribed medication unless he or she has first obtained the consent of the prescribing Physician.

Restriction on substitution of Brand-name Drugs

4.2 A Pharmacist must not dispense a Generic Drug in place of a prescribed Brand-name Drug where the prescribing Physician has placed the phrase 'Do Not Substitute' or the initials 'DNS' next to the name of the item being prescribed, but

Duties when dispensing

4.3 A Pharmacist must review a patient's medication on each occasion before dispensing drugs to that patient.

4.4 A Pharmacist must, in dispensing to patients on long term therapy -

(a) be consistent over time in the selection of Generic Drugs that are dispensed, and

(b) where it is necessary to dispense a Generic Drug under a different brand name to that of the same Generic Drug which was previously dispensed to the patient, explain to the patient that the medication remains the same in substance.

4.5 Subject to the prohibitions and restriction as per sections 4.1 and 4.2, a Pharmacist may offer the patient different drug product alternatives of the same chemical entity with the same dose and dosage form as prescribed by the Physician and allow the patient the opportunity to choose which product he/she would prefer.

4 The Duty on Healthcare Providers

5.1 Each Healthcare Provider must

(a) ensure that Healthcare Professionals employed by it at the healthcare facilities that it operates comply with any duties placed on them under this Policy.

(b) have sufficient stocks of drug products to facilitate patient access to quality and cost-effective drugs and
achieve compliance with the provisions of this Policy.

(c) maintain, and make available for HAAD audit, a list of all drug products, brand name and their generic names along with their prices available at the pharmacy.

(d) maintain, and make available for HAAD audit, a list of all drug products dispensed at the pharmacy.

(e) comply and cooperate with the HAAD authorized auditors, as required for inspections and audits by
HAAD.

6 Enforcement and Sanctions

6.1 Where a Healthcare Professional or Healthcare Provider is in breach of a duty under this Policy, HAAD may take any or all of the following actions –

(a) suspend the licence of the Healthcare Professional or Healthcare Provider for a period of time that HAAD determines to be appropriate in the circumstances of the case,

(c) revoke the licence of the Healthcare Professional or Healthcare Provider.

HAAD may impose sanctions in relation to any breach of this Policy in accordance with [the HAAD Policy on Enforcement and Sanctions]. Decisions on suspending and/or revoking of licences will be determined by considering the circumstances of the case and consistent with the terms and procedures of the HAAD Licensing Committee and in accordance with the measures under the law.

7 Definitions

7.1 In this Policy, the following words and phrases shall be taken to have the meanings given below .

Brand-name Drug	A pharmaceutical product that is manufactured and sold by its originator or by a company acting on behalf of the originator.
Generic Drug	A pharmaceutical product that is no longer protected by a patent or exclusive licence held by its originator, and which is manufactured and sold (whether under its Generic Name or a brand name) by a company which is neither the originator nor a company acting on behalf of the originator.
Generic Name	The name of the active pharmaceutical ingredient within a form of medication.
Healthcare Professional	An individual working in the healthcare sector in the Emirate of Abu Dhabi who is required to hold a licence from HAAD.
Generic substitution	Pharmacist initiated act by which a different brand or unbranded drug product is dispensed by the Pharmacists without substituting the chemical entity and in the same dose and dosage form as prescribed by the Physician.
Healthcare Provider	An entity operating a healthcare facility in the Emirate of Abu Dhabi which is required to hold a licence from HAAD.

Pharmacist	A Healthcare Professional who is authorised by HAAD to practice as a pharmacist in the Emirate of Abu Dhabi.
Physician	A Healthcare Professional who is authorised by HAAD to prescribe drugs in the Emirate of Abu Dhabi.
Therapeutic Substitution	A drug which, in its relationship to a prescribed drug, is – (i) within the same therapeutic category but chemically different (e.g. which has the same relationship to the prescribed drug as ranitidine has to cimetidine, or chloramphenicol has to erythromycin), or (ii) a different moiety of the same parent compound (e.g. which has the same relationship to the prescribed drug as ofloxacin has to ciprofloxacin).

8 Guidance

8.1 Further information for guidance on the operation of this Policy is set out at Appendix C.

APPENDIX A-

Standard Prescription format

Facility Logo / Address

Patient Full Name ----------

Age ---------- **Address** ----------

Weight ---------- **Medical Record No** ----------

Phone number ----------

Diagnosis		Generic Name / Dose / Form	Instructions and Route	Duration	Quantity	Refill
Primary / Secondary Diagnosis Code(s)	_ _ _._ _	**1.**				
	_ _ _ _._ _	**2.**				
	_ _ _ _._ _	**3.**				
	_ _ _ _._ _	**4.**				
	_ _ _ _._ _	**5.**				
	_ _ _ _._ _	**6.**				
	_ _ _ _._ _	**7.**				

Doctor name **License Number** **Day** **Month** **Year** **Signature and Stamp**

APPENDIX B

MEDICATION WHICH MAY BE PRESCRIBED BY REFERENCE TO BRAND-NAME DRUGS

The lists in this Appendix are subject to periodic review and alteration at the discretion of HAAD.

The pharmaceutical products listed below are not required to be prescribed by reference to their Generic Names. They have been included on the list based on the specific characteristics of the drug and/or disease to be treated.

PART I

Drugs with a Narrow Therapeutic Range

These Drugs contain certain substances which are subject to therapeutic drug concentration or pharmacodynamic monitoring.

(1) Carbamazipine

(2) Cyclosporin

(3) Digoxin

(4) Ethosuximide

(5) Lithium

(6) Methotrexate

(7) Phenytoin

(8) Valproic acid

(9) Warfarin

(10) Theophylline

PART II

Other Drugs- Other than drugs of a narrow therapeutic range.

[None currently listed]

APPENDIX C

General Guidance

(1) HAAD Pharma /Medicines and Medical Products Department will oversee the implementation of the Generic Drug Policy in the Emirate of Abu Dhabi. It will work collaboratively with all concerned stakeholders including the Health Compliance Division and Health Insurance companies to establish good generic drug prescribing and dispensing practices in the Emirate.

(2) HAAD encourages generic substitution by Pharmacists. In doing so, Pharmacists should prioritize and choose the most cost-effective generic drugs for the patients.

(3) Physicians and Pharmacists will be trained and encouraged to the proper way of utilisation and the economic benefits of generic drugs. HAAD, in conjunction with the Federal Ministry of Health, will where appropriate inform Healthcare Professionals about the bioequivalence of generic drugs, including the decisional criteria used to determine the bioequivalence of individual products.

(3) Physicians should use the standard prescription format (Refer appendix II) for prescribing drugs to their patients. They should legibly fill in all the fields and have the prescription duly signed and stamped before issuing it to the patient.

(4) Physicians have to prescribe using the generic name of the drugs, unless specified otherwise, as in the Policy. The generic prescribing should be, for example as:

Diagnosis code	Generic name /dose and form	Instructions and route	Duration	Quantity	Refill
250.0	metformin 500mg tablets	1 tablet twice daily, oral.	1 month	60	1
250.0	Gliclazide 80mg	1 tablet once daily, oral	1 month	30	1
272.2	Atorvastatin 10mg tablets	1 tablet once daily, oral	1 month	30	1

(5) 'Refill' denotes the process to facilitate the patients receiving their maintenance medications from the Pharmacist, without referring to the Physician, within the limits of the law. In the above prescription, as the Physician denoted 1 under refill, the patient can approach the Pharmacy again (after consumption of his first month medication) and get his prescription filled (refilled) for another month, without referring back to his Physician. Pharmacists shall then document the number of refills with the date on the back of prescription.

(6) Physicians may prescribe brand-name medications (other than those listed at paragraph 3.3 of the Policy) by designating the phrase "DNS" only for those circumstances mentioned in paragraph 3.4.

(7) Healthcare Professionals must report all Adverse Reactions and Medication Errors to the HAAD Pharmacovigilance Center through the Adverse Reaction and Medication Error Reporting Forms (please see contact details below). They should be particularly vigilant in identifying and reporting adverse events that may be related to generic substitution.

(7) The dispensing Pharmacist should counsel the patient, and explain to him/her about differing brand names, so that the patient appreciates the continuity of his/her medicines. The three parties involved in the medicine supply process (Physician, Pharmacist and patient) may all use different names for a medicine, which may be confusing and potentially risky. When a prescription for a generic drug is refilled (e.g. for a patient with a chronic disease), changing the manufacturer should be discouraged, whenever possible, to avoid confusion for the patient.

(8) Physicians may submit a request to HAAD, if they consider that a particular drug/drug molecule (other than those listed at paragraph 3.3 of the Policy), needs to be permanently exempted from generic prescribing. All requests in this regard should be made only through the 'Exemption Request Form' (see below). Applicable sections of the form should be filled in as completely as possible and submitted directly to HAAD Pharma/Medicines and Medical Products Department or through email or fax (see contact details below).

(9) A committee comprised of experts from 'Pharma/Medicines and Medical Products Department' and 'Pharmacy and Therapeutic Committee' at HAAD will scientifically review a Physician's request for exemption. If required, the Physician may be called upon before the committee to provide his medical judgments with cost consideration to substantiate his request.

(10) The decision of the expert committee shall be final and binding and will be communicated to the concerned Physician through email and/or fax. If the committee recommends the drug for exemption from Generic Prescribing, it will be added to the list at Appendix B of the Policy.

(11) For more information on the Generic Drug Policy, copies of the Adverse Reaction reporting form, or to submit an Exemption Request Form, Healthcare Professionals are requested to contact the following through any of their preferred means:

Health Authority - Abu Dhabi
Pharma /Medicines and Medical Products Department
Pharmacovigilance Center.

Phone: 02 4193 586, 348, 580.
Fax: 02 449 6679
Email: pv@haad.ae

Exemption Request Form

Health Authority – Abu Dhabi
Reliable Excellence in Health Care
Pharma/Medicines and Medical Products Department

Mandatory Generic Drug Program
Exemption Request Form

PV

Request No
For office use / Do not complete

Prescriber Name:	
Specialty:	Facility:
Phone:	Email:
Fax:	Date of submission:

PROGRAM INFORMATION: The Form is to be completed and submitted to Health Authority Abu Dhabi Pharmacovigilence Center by the Physician requesting permanent exemption for a particular drug/drug molecule from generic prescribing (and to be considered for inclusion under clause 3.2 of the Generic Drug Policy).

PRESCRIBER PROCEDURE:

Drug molecule you recommend for permanent exemption ----------

Brand–Name medication pertaining to the Drug Molecule ----------

Please provide Medical reasons (judgments) substantiating your request for permanent exemption: (Tick the applicable)

- Reports of Adverse Reaction to a particular generic drug.
- Incidence of Medication Errors due to generic substitution.
- Documented history of successful therapeutic control with a particular brand.
- Others - Please specify .....

Please provide full medical rationale, extra sheets may be added as required.

Heath Authority Abu Dhabi Pharmacovigilance Center.
Phone: 02 4193 586, 348, 580. Email: pv@haad.ae. Fax: 02 4496679