UNITED ARAB EMIRATES
MINISTRY OF HEALTH
MoH Formulary Committee

Form No:

FORMULARY APPLICATION FORM

For Official Use Only	
Application No.:	
Date	
Received By	

- ***Before filling the application please review the instructions and the procedure in the given appendix carefully***

Section 1 : Completed by

Hospital & Emirate			
Name of the Doctor *(mention Consultant/Specialist/GP)*			
Specialty & Position			
Place of work & Department			
Telephone & Mobile		**Fax**	
Email			
Chief pharmacists / Clinical Pharmacist *(Name & Telephone)*			
PTC Member *(Name & Telephone)*			
Approved by Clinical Director *Name, Signature, Date & Stamp*			

Section 2: Background Information

2A – General

Active Ingredient(s) INN Name(s)	
Dosage Form	
Route of Administration	
Dosage Unit Size	
Strength(s) available: *(expressed per dosage unit)*	

2B - The Anatomical Therapeutic Chemical Classification System (Place in MOH Formulary)

2C- Principal reason for formulary request (indicate category)

☐ New product where no existing therapy available.

☐ New type or class of product but existing therapy of a different type available.

☐ Me too" product – similar to existing and with similar mechanism of action.

- ☐ of better safety profile
- ☐ superior efficacy
- ☐ minimize cost(direct)
- ☐ cost effective
- ☐ can act as a second choice

Section 3: Clinical and Safety

3A- Indications

Sl. #	Indication and attachment number	Target patient (Age)	Principal outcomes expected	SDR	Course	Total dosage units
1						
2						
3						
4						
5						

3B- evidence on clinical effectiveness issues (Summary)
•   •   •

3C- Comparable products in formulary
Should this medicine (candidate product) replace or supplement one already in the current edition of MOH Formulary? *(please tick appropriate box)*:   ☐ Replace ☐ Supplement ☐ Both   **State the medicine to be replaced:**   **State the products the candidate product is expected to supplement:**   **Is this medicine proposed as** *(please tick appropriate box)*:   (a) first choice ☐ (b) second choice ☐
If the candidate product is expected to be used as first or second choice explain reasons and % of patients diagnosed with the indication expected to use the product.

Section 4: Protocols and restrictions (Attachment no ….)

4A- outline

Has a MOH Standard Treatment Protocol been developed for conditions stated using the candidate product or its equivalents from the same therapeutic class (to be replaced or used as first or second choice)?

☐ **Yes** ☐ **No**

If yes, please attach a copy of the protocol with this report.

Is protocol consistent with WHO and other recognized bodies recommendation?

☐ **Yes** **mention the reference:**

☐ **No** (protocol tailored by ……Committee) **please explain:**

If no, please summarize in below how it is proposed that the medicine will be used

Please specify the criteria for patient selection:

Please specify place in therapy in relation to existing medicines:

Please specify prescribing (primary care, secondary care or if shared care protocol is considered appropriate):

4B- In case the product is indicated to be used with other products, give details of the concomitant treatments with their recommended dosage regimens.

4C- Restrictions: **State & explain the kind of restrictions on use you advice to be implemented when product is accepted (to guarantee maximum benefit):**
☐ **Order in prescribing (describe the order) ……..** ☐ **Target patients according to risk group (include pregnancy and pediatrics)……..** ☐ **Primary Prescriber category ……..** ☐ **Refill Prescriber Category, if any ……**

4D- evidence on comparative efficacy (Summary): (attach available evidence) List comparable products from the MOH formulary the product is expected to replace, be first choice or a second choice to List those mostly expected to replace including the current first choice, you can compare single products or the suggested new treatment protocol with the previous ones.						
	Candidate product / protocol	Comparable product1	Comparable product2	Comparable product3	Available evidence (name, type & level of evidence)	Attch number
Outcome1: (specified) & monitoring requirements						
Outcome 2:(specified) & monitoring requirements						
4E- Evidence on comparative safety (Summary): Are there any safety issues regarding this medicine in comparison to existing medicines? (attach available evidence)						
	Candidate product	Comparable product1	Comparable product2	Comparable product3	Available evidence (name, type & level of evidence)	Attacht number
Side effect 1						
Side effect 2						

Section5 : Pharmacoeconomics	
5A- The Disease Epidemiology (related for main indication or therapeutic category)	
Latest Prevalence rate: ***(Number of patients with condition in UAE from total population)***	
Latest Incidence rate: ***(Number of newly diagnosed patients per annum in UAE from total population)***	
Reference & estimation basis:	

5B- MOH consumption size of the product's therapeutic class (equivalents that the candidate product expected to substitute) (dosage units)/(last three years) (if available) (consult the therapeutic committee secretary for filling this part)			
Year			
Consumption size (dosage units & value)			
No of patients treated at your facility with the condition			
No of patients at MOH facilities with the condition			

state % of patients expected to benefit from the candidate product with reasons:

- ☐ **in case only choice:**
- ☐ **in case of first or second choice:**
- ☐ **in case it will supplement:**

5C- Cost minimizing study: only in case of replacing a formulary product)					
INN name of equivalent product and strength	**Standard dosage regimen (dosage units per day x number of days)**	**MOH tender price** per dosage unit	**Market CIF price** per dosage unit	Cost of treatment (based on MOH tender)	Latest MOH annual **Consumption size (dosage units & value**
Candidate product innovator (include all strengths)					Estimate
Candidate product cheapest generic in market (include all strengths)					Estimate
Currently used Substitutes available in MOH (INN) including all strengths					Actual
Cost savings expected (on individual patient level and in total MOH level)					

5D- Cost analysis In case of different treatment protocol						
INN name of equivalent product and strength		**Standard dosage regimen (dosage units per day x number of days) for each**	**MOH tender price** per dosage unit	**Market CIF price** per dosage unit	Cost of treatment (based on MOH tender)	Latest MOH annual **Consumption size (dosage units & value**
Proposed protocol (name products)						Estimate
						Total
Current protocol						Estimate
						Total
***Cost savings expected (on individual patient level and in total MOH level) i.e.* Calculation of total expense of addition:**						

5E- Additional costs associated with medicine, i.e. additional lab tests, X-rays for monitoring purposes, training costs associated with new medicine, additional treatments needed (i.e. adding in treatments to minimize side effects):
5F- Added Benefits of the candidate product in terms of "suitability for patient's use" compared to other similar (MOH available) products in the same therapeutic class & effect on costs and Quality of Life
• **Within the same Chemical Group:** • **Within the same general Therapeutic Class:**

Section 6: Declaration of Interests

Policy on Declaration of Involvement and Competing Interests with the Pharmaceutical Industry

The lead Clinician(s) and Pharmacist(s) responsible for completing formulary application form, &/or providing information to the Formulary Review Committee, are asked to declare and describe to the Head, Formulary Review Committee, any involvement that they may have with the relevant pharmaceutical company, or with the manufacturers of any comparator products.

1. Personal interests over the last 12 months

This involves payments* (or other support) from any one company to an individual member or their spouse/partner or close relative. The main examples are consultancies, fee-paid work, travel grants, conference attending grants or pharmaceutical company shares. (The amount of money involved does not have to be declared).

Company	Nature or purpose of support from the company	Period of support	
		From	To
Name of Clinician:		**Date:**	
Name of Pharmacist:		**Date:**	

* For practical purposes, payments &/or support to a value in excess of AED1000/= annually should be declared. (Threshold specified is chosen to exclude amounts for trivial items such as pens, post-its, books, etc)

2. Non-Personal interests over the last 12 months

This implies support* from any one company for your unit or place of work. It may be financial or in kind, e.g. funding of a nurse, colleague, building or piece of equipment. (The amount of money involved does not have to be declared).

Company	Nature or purpose of support from the company	Period of support	
		From	To
Name of Clinician:		**Date:**	
Name of Pharmacist:		**Date:**	

* For practical purposes, payments and/or support to a value in excess of AED5000/= annually should be declared.

Section 7: Summary

The product "..... " indicated for the treatment of .....

The estimated MOH tender price is (cheapest generic if not include innovator) .....and the cost of full course is ……
MOH consumes (expected to consume if new) AED ……. in this class, expected to:

- **Save ……. AED (per treatment course, and total savings)**
- **reduce the following side effects which each costs MOH**
- **add value for the quality of care**
- **add the following benefits for the patients quality of life**

Declaration of Responsibility

We hereby declare our responsibility for information included in this application

Head of Pharmacy & Therapeutic Committee
Name, Signature & Date, Designation Stamp

Medical Director
Name, Signature & Date, Designation & Hospital Stamps

Declaration of Completion of Application

It is hereby declared that I have reviewed this application and have found to be proper & complete

PTC Coordinator
Name, signature & date, designation stamp

UNITED ARAB EMIRATES
MINISTRY OF HEALTH
MoH Formulary Committee

For FRC Official Use Only

Date: **FRC Meeting No:**

Committee recommendation

Please indicate proposed place of medicine in the MOH formulary :

- Add to the MOH Formulary as first or second choice ☐ First ☐ Second
- Add to the MOH Formulary as a prescribing note ☐
- Add to the Additional List ☐
  (i.e. useful in some patients when MoH Formulary medicines are ineffective, not tolerated, contra-indicated or specialist practice)
- Non-formulary: 'Not preferred' as effective alternatives available ☐
- Unsure - deferred for further study ☐
- Rejected ☐

The product will be used in the following practice setting(s):

☐ **PHC** ☐ **Specialists (specify)……**

☐ **Only Hospital Use** ☐ **All** ☐ **Others *(specify)***

If, Others please give detail(s):

The product's place in The MOH formulary will be ……..

& it will replace the following existing product …….

The recommended guidelines for use is attached

Appendix 1- **Guidance**

Guidance for completing Formulary Application Form

Section 1 – Completed by:

- *The Information should be filled by the Consultant/Specialist, Member from PTC and the Pharmacists in charge/Clinical Pharmacist*
- *For the fields which require further verification could be filled in red by formulary committee secretary in coordination with the Supplies department at Ministry Of Health*
- *The application should be addressed to the committee and referred by the Medical Director directly.*

Section 2: Background Information

2A- General: Provided for candidate Product, given that the product is new and not included in the formulary. Formulary could be accessed on the MoH website (www.moh.gov.ae)

2B- The Anatomical Therapeutic Chemical Classification System: (place in MoH Formulary), indicate the main section were the product will be placed according to WHO Anatomic, Therapeutic, Chemical Classification system followed by BNF and other leading formularies**.**

Section 3: Clinical and Safety

Grading for Level of Evidence:

Level I Evidence: Obtained from systematic review of relevant randomized controlled trials

Level II Evidence: Obtained from one or more well-designed, randomized controlled trials

Level III Evidence: Obtained from well-designed, non-randomized controlled trials or from well designed Cohort, case control or interrupted time series studies

Level IV: Case series with either post-test or pre-test/post-test outcomes

3A- Indications:

Summarize briefly the internationally approved indication(s) for the candidate product & Standard Dosage Regimen (SDR) recommended for each by Patient target group

- **Standard Dosage Regimen (SDR) to be expressed in (No. of dose units/day)**
- **Full Course Period in days for acute conditions only.**
- **Total Number of dosage units needed for full course of treatment**

3B- Evidence on clinical effectiveness issues (Summary):

State the principal trials supporting the indication(s) described in the section 3A and the overall results regarding outcomes (e.g. absolute or relative risk reduction , rate of recovery….) and efficacy? Please state what the principal outcome measures are and provide copies of up to 3 (maximum) relevant references. **(References from FDA & EMEA regarding approved indications are desirable)**

3C- Comparable products in formulary

Comparable products from the formulary are either:

- Products to be replaced by the product
- Products expected to be used for the same conditions as the candidate product but either as 1st or second choice.
- Products the candidate product is expected to be used in addition to them (the current treatment protocol to be changed)

- List comparable products from the MoH Formulary in the same therapeutic class the product is expected to replace, be first choice to or be a second choice.

Section 4: Protocols and Restrictions

Protocol for use

- What is consensus opinion on place in therapy?
- Would use of new medicine require specific training?
- Would use of new medicine require specific guidelines for use?
- Will it replace an existing therapy, is it suitable as an alternative to existing therapy, is it a 'me-too' medicine?
- Where will prescribing take place? (primary/secondary/tertiary care)
- Would a care protocol be required?
- Is this consistent with recognized bodies' advice?

4D- Evidence on comparative efficacy (Summary): (attach available evidence)

- List comparable products from the MOH formulary the product is expected to replace, be first choice or a second choice to
- List those mostly expected to be replaced including the current first choice, you can compare single products or the suggested new treatment protocol with the previous ones (in case of the candidate product is expected to supplement the current formulary products).
- List the advantages of candidate medicine within the suggested treatment protocol compared to other treatment protocols to be replaced in terms of efficacy (clinical outcome).
- Attach available evidence.
- Outcomes is expressed in terms of clinical effectiveness in regard to the proposed indications, examples are recovery rate, stabilizing the patient condition etc.
- Monitoring requirements: Describe the objective criteria that will be used to monitor effectiveness.

4E- Evidence on comparative safety (Summary):

- Are there any safety issues regarding this medicine in comparison to existing medicines? (attach available evidence)

Section 5 : Pharmacoeconomics:

The Disease Epidemiology:

(Related for main indication or therapeutic category)

Estimates could be derived from consumption size, consult the therapeutic committee secretary.

Sources for prevalence and incidence, Consumption, MOH tender prices data include:

- In-house/specialist/local information
- Local reports,
- MOH Statistics Division

Number of patients/year and costs (primary and secondary care)

- Estimate from figures obtained from the prevalence and incidence data. Is it a 'me-too' medicine or a replacement treatment?
- pharmacy stock management systems will provide supporting data from MOH supplies department

- Medical Records statistics

5B- MoH consumption size of the product's therapeutic class (equivalents that the candidate product expected to substitute) (dosage units)/(last three years) *(if available)* (This part is preferred to be filled by supplies department in consultation with the formulary committee secretary)

5C- Cost minimizing study (in case of replacing a formulary product)

- List MOH formulary products the candidate product is expected to replace for the same indication (therapeutic class).
- (start the comparison with the candidate product (using available innovator and cheapest generic available)
- Use Market CIF price if MOH tender price is not available (applies on new chemical entities)
- It is advisable to leave Market CIF Price and MOH Tender Price to be filled by coordination with formulary secretary)
- Fill separate section for each strength available starting with the highest strength.

5D- Cost analysis (In case of different treatment protocol)

- Cost of Treatment (for the main indication)= cost of full course in case of acute or/ cost of a monthly course in case of chronic (calculated from MOH tender rates if available or Market CIF)
- Cost savings (Cost of current treatment – Cost of the candidate treatment)

Financial Information:

Add name of medicine (both Generic and Brand names)

Completion of Table Columns

- No. of patients eligible for treatment per annum in current financial year (refer to local data - see notes for Section 5, above)
- Cost per annum per patient (multiply for all patients) for the current financial year, calculated: (treatment cost) x (average no. days treatment) x (1) or (no. of patients in current financial year)

Completion of Table Rows

- Substitution effect (if any) from switching from current recommended therapy - evaluate cost implications (+) or (-) if this medicine is introduced in MOH; specify which medicine will be replaced; calculate for secondary and primary care separately if possible
- Other cost implications - include any additional costs associated with medicine, i.e. additional lab tests, X-rays for monitoring purposes, training costs associated with new medicine, additional treatments needed (i.e. adding in treatments to minimize side effects)

5E- Additional costs associated with medicine: i.e. additional lab tests, X-rays for monitoring purposes, training costs associated with new medicine, additional treatments needed (i.e. adding in treatments to minimize side effects):

5F- Cost Benefit study:

- Added Benefits of the candidate product in terms of "suitability for patient's use" compared to other similar (MOH available) products in the same therapeutic class? Add attachments if any studies and calculations are available.

SECTION 6: Declaration of Interest

- Ensure that persons completing the Application Form have completed declaration of interest prior to submission of report to the Formulary Committee.

SECTION 7: Summary & Declaration

- The summary is to be completed & the declarations are to be signed & stamped as mentioned.

The PTC Coordinator to email the soft copy of the completed application to kmabdussamed@moh.gov.ae or wafa.hussaini@moh.gov.ae and to submit the hard copy to

- **Dr. Amal Awadi, the Deputy Director of Registration & Drug Control Department, Ministry of Health, Dubai**

  or

- **Head of Formulary Review Committee, Drug Registration and Control Department, Ministry of Health, Abu Dhabi**

Appendix 2- **FORMULARY APPLICATION PROCEDURE & PROCESSING FLOW-CHART**