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Registration and Marketing Authorization in UAE

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ABSTRACT

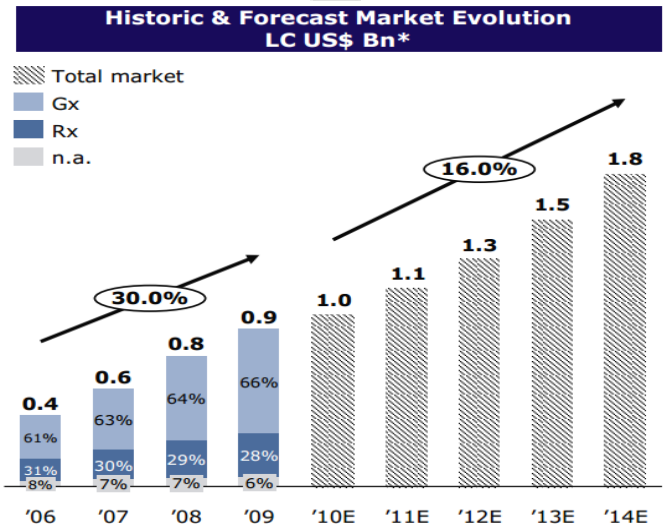
Rapidly rising costs of health care and high medicine prices are a growing concern worldwide, especially in developing and transitional countries where patients often have to pay the full price of medicines. The United Arab Emirates (UAE) has started to make strides on the global pharmaceutical map. Although the drug industry is still in its nascent stage in the country, it is the high per capita drugs consumption that has attracted several pharma companies to invest in UAE. Despite the global economic downturn, the UAE is an attractive market for pharmaceuticals, with forecasted double-digit growth being driven by a growing population and increased government investment. The UAE may not be the largest pharmaceutical market in the Middle East and Africa (MEA), but it possesses several advantages that make it an attractive prospect. In the UAE, growth prospects for the sector are amplified partly because of the population dynamic of an emerging yet sizeable growing middle-income class. As incomes rise, spending on health care typically rises as consumers tend to become more health-focused. So, the present study focuses on the current need of the industry i.e., requirements for drug product registration for a New Drug and Generics in UAE as the market holds high potential.

INTRODUCTION:

The pharmaceutical industry is widely valued as one of the most profitable in the world, with global spending on medicines set to reach Dhs 4.04bn ($1,100 bn) by 2015. Across the Middle East and Africa, CAGR has been prospectively set at between 7% and 10% (2011-2015) for the industry from the 2011 estimated size of Dhs 128.6 bn-165.3 bn ($35 bn-45 bn).[1]

Healthcare is among the priority sectors identified by the UAE government and, as a result, the UAE healthcare industry has displayed extraordinary growth and significant progress in the past few years. The government's focus on healthcare is aimed not only to diversify the oil-reliant economy but also to develop unprecedented healthcare infrastructure to ensure that adequate services are provided in the Emirates.[2]

The UAE pharma market has retained a strong preference for the originator, branded products. [3]



Source: IMS Market Prognosis; BMI; IMS analyses

Figure 1: Market Evolution in UAE

General Market Drivers & Constraints[3]

Drivers

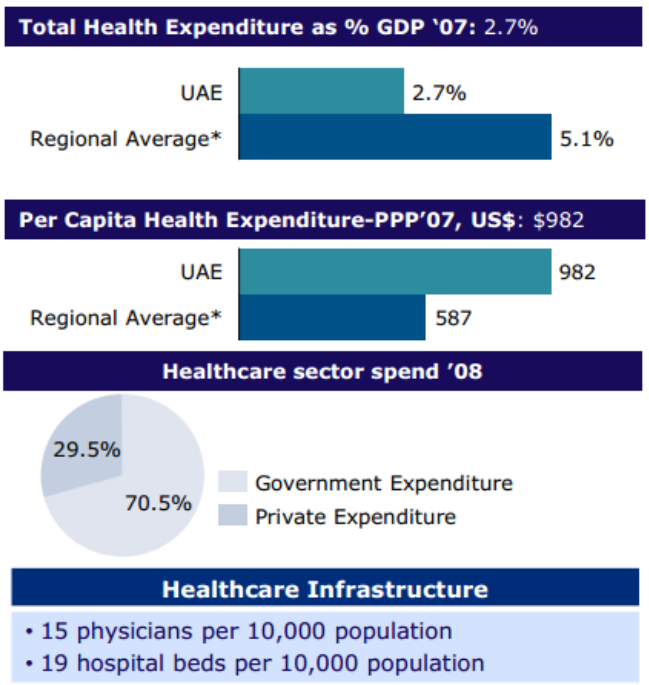
- Small but growing and wealthy population base
- Government's significant investment in health infrastructure

- Expansion of the private health sector
- Promising economic outlook
- Prescriber's reference for branded products
- Increasing public-private partnerships
- Exports

Constraints

- Increasing generics usage in Abu Dhabi following the basic insurance policies
- Regionally fragmented healthcare system and insurance coverage, leading to uneven access to healthcare services

UAE has the highest per capita health spending in the region; the government is committed to providing a high quality of care. UAE has a comprehensive, government-funded healthcare system although the level of insurance coverage varies in the different emirates. UAE nationals receive free healthcare funded by the government.



Source: WHO; BMI; IMS analyses

Figure 2: Healthcare Spending in UAE

The UAE Pharmaceutical market in 2012: AED5.56 bn (US$1.51 bn) in 2011 to AED5.72 bn (US$1.56 bn) in 2012; +2.8% in local currency terms and +2.9% in US dollar terms.[4] Hence, there is a lot of scope and opportunities for the pharma companies to invest in the UAE and grow tremendously.

Provides services on:

1. Classification of Pharmaceutical Products service.
2. Registration of Conventional products service.
3. Registration of complementary Products.
4. Registration of veterinary products service.
5. Registration of medical devices service.
6. Registration of Pharmaceutical manufacturing facility

Medicinal Product Classification Procedure

- The customer will submit a sample of the medicinal product along with the inquiry form and a composition certificate issued by the competent authority from the country of origin.
- The medicinal product will be discussed in the classification committee.

Regulatory Information Regarding New Medicinal Product[12]

- CTD format (one hard copy of module 1 & 3, and five soft copies (pdf format) of modules 1,2,3,4 & 5)
- Application form
- Legalized CPP, the mentioned site should be the batch releaser and correspond to the site mentioned in CPP
- SPC or PIL either attached to CPP or attested
- Registration certificate for another manufacturing site (s) involved in the manufacturing process
- Worldwide registration/marketing status

- Statements regarding alcohol, hormones, animal origin, etc.
- Active ingredients specification, copy of GMP certificate, the active ingredient needs to be registered (Circular 11/2007)
- Method of preparation/Method of analysis
- Clinical/Pharmacological/Toxicological Studies
- Stability study (Climatic zone IV)
- Finished product samples + CoA
- Outer pack and label or artworks on company letterhead, duly signed and stamped + CD containing the same in JPEG format
- Legalized price certificate
- Approval time: 9 – 24 months

Check List for NDA[12]

General Notes

New Drug Application should be following the CTD Modules and structure (One hard copy of Module 1 & 3, and five soft copies (PDF format) of Modules 1,2,3,4 &5).

The hard copy of Module 1 should be kept in a separate file properly labeled as the following:

* Dossier's name,

* Product's name, generic name, strength, dosage form, and pack size(s),

* Company name, country, and city,

* Local authorized Distributor's name and city.

Soft copies of other modules should be properly labeled as per module 1 file.

The hard copy of Module 3 related to the quality and stability, and the hard copy of the bioequivalence studies should be kept in a separate file properly labeled as per module 1 file.

The Authorized Person has to submit one hard copy and 1 soft copy of module 3 (quality and

stability) & bioequivalence studies dossiers to the drug analysis section upon prior fixed appointments, after the registration dossier is submitted to the drug registration section. The authorized person will send a copy of the receipt and checklist (signed as received by the drug analysis section) to the drug registration section.

Requirements based on the RDCD/MOH/UAE Guidelines and Regulations[12]

1.0 Payment receipts

1.1 Covering letter

1.2 Comprehensive table of content

1.3 Application form properly filled and signed by the qualified responsible person (MAH), and word document soft copy

1.4 Product information

1.4.1 Summary of Product Characteristics (SmPC)

1.4.2 Labelling information

1.4.3 Patient Information Leaflet (PIL)

1.4.3.1 Arabic leaflet

1.4.3.2 English leaflet

1.4.4 Artworks (Mock-ups) (outer label, inner label, and leaflet artworks as hard copy and JPEG format soft copy)

1.4.5 Samples (two original finished samples)

1.5 Quality on the experts

1.5.1 Quality information (soft copy)

1.5.2 Non-clinical information (soft copy)

1.5.3 Clinical information (soft copy)

1.6 Environmental risk assessment

1.6.1 Non-Genetically Modified Organism (Non-GMO)

1.6.2 GMO

1.7 Pharmacovigilance

1.7.1 Pharmacovigilance System (soft copy)

1.7.2 Risk Management Plan (soft copy)

1.8 Certificates and Letters

1.8.1 Original legalized valid Certificate of a Pharmaceutical Product (CPP)

1.8.2 Copy of valid GMP certificates for the manufacturing site(s)

1.8.3 Certificate of Analysis - Drug Substance (at least three batches for non-local and one batch for local manufacturer)

1.8.4 Certificate of Analysis - Finished Product (at least three batches for non-local and one batch for local manufacturer)

1.8.5 Alcohol-content declaration

1.8.6 Pork-free declaration

1.8.7 TSE/BSE free certificate

1.8.8 API certificate of suitability or US-FDA approval of the DMF

1.8.9 Copy of valid GMP certificate for the API source

1.8.10 API acknowledgment letter

1.8.11 Relation-ship letter between two parties (if applicable)

1.8.12 Appointment letter for the local distributor

1.8.13 Copy of the manufacturing site(s) registration certificate(s)

1.8.14 Composition certificate with active ingredient(s), inactive ingredient(s) quantities per unit dose, and functions

1.8.15 The diluents and coloring agents in the product formula

1.8.16 Patent letter with a copy of the patent reference

1.8.17 Registration and marketing status in other countries (with copies of registration certificates)

1.9 Pricing

1.9.1 Original legalized price certificate

1.9.2 Other documents related (comparative studies)

1.10 responses to questions and other requested documents (updates, questions, queries)

1.11 Module 1 (5 soft copies)

2.0. Module 2 (5 soft copies)

3.0. Module 3 (1 hard copy and 5 soft copies)

4.0. Module 4 (5 soft copies)

5.0. Module 5 (5 soft copies)

6.0 Summary and protocol of the bioequivalence study (soft copy)

7.0 Approval of the bioequivalence study by the Health Authorities

Registration Procedure for conventional medicinal product[13]

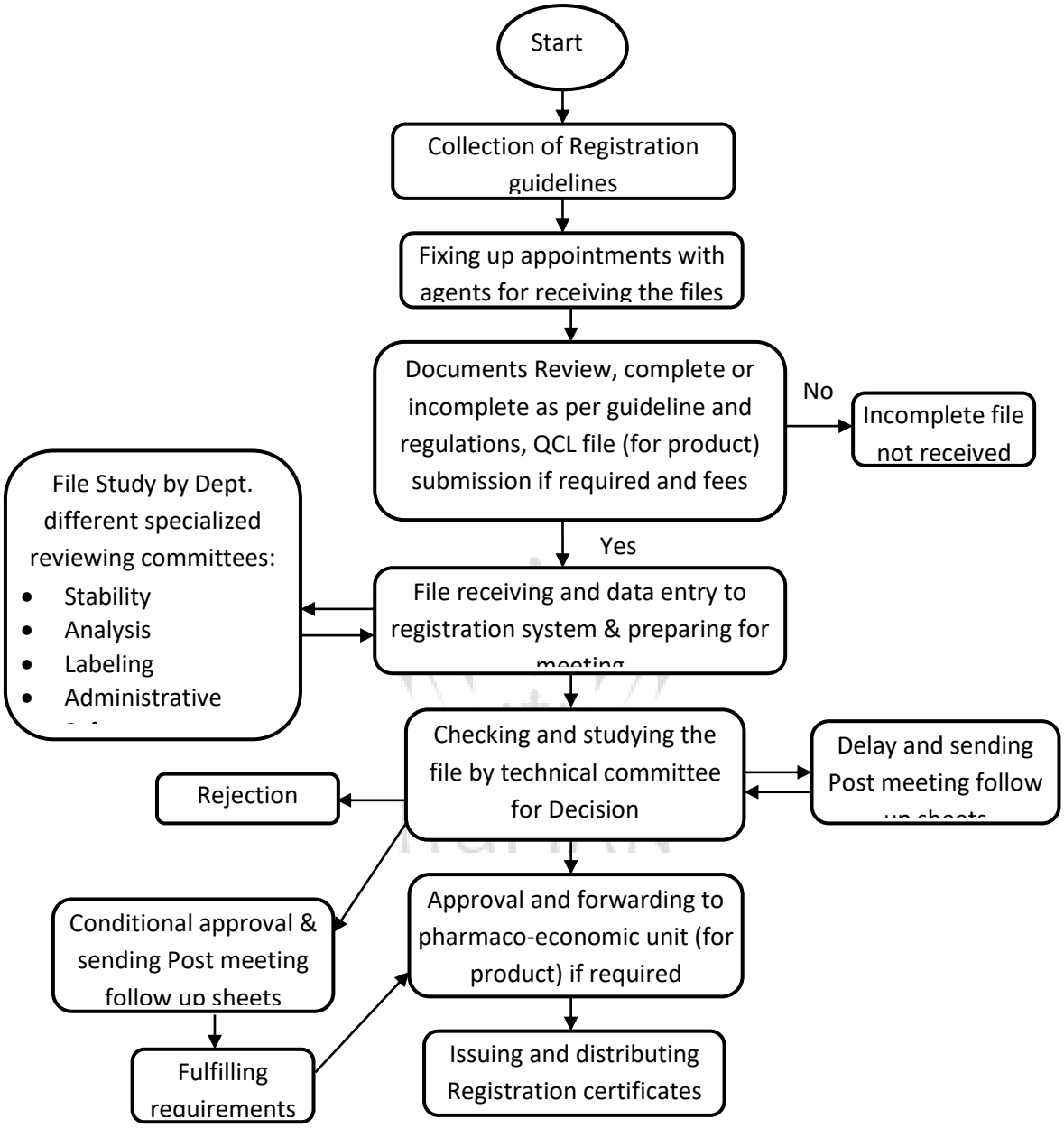


Figure 3: Registration Procedure for the conventional medicinal product

Registration Guidelines and Requirements of an Ethical Conventional Medicinal Product[14]

A. QCL Dossier and samples

- Quality Control Laboratory dossier should be properly labeled.

- Documents to be kept in a hard labeled box file product's name, strength, and pack size(s), company name, country, and city should be mentioned distributor's name and city are to be also mentioned.

- Dossier label is to be mentioned i.e Quality Control Laboratory Dossier.

Table 1: QCL Dossier and samples

S. No.	Contents
1.	Complete QCL Analysis Dossier (As a Separate Dossier)
2.	Sample
3.	Certificate Of Analysis

1. Complete QCL Analysis Dossier

1.1 Index

1.2 Composition Certificate - The Composition formula includes both Q & Q formula and the Batch formula.

1.3 Drug Release Specification - The Release Specification for Finished product.

1.4 Method of analysis of finished product and validation - The Method of Analysis as per the Release specification and Method Validation for the finished product.

1.5 2 CD's containing full QCL data - 2 CD's containing full QCL data i.e from sections 1 to 1.4 of the QCL dossier needs to be given.

2. Sample

2.1 One sample - one pack of samples is to be provided.

3. Certificate of analysis.

3.1 On company letter-head

3.2 Signed by the company or the concerned center or laboratory that held the analysis

3.3 Stamped by the Company or the concerned center or laboratory that held the analysis

3.4 Product name, strength, and form

3.5 Manufacturing date

3.6 Expiry date

3.7 Batch number

The finished product Certificate of Analysis should be enclosed.

B. Stability Dossier and samples

- Stability studies dossier should be properly labeled.
- Documents to be kept in a hard labeled box file product's name, strength, and pack size(s) are mentioned company name, country and city are mentioned distributor's name and city are mentioned.
- Dossier label is to be mentioned i.e Stability Studies Dossier

Table 2: Stability Dossier and samples

S. No.	Contents
1.	Complete Stability Studies Dossier (As a Separate Dossier)
2.	Sample
3.	Certificate Of Analysis

1. Complete Stability Studies Dossier

1.1 Index

1.2 Stability Study protocol

1.3 Stability indicating method

The analytical methods used for assay and related substances should be enclosed.

1.4 Pack declaration certificate

A declaration certificate for the pack that is subjected to stability studies in which the same pack is going to be marketed.

1.5 Stability specification

1.6 Stability data (long term & accelerated)

The Stability data is to be given as per the conditions given below.

Accelerated Stability ($40^{o}C \pm 2^{0}C$ & RH 75%± 5%)

Real-Time Stability ($25^{0}C \pm 2^{0}C$ & RH 60%± 5%)

1.7 2 CD's containing full stability data

2 CD's containing full stability data i.e from section 1 to 1.6 of the Stability dossier needs to be given.

2. Sample

2.1 One sample

One pack of the sample is to be provided.

3. Certificate of analysis.

3.1 On company letter-head

3.2 Signed by the company or the concerned center or laboratory that held the analysis

3.3 Stamped by the Company or the concerned center or laboratory that held the analysis

3.4 Product name, strength, and form

3.5 Manufacturing date

3.6 Expiry date

3.7 Batch number

The finished product Certificate of Analysis is to be enclosed.

C. Registration Dossier and samples

- Registration dossier should be properly labeled.
- Documents to be kept in a hard labeled box file product's name, strength, and pack size(s) are mentioned company name, country and city are mentioned distributor's name and city are mentioned.

- Dossier label is to be mentioned i.e Registration Dossier.

Table 3: Registration Dossier and Samples

S. No.	Contents
C.	**Registration Dossier and Samples**
1.	Index
2.	Receipt for registration
3.	Covering letter from the local distributor
4.	Patent letter from the company with patent references (if applicable)
5.	Copy of the UAE Company registration certificate and copy of agency agreement/distribution agreement with mentioning company's name, distributor's name, and list of products covered by this agreement
6.	Application form for conventional (medicinal) product registration
7.	CPP issued by competent authorities in the country of Origin
8.	Composition Certificate
9.	Active ingredient (API) specifications
10.	Attested Package insert (leaflet) if not attached to the CPP
11.	Package insert (leaflet) of the product (for the COO product and the proposed UAE product)
12.	TSE free certificate (if the product contains magnesium stearate, lactose, or gelatin derived from animal source)
13.	Letter issued from the company stating that magnesium stearate, lactose, or gelatin are derived from a non-animal source
14.	Price List
15.	Certificate of Analysis
16.	Outer label of the Product (or art work) (for the COO product and the proposed UAE product)
17.	Inner label of the Product (or art work) (If applicable) (for the COO product and the proposed UAE product)
18.	Sample (2 sample are required)
19	Scientific documents
20	Registration in other countries than the COO (if applicable)
21	Relationship Letter (if applicable)
22	Art works in a "JPEG" Format CD
23	Executive summary of stability protocol

D. Bioequivalence File (if applicable)

- Bioequivalence Study dossier should be properly labeled.

- Documents to be kept in a hard labeled box file product's name, strength, and pack size(s)

are mentioned company name, country and city are mentioned distributor's name and city are mentioned.

- Dossier label is to be mentioned i.e Bioequivalence Study Dossier)

Table 4: Bioequivalence Dossier Requirements

1.	Complete Bioequivalence Study dossier (as a separate dossier)
1.1	Index
1.2	CRO's requirements:
1.3	Full Bioequivalence Study data (as mentioned in point no. 2).
1.4	2 CDs containing full Bioequivalence data
2.	Full Bioequivalence Study data
2.1	Synopsis of the Report
2.2	Table of contents for the individual clinical study report
2.3	List of abbreviations and definition of items
2.4	Ethics
2.5	Investigators And Study Administrative Structure
2.6	Introduction
2.7	Study Objectives
2.8	Investigational Plan
2.9	Study Subjects
2.10	Efficacy Evaluation
2.11	Safety Evaluation
2.12	Discussion And Overall Conclusions
2.13	Tables, Figures & Graphs Referred to but not included in the text 2.13.1 Demographic Data 2.13.2 Efficacy Data 2.13.3 Safety Data
2.14	Reference List

Renewal of Registration of Pharmaceutical Conventional Drug[15]

Declarations are to be made For the Renewal of Registration of a Conventional Pharmaceutical Product.

- The declaration should be properly filled, signed, and stamped and no handwriting or correction is accepted.
- The original certificate of principle product and (2) samples+ Certificate of analysis should be submitted along with this declaration.
- A copy of CPP should be submitted along with this declaration.
- Two sets of the outer pack, inner label, and package insert with a soft copy in a labeled CD in a JPEG format should be submitted along with this declaration.
- Soft copy of renewal file should be submitted in a labeled CD.
- The form is for each product strength.
- This Declaration should be submitted during 3 months before the registration of principle product expiry, otherwise, the registration of the product will be canceled.
- A scanned copy of the Renewal Declaration [Section B] is accepted until the original declaration is ready for submission.
- Fees should be paid before submission.

∗ The declaration form is added as an annexure

Then the receipt of declaration is received.

Minor Variation of Conventional Registered Product[16]

Minor variations are applied in the application form for Minor Variations.

Three types of procedures acc to impact of variations:

Changed medicine Type I/A:

Approval of Drug Control Department is required.

(The evaluation through minor change committee, and the certificate will be issued for the approval of variation).

Changed medicine Type I/B:

Approval Quality Control Laboratory only is required (The evaluation through minor change committee is not required, and the certificate will be issued for the approval of variation).

Changed medicine Type II*:*

Notification to Drug Control Department with immediate implementation (The variation will be accepted /or rejected at the time of submission of the file, and the certificate will issue within 30 days.

Changed medicine Type III:

Notification to Drug Control Department with immediate implementation (This type of variation doesn't require approval from the Drug Control Department, but notification of variation should be submitted among with the application form); a certificate will not be issued.

Table 5: Minor Variation of Conventional Registered Product

No, if variation	**Description of Changes**	**Procedure Type**
1	**EXCIPIENT: Replacement of an excipient with a comparable excipient of the drug product: same or different functional characteristics of the excipient.**	**I/B**
Documentation		
1. The exact composition of the Drug Product 2. Quality control laboratory File includes the new release and shelf-life specifications and method of analysis of the finished product and its validation. 3. Stability study (long term & accelerated) following the UAE stability guideline. 4. Shelf life statement. 5. Justification of the change (if applicable), and for not submitting Bioequivalence studies. 6. For solid dosage forms, comparative dissolution profile data of at least 2 pilot-scale batches of the finished product in the new and old composition and justification for not submitting a new bioequivalence study. 7. If the excipient, e.g. magnesium or calcium stearate, stearic acid, gelatin, lactose …etc.)		

that is, or potentially of animal origin, or comes into contact with the material of animal origin during manufacture, the source of the material (or contact) must be declared, and evidence must be provided that the product is free from viruses, other micro-organisms, and transmissible spongiform encephalopathy (TSE) agents, by submitting relevant EDQM certificates. 8. Samples with Certificate of Analysis. Note: Change in the source of an excipient, from a TSE risk to vegetable or synthetic source: Declaration, that the specification remains unchanged and study or where possible declaration on the equivalent of material.		
2	**EXCIPIENT: Change in coloring system used in the drug product: type or amount of one or more components**	**I/B**
Documentation		
1. Exact Composition of the drug product 2. Updated the finished product specification in respect of appearance/odour/taste and if relevant) 3. Stability study (long term & accelerated) by the UAE Stability Guideline. Quality control laboratory file includes the new release and shelf-life specifications and method of analysis of finished product in case of increased addition or replacement. 4. Sample of the new product 5. Documentary evidence that the specific source of the transmitting animal spongiform encephalopathies TSE risk material has been assessed by the competent authority and proved that it's free from TSE contamination.		
3	**EXCIPIENT: Change in flavoring system used in the drug product: type or amount of one or more components**	**II**
Documentation		
1. The exact composition of the drug product 2. Documentary evidence that the specific source of the Transmitting Animal Spongiform Encephalopathies TSE risk material has been assessed by the competent authority and proved that it's free from TSE contamination. 3. Sample of the new product		

4	**EXCIPIENT:** **-Change in the quantitative of excipient ±5%** **-Change in the quantitative composition of the coating of tablet or capsules amounting to 2% of total weight.** **-Change the volume of the granulating fluid to ±15%**	**III**
Documentation		
1. Exact Composition of the drug product 2. In the case of coating, a declaration from the company states that coating has no modified release properties.		
5	**MANUFACTURING SITE: change in site for the total process: bulk manufacturing + packaging + batch control/testing except releasing the finished product**	**II**
Documentation		
1. Letter from the pharmaceutical company specifying the operation that will hold on the site 2. Copy of manufacturing site registration certificate. 3. Declaration from the company, states that no change in the quantitative & qualitative of the composition and manufacturing process. The declaration should be on the company's original letterhead and be dated and signed by a qualified person that holds a product license in the company.		
6	**LABORATORY SITE: change in site for batch control/testing of drug product**	**III**
Documentation		
1. Covering letter to Drug Control Department 2. Formal accreditation as test laboratory or quality control standard certificate for the Laboratory issued by the relevant competent authority. 3. Updated release & end-shelf life specification for the product		
7	**MANUFACTURING SITE: change in**	**II**

	site for the release of drug products within the same country.	
Documentation		
1. Registration certificate for the manufacturing site issued by the UAE drug control department 2. Declaration from the company, states that no change in the quantitative & qualitative of the composition and manufacturing process. The declaration should be on the company's original letterhead and be dated and signed by a qualified person that holds a product license in the company. 3. Sample with new site name & address (If applicable).		
8	**MANUFACTURING SITE (SOURCE TRANSFER): change in site for the release of the drug product to a site in a different country.**	**II**
Documentation		
1. Registration certificate for the site issued by the UAE drug control department 2. Declaration from the company, states that no change in the quantitative & qualitative of the composition and manufacturing process. The declaration should be on the company's original letterhead and be dated and signed by a qualified person that holds a product license in the company. 3. Sample with new site name & address (If applicable). 4. Change of the country of origin for a site that releases the drug product, the following point is required addition to the above points: a) Authenticated CPP of each product from a new source. b) price Certificate from the new source		
9	**Marketing Authorization Holder in COO: change in the name and/or address of a company of the finished products**	**I/A**
Documentation		
1. Company Application form Part 1. 2. Declaration from the company state that the manufacturing site shall remain the same. The declaration should be on the company's original letterhead and be dated and signed by a qualified person that holds a manufacturer license in the company.		

3. List of the related products. 4. Outer & Inner label of each Product (or artwork), on company letterhead, signed & stamped. (on CD preferably) 5. Sample with new company name & address (If applicable).		
10	**MANUFACTURING SITE: Deletion of any manufacturing site (including for an active substance, intermediate or finished product, packaging site, the manufacturer responsible for batch release, the site where batch control take place)**	**III**
Documentation		
1. Letter from company outline the present and the proposed manufacturing site that take place in the manufacturing process. 2. Declaration from the company, states that no change in the quantitative & qualitative of the composition. The declaration should be on the company original letterhead and be dated and signed by a qualified person that holds a product license in the company		
11	**CONTAINER: Change in any part of the primary packaging material, not in contact with the finished product formulation (change in colour shape or dimensions of the container &/or closure system such as colour of flip-off cap, colour code rings on ampoules, change of needle shield, logos, diagram, or picture)**	**III**
Documentation		
1. The Variation application form should clearly outline the present and proposed container. 2. Outer & Inner label of each Product (or artwork), on company letterhead, signed & stamped. (on CD preferably) 3. Sample of new container/closure (If applicable).		
12	**CONTAINER: Change in the qualitative and/or quantitative composition of the immediate packaging material**	**I/B**
Documentation		

1. The Variation application form should clearly outline the present and proposed container. 2. Stability study (long term & accelerated) by the UAE Stability Guideline. 3. Approved end shelf life finished product specification. 4. Outer & Inner label of each Product (or artwork), on company letterhead, signed & stamped. (on CD preferably) 5. Sample of new container/closure (If applicable).		
13	**CONTAINER: Addition or replacement or deletion of a measuring or administration device not being an integrated part of the primary packaging (spacer devices for metered-dose inhalers are excluded)**	**II**
Documentation		
1. Letter from the company describing, detailed drawing and composition of the device material. 2. Proof of CE marking 3. Data to demonstrate accuracy precision and compatibility of the device if NO CE marking is available 4. Sample of the new device (If applicable)		
14	**PRODUCT NAME: New product name to replace existing name (no change in formulation and test specification)**	**III**
Documentation		
1. Approval of health authority in the country of origin of the newly invented name. (Authenticated) 2. Declaration from the company, state that no change in the quantitative & qualitative of the composition and manufacturing site and process. The declaration should be on the company original letterhead and be dated and signed by a qualified person that holds product license in the company. 3. Outer & Inner label of the Product (or artwork), on company letter head signed & stamped. (on CD preferably) 4. Sample with new name (If applicable		
15	**ACTIVE SUBSTANCE: Change in the**	**IA**

	name and/or address of a manufacturer of the active substance where no European pharmacopeia certificate of suitability or any equivalent document is available	
Documentation		
1. Copy of manufacturing license issued by the relevant drug regulatory agency in which the new name and/or new address is stated.		
16	**ACTIVE SUBSTANCE: change in the manufacturer of the active substance**	**II**
Documentation		
1. Certificate of Suitability or Equivalent documents been issued for the active substance. 2. Company statement confirming no change to active substance Specifications.		
17	**FINISHED PRODUCT SPECIFICATIONS/TEST METHODS: revised specifications/test methods (no change in the manufacturing process) product controlled according to a pharmacopeia monograph (resulting from a change to a different pharmacopeia, not simply updating to the latest edition. or/ tightening of limits for active substance no other changes to specifications and no changes to test methods or/ adoption of additional or different specifications/test methods not specified in the pharmacopoeial monograph for a product otherwise controlled according to a pharmacopoeial monograph**	**III**
Documentation		
1. New shelf-life specification 2. New release specification 3. Test procedure (Statement, that old & new methods are at least equivalent)		

4. Validation of test for assay and Impurities 5. Copies of new and old certificates of analysis		
18	**FINISHED PRODUCT: Change of dimensions of tablets, capsules, suppositories, or pessaries without change in qualitative or quantitative composition and mean mass.**	**III**
Documentation		
1. Comparative dissolution data on at least one pilot batch of the current and proposed dimensions. 2. Where applicable, data on breakability test of tablets at release must be given and commitment to submit data on breakability at the end of shelf life. 3. Samples of the finished product (If applicable)		
19	**FINISHED PRODUCT: change in a coating weight of tablets or change in weight of capsule shell (in case of immediate-release oral pharmaceutical forms, or modified or prolonged-release pharmaceutical forms)**	**IB**
Documentation		
1. Exact Composition of the drug product 2. Comparative dissolution data on at least one pilot batch of the current and proposed dimensions. 3. Stability study (long term & accelerated) following the UAE Stability Guideline. 4. Approved end shelf life finished product specification. 5. Samples of the finished product (If applicable)		
20	**FINISHED PRODUCT: Change or addition of imprints, bossing, or other markings (except scoring/break lines) on tablets or printing on capsules, including replacement, or addition of inks used for product marking**	**III**
Documentation		
1. Description of the drug product 2. Samples of the finished product (If applicable) Note: Finished product test method, release and shelf-life specification have not been		

changed.		
21	**STORAGE CONDITION: Change in storage condition without change in shelf life and no other changes or • addition of a statement such as "protect from light", change in storage conditions of reconstituted/diluted drug product**	**IB**
Documentation		
1. Stability study (long term & accelerated) following the UAE Stability Guideline. 2. Approved end shelf life finished product specification and where applicable specification after dilution/reconstitution or first opening 3. Description of packaging material (primary & Secondary) 4. Justification for the change. 5. Outer & Inner label of the product (or artwork), on company letterhead, signed & stamped. (CD preferably) 6. Samples of the finished product (If applicable)		
22	**SHELF LIFE: Extension of shelf life drug product and/or change in shelf life after first opening of the drug product and/or change in shelf life after dilution/reconstitution of drug product**	**IB**
Documentation		
1. Stability study (long term & accelerated) following the UAE Stability Guideline. 2. Approved end shelf life finished product specification and where applicable specification after dilution/reconstitution or first opening 3. Description of packaging material (primary & Secondary) 4. Outer & Inner label of the Product (or artwork), on company letterhead, signed & stamped. (CD preferably) 5. Samples of the finished product (If applicable) Note: The shelf life does not exceed five years		
23	**SHELF LIFE: Reduction of shelf life without a change in the storage condition.**	**II**

Documentation		
1. Justification for the reduction of shelf life.		
24	**PACK SIZE:** **Change/ addition of pack size without a change in container or closure system and/or without change in packaging material and doesn't affect dose measurement or dose delivery: 1- change in the number of units (e.g. tablets, ampoules) in a pack) 2- change in the fill weight/fill volume of non-parental unit-dose products**	**IA**
Documentation		
1. Cover letter explaining the change 2. New Price certificate. 3. Outer & Inner label of the product of new pack size (or artwork), on company letterhead, signed &stamped. (CD preferably). 4. Samples of the new pack size (If applicable)		
25	**PACK SIZE:** **Adding of new pack size with new container or closure type and/or new packaging material type and/or new shelf life and/or storage conditions and** **affects dose measurement or dose delivery**	**IA**
Documentation		
1. CPP or Approval letter from the regulatory authorities in the country of origin for the pack size change. (Authenticated) 2. New Price certificate.		

3. Justification for the new pack size, showing that the new pack size is consistent with the dosage regimen and duration of use as approved in the SmPC. 4. Stability study (long term & accelerated) following the UAE Stability Guideline. 5. Approved end shelf life finished product specification where applicable. 6. Outer & Inner label of the Product of new pack size (or artwork), on company letterhead, signed & stamped. (CD preferably) 7. Samples of the new pack size (If applicable)		
26	**PACK INSERT CHANGES**	
Three Main Grades		
Grade A	**- Addition of new indications or modified indications and consequential changes included new dosage instructions.** **- New dosage regimen with no change to indication.** **- Deletion of (contraindications, warnings, side effects, precautions & drug interaction).**	**IA**
Documentation		
1. Declaration letter explaining the new changes. 2. Legalized approval of the health authorities of the country of origin for the new changes. 3. Supportive clinical literature if the changes are related to new indications or a new dosage regimen. 4. Comparison table between old & new pack insert. 5. Artwork or word document of old & new pack insert.		
Grade B	**Addition of (contraindications, warnings, side effects, precautions & drug interaction).**	**II**
Documentation		

1. Declaration letter explaining the new changes. 2. Company core data sheet (CDDS) supporting the new changes. 3. Comparison table between old & new pack insert. 4. Artwork or word document of old & new pack insert. 5. Acceptance in other countries (if applicable).		
Grade C	**- Revised wording of the package insert with no actual changes to the approved information.** **- Re-design of a label with no changes in the approved information.** **- Change in the size of label, printing color, font, etc.....**	**III**
Documentation		
1. Justification letter explaining the new changes. 2. Copy of the proposed pack insert.		

License Maintenance

- Renewal

Every 5 years, documents should be submitted 3 months before expiry:

- Renewal declaration
- Original certificate of registration
- Receipt of fees payment
- 2 samples of each pack size and CoA's of the same batch.
- Copy of UAE valid registration certificate for the manufacturing site of the product all manufacturing sites need to be registered and renewed.

➢ Renewal of all registered products in the UAE. Companies have to provide lists of products they wish to renew or to cancel together with certificates of Suitability for API.

Declaration with the renewal documents that no variations in the product for the past 5 years, signed and stamped by the company.

Registration Fees

Table 6: Registration Fees for an Application

Registration Fees	
➢ Company	• ~US$ 272 (1,000 AED)
➢ Each manufacturing site	• ~US$ 272 (1,000 AED)
➢ Product	• ~US$ 136 (500 AED) • Renewal - $ 136 • Analysis - $ 136 • Variation - $ 15

Regulatory Information and point to remember!!!

- Study centers e.g. bioavailability need to be registered.
- Application to market generic drugs will be accepted 12 months before the expiry of the UAE protection of the original product.
- If the dossier is incomplete, the applicant has 3 months for completion before rejection.

SUMMARY AND CONCLUSION:

The pharmaceutical industry in UAE, broadly understood as generic drugs, over-the-counter (OTC) medicine, and patented drugs, is proving attractive for manufacturers for several reasons. Perhaps the most important factor is that the health industry typically bucks the trend of the economic cycle. Healthcare and therefore pharmaceutical products are often considered a daily necessity and therefore exhibit stable sales to the economy.

In the UAE, and the wider GCC, growth prospects for the sector are amplified partly because of the population dynamic of an emerging yet sizeable growing middle-income class. According to economist intelligence unit forecasts, the GCC population will reach 53 million

by 2020. As incomes rise, spending on healthcare typically rises as consumers tend to become more health-focused[17].

Registration and Drug Control Department under MOH holds good for the registration of Pharmaceuticals in UAE. The study points towards a positive trend stating that despite prevailing challenges, the market for pharmaceutical products is likely to remain strong in the wake of lifestyle changes region-wide. The prospects for the sector are likely to improve over time as local and national legislation continues to be in closer agreement with international standards. Growing population and incomes underpin the growth dynamic for the foreseeable future.

REFERENCES

1. AME Info. UAE pharmaceutical industry to lead regional growth. June 2012.
2. Latham & Watkins. Healthcare Regulation in the UAE. 2011
3. Pender-CudlipMichael. Global & GCC Pharmaceutical Market trends. April 2011.
4. Business Monitor International. United Arab Emirates Pharmaceuticals and Healthcare Report Q4 2012. October 2012. 104 p.
5. Frost & Sullivan. Economic 360 for the UAE: Growth Prospects and Emerging Opportunities in the Healthcare Industry. March 2012. 88 p.
6. UAE. Unique demands in the Pharmaceuticals & Healthcare Industry
7. RNCOS. UAE Healthcare Sector Forecast to 2012. November 2011. 95 p
8. Global Data. Brand Power to Fade in UAE Pharmaceuticals? November 2012
9. Ministry of Health, UAE.
10. Ministry of Health, UAE. Drug Control & Licenses. Last Updated: January 2011.
11. Ministry of Health, UAE. Organization Structure. Last updated: January 2011.
12. Check List - for Conventional products - Amended in November 2012Ministry of Health, UAE
13. Conventional manufacturers and products Registration. Ministry of Health, UAE.
14. Guidance for registration of an ethical conventional medicinal product. Ministry of Health, UAE.
15. Updated Renewal Declaration.19-2-2009. Ministry of Health, UAE
16. Minor variation guidelines. Ministry of Health, UAE.
17. UAE pharmaceutical industry set to benefit from lifestyle changes. Zawya.2011 August.