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Regulatory Requirements for Pharmaceutical Product Registration in UAE

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Abstract

Over the past decade, the healthcare industry in the United Arab Emirates (UAE) has experienced remarkable growth, positioning itself as the second-largest healthcare industry in the Middle East, trailing only Saudi Arabia. Recognizing the significance of healthcare, the UAE government has prioritized its development and actively promoted it as part of the national development plan. The Ministry of Health (MOH) has played a crucial role in this endeavor by allocating substantial funds to the public sector and focusing on the private market. The UAE has become an attractive market for pharmaceutical and healthcare industries due to several factors. Firstly, the country has witnessed a rise in public and private wealth, primarily driven by the oil boom, resulting in increased healthcare spending. Additionally, the UAE has a strong and continuously improving healthcare infrastructure that enables the delivery of high-quality healthcare services. Moreover, the UAE has established a relatively favorable regulatory environment, facilitating the approval process for pharmaceutical companies to introduce their medicines. This regulatory landscape, combined with the absence of significant local competitors, has made the UAE a desirable market for pharmaceutical and healthcare industries. The objectives of the mentioned study are to provide a comprehensive understanding of the organizational structure of the Ministry of Health (MOH) in the UAE. Additionally, the study aims to offer insights into the pharmaceutical regulatory body in the UAE and provide information on the registration requirements for pharmaceutical products. In summary, the healthcare industry in the UAE has witnessed significant growth, supported by government initiatives, increased healthcare spending, and a favorable regulatory environment. The study seeks to provide valuable insights into the organizational structure of the MOH, the pharmaceutical regulatory framework, and the registration process for pharmaceutical products in the UAE.

Keywords: United Arab Emirates (UAE), Health Authority-Abu Dhabi (HAAD), Dubai Health Authority (DHA), National Defense Academy (NDA), Common Technical Document Modules (CTD)

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INTRODUCTION

Healthcare is a key sector prioritized by the UAE government, leading to remarkable growth and progress in the UAE healthcare industry in recent years. The government's objective is to not only diversify the oil-dependent economy but also establish a robust healthcare infrastructure to ensure adequate services across the Emirates [1]. Healthcare in the UAE is regulated at both the Federal and Emirate levels. Federal legislation has been in place since the 1970s and 1980s, with ongoing efforts to reform the legislation and promote the development of the healthcare industry. Dubai has two healthcare free zones, namely Dubai Healthcare City and Dubai Biotechnology and Research Park, each with its own regulatory bodies.

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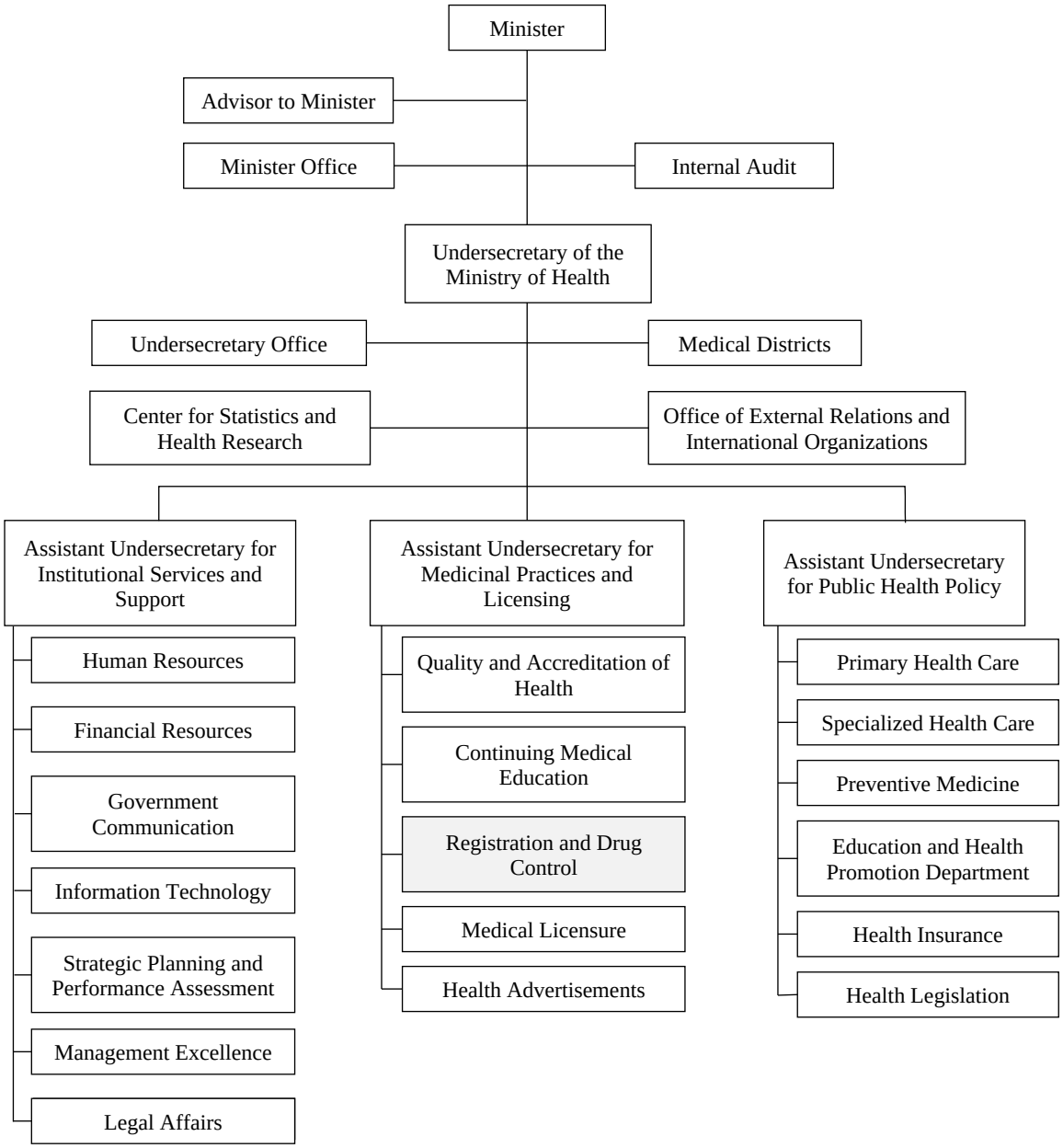

Figure 1. Organizational structure of MoH UAE [2].

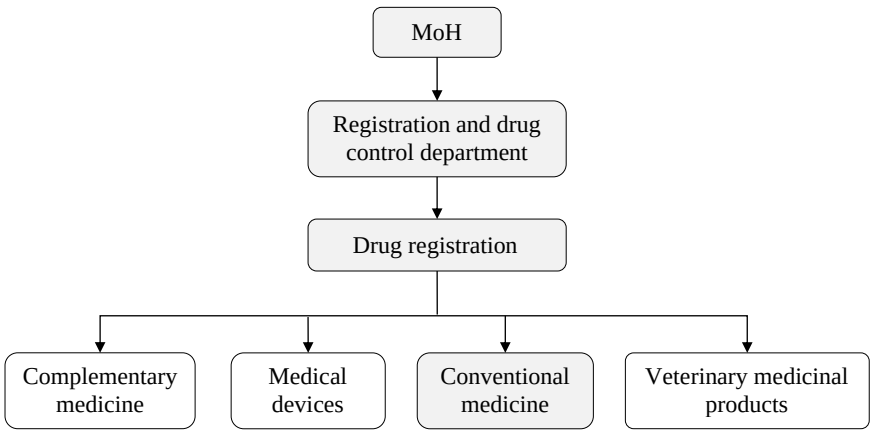

Figure 2. Registration and drug control department.

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Public healthcare services in the United Arab Emirates are overseen by various regulatory authorities, including the Ministry of Health (Ministry), the Health Authority-Abu Dhabi (HAAD), the Dubai Health Authority (DHA), and the recently established Emirates Health Authority (EHA) (Figures 1 and 2).

Registration Guidelines and Requirements of a Conventional Medicinal Product [2, 3]

New drug application should be submitted in accordance with the CTD Modules and structure (One hard copy of Module 1 and 3, and five soft copies (PDF format) of Modules 1, 2, 3, 4 and 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; and
- Local authorized Distributor's name and city.

Soft copies of other modules should be appropriately labeled according to the Module 1 file. The hard copy of Module 3, which pertains to quality and stability, as well as the hard copy of the bioequivalence

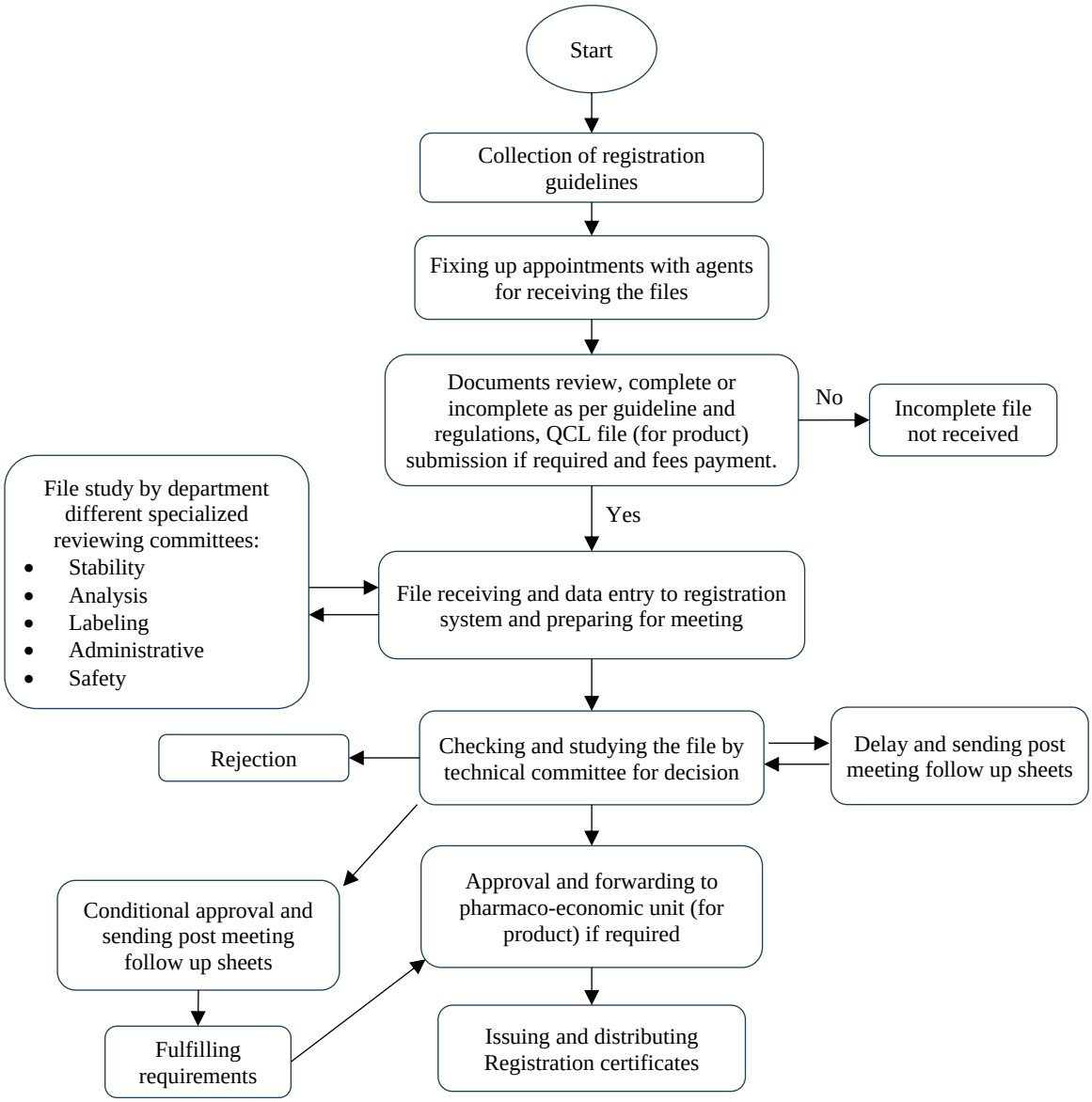

Figure 3. Registration procedure for conventional medicinal product Registration guidelines and requirements of an conventional medicinal product [3].

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studies, should be stored in a separate file that is properly labeled based on the Module 1 file. The authorized individual should submit one hard copy and one soft copy of Module 3 (quality and stability) and the bioequivalence studies dossier to the drug analysis section through prearranged appointments, subsequent to the submission of the registration dossier 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 (Summarized process in Figure 3).

GENERAL REQUIREMENTS FOR DOSSIER SUBMISSION IN UAE [3]

1. QCL dossier and samples:
   i. Quality control laboratory dossier should be properly labeled.
   ii. 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.
   iii. Dossier label is to be mentioned i.e., quality control laboratory dossier.
2. Stability dossier and samples:
   i. Stability studies dossier should be properly labeled.
   ii. 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.
   iii. Dossier label is to be mentioned i.e., stability studies dossier.
   iv. Stability dossier should contain Complete Stability Studies Dossier (As a Separate Dossier), Samples and Certificate of Analysis.
3. Registration dossier and samples:
   i. Registration dossier (requirements in Table 1) should be properly labeled.
   ii. 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.
   iii. Dossier label is to be mentioned i.e., registration dossier.

Table 1. Registration dossier and samples.

S.N.	Contents for 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 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 artwork) (for the COO product and the proposed UAE product)
17.	Inner label of the product (or artwork) (if applicable) (for the COO product and the proposed UAE product)
18.	Sample (two samples 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

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4. Receipt for registration.
5. Covering letter from the local distributor.
6. Patent letter from the company with patent references (if applicable).
7. 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.
8. Application form for conventional (medicinal) product registration.
9. CPP issued by competent authorities in country of origin.
10. Composition certificate.
11. Active ingredient (API) specifications.
12. Attested package insert (leaflet) if not attached to the CPP (the package insert legalized by UAE embassy).
13. Package insert (leaflet) of the product (for the COO product and the proposed UAE product).
14. TSE free certificate (if the product contains magnesium stearate, lactose, or gelatin derived from animal source).
15. Letter issued from the company stating that magnesium stearate, lactose, or gelatin are derived from non-animal source.
16. Certificate of analysis.
17. Outer label of the product (or artwork) (for the COO product and the proposed UAE product).
18. Inner label of the product (or artwork) (If applicable) (for the COO product and the proposed UAE product).
19. Samples (two samples are required).
20. Scientific documents (The toxicology, pharmacology and clinical studies of the concerned product or active ingredient in a labelled CD).
21. Registration in other countries than the COO (if applicable).
22. Relationship letter (if applicable) (authenticated letter issued from the company stating the relation between the company responsible for the application and other concerned parties).
23. Executive summary of stability protocol.
24. Bioequivalence File (if applicable).

Renewal of Registration of Pharmaceutical Conventional Drug [4]

Declarations are to be made for renewal of registration of a conventional pharmaceutical product. Every 5 years, documents should be submitted 3 months prior to expiry.

- Declaration should be properly filled, signed, and stamped and no handwriting or correction is accepted.
- The original certificate of principal 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.
- 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 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.

Minor Variation of Conventional Registered Product [5–10]

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).

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- *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 on the time of submission 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 does not require approval from Drug Control Department, but notification of variation should be submitted among with application form); certificate will not be issued.

Registration and Renewal Fees [3, 4]

1. *Registration of a manufacturer of medical products:*
   i. *Application:* AED 100.
   ii. *Registration of a medical products manufacturer:* AED 10,000.
2. *Registration of a conventional pharmaceutical product:*
   i. *Application:* AED 100.
   ii. *Registration of a conventional pharmaceutical product:* AED 7,000.
   iii. *Analysis or re-analysis of a medical product:* AED 3,500.
   iv. *Pricing certificate after committee approval:* AED 500.
   v. *For PV plan evaluation:* AED 1000.
3. *Renewal of a conventional pharmaceutical product:*
   i. *Application:* 100 AED.
   ii. *Renewal of the registration of a pharmaceutical product derived from natural sources:* 2,500 AED.

CONCLUSION

In the UAE and the wider GCC region, the growth prospects for the healthcare sector are promising due in part to the emergence of a sizable and expanding middle-income class. According to forecasts from the Economist Intelligence Unit, the population of the GCC is projected to reach 54.6 million by 2030. As incomes rise, there is typically an increase in healthcare spending, as consumers become more health conscious.

In the UAE, the Registration and Drug Control Department under the Ministry of Health (MOH) is responsible for the registration of pharmaceuticals. Despite existing challenges, the market for pharmaceutical products is expected to remain robust due to lifestyle changes throughout the region. Furthermore, as local and national legislation aligns more closely with international standards, the prospects for the sector are likely to improve over time. The combination of a growing population and increasing incomes serves as the driving force behind the sector's growth for the foreseeable future.

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