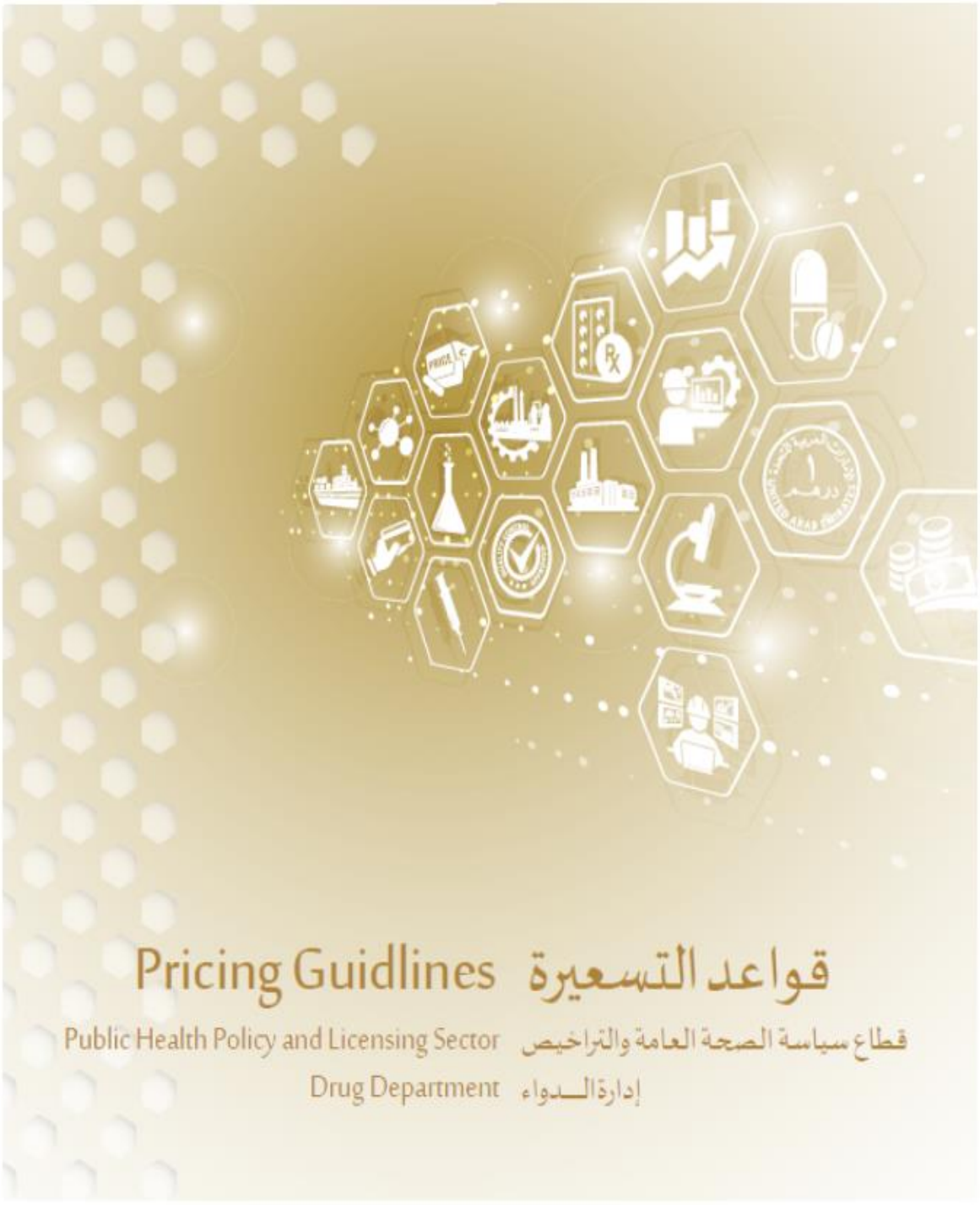
UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION



Version No. 1 of 2018

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Article (1) Definitions

In these Guidelines, the following words and expressions shall have the meanings ascribed thereto hereunder unless the context indicates otherwise:

Drug: Any product that contains an active ingredient or a group of active ingredients that accomplish the intended purpose when applied on human or animal under a biological effect. This product is to be manufactured, sold or made available to be applied in the following cases:

1) Diagnosis, treatment, cure, mitigation, or prevention of illness.
2) Restoration, renovation, modification or correction of organ's functions.

Committee of Drug Registration and Pricing and Drug Companies: Higher Committee for Drug Registration and Pricing.

Pricing Committee: A competent technical Committee that studies the proposed prices of drugs under registration. The Committee shall also review the price of registered drugs or which undergone minor changes that require review of price thereof, and shall submit such study to the members of Committee of Drug Registration and Pricing and Drug Companies to be reviewed and take the necessary decisions thereto and be approved by Higher Committee of Drug Registration or his deputy.

Competent Department: Drug Department at Ministry of Health and Prevention concerned with medical product registration, pricing and quality control processes.

Medical Product Pricing Guidelines: The method followed by the competent medical product pricing committees, with a view to set the price of the product submitted for registration.

Drug Re-Pricing: Procedures and requirements followed by the competent medical product pricing committees, in order to re-evaluate the registered drug's price.

Country of Manufacture: The country in which the initial pharmaceutical form of a drug (tablets, capsules, injections… etc.) is produced.

Country of Origin: The country from which Certificate of Pharmaceutical Product (CPP) is issued.

Innovated Drugs: Drugs that contain partially or fully new active ingredient.

Generic Drugs: Products that is similar to another pharmaceutical product with the same quality and quantity of active ingredients, pharmaceutical form and bioequivalent thereto.

Orphan Drugs: Medicinal products intended for treatment, diagnosis or, prevention of rare diseases.

Locally Manufactured Product: A pharmaceutical product that all or some manufacturing phases of which were carried out in a local factory.

Therapeutic Alternatives: Drugs that may have different active ingredients but are purported to have the same effect as other drugs for treating a condition. Therapeutic Alternatives may and may not be from the same therapeutic group.

Licensee under Marketing Authorization / Scientific Office: A pharmaceutical facility licensed by MOHAP and holding the marketing authorization of the medical product from the Relevant Authority within the State, under which it shall be legally responsible of all scientific, technical and financial aspects of the product, as well as product marketing, promotion and follow-up within the State.

Ex-Factory Price: The product price in the Country of Origin plus Cost, Insurance and Freight (CIF) and the profit of the agent and the pharmacy.

Cost, Insurance and Freight (CIF): Ex-factory plus freight and insurance expenses.

Whole Sale Price: Ex-factory plus the profit of wholesaler.

Certificate of Price: A statement of price submitted by the manufacturer and/or marketer, documented by the competent authorities in the Country of Origin and attested by the Embassy of United Arab Emirates in the relevant country, according to Annex No. 1 attached hereto.

Article (2) Facts to be Considered in Drug Pricing

Drug shall be priced at a reasonable price. The following facts shall be considered in drug pricing:

1. Therapeutic significance of drugs;
2. Prices of similarly registered or therapeutically equivalent (if any) or alternative drugs;
3. Pharmacoeconomic studies;
4. Ex-factory in USD;
5. Wholesale price in the country of origin in USD;
6. Public price in the country of origin in USD;
7. The price proposed by the manufacturer in USD or AED including CIF inside the ports of the State;
8. Export price to International Reference Countries at the time the price is submitted according to Annex No. 1 Price Certificate Form attached hereto;
9. Guidance on the price of countries that product is marketed.

Article (3) Certificate of Prices

Certificate of Prices include the following requirements:

The issuer of Certificate must be a manufacturer or a marketing authorization holder and the Certificate must be signed and sealed therefrom, indicating ex-factory registered in the product registration records.

In case the country of origin is a member State of European Union, the Certificate of Prices may be approved from the country of origin noted in registration document thereof, or to be issued by a member State of European Union with a reasonable justification (such as being a marketer but not a manufacturer) and shall be addressed to Ministry of Health and Prevention in the United Arab Emirates (must be duly signed and sealed):

1. The issuance date of the Certificate must not be beyond one year.
2. The Certificate must include the following pricing information (shown in Annex No. 1):
   - Product name, scientific name, pharmaceutical form, pack size, concentration and pack description.
   - USD or AED CIF to UAE.
   - USD or AED CIF ex-factory.
   - USD or AED sale price to the pharmacy / Wholesale price in the country of origin. In the event of its absence reasons and justifications must be provided.
   - USD or AED CIF to reference countries that product is marketed.
3. The Certificate must be approved by Ministry of Health, Ministry of Economy or Chamber of Commerce at the country of origin or an equivalent thereto.
4. The Certificate must be approved by the Embassy of the United Arab Emirates at the country of origin. In the event of absence of embassy in the country of origin, it may be approved by one the embassies of the Gulf Cooperation Council States.
   Gulf-state products are excepted from UAE embassy approval for the Certificate of Prices.
5. The Certificate of Prices may be issued by the Scientific Office (Local Marketing Authorization Holder), representing global firms, on condition that the above information are provided.

Article (4) Profit Margins

The profit margins for the pharmacy price and agent price are set according to the decisions issued in this regard.

1. Agent or distributor's profit (pharmacy price) shall be 15% of CIF.
2. The pharmacy's profit (public price) shall be set according to the specified CIF:
   - AED 0-250: 28% of the pharmacy price
   - AED 250-500: 24% of the pharmacy price
   - More than AED 500: 20% of the pharmacy price

Article (5) Pricing Innovated Drugs

1. The prices of Innovated Drugs are set according to the lowest price of the following:
   - Ex-factory price in the country of origin;
   - Import price proposed by the company including CIF until the delivery at the State port;
   - The median of the CIF price of the product until delivery to the approved port in the list of the reference countries (taking into account the company's remarks stated in Pricing Application Form on any of the Reference Countries Prices).
2. The prices of Innovated Fast Track Drug are set according to the lowest price of the following:
   - Ex-factory price in the country of origin;
   - Export price proposed by the company including CIF until the delivery at the State port.
3. Local manufacture of Innovated Drugs:

3.1. If the company that owns the Innovated Product wishes to manufacture its product locally or move a manufacturing phase to a local factory that sets the same approved price of the Innovated Drug (according to the guidelines of Item No. 1 herein) and a 5-year protection from review of prices shall be granted as of the date of contract.

3.2. If the company that owns the Innovated Product wishes to grant a license of Second Brand to a local factory. The Second Bran shall have the same price of the Innovated Drug (according to the guidelines of Item No. 1 herein) during patent protection period.

4. Combination Drugs:
   - Pricing of Innovated Drug in case of adding an innovated active ingredient from the same company: Procedures of Innovated Product pricing set forth in Item No. 1 herein shall be followed.
   - Pricing of Innovated Drug in case of adding an innovated active ingredient from the another source: Procedures of Innovated Product pricing set forth in Item No. 1 herein shall be followed.

5. Pricing of Innovated Drugs after registration of Generic Drugs: Procedures of Innovated Product pricing set forth in Item No. 1 herein shall be followed, taking into consideration that the drug's public price should not exceed the first Generic Drug's price.

Remarks

In the event of difficult of evaluation of export price including CIF to the State's port, the following shall be considered:

- Guidance on the price of therapeutic alternatives or therapeutically equivalent drugs or the price of medicinal product in international

references: NBF UK, Chemist & Druggist Price-List: UK, Vidal Dictionary; UK, etc.

- Guidance on the price of countries that product is priced, taking into consideration the purchasing power of the United Arab Emirates compared with the other states of the region and the world.
- In absence of reference prices, the product shall be temporarily priced for 6 months. The company may, after obtaining approval of Committee of Drug Registration and Pricing and Drug Companies, extend the validity of pricing to two additional periods, each of 6 months (the temporary pricing validity shall not exceed 18 months).
- An undertaking to keep the Ministry updated with the price list wherever registered shall be provided.
- After expiry of Innovated Drug's patent, Committee of Drug Registration and Pricing and Drug Companies shall have the right to review the price and consider 20% decrease thereof, provided that at least 3 Generic Drugs are registered in the market, to ensure availability of the drug within the State. In the event that the Innovated Drug price is reviewed, the prices of registered Generic Drug of the re-priced Innovated Drug shall be reviewed and their prices shall be accordingly reduced at the same rate according to a decision from Committee of Drug Registration and Pricing and Drug Companies.
- The Company must provide a new duly attested Certificate of Prices according to the applicable procedures in the event any of the below minor changes applies:
  1) Change of source or location of manufacturer (or) the country of origin.
  2) Making significant changes to the product's technology or manufacturing.

Article (6) Pricing Biosimilar Drugs

The prices of Biosimilar Drugs are set according to the lowest price of the following:

- 70% of approved drug's CIF price before reduction;
- Ex-factory price in the country of origin;
- CIF price proposed by the company;
- The median of the approved CIF price of the product in the list of the reference countries;
- Guidance on the price of country of origin.

Remark:

In the event that the Innovated Drug price is reviewed, the prices of registered Biosimilar Drugs of the re-priced Innovated Drug shall be reviewed and their prices shall be accordingly reduced at the same rate.

Article (7) Pricing Generic Drugs

The prices of Generic Drugs are set according to chronological order of their submission and based on the source of manufacture as follows:

1. 1st Generic:
   - The price of imported 1st Generic Drug is set according to the lowest price of the following:
   - 60% of approved drug's CIF price before reduction;
   - Ex-factory price in the country of origin plus 20%;
   - CIF price proposed by the company;
   - The median of the approved CIF price of the product in the list of the reference countries.

2. 2nd Generic:
   - The price of imported 2nd Generic Drug is set according to the lowest price of the following:
   - 50% of approved drug's CIF price before reduction;
   - Ex-factory price in the country of origin plus 20%;
   - CIF price proposed by the company;
   - The median of the approved CIF price of the product in the list of the reference countries.

3. 3rd Generic:
   - The price of imported 3rd Generic Drug is set according to the lowest price of the following:
   - 40% of approved drug's CIF price before reduction;
   - Ex-factory price in the country of origin plus 20%;
   - CIF price proposed by the company;
   - The median of the approved CIF price of the product in the list of the reference countries.

4. Locally (nationally) manufactured Generic Drug
   - Fully locally manufactured Generic Drug (all manufacturing processes): 70% of the Innovated Drug price is set as its price (30% reduction of the Innovated Drug) regardless of its chronological order and number of products.
   - Partially locally manufactured Generic Drug (part of manufacturing processes or contractually manufactured): to be priced according to the rules of Generic Drugs' pricing set forth in Item 1.3 herein according to its chronological order.

A	Fully locally manufactured Generic Drug	All manufacturing processes regardless of its chronological order and number of products	70% of the Innovated Drug price
B	Partially locally manufactured Generic Drug (part of manufacturing processes or contractually manufactured)	1. 1st Generic	60% of the Innovated Drug price
		1. 2nd Generic	50% of the Innovated Drug price
		1. 3rd Generic	40% of the Innovated Drug price

5. Market Leader Product (where no Alternatives or Innovated Drugs are registered in the State):
   - In the event of absence of Innovated Drug and a local or offshore company is willing to register its product locally as a Market Leader Product, Innovated Drug pricing rules set forth in Article No. 5 herein shall apply.
   - The competent authority may review granting a pricing advantage to drugs with limited advantages, and which contain additional substances or technology that leads to increase of drug effectiveness or adds therapeutic advantages.

Remark:

- In the event another active ingredient is added to Generic Drug's formula, the pricing shall be as follows:
  - If the drug that innovated the new formula is registered and priced at the Ministry of Health and Prevention, the provision of Article No. 7 applies.
  - Otherwise, the new product shall be priced according Innovated Drug pricing procedures set forth in Article No. 5 herein.
- Guidance on the public price in the country of origin shall be conducted when pricing the Generic Drug.
- In the event Generic Drug's registration is cancelled, the next Generic Drug's price shall not be increased.
- It is necessary to market the Generic Drug in the country of origin for at least one year before registration of the drug within the State.

Article (8) Pricing Drugs of Various Pack Sizes and Strengths

Drugs of various pack sizes and strengths shall be priced as follows:

a) The ratios set forth in Annex 4 attached hereto shall apply in case strengths vary.
b) If the Company presented a group of strengths at the same time, the lowest strength price shall be set according to the rules stipulated in Articles No. 5, 6 and 7 hereof and the remaining strengths shall be priced accordingly as set forth in Annex No. 4.

c) Drugs administered by injection and which strengths are by means of units, prices shall be set according to such units.
d) The price variance of product pack that contains various pharmaceutical forms shall be considered according to Table No. 4 attached hereto.

Article (9) Pricing Procedures

First: The following procedures shall be followed when a new (Innovated) drug or Generic Drug is submitted:

1. When a new product is submitted for registration to Ministry of Health and Prevention, the employee in charge shall consider the pricing, file a report according to the above regulations and prepare the Innovated Drug or Generic Drug pricing form (Annex No. 2) or (Annex No. 3) within 10 working days.
2. The pricing forms shall be sent by email to all the Technical Review Committee members before the meeting date.
3. Technical Review Committee shall be convened monthly before the meeting of Higher Committee of Drug Registration and Pricing and Drug Companies to consider the pricing forms and raise its recommendations.
4. The pricing forms shall be sent by email containing the Technical Committee's recommendations to all members of Higher Committee of Drug Registration and Pricing and Drug Companies immediately after end of the Committee's meeting.
5. All pricing forms shall be reported to Committee of Drug Registration and Pricing and Drug Companies for final review and approval. The Committee shall be convened once every two months.
6. The Ministerial decision regarding pricing shall be issued after the meeting of Committee of Drug Registration and Pricing and Drug Companies, containing the approved prices.

Second: Objecting (modifying) the registered product prices:

The Company may object the price and provide the required documents and exhibits

1. When the objection is submitted, the pricing employee in charge shall consider the objection. The company's letter shall be considered by following 1 to 5 steps set forth in Item No. 1 of Pricing Procedures.
2. The company may object the price in case pricing information is provided in a Gulf Cooperation Council State or if the product price is provided by Gulf Committee for Drug Pricing.
3. The product modified price shall be approved by virtue of Ministerial resolution of drug price after the Technical Committee and Drug Registration and Pricing and Drug Companies meet.

Article (10) Re-Pricing

1. Periodic Review:
    - MOHAP, through Pricing Committee and Committee of Drug Registration and Pricing and Drug Companies, shall conduct period review of all product prices in the State every 5 years along with renewal of product registration.
    - The above rules shall apply to Innovated and Generic Drugs.
    - In the event of Innovated Drug patent expiry, 20% of its price shall be reduced without referring to Reference Countries prices once, provided that at least 3 Generic Drugs are registered in the market, subject to approval of Committee of Drug Registration and Pricing and Drug Companies.
    - In the event that the Innovated Drug price is reviewed, the prices of registered Generic Drug of the re-priced Innovated Drug shall be reviewed and their prices shall be accordingly reduced at the same rate.

2. Exceptional Review
   MOHAP, through Pricing Committee and Committee of Drug Registration and Pricing and Drug Companies, shall consider exceptional review of medicinal products in the following cases:
    - Expiry of Innovated Drug patent;
    - Existence of any minor changes of the product that require re-price;
    - If the company requested re-price of the approved price;
    - Re-pricing drugs at their registration renewal every 5 years; or
    - Whenever required by health authorities in the State.

3. An exception from re-price is granted to any drug which sale price does not exceed AED (Eighteen UAE Dirhams) or USD $5.
4. If the Technical Committee or Committee of Drug Registration and Pricing and Drug Companies sees that the proposed price is high in light of the current updates. MOHAP's concerned department shall communicate with the company to reduce the period within one month according to the recommendations of the concerned committee.

Article (11) General Rules

1. Ex-factory of the countries that product is marketed, plus CIF at a maximum of 2-3% shall be set in case of the company's failure to provide export price to the countries that the product is marketed in Certificate of Prices.
2. Taking into account the company's remarks in the pricing form, including remarks on Reference Countries' prices.
3. Offshore company's product price shall be fixed without change if it contracted with a local company to carry out any manufacturing phases during patent protection period.

4. If a new pack size, strength or pharmaceutical form is added, the pricing rules set forth in Articles 5, 6 and 7 hereof shall apply, taking into consideration the price of the same registered product.
5. Higher Drug Registration and Pricing, by virtue of a recommendation from Ministry of Health and Prevention, local health authorities or Higher Drug Registration and Pricing apply exception for the necessary Innovated Drugs from some rules set out in Articles 5, 6 and 7 hereof, to ensure Innovated Drugs availability in the market at a reasonable price.
6. Higher Drug Registration and Pricing, by virtue of a written recommendation from Ministry of Health and Prevention or local health authorities apply exception for the necessary Generic Drugs from some pricing rules if there is there is a great price difference between Generic Drug and Innovated Drug or the latest registered Generic Drug, taking into consideration the following conditions:
    a) The drug is intended for treatment of chronic diseases or dangerous communicable diseases or if it is an orphan drug.
    b) The drug is therapeutically significant.
7. In case of absence of the necessary and required alternatives that must be available in the State, the price shall be negotiated with the company, regardless of the source of the product in accordance with the provisions of Articles 5, 6 and 7 hereof.
8. In case of absence of a reference price of a life-saving drug or Innovated Drug, Committee of Drug Registration and Pricing and Drug Companies may approve temporary pricing of the proposed drug until provision of the drug in the State. The product shall be temporarily priced for 6 months. The company may, after obtaining approval of Committee of Drug Registration and Pricing and Drug Companies, extend the validity of pricing to two additional periods, each of 6 months (the temporary pricing validity shall not exceed 18 months). The product price shall be reviewed once the reference prices are provided. The company's agent is committed to provide reference price documents and exhibits to MOHAP as soon as possible.
9. The department concerned with pricing submissions, Technical Committee or Drug Registration and Pricing and Drug Companies may reject the proposed price or postpone consideration thereof if a variation is found in product pricing document or over-pricing without a reasonable or scientific justification and the applicant shall be informed of the same. The applicant (agent) may resubmit product pricing application after providing the necessary information or after making the necessary changes.
10. The Marketing Authorization Holder may decide to reduce the products' price at any time during the marketing process and shall submit an application thereof to be approved by Committee of Drug Registration and Pricing and Drug Companies.
11. In the event increase of price is approved, the new modified price shall be applied two months as of the date of approval issued in this regard.
12. The following products are expected in the present time from pricing:

- All registered public sale products;

- Registered herbal products dispensed and prescribed only by a pharmacist, i.e., without a medial prescription.
- Paracetamol tablets or Aspirin tablets with or without caffeine, 100-tablet Vitamin C pack size as a maximum.
- Typical throat or cavum oris lozenges;
- Medical tools, unless otherwise decided by the competent registration committee; and
- Any products a resolution issued thereto by the Pricing Committee and to be approved by Committee of Drug Registration and Pricing and Drug Companies**.**

13. Ministerial Resolution: A resolution shall be issued by the Minister after the approval of Committee of Drug Registration and Pricing and Drug Companies on the adopted drug prices, indicating the pharmacy price and public price.
14. CIF drug price approval
    The competent department shall serve emails to the companies' agent to notify them of CIF of their products and their approval status, in order to initiate marketing and importation processes.

Article (12) Obligations and Responsibilities of Local Manufacturers, Agents and Companies

Local manufacturers, agents and distributors are committed follows:

- To provide the documents and certificate of price and deliver the same to the competent department in MOHAP for consideration.
- To comply with the periodically published prices prescribed by MOHAP.
- Authorized agents shall place the pricing label on the medicinal product, indicating the public sale on each product pack. In case large pack sizes are provided, the pricing label must be placed on smaller items such as tapes as approved by MOHAP.
- In the event of violation or breach of the MOHAP approved product price, either by increase or decrease thereof, infringers shall be subject to legal and punitive actions. In case of suspicion fraud or tampering with the pricing label placed by the authorized agent, similar actions shall be taken.

Annex (1) Price Certificate Form for Innovated Drugs

General Information	Product Name		Concentration		Pack Size	
	Scientific Name		Pharmaceutical Form		Company Name & Nationality	

Country of Origin	Ex-Factory Price ($ or AED)	Wholesale Price (if available)	Public Price (if available)	Proposed CIF to UAE ($ or AED)	Note

OTHER PRICES IN International Reference Countries

No	Country Name	Pack Size	Ex-Factory Price ($)	CIF Price ($)	Public Price ($)	Notes
1	Austria					
2	Belgium					
3	Canada					
4	Denmark					
5	Finland					
6	France					
7	Germany					
8	Ireland					
9	Italy					
10	Netherlands					
11	Norway					
12	Spain					
13	Sweden					
14	Switzerland					
15	United Kingdom					
16	Kuwait					
17	Saudi Arabia					
18	Bahrain					

We:

Certify that all prices in this form are true.

Name of the person authorized to sign on behalf of the company

Stamp

Annex (2) Pricing Form for Innovated Product

General Information	Product Name		Concentration		Pack Size
	Pharmaceutical Form		Company Name & Nationality		

Country of Origin	Ex-Factory Price ($ or AED)	Wholesale Price (if available)	Public Price (if available)	Proposed CIF to UAE ($ or AED)	Median price of the reference countries ($ or AED)	Comments

Is the item "Breakthrough" or "Orphan Drug"		Is the item locally manufactured	
No	Yes Attach List of therapeutic alternative (Equivalences) & Prices	Original Brand	Second Brand

Technical Committee Evaluation & Recommendation		
Recommended CIF	Justification	Remarks

Technical Committee Signatures			
Name	Signature	Name	Signature

Higher Committee Approval		
Approval	Justification (if not approved)	Remarks
TC Recommendation: Approved Not approved		

Higher Committee Signatures			
Name	Signature	Name	Signature

Annex (3) Pricing Form for Generic Product

General Information	Product Name		Concentration		Pack Size	
	Pharmaceutical Form		Company Name & Nationality			

Country of Origin	Ex-Factory Price ($ or AED)	Wholesale Price (if available)	Public Price (if available)	Proposed CIF to UAE ($ or AED)	Median price of the reference countries ($ or AED)	Comments

If the product a Biosimilar		Is the Innovated Product available		Is the product locally manufactured	
Yes:	No	Yes:	No	Yes: Fully manufactured Partially manufactured (contractual)	No

Available Generics (attach list of registered generics & prices)			
1st Generic	2nd Generic	3rd Generic	Other

Technical Committee Evaluation & Recommendation		
Recommended CIF	Justification	Remarks

Technical Committee Signatures			
Name	Signature	Name	Signature

Higher Committee Approval		
Approval	Justification (if not approved)	Remarks
TC Recommendation: Approved Not approved		

Higher Committee Signatures			
Name	Signature	Name	Signature

Annex (4) Pricing drugs when strength varies while pack size is fixed

Pharmaceutical Forms	Ration between Strengths	% of price to be reduced from the multiple
Solid pharmaceuticals (tablets, capsules, sacks)	1:2 1:3 1:4 1:5 1:6 Etc.	-18% -24% -30% -30% -30%
Liquids (syrup, orally administered liquids)	1:2 1:3 1:4 1:5 1:6 Etc.	-15% -20% -30% -30% -30%
Suppositoria and topical medications	1:2 1:3 1:4 1:5 1:6 Etc.	-20% -25% -30% -30% -30%
Ampoules and Vials	1:2 1:3 1:4 1:5 1:6 Etc.	-15% -20% -30% -30% -30%

- For example, assuming that Product A is registered and priced as AED 100 to the public with 35 Mg Strength (tablets), and Product B is submitted to be priced with 70 Mg Strength, it shall be priced as follows:

Strength of A	Strength of B	Difference between Strengths	% Price Variation
35 Mg	70 Mg	35:70 = 1: 2	-18%

$$\frac{\text{Price of Product A} * \text{Strength of Product B}}{\text{Strength of Product A}} + \frac{\text{Price of Product B} * \text{Strength of Product A}}{\text{Strength of Product B}} * -18\%$$

= (100 * 70 / 35) + (100 * 70 / 35 * -18%)
= 200 + (200 * -18 / 100)
= 200 – 36 – 164
Therefore, the price of Product B is = AED 164