REGULATORY PREREQUISITE FOR PHARMACEUTICAL PRODUCTS AS PER UAE GUIDELINES


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ABSTRACT

This contemplative approach on pharmaceutical product registration in UAE can be done only as per the regulatory guidelines of UAE. This retrospective approach provides the information on Roles and responsibilities of Health authorities as per UAE guidelines for export Application for registration of medicinal product, Drug application appointment sheet, checklist for conventional new drug application, Renewal of registration of conventional pharmaceutical product, Requirements of drug control lab, Registration of food supplement Requirements of Drug Registration in the United Arab Emirates, Receipt and checklist for receiving a conventional new drug application, Public healthcare services are administered by different regulatory authorities in the UAE. The Ministry of Health, HAAD, DHA and EHA are the main authorities. Despite the government’s efforts at modernizing the healthcare system by creating new authorities and issuing new regulations in the last decade, the division of powers and authorities among the various regulatory entities (between the Federal and Emirates levels and between different entities at each level). The main principle according to the UAE Regulation is implementing the registration of all medicines with the Ministry of Health (MOH) in order to be legally circulated in the UAE market. Any medical company which plans the marketing of its production in the country should be registered in the Ministry.

KEYWORDS: Health Authority-Abu Dhabi (HAAD), the Dubai Health Authority (DHA), Emirates Health Authority (EHA), United Arab Emirates (UAE).
INTRODUCTION

UAE is the second largest pharmaceutical market in the gulf region. It is the regional leader in the manufacturing of pharmaceutical products and it is likely to grow steadily for some years. The total market value is estimated at US$ 1.8 Billion. Strong government support has resulted in growth of healthcare segment. Previously many of the drugs used to be imported but now due to government support local manufacturing of drugs are promoted. Use of generic drugs is promoted to reduce the healthcare cost. Many multinational companies started their operation in Dubai in order to access the market and develop drugs.[1]

UAE, which is the second largest destination for Indian exports after the United States, has emerged as an economic powerhouse. Its free economy, proximity to India, good communication links, excellent infrastructure facilities and the presence of a substantial Indian business community in the country, has made it a very attractive destination for Indian exports and investments[2]. The United Arab Emirates' pharmaceutical market was estimated to have been worth $2.4 billion in 2013 and is expected to reach $3.7 billion by 2020.

Figure 1: UAE map

The positive trends in UAE's healthcare market can primarily be attributed to the increasing coverage of healthcare insurance and government initiatives to improve healthcare facilities. Healthcare, Regulatory and Reimbursement Landscape - United Arab Emirates research report, UAE is benefiting from the establishment of health-related free zones, such as the Dubai Biotechnology and Research Park (DuBiotech), which have encouraged global pharmaceutical players to set up regional centers in the country. Expenditure on pharmaceutical research and development in the UAE is very low compared to other
countries, meaning that novel medicines must be imported at a high price, but projects such as Du Biotech may help to redress the balance.\textsuperscript{[3]}

The United Arab Emirates government is keen to attract foreign investment the government United Arab Emirates Authorities have created two notable free zones to attract foreign investment these are Du Biotech and Dubai Healthcare City (DHCC) biotech industry,. Du Biotech is aimed at developing the UAE's biotech industry, while Dubai Healthcare City (DHCC) should enhance the country's healthcare system and should enhance the UAE's reputation as a centre for premium healthcare.\textsuperscript{[4]}

\textbf{Requirements of Drug Registration in the United Arab Emirates}

The regulatory requirements of various countries of the world vary from each other. Therefore, it is challenging for the companies to develop a single drug which can be simultaneously submitted in all the countries for approval. The rules and regulations enforced by the government to protect the health and well-being of the public. Therefore, the aim of the pharmaceutical industry is to identify and develop a generic drug product which can be tailor made to meet the diverse market requirements.\textsuperscript{[5]}

The importation of pharmaceuticals into the UAE is controlled by the Ministry of Health. While federal law states that no medicine or pharmaceutical preparation should be put into circulation, except after registration of the product with the Ministry. While in the past there was a requirement that only companies wholly owned by UAE nationals could apply for registration, it is now possible for companies owned by both a UAE shareholder and a foreign shareholder to apply for registration.

Therefore, for companies wishing to import pharmaceuticals or medical devices into the UAE must be register according to UAE regulations.\textsuperscript{[6]} Any pharmaceutical company wants to be registering their drug products into the UAE they must know the registration procedures and regulations for better understanding and ease of access. In this article we are discussing about the procedures and regulations for product registration in UAE.

\textbf{Roles and responsibilities of Health authorities as per UAE guidelines}

Before a new drug or biologic can go to market, a drug submission must be compiled and filed with all relevant regulatory agencies to seek a review and, ultimately, regulatory approval.\textsuperscript{[7]} Product assessment and registration (also known as marketing authorization and
product licensing) are carried out by drug regulatory authorities to ensure that a pharmaceutical product has been adequately tested and evaluated for safety, efficacy and quality and that the product information provided by the manufacturer is accurate.

They involve evaluating technical and administrative data submitted about a drug product, deciding whether to approve or reject the product, issuing a marketing authorization (certificate) and conducting ADR monitoring.[8] Medicines regulation incorporates several mutually reinforcing activities all aimed at promoting and protecting public health. These activities vary from country to country in scope and implementation, but generally include the functions listed below.[9]

**Principal medicines regulatory functions**

- Licensing of the manufacture, import, export, distribution, promotion and advertising of medicines
- Assessing the safety, efficacy and quality of medicines, and issuing marketing authorization for individual products
- Inspecting and surveillance of manufacturers, importers, wholesalers and dispensers of medicines
- Controlling and monitoring the quality of medicines on the market
- Controlling promotion and advertising of medicines
- Monitoring safety of marketed medicines including collecting and analysing adverse reaction reports
- Providing independent information on medicines to professionals and the public

Currently different countries have to follow different regulatory requirements for approval of new drug. For marketing authorization application (MAA) a single regulatory approach is applicable to various countries is almost a difficult task. Therefore it is necessary to have knowledge about regulatory requirement for MAA of each country.[9] Regulatory authorities in both developed and developing countries share the responsibility of ensuring the access of safe and effective medicines to patients; however their structures, strategies, and practices vary significant.
Table no.1 Roles and responsibilities of Health authorities in UAE [10,11]

<table>
<thead>
<tr>
<th>Name of the Authority &amp; Established Year</th>
<th>Role and Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>UAE Ministry of Health Pursuant to Federal Law No. 1 of 1972</td>
<td>Established pursuant to Federal Law No. 1 of 1972, providing healthcare services, build and manage health facilities and regulate various areas of healthcare (practice of medicine, dentistry, nursing, pharmaceuticals and laboratories) Administrates a number of federal healthcare laws</td>
</tr>
<tr>
<td>General Authority of Health Services (GAHS-2001)</td>
<td>Mandate to oversee all public health care institutions in the Emirates of Abu Dhabi In 2007 GAHS was split into two organizations i.e. HAAD and SEHA</td>
</tr>
<tr>
<td>Dubai Healthcare City (DHC-2002)</td>
<td>Medical community - Clinical services for disease treatment and prevention comprises two hospitals and medical, dental, nursing facilities and associated health schools. Wellness community houses outpatient clinics, spa resorts, and other providers of wellness services. DHC pursuant to various rules, policies, standards and guidelines that are intended to comport with international best practice.</td>
</tr>
</tbody>
</table>
❖ Monitoring and regulating the health care industry in Abu Dhabi  
Public authority with financial and administrative independence pursuant to Abu Dhabi Law No.1  
Provide Highest levels of Medical and Health insurance services & developed health related policies in Abu Dhabi  
❖ Opportunities for private investment |
| Emirates Health Authority (EHA-2009) | Similar regulatory functions and initiatives as HAAD and DHA  
Main objective is to encourage cooperation between the federal and local health authorities and between such authorities and the private sector. |
| HAAD-2012 December | Released new set of policies and regulations  
Aim to enhance quality control, transparency, good governance and access to health care aim to enhance coordination between the major stakeholders and define the division of roles, responsibilities |
| Abu Dhabi Health Services Company (SEHA-2007) | ❖ Manages public Health facilities and implement the policies, projects and Strategies approved by HAAD  
SEHA Collaborated with Johns Hopkins for the management of Tawam hospital in Al Ain, Al Rahba hospital and Corniche Matenity Hospital in Abu Dhabi  
Cleveland Clinic to manage Sheikh Khalifa Medical city in Abu Dhabi  
Vienna Medical University for management of Central hospital in Al-Ain |
| Dubai Health Authority June(DHA-2007) | Pursuant to Law No.13, Main Authority for the, regulating health care services in Emirate of Dubai.  
Improving Health care quality through information systems and standards  
Health care planning and promotion of health care investment in Dubai, Developing a health care insurance and funding policy medical education and research and owning and operating Dubai government Health care facilities  
Health care facilities and Professionals in Dubai must be licensed by DHA(Hospital and day surgical centers, ambulatory care facilities, |
Drug Registration Regulatory guidelines in UAE
Registration of drugs, also known as product licensing or marketing authorization, is an essential element of drug regulation. All drugs that are marketed, distributed and used in the country should be registered by the national competent regulatory authority. Only the inspection of manufacturing plants and laboratory quality control analysis certainly does not guarantee product quality and safety. Drug regulation should therefore include the scientific evaluation of products before registration, to ensure that all marketed pharmaceutical products meet the criteria of safety, efficacy and quality.\(^{[12]}\)

The majority of companies find that a legalized CPP from the source country is required at the time of Marketing Authorization (MA) application. However, although Ministries will not grant final approval until a CPP has been received from companies, a number are now willing to accept CPPs at the time of MA.\(^{[13]}\)

Application for registration of Medicinal Product
Manufacturers who are willing to market their products into UAE, their product must be registered before going to market according to UAE regulatory guidelines. The application for registration of a Medicinal product should states that Detail of local distributor, Detail of the Manufacturing site responsible for batch release of finished product, Detail of the Marketing Authorization holder, Detail of Manufacture (s) of API (s), Details of Product, Product packaging, Patient information, Storage conditions & Shelf life, Product composition, Ingredients of Animal origin, Leaflet Information, Pharmacological Properties, Bio equivalence Details for generic product, Price details and Declaration.\(^{[14]}\)
Fig.no.2 Drug Registration appointment sheet in UAE  

<table>
<thead>
<tr>
<th><strong>Drug Registration Appointment Sheet</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Applicant Name and Address (Agent)</strong></td>
</tr>
<tr>
<td><strong>Applicant Authorized Representative</strong></td>
</tr>
<tr>
<td><strong>e-mail:</strong></td>
</tr>
<tr>
<td><strong>Appointments Date and Time</strong></td>
</tr>
<tr>
<td><strong>Appointments No. of Files To Be Submitted</strong></td>
</tr>
<tr>
<td><strong>Appointments Authorized person name &amp; signature</strong></td>
</tr>
</tbody>
</table>

FOR CLASSIFICATION REQUESTS:
FILL AND STAMP INQUIRY FORM COMPLETELY INCLUDING NAME OF ALL INGREDIENTS AND THEIR QUANTITIES, LOCAL AGENT, APPLICANT NAME, NAME OF MANUFACTURER AND COUNTRY OF ORIGIN ALL IN THE PAPER FORM AND ALSO PROVIDE THE ABOVE AS SOFTCOPY WRITTEN IN MICROSOFT WORD OFFICE ON CD.
Check list for New drug Application in UAE

Check list for New Drug Application in UAE [9]

United Arab Emirates
Ministry of Health
Medical Licensing & Practices Sector
Registration and Drug Control Department

**RECEIPT AND CHECK LIST FOR RECEIVING A CONVENTIONAL NEW DRUG APPLICATION**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local authorized Distributor’s name and city</td>
<td></td>
</tr>
<tr>
<td>Store license no. and validity</td>
<td></td>
</tr>
<tr>
<td>Product’s name</td>
<td></td>
</tr>
<tr>
<td>Generic name</td>
<td></td>
</tr>
<tr>
<td>Dosage form</td>
<td></td>
</tr>
<tr>
<td>Strength</td>
<td></td>
</tr>
<tr>
<td>Pack size(s)</td>
<td></td>
</tr>
<tr>
<td>MAH for UAE Name , City, Country</td>
<td></td>
</tr>
<tr>
<td>Batch releaser Name, City, Country</td>
<td></td>
</tr>
<tr>
<td>Manufacturing site(s) for Bulk dosage form</td>
<td></td>
</tr>
</tbody>
</table>

**Quality Control Laboratory**

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>QCL &amp; Stability Studies</td>
<td>Received by the DAS</td>
</tr>
<tr>
<td>B.E. Study</td>
<td>Not required</td>
</tr>
<tr>
<td></td>
<td>Received by the DAS</td>
</tr>
<tr>
<td>Pre-registration analysis</td>
<td>Exempted</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DRCD Representative</th>
<th>Applicant (Agent) Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>Name</td>
</tr>
<tr>
<td>Signature</td>
<td>Signature</td>
</tr>
<tr>
<td>Date</td>
<td>Date</td>
</tr>
</tbody>
</table>

Fig. No.3 Requirements of Drug Registration in the United Arab Emirates
Drug Registration Guidelines in UAE

**General Notes**
- New Drug Application should be in accordance with 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 labelled 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 labelled 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 labelled as per Module 1 file.
- The Authorized Person is kindly requested to submit one hard copy and 1 soft copy of Module 3 (Quality and Stability) & Bioequivalence Studies dosiers 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 check list (signed as received by the Drug Analysis Section) to the Drug Registration Section.

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Requirements based on the RDCD/MOH/UAU Guidelines and Regulations</th>
<th>Availability * (A / Nav / Nap)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>Payment receipts</td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>Covering letter</td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td>Comprehensive Table of content</td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>Application form properly filled and signed by the qualified responsible person (MAH), and word document soft copy</td>
<td></td>
</tr>
<tr>
<td>1.4</td>
<td><strong>Product Information</strong></td>
<td></td>
</tr>
<tr>
<td>1.4.1</td>
<td>Summary of Product Characteristics (SmPC)</td>
<td></td>
</tr>
<tr>
<td>1.4.2</td>
<td>Labelling Information</td>
<td></td>
</tr>
<tr>
<td>1.4.3</td>
<td>Patient Information Leaflet (PIL)</td>
<td></td>
</tr>
<tr>
<td>1.4.3.1</td>
<td>Arabic leaflet</td>
<td></td>
</tr>
<tr>
<td>1.4.3.2</td>
<td>English leaflet</td>
<td></td>
</tr>
<tr>
<td>1.4.4</td>
<td>Artworks (Mock-ups) [outer label, inner label and leaflet artworks as hard copy and JPEG format soft copy]</td>
<td></td>
</tr>
<tr>
<td>1.4.5</td>
<td>Samples [two original finished samples]</td>
<td></td>
</tr>
<tr>
<td>1.5</td>
<td><strong>Quality on the experts</strong></td>
<td></td>
</tr>
<tr>
<td>1.5.1</td>
<td>Quality information (soft copy)</td>
<td></td>
</tr>
<tr>
<td>1.5.2</td>
<td>Non-clinical information (soft copy)</td>
<td></td>
</tr>
<tr>
<td>1.5.3</td>
<td>Clinical information (soft copy)</td>
<td></td>
</tr>
<tr>
<td>1.6</td>
<td><strong>Environmental Risk Assessment</strong></td>
<td></td>
</tr>
<tr>
<td>1.6.1</td>
<td>Non-Genetically Modified Organism (Non-GMO)</td>
<td></td>
</tr>
<tr>
<td>1.6.2</td>
<td>GMO</td>
<td></td>
</tr>
<tr>
<td>1.7</td>
<td><strong>Pharmacovigilance</strong></td>
<td></td>
</tr>
<tr>
<td>1.7.1</td>
<td>Pharmacovigilance System (soft copy)</td>
<td></td>
</tr>
<tr>
<td>1.7.2</td>
<td>Risk Management Plan (soft copy)</td>
<td></td>
</tr>
<tr>
<td>1.8</td>
<td><strong>Certificates and Letters</strong></td>
<td></td>
</tr>
<tr>
<td>1.8.1</td>
<td>Original legalised valid Certificate of a Pharmaceutical Product (CPP)</td>
<td></td>
</tr>
<tr>
<td>1.8.2</td>
<td>Copy of valid GMP certificates for the manufacturing site(s)</td>
<td></td>
</tr>
<tr>
<td>1.8.3</td>
<td>Certificate of Analysis - Drug Substance (At least three batches for non-local and one batch for local manufacturer)</td>
<td></td>
</tr>
<tr>
<td>1.8.4</td>
<td>Certificate of Analysis - Finished Product (At least three batches for non-local and one batch for local manufacturer)</td>
<td></td>
</tr>
<tr>
<td>1.8.5</td>
<td>Alcohol-content declaration</td>
<td></td>
</tr>
<tr>
<td>1.8.6</td>
<td>P Mara - free declaration</td>
<td></td>
</tr>
<tr>
<td>1.8.7</td>
<td>TSE/BSE free certificate</td>
<td></td>
</tr>
<tr>
<td>1.8.8</td>
<td>API certificate of suitability or US-FDA approval of the DMF</td>
<td></td>
</tr>
<tr>
<td>1.8.9</td>
<td>Copy of valid GMP certificate for the API source</td>
<td></td>
</tr>
<tr>
<td>1.8.10</td>
<td>API Acknowledgment letter</td>
<td></td>
</tr>
</tbody>
</table>
1.8.11 Relationship 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 colouring agents in the product formula
1.8.16 Patent letter with 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 legalised 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

*A: Available, Nav: Not Available, Nap: Not Applicable

The presented New Drug Application is verified according to regulations and is

Received
Not received
Other requested documents or information:

Received by:
Signature:
Receipt no.: Date:
Guidance for Registration of an Ethical Conventional Medicinal Product.[17]

A. QCL Dossier and samples
- Quality Control Laboratory dossier should be properly labeled
  1. Complete QCL analysis dossier is available (as a separate dossier)
  2. Sample
  3. Certificate of Analysis

B. B. Stability Dossier and samples
- Stability studies dossier should be properly labeled
  1. Complete Stability studies Dossier is available (as a separate Dossier)
  2. Sample
  3. Certificate of Analysis

C. Registration Dossier and samples
- Registration dossier should be properly labeled
  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 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 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 is available

D. Bioequivalence File (if applicable)
- Bioequivalence Study dossier should be properly labeled
  1. Complete Bioequivalence Study dossier is available (as a separate dossier)
  2. Full Bioequivalence Study data
  3. Sample

Renewal of Registration of a conventional Pharmaceutical Product
Renewal of registered Conventional pharmaceutical product in UAE should be done with in the three months of expiry of registration of pharmaceutical product. While renewal of conventional Pharmaceutical product we must know the requirements for registration because of any incorrect Information will delay the process of registration for the product. Declaration should be properly filled, signed and stamped and no hand writing 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 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. This Form is for each product strength, Declaration should be submitted during 3 months before the registration of principle product expiry, otherwise the registration of the product will be cancelled 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.
Renewal Application form contains two sections that is Section A and Section B, former one States that Product details and Section B states that Product Formulation Detail.\[^{18}\]

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**Fig No.4 Flow Chart of Renewal of Registration of a conventional Pharmaceutical Product**

**New submissions or re-registration (RR)\[^{19}\]**

The applicant shall fill the form DRS No: 52-A (to be filled by New Medical Centre) accompanied with the following arranged in a separate dossier with separate partitions numbered according to the following order

1. Serial Number.
2. Statement covering letter on the company letter head stating: New product / or re-registration.
3. Product Name
4. Form
5. Pack
6. Patency - Certificate or information that the product is out of Patent.
7. Certificate of Pharm. Product - authenticated by UAE Embassy in the country of origin. The certificate should mention the following:

- Name and address of the manufacturer and the year of incorporation together with registration number
- The manufacturer is licensed to manufacture the preparation the country of origin.
- The manufacturer is permitted to sell freely the preparation the country of origin, mentioning the date of commencement of marketing.
- Formula of the preparation of active and inactive ingredients with quantities in detail
- Shelf life of the preparation
- Validity of the preparation and storage conditions
- Insert leaflet of the preparation
- The preparation is fully conforming to the name, formula and specifications of the product marketed in the country of origin. In case the name of the product requested to be re-registered is different than its name in the country of origin, the certificate should mention two names, confirming that the formula and specification of both the names are same

8. Shelf life on the (C.P.P.)
9. Shelf life on the sample.
10. Pharmacology
11. Toxicology
12. Clinical Studies
13. Research
15. Registration in the other countries (Photocopies to be attached)
16. Price Certificate authenticated UAE Embassy in the country of origin & should mention following details:

- Ex-factory price in the country of origin.
- Wholesale price in the country of origin.
- Retail price in the country of origin
- CIF price to U.A.E.
- CIF price to GCC Countries (like Saudi Arabia, Kuwait)

17. Two Number of samples. (batch no, expiry date & Mfg date printed on both outer and inner pack.
18. Samples of outer and inner pack.
19. Remarks

Requirements of Drug Control Lab. (D.C.L.).[19]
For new submissions & re-registration (RR) the applicant shall fill in the form DRS No: 53 (to be filled by New Medical Center) accompanied with the following arranged in a separate dossier with separate partitions numbered according to the following order:
1. Serial Number
2. Statement whether it is new product or re-registration (Covering letter)
3. Product Name.
4. Form
5. Pack
6. Number of samples submitted
7. Certificate Of composition
8. Shelf life of the sample
9. Finished product release specifications
10. Method of analysis and specifications
11. Certificate of Analysis of the finished product
12. Stability studies specifications.
13. Stability studies - studies more than 12 months.
14. Stability studies - undertaking letter for ongoing stability studies for climatic zone IV.
15. Bioavailability or bioequivalence studies.

- Active ingredient(s) along with a certificate of analysis
17. Preservative(s) along with a certificate of analysis
18. Colorant(s) along with a certificate of analysis.
19. Internal standards.
20. Degradation standards
21. Certificate Of Analysis (where applicable)
**Fig No 5. Receipt for Renewal Declaration of conventional Medicinal products**
Documents required by Ministry of Health for Health Food or Food Supplementary Preparation Registration Requirement. The local agent should submit to the Technical Affairs Division of the Medicine Control Department at the Ministry an application requesting to register the preparations having medical claim and the producer thereof, accompanied with the following documents:

1. Table of contents (Index)
2. Application form for registration duly filled (To be filled by New Medical Centre)
3. Copy of commercial licenses granted for the applicant (local agent) by the Municipality, Chamber of Commerce and the Economy department (To be attached by New Medical Centre).
4. Copy of registration certificate of the agency of manufacturing company and its products for the applicant (local agent) in the Ministry of Commerce and Economy, U.A.E.
5. Certificate(s) issued by competent authority in the country of origin and attested by Embassy of UAE or any other GCC country, stating the following.
   - Name and address of the establishment of the manufacturer and any other information
   - Capital and Annual turnover
   - Manufacturing Licence in the country of origin. (State the licence number and date)
   - Good Manufacturing Practice (GMP) Certificate
   - Free Sale Certificate, should also state the date of introduction of the product into the country of origin market.
   - The product intended for registration in UAE is marketed in the country of origin at least for the last two years with the same name, composition and other specifications. If the trade name of the product intended for registration in UAE is different from that in the country of origin, difference(s) should be explained clearly, and both names should be mentioned with confirmation of similarly in composition and other specifications.
6. Certificates issued from the countries where the product is being marketed mentioning the date of registration and marketing in those countries.
7. List of vademecum (catalogue) of the products manufactured by the manufacturer
8. Product information including:
- Trade name of the product
- Composition and scientific names of the active ingredient(s) (dietary ingredients in dietary supplements) and inactive ingredients with their quantities.
- Indications
- Method of preparation and analysis of the product
- Dosage and direction of use
- Contraindication & Precautions
- Storage conditions
- Validity (expiry date)
- Weight and size of the pack

9. Insert leaflet duly authenticated

10. Dietary supplement must be devoid of hormones, heavy metals (minerals), antibiotics, Steroid, derivatives of pork meat and any natural or chemical ingredients' having harmful effects on human biological or behavioral functions. If the product contains any ingredient from animal source, the kind of animal and extract from it be specified. Percentage of alcohol, if any, must, be mentioned together with reasons thereof.

11. Six samples of the preparation in their original packets together with certificate of analysis of the same batch number.

12. Certificate confirming that the printed information on the outer and the inner label of the product and the leaflet (Arabic and/or English) are similar to that used in the country of origin. The art work in color of the outlet and inner label should be attached.

13. The outer & inner label should include the following information:

- Name of the product
- Active (dietary ingredients) and inactive ingredients, with their quantities.
- Dose and direction of use
- Pack size
- Batch Number
- Date of expiry
- Storage conditions
- Name and address of manufacturing company in the country of origin
14. Any other additional information or documents required by the ministry. All the above mentioned documents of registration must be in Arabic language and/or English language used in the country of origin and attested by one of the embassies or consulates of GCC countries in the country of origin

Table no.2 Fees for registration\[^{[21]}\]

<table>
<thead>
<tr>
<th>S. No</th>
<th>Company registration</th>
<th>Product registration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>SR. 5000 which shall be the 50% fee against studying the company’s file</td>
<td>SR.3000 which shall be 50% of registration fee against studying the company’s file</td>
</tr>
<tr>
<td>2.</td>
<td>SR. 5000 which shall represent 50% of remainder fee upon the final consent and approval for their registration</td>
<td>SR. 3000 which shall represent 50% of remainder fee upon the final consent and approval for their registration</td>
</tr>
</tbody>
</table>

CONCLUSION

United Arab Emirates (UAE) is second only to Saudi Arabia in terms of pharmaceutical investment in Middle East countries, with the creation of tax-exempt drug development zones helping to ensure excellent growth prospects. It states that medical tourism, straightforward regulatory guidelines and increasing healthcare expenditure will also be key factors driving the UAE's pharmaceutical market, which is forecast to be worth $3.7 billion by 2020. Many of the high profile drugs are still imported from Europe, India. Many of the diseases of the region are lifestyle oriented as cost of living have increased people are able to spend more on the medicine. With the economic growth now many people have western standard of living which results in more western diseases in the region

REFERENCES

2. Conference of commercial representatives of India based in select WANA countries Algeria, Egypt, Iran, Israel, Kuwait, Oman, Saudi Arabia, Sudan, UAE, and Yemen. [Internet]. Available From: http://commerce.nic.in/publications/conf_wana.pdf


15. Drug Registration Appointment Sheet [Internet]. Available From: http://cpd-pharma.ae/downloads/1-Common/Appointment.pdf
16. Receipt and check list for receiving a conventional new drug application [Internet]. Available From: http://www.cpd-pharma.ae/downloads/3-Conventional%20%20Reg/conventional.pdf

17. Guidance For Registration of An Ethical Conventional Medicinal Product [Internet]. Available From: http://www.cpd-pharma.ae/downloads/3-Conventional%20%20Reg/Form%20F048%20%20Guidance%20for%20registration%20of%20a%20medicinal%20product.pdf


