National Drug Policy
in the United Arab Emirates

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- *In case of any misinterpretation, the Arabic version of this policy prevails.*

Introduction:

Due to their close relationship to human health, pharmaceutical products are deemed to be among the most essential biological products in the world.

A pharmaceutical product is any product that contains an active substance or a group of active substances that achieve the desired goal of using such in or on human or animal body through a biological effect. It is manufactured, sold or offered for use in the following cases:

1- Diagnosing, treating, curing, mitigating or preventing a disease.
2- Restoring, renewing, modifying or correcting the functions of body organs.

Pharmaceutical security is in no way less significant than food security; as life means nothing if one's health is at risk. In addition, health can only be maintained upon the availability of the two components of food and medicine which are complementary to each other. If we perceive the definition of the term "Pharmaceutical Security" of countries from a scientific point of view, we find out that- in short- it is the Country's ability to secure a sufficient amount of essential medicines, which society needs for all its segments, whether in ordinary times or in times of crisis. Moreover, the provision of such medicines in addition to vaccines that are deemed permanent does fall under such concept. It also covers the provision of the raw materials used in the formulation or the manufacture of the medical products that are needed for the local pharmaceutical industry.

There are various areas of pharmaceutical security ranging from the provision of sufficient quantities of essential medicines in due course to the provision of medicines of continuous usage in quantities sufficient for national consumption for future periods.

On March 17th, 2020, His Highness Sheikh Mohamed bin Zayed Al Nahyan, Crown Prince of Abu Dhabi and Deputy Supreme Commander of the United Arab Emirates Armed Forces (may Allah protect him) addressed his nation in the United Arab Emirates stating that **"In the United Arab Emirates, Medicine and Food constitute a red line in that cannot be crossed!".** They must be secured for our people indefinitely, regardless of any challenges". His Highness indicates that the plans to secure the necessary supplies in the Country are in place and active. He also adds that waiting for emergencies and crises in order to schedule the Country's concerns has no place in the United Arab Emirates, which depends on extrapolating the future and setting proactive plans in all areas of life. Therefore, the pharmaceutical sector has already been occupying its place in Country's health strategies prior to the occurrence of any pandemic.

Within the framework of such planning for the future and to grant the pharmaceutical industry more recognition, preparations are carried out to develop an integrated policy that focuses on increasing the share of drug production in the country while strengthening the capabilities of the local factories to conclude various partnerships with international leading companies in order to enable them to produce innovative medicines and vaccines; as the pharmaceutical industry is deemed to be one of the most vital industries in the world due to its close connection with human health.

The scientific development achieved by the Country is deemed to be one of the foundations upon which the new policy is grounded; which policy focuses on "providing the base of pharmaceutical manufacturing with various technological and vital techniques while relying on artificial intelligence in the manufacture process of medicines." In the same direction, it should enhance scientific research in pharmaceutical industry, and work on transferring innovative and biological pharmaceutical industry technology to the laboratories of local pharmaceutical companies.

As for the economic dimension thereof, reducing manufacturing costs, increasing the quality and efficiency of pharmaceutical products in addition to expanding export markets; so that new countries are reached while supplying local factories with raw materials, are deemed to be some of the key elements that contribute to strengthening the pharmaceutical sector. From such angle, the Country is committed to supporting the pharmaceutical industry through enacting modern legislation and regulations that encourage investment in the sector as well as to providing all the technical assistance required to upgrade pharmaceutical products formulated and manufactured therein.

Such new steps do achieve more "pharmaceutical security" in the Stat by expanding opportunities to manufacture generic medicines, supporting local pharmaceutical companies, providing the most appropriate environment for developing their capabilities and enhancing confidence in the safety of medicines. Hence, the United Arab Emirates is taking advanced steps on the path to providing the best opportunities and services in the field of health, which forms one of the most significant areas to which human life relates.

However, the risks of the spread of fraudulent medicines is still more threatening than the availability of the medicine itself; as such does not only deprive patients of treatment, but also leads to death or permanent disability in addition to draining the financial resources of the Country.

A fraudulent medicine is defined as "a medicine that is intentionally or deceptively counterfeit in the name, composition or source thereof. It also covers products with real or false ingredients, without active ingredients or with insufficient active ingredients. As for the fake medicine, it is the one known for stealing the trademark of a well-known medicine which contains some active substances, whether such are sufficient or not.

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Researchers argue that drug falsification is a concept that covers falsification in brand or manipulation of the expiration date or the components of the drug itself, with the intent of falsification to gain quick financial profit while resulting in harms to the patient which may lead to his death.

The phenomenon of fraudulent medicines is a global one; as those plotting such crime are organized clans looking for financial gain at the expense of human health. A study conducted by the World Health Organization indicates that 48.7% of drug falsification cases occur in Asian countries, 18.7% in African countries and 13.6% in some European countries.

Fake medicine may contain active ingredients in the wrong percentage i.e. lower or higher than the exact therapeutic dose. It may also contain incorrect and ineffective ingredients or even harmful and- sometimes- toxic ingredients. Moreover, such may be manufactured in contaminated conditions, which leads to the contamination thereof. Counterfeit medicines range from "useless" to "hazardous". A person, who consumes a counterfeit medicine puts his own health and even his life at risk; as- according to studies and research- it was found that drug falsification methods include 32.1% of products that do not contain the active substance, 21.4% of products with the wrong ingredients, 20.2% of products with incorrect amounts of the active ingredient, 15.6% of products with counterfeit packaging, 8,5% of products with high levels of impurities, toxins and pollutants in addition to 1% of empty containers.

In order to reduce the consequences of such problem, we must control and monitor the entry of medicines, by defining specific customs ports for the entry of such while appointing qualified pharmacists to work at such ports. The pharmaceutical market must also be monitored by inspecting drug warehouses and pharmacies constantly, developing a mechanism to ensure that all marketed drugs are examined according to a studied scientific program, increasing the approved budget for health awareness for all members of society and activating the meaningful participation of all members of society in the supervisory work by reporting any institution that sells or promotes for such counterfeit medicines.

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Overview of the Global Situation

Global trade of medical products:

Medicinal products make up about 5% of total world trade.

- Trade of medical products amounted to about $2 trillion and accounted for 5% of the total merchandise trade in 2019
- "Pharmaceuticals" forms the largest category in the trade of medical products in terms of value, which represents 56% of the total value of medical products imports. It is followed by "medical supplies" with a rate of 17%, "medical equipment" 14% and "personal protective equipment" 13 %.
- Germany, the USA and Switzerland account for 35% of the world's medical products and represent the largest exporters with nearly three quarters of global exports.
- Global exports of medical products grew by a rate of 9% in 2018 and a rate of 6% in 2019 from $859 billion in 2017 to about $995.8 billion in 2019.
- 40% of exports of personal protective equipment come from China, Germany and the United States of America.
- The total trade in products described as critical with a severe deficiency during the COVID-19 crisis reached $597 billion, or 1.7 percent of total global trade in 2019.

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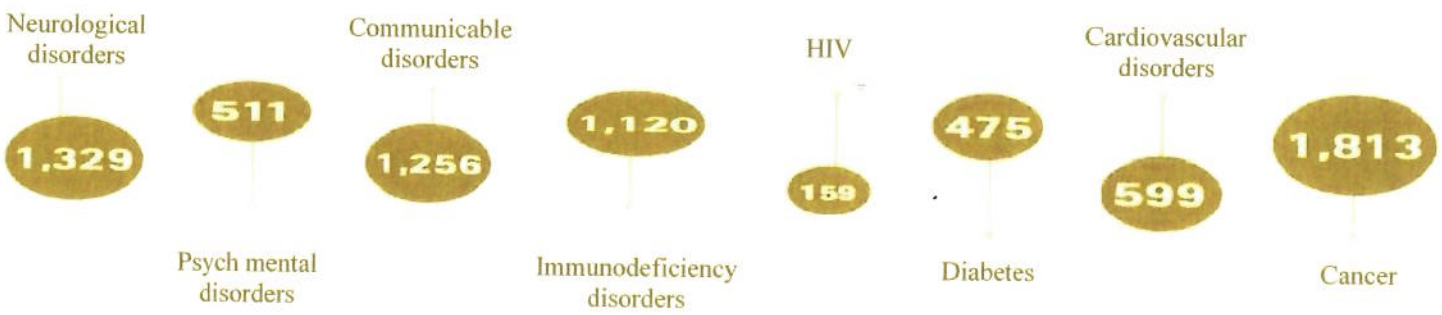
Global innovations in the field of medicine

With more than 7,000 drugs under development globally, an exciting new wave of medical innovation shall play a major role in addressing the challenges faced by patients and healthcare systems



Source: Value of Medicines I Report Database. EFPIA QI 2020

A study of the current situation in the United Arab Emirates

In the light of the directions of the United Arab Emirates to promote community health as well as to create a comprehensive and sustainable health system for a happy society, the provision of health care according to international standards is deemed to be one of the key six pillars, upon which the National Agenda of the United Arab Emirates is based by seeking pioneering innovation in the field of Health along with the contributions made by the Country to eradicate diseases.

This comes as part of the Country's efforts exerted to combat deadly diseases standing in the way of economic development and to improve the health of members of society. Therefore, it is necessary to emphasize the significancy of establishing strong and purposeful partnerships that push global and local efforts to eradicate diseases, as well as to provide distinguished pharmaceutical services and to achieve health care quality indicators ensuring the health and social and economic development process in the Country.

The government is exerting continuous efforts to enhance the welfare and health care of the population (both citizens and residents) by targeting the coverage of the basic health services through the cooperation and solidarity of the concerned partners.

The budget set for the fiscal year of 2020 reflects the strength of the national economy, where the social development and social benefits sectors received the largest share; as AED 21.90 billion were allocated from the total budget to the social development sector (31.13%) including health care and community protection, which represented 6.89% of the total budget (equivalent to AED 4.84 billion).

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Pharmaceutical services in the Country:

The United Arab Emirates, represented by the Ministry of Health and Prevention (MOHAP) and the concerned authorities, is proceeding on the path of developing the pharmaceutical sector. Moreover, it is committed to the principle of providing treatment to patients as promptly as possible by giving priority to receiving, evaluating and registering essential medicines in addition to innovative and orphan medicines. The supervision conducted by the Ministry of Health and Prevention (MOHAP) and the concerned authorities over the management of the pharmaceutical sector and the quality and safety of medicines in the United Arab Emirates, through the drug registration system, controlling the prices of medicines, conducting the required analyzes of pharmaceutical products and medicines in the reference laboratory, as well as protecting the intellectual property of medicines is one of the key elements of excellence in such field.

The United Arab Emirates takes precedence in registering medicines globally

When it comes to the registration of medicines under standards and controls that comply with international best practices, the United Arab Emirates is deemed to be a global leader in such arena; as the majority of innovative medicines are registered in the Country in conjunction with their producing countries. This reflects the keenness of innovative international companies to offer their products within the Country. The United Arab Emirates is deemed to be the first or second country in the world to receive such medicines after their approval by international authorities and organizations such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) as they are confident in the advanced regulations and standards applied in the Country in pharmaceutical and health fields. The Country does follow the highest international standards in the drug evaluation process, which includes a review of clinical studies, bioequivalence studies as well as stability studies.

The drug registration mechanism is subject to strict standards

The mechanism applied for considering requests for drug registration is subject to high standards; as the product is given a deadline to submit the registration request in a specific period. In the event that the electronic registration systems are applied, the request is included in the fast track for the registration of innovative and orphan drugs, where the registration file is accepted by the electronic common technical document (e-CTD) and the registration files (safety + quality + pricing) submitted to the Ministry are evaluated by the Higher Committee for Drug Policies in a specified period of time.

Then, the product is priced after being guided by the price of the country of origin as well as the price of the Gulf Cooperation Council countries and according to the pricing controls applied within the Country. The registration requests shall be decided upon for approval by

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the members within a short period of time as from the evaluation of the file of registration. Following the approval of the registration of the medicinal product by the majority of members, the competent department shall prepare a draft of the ministerial resolution for the pricing approved by the Higher Committee for Drug Policies and submit such to the Minister of Health and Prevention or to the representative thereof for approval. Finally, a registration and pricing certificate for the medicinal product shall be issued.

Fast track for drug registration

Moreover, files of registration for Breakthrough medicines, those categorized as Orphan Drugs or those placed under the Accelerate process may be submitted prior to the final approval of one of the accredited international bodies. The registration is included within the Fast Track evaluation system, where the registration files are accepted based on a letter with the positive opinion as issued by one of the accredited international bodies, provided that the certificate of pharmaceutical product (CPP) shall be delivered later. In the event that the price of the country of origin is temporarily not available, the pricing of the product shall be based on the price proposed by the holder of the marketing right. The approval of the majority of the members of the Higher Committee for Drug Policies to register the product shall be required.

Combating drug falsification and ensuring drug safety

In a synchronal step that supports drug safety, the Ministry of Health and Prevention (MOHAP) has launched the "Tatmeen" platform; the first of its kind in the region, to track and trace the stages of pharmaceutical products manufacture with the aim of securing the supply of such products to health care facilities based in the Country.

"Tatmeen" platform; the digital platform based on advanced sequencing and tracking technology, contributes to tracking medicines at production stages till such are consumed by patients in order to raise the levels of efficiency of health and smart services within the Ministry and to efficiently handle fraudulent, expired and unauthorized medical products.

Regulatory authorities shall be able to use "Tatmeen" platform in order to facilitate their task preventing fraudulent or unauthorized medicines from entering the Country by verifying the two-dimensional serial code "GS1" and by using a secure website or mobile application. On the other hand, "Tatmeen" platform shall support consumers by enabling them to confirm the shelf life and reliability of medicines upon purchasing such through a secure application, which helps them to avoid purchasing unauthorized or fraudulent medicines and provides a

clear and comprehensive view of the sources, safety and shelf life of products by scanning the two-dimensional serial number. This procedure shall increase the confidence in the existing medicines traded within the Country.

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Obligations of the company holder of the marketing right and the importer

The company that holds the marketing right shall be committed to submitting the designs for the package and the internal leaflet as well as for applying the procedures for following up the post-marketing products in terms of following the principles of good pharmacovigilance by providing a comprehensive plan that includes procedures for monitoring side effects, a risk management plan in addition to other documents. The importer on the other hand shall be obligated to import medicines in the packages same as the country of origin's after the medicine leaflet is evaluated and approved by the Higher Committee for Drug Policies. A preliminary document has been prepared to set temperature monitors for all medicines in addition to providing the special analysis requirements for the Quality Control Department of Medical and Health Products affiliated to the Ministry of Health and Prevention (MOHAP).

Local pharmaceutical industries

Considering the reality of the pharmaceutical industry in the Country, we find out that, despite the positivity of the presence of many licensed pharmaceutical factories in the Country, which do use the latest setups and equipment while applying the latest and highest international quality manufacturing standards, they are still below the required level with regard to raw materials used in pharmaceutical manufacturing i.e. the pharmaceutical industry in the Country is completely dependent on imports to cover its needs of the primary raw materials necessary for the management and operation of such factories. Some of such factories did not work adequately to attract qualified nationals as a workforce; however, they recruited trained workforce from other several countries. In addition, our local factories do lack a critical aspect, which is the weak presence of the global competitiveness in the pharmaceutical sector due to the weak presence of research and development efforts exerted in such field. Most of the medicines produced in national factories depend on packing pharmaceutical chemicals imported from abroad which is undoubtedly closer to the industry of assembly rather than it is to an industry that relies on innovation and development in order to formulate new pharmaceutical products.

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A- Medicine Services

1- Registering companies that handle chemical precursors

Service description	The service permits the registration of companies that handle chemical precursors for the purpose of internal trade, importing for the end use and trade (importing and exporting), as an intermediary for trade and an end user for factories and companies that handle chemical precursors

2- Renewing the registration of companies that handle chemical precursors

Service description	The service permits the renewal of the registration of companies that handle chemical precursors for the purpose of internal trade, importing for the end use or for importing and exporting, as an intermediary for trade or as an end user for factories and companies that handle chemical precursors

3- Licensing a pharmaceutical institution (scientific office)

4- Licensing a pharmaceutical institution (factory for medical products)

Service description	Obtaining the license necessary for establishing a pharmaceutical institution to sell pharmaceutical products and medical supplies, register, import and distribute pharmaceutical products and medical supplies, represent international companies and drug and medical supplies factories registered within the Country, export and re-export pharmaceutical products and medical supplies or manufacture pharmaceutical products and medical supplies
	Remark: The service describes the licensing of scientific offices and medical factories as provided by the Drug Department. The rest of the description of the facilities is subject to the Licensing Department

5- Renewing the license of a pharmaceutical institution (scientific office)

6- Renewing the license of a pharmaceutical institution (factory for medical products)

Service description	Renewing the license of a pharmaceutical institution issued to sell pharmaceutical products and medical supplies, register, import and distribute pharmaceutical products and medical supplies, represent international companies and drug and medical supplies factories registered within the Country, export and re-export pharmaceutical products and medical supplies or manufacture pharmaceutical products and medical supplies

	Remark: The service describes the licensing of scientific offices and medical factories as provided by the Drug Department. The rest of the description of the facilities is subject to the Licensing Department

B- Licensing services for pharmaceutical professionals

- Licensure: The service permits medical and pharmaceutical facilities to issue a license to workers in pharmaceutical facilities who practice the profession of pharmacy in the position of a person In-charge, a deputy in-charge, or a pharmacist assistant according to the unified standards for licensing health professions.
- Renewing the licensure: The service permits medical and pharmaceutical facilities to submit their requests to renew the licenses of workers in the profession of pharmacy in the position of a person In-charge, a deputy in-charge, or a pharmacist assistant.

C- Registration services of medicines and medical products

7- Evaluation of medical products for the purposes of drug research and clinical studies of the drug

Service description	The service permits receiving, evaluating and approving medical products for drug research and clinical studies of drugs in accordance with the "Guidelines for Conducting Clinical Studies on Drugs/Medical setups and Good Clinical Practices for the Year of 2006"

8- Product rating

Service description	The service permits the classification of products based on the type of active ingredients included therein, their quantities, dosage and number as well as the maximum daily dose of vitamins and mineral salts and the therapeutic use of the product

9- Registering a conventional pharmaceutical product

Service description	Registering conventional or biological human pharmaceutical products and others for the purpose of importing and circulating such within the Country

10- Renewing the registration of a conventional pharmaceutical product

Service description	The service permits the submission of a request to renew the registration of conventional or biological human pharmaceutical products and others for the purpose of importing and circulating such within the Country

11- Registering a pharmaceutical product extracted from natural sources

Service description	The service permits the registration of pharmaceutical products extracted from natural sources such as medicinal plants and animal sources

12- Renewing the registration of a pharmaceutical product extracted from natural sources

Service description	The service permits the renewal of the registration of a pharmaceutical products extracted from natural sources such as medicinal plants and animal sources

13- Registering a pharmaceutical product for general sale

Service description	The service permits the registration of general sale products i.e. simple pharmaceutical products with limited medicinal usage and cannot be considered medicines. These include products such as dietary supplements, medical cosmetics and medical disinfectants

14- Renewing the registration of a pharmaceutical product for general sale (health care product)

Service description	The service permits the renewal of the registration of general sale products i.e. simple pharmaceutical products with limited medicinal usage and cannot be considered medicines. These include products such as dietary supplements, medical cosmetics and medical disinfectants

15- Registering a medical device

Service description	The service permits the registration of medical devices to be imported and circulated within the Country

16- Renewing the registration of a medical device

Service description	The service permits the renewal of the registration of medical devices to be imported and circulated within the Country

17- Approving changes in registered pharmaceuticals

Service description	The service permits the clarification of the mechanism of action applied to approve minor changes in human pharmaceutical products (conventional, biological, etc.) as well as in pharmaceutical products extracted from natural sources, herbal medicines, homeopathic pharmaceuticals, pharmaceutical products for general

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	sale, dietary supplements, disinfectants, medical cosmetics and miscellaneous (medicinal devices, reagents and veterinary medicinal products (conventional, biological, herbal and others).

18- Issuing a certificate to amend any of the medical product registration data

Service description	The service permits the issuance of certificates to amend any of the data of any previously registered products.

19- Issuing a single product pricing certificate

Service description	The service permits the issuance of a single product pricing certificate for pharmaceutical companies that have registered pharmaceutical products for the purpose of importing and marketing pharmaceutical products within the Country

20- Re-pricing of a single medical product

Service description	The service permits the re-pricing of a single product for pharmaceutical companies that have registered pharmaceutical products for the purpose of importing and marketing pharmaceutical products within the Country

21- Requesting a price list of the company's medicines

Service description	The service permits the submission of a request to obtain a price list of medicines for companies registered within the Country to be used later Key service: Licensing and registering medical and pharmaceutical products

22- Requesting a price list of the medical products priced in the Country

Service description	The service permits the submission of a request to obtain a price list of the priced products for companies registered within the Country to be used later
	Key service: Licensing and registering medical and pharmaceutical products

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23- Registering a manufacturer of medical products

Service description	The service permits the registration of medical products manufacturing plants (human and veterinary) within the United Arab Emirates

24- Issuing a certificate to amend any of the registration data of a medical company or factory holder of a marketing right

Service description	The service permits medical companies and factories to amend their registration data to be used later

25- Issuing a certificate of accreditation for a clinical studies center or a bioequivalence center

Service description	The service permits the accreditation of centers that are not accredited by the Gulf Cooperation Council (GCC) countries for clinical studies or bioequivalence

26- Issuing a certificate for a pharmaceutical product for the purpose of exporting

Service description	The service permits the issuance of a (Certificate of pharmaceutical product (CPP) for pharmaceutical factories based within the Country for the purpose of exporting such outside the Country

27- Issuing a free-sale certificate for a medical product for the purpose of exporting

Service description	The service permits the issuance of a free-sale certificate for a medical product for pharmaceutical factories inside the Country for the purpose of using such for export outside the Country

D- Good practices services for institutions and factories

28- Requesting an inspection to verify the extent of compliance with the standards of good practice for the pharmaceutical institution

Service description	The service permits the submission of a request to verify the extent of compliance with the standards of good practice for the pharmaceutical institution, which form part of the quality management system, which ensures the quality of pharmaceutical or medical products by controlling all activities related to good warehouse storage procedures and good clinical practices for pharmacies GSP - GCP

29- Issuing a certificate (of obligation) to verify compliance with the standards of good practice set for pharmaceutical institutions

Service description	The service permits the submission of a request to issue a certificate of compliance with the standards of good practice for pharmaceutical institutions, which form part of the quality management system, which ensures the quality of pharmaceutical or medical products by controlling all activities related to good warehouse storage procedures and good clinical practices for pharmacies GSP - GCP

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30- Requesting an inspection to verify the extent of compliance with the Good Manufacturing Practices (GMP) for factories

Service description	The service permits the submission of a request to verify the extent of compliance with the Good Manufacturing Practices (GMP) for the manufacturing sites based within the Country. The GMP is part of the quality assurance system which ensures that the products are continuously produced and monitored in compliance with the quality standards and specifications that are commensurate with the intended uses whose products are highly sensitive with a direct or indirect impacts on human health

31- Issuing a certificate of compliance with good manufacturing standards

Service description	The service permits the issuance of a Good Manufacturing Practice Certificate after checking the requirements and controls that must be met in the pharmaceutical industries, such as facilities, environment, methods of documentation, work progress and post-marketing follow-ups. The service is concerned with production and quality control

E- Import & export services

32- Issuing a permission to import medicines for exhibitions

Service description	Requesting a permission to import innovative medical products from outside the Country for the purpose of displaying such in exhibitions, health forums and conferences for a limited period of time without selling them Key service: Clearance and import and export permissions

33- Issuing a permission to import narcotic drugs

Service description	Requesting a permission to import narcotic drugs from outside the Country for the purpose of selling or using such under the laws in force in the Country

34- Issuing a permission to import medicines from a local agent

Service description	Requesting a permission to import medical drugs or (veterinary, controlled or semi-controlled drugs) registered or not registered by the local agent for the purpose of reselling and trading such

	Key service: Clearance and import and export permissions

35- Issuing a permission to import raw materials

Service description	Request for permission to import raw materials to be used in manufacturing processes Key service: Clearance and import and export permissions

36- Issuing a permission to import chemical precursors

Service description	The service permits the obtaining of an approval to import chemical precursors from outside the Country Key service: Clearance and import and export permissions

37- Issuing a permission to import medical equipment

Service description	Requesting a permission to import medical equipment, laboratory or dental materials, registered or not registered by the local agent for the purpose of reselling and trading such Key service: Clearance and import and export permissions

38- Issuing a permission to export drugs

Service description	Requesting a permission for medical companies and factories to export registered drugs Key service: Clearance and import and export permissions

39- Issuing a permission to export chemical precursors

Service description	The service permits the obtaining of an approval to export chemical precursors outside the Country Key service: Clearance and import and export permissions

40- Permission to export medicines and narcotic drugs

Service description	Permitting medical companies and factories to export narcotic drugs outside the country under a prior authorizing permission

41- A certificate of release issued for a shipment of medicinal products extracted from biological sources

Service description	Clarifying the procedures set for releasing a shipment of medicinal products extracted from biological sources in order to facilitate and finalize the import permission, match papers and certificates and verify that the product is valid for safe treatment

F- Pharmacovigilance and quality control services

42- Analysis of a medical product manufactured by a pharmaceutical institution and subsidiaries thereof

Service description	The service permits the medical products to be analyzed in order to verify their ingredients, active substances, preservatives and their suitability for use

43- Re-analysis of a medical product manufactured by a pharmaceutical institution and the subsidiaries thereof

Service description	The service permits the medical products to be re-analyzed in order to verify their ingredients, active substances, preservatives and their suitability for use

44- Issuing a medical product quality report by the Quality Control and Research Laboratory in order to control drug quality

Service description	The service permits the issuance of a quality report for a medical product that has been analyzed in the Quality Control and Research Laboratory in order to control drug quality and to verify the product's suitability for use

45- Approving the pharmacovigilance liaison officer for pharmaceutical facilities

Service description	The service permits companies to approve the pharmacovigilance liaison officer

46- Evaluating mandatory reports of side effects and local adverse reactions to drugs

Service description	The service permits the evaluation of mandatory reports of side effects and adverse reactions to drugs manufactured locally and globally and imported into the Country

47- Reporting side effects of medicines and medical products

Service description	The service permits healthcare providers and pharmaceutical companies to report side effects of medicines and medical products

48- Evaluating the pharmacovigilance plan for a pharmaceutical institution and subsidiaries thereof

Service description	The service permits the evaluation of the pharmacovigilance plan for pharmaceutical institutions and subsidiaries thereof for medicines registered and marketed within the Country

G- Services regulating materials, controlled products and chemical precursors

49- Dispensing the controlled drugs prescription (CD) register book

Service description	The service permits the submission of a request to obtain a book of prescriptions for controlled drugs (CD) for the purpose of using such internally within medical facilities to prescribe controlled medicines by licensed doctors according to the regulations and laws applied

50- Requesting the release of a register of the inventory of controlled or semi-controlled medicines (CD/SCD)

Service description	The service permits the submission of a request to obtain a register of the inventory of controlled or semi-controlled medicines (CD/SCD) for pharmacies, medical warehouses and hospital wards

51- Requesting the specification or the modification of the quotas of narcotic drugs for a private health facility or for a pharmaceutical institution

Service description	The service permits the submission of a request to obtain an approval to specify the quotas of narcotic drugs for new facilities or to modify such quotas of narcotic drugs in registered facilities to be used later

52- Requesting a price list for controlled or semi-controlled drugs (CD/SCD) within the Country

Service description	The service permits the submission of a request to obtain a price list of controlled or semi-controlled drugs (CD/SCD) registered within the Country to be used later

53- Approving narcotic drugs for internal pharmacies based in private hospitals

Service description	The service permits the submission of a request to approve narcotic drugs for internal pharmacies based in private and semi-governmental hospitals for such to be dispensed from the local agent or the warehouses affiliated to the Ministry of Health and Prevention (MOHAP)

54- Approving a pharmacist's signature for the inventory of narcotic drugs

Service description	The service permits the obtaining of the signature of the physician/pharmacist responsible for the inventory of narcotic drugs in hospitals and one-day surgery centers

55- Requesting the handing over of narcotic drugs' inventory between pharmacists

Service description	The service permits the submission of a request to hand over the inventory of narcotic drugs between those responsible for the inventory of the drug, including physicians and pharmacists

56- Approving emergency medications (lifesaving items) and psychotropic substances for hospitals

Service description	Submission of a request to approve the transfer of narcotic and controlled drugs between private and government hospitals for cases of emergency Key service: Regulating controlled substances and products, narcotics and chemical precursors

57- Requesting a price list for controlled or semi-controlled drugs (CD/SCD) within the Country

Service description	The service permits the submission of a request to obtain a price list of controlled or semi-controlled drugs (CD/SCD) registered within the Country to be used later

58- Approving narcotic drugs for one-day surgery centers

Service description	The service permits the submission of a request to obtain an approval of narcotic drugs for one-day surgery centers for such to be dispensed from the local agent or the warehouses affiliated to the Ministry of Health and Prevention (MOHAP)

59- Requesting an inventory of narcotics for a hospital

Service description	The service permits the submission of a request to obtain an approval for an inventory of narcotics for one-day surgery centers and hospitals

60- Issuing a permission to import personal medicines

Service description	The service permits individual customers to submit a request to obtain a permission to import controlled drugs (CD) from outside the Country for the purpose of personal use. This includes narcotic, psychotropic and controlled drugs specified in the related legislation and shown in the lists annexed.

61- Issuing a permission to export personal medicines

Service description	The service permits individual customers to submit a request to obtain a permission to export controlled drugs (CD) for the purpose of personal use.

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	This includes narcotic, psychotropic and controlled drugs specified in the related legislation and shown in the lists annexed.

Supportive national policies associated with enhancing medicine services in the Country:

- The National Intellectual Property Policy in the Health Field in the United Arab Emirates
- The United Arab Emirates' National Communicable Disease Control Policy
- The National Policy on Vaccinations in the United Arab Emirates

Legislations supporting the promotion of medicine services in the Country:

- Federal Law No 17/2002 regarding the Regulation and Protection of Industrial Property of Patents, Industrial Drawings and Designs
- Cabinet Resolution No. 39/2015 regarding the strategic medical stockpile
- Federal Decree-Law No.8/2016 amending some provisions of Federal Law No. 14 /1995 in the matter of combating narcotics and psychotropic substances
- Ministerial Resolution No. 872/ 2016 regarding the strategic medical stockpile
- Ministerial Resolution No. 888/ 2016 regarding controls and rules for prescribing and dispensing narcotic and controlled drugs
- Ministerial Resolution No. 1110 /2016 regarding scientific offices
- Federal Law No. 9/2017 regarding veterinary products
- Ministerial Resolution No. 1412 /2017 regarding the approval of a guide for practices of marketing and circulation of medical products
- Ministerial Resolution No. 1448 /2017 regarding the approval of a code of ethical and professional conduct for health professionals
- Ministerial Resolution No.28/ 2018 regarding the registration of innovative and orphan medicines
- Administrative Circular No. 1839/2018 regarding the approval of the Good Pharmacovigilance Practice Guide
- Federal Law No. 2/ 2019 regarding the use of information technology and communication technology in health fields
- Cabinet Resolution No. 21 /2019 amending some schedules attached to Federal Law No. 14 /1995 regarding combating narcotics and psychotropic substances
- Ministerial Resolution No. 479/2019 regarding the National vaccination Program
- Ministerial Resolution No. 379/ 2019 regarding the unified electronic platform for prescribing and dispensing narcotic drugs, controlled drugs and semi controlled drugs

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- Ministerial Resolution No. 677/2019 regarding the procedures and controls applied for carrying narcotic or controlled drugs by travelers upon entry or exit from the Country
- Federal Law No. 8/2019 regulating the profession of pharmacy, pharmaceutical facilities and medical products
- Ministerial Resolution No. 253/ 2020 regarding the controls and rules for prescribing and dispensing some controlled drugs
- Ministerial Resolution No. 271/2020 regarding the approval of a manual on biosecurity in laboratories
- Ministerial Resolution No. 321/2020 regarding the use of information and data on innovative pharmaceutical products
- Cabinet Resolution No. 59/2020 regarding drug tracking and monitoring
- Cabinet Resolution No. 63 /2020 regarding the freezing of red blood cells, the components thereof and rare blood groups for cases of emergency and for the purposes of emergencies, crises and disasters
- Federal Law No. 13/ 2020 regarding Public Health
- Ministerial Resolution No. 380/ 2020 regarding the subjection of some medical equipment to the zero-rate tax
- Ministerial Resolution No. 382/ 2020 regarding the inclusion of drugs on the electronic platform for narcotic drugs and controlled drugs
- Ministerial Resolution No.49/2021 regarding the list of semi-controlled medical materials and products

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Data and statistics on medicine in the Country:

During the last century, the United Arab Emirates has made headway at all levels, including in the provision of health care services; especially those related to the pharmaceutical sector, which led to a reduction in the rates of disease and death.

The value of the drug market is rapidly developing; in 2020, the value of the drug market in the Country reached AED 12.9 billion. Moreover, it is expected that at the end of 2021 the expenditures on medicine shall reach AED 13.6 billion and by 2025, the same shall reach AED 17.1 billion. This increase shall be driven by growth of population, changes to the disease situation and the use of modern medicines such as biotechnological drugs.

In 2021 in the United Arab Emirates, there are 21 pharmaceutical factories and the number is expected to reach 30 factories by 2022. As for the number of scientific offices, it has reached 84 offices that represent international drug manufacturers in the world (2021). The number of such offices is expected to reach 95 by 2022. This is a solid indication of the boom occurring in pharmaceutical manufacturing sector in the United Arab Emirates and is deemed to be the Country's ticket into the club of drug innovators which supports the its efforts in the global competitiveness indicators in the pharmaceutical economy.

Fitch Solutions United Arab Emirates Pharmaceuticals and Healthcare Report Q2 2021

Along with related decrees, Federal Law No. 8/2019 regulating the profession of pharmacy, pharmaceutical facilities and medical products has upgraded the regulations on the review and authorization of marketing medical products and the licensing of pharmaceutical facilities. This step was followed by the issuance of Cabinet Resolution No. 59 /2020 regarding the tracking and tracing of medicines in order to ensure sustainable supply and effectively combat fraudulent and low-quality medicines. Moreover, the capacity of the functions affiliated has been developed by attracting talents and developing a quality control laboratory with equipment and analytical methods. Accordingly, drug testing activities increased by a rate of 78% between the years of 2018 and 2020.

In terms of safety monitoring, the United Arab Emirates has updated its guidelines on pharmacovigilance by issuing Administrative Circular No. 1836 /2018 on Good Pharmacovigilance Practices. It also finalized its full membership in the UMC Uppsala Monitoring Center and introduced the Adverse Drug Reactions (ADR) Reporting Application to phone mobile users in cooperation with the Medicines and Healthcare products Regulatory Agency (MHRA). All these efforts exerted have increased the number of adverse drug reactions cases reported to the Uppsala Control Center from 2.042 in 2018 to 3.290 in 2020.

Achievements made in the healthcare and pharmaceutical sectors

Expenditures on healthcare and pharmaceutical sector in the United Arab Emirates during the period 2018 to 2024

Healthcare expenditures in the United Arab Emirates topped the list during the period 2018 to 2024

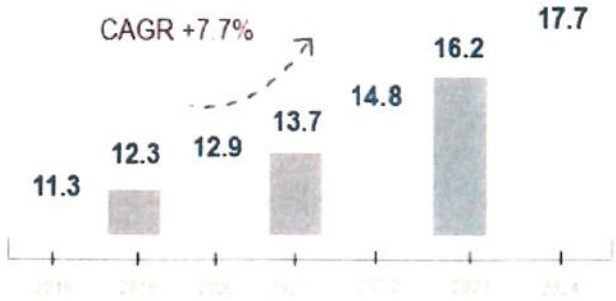
	2018	2019	2020	2021	2022	2023	2024
Total value in AED (Billion)	51.38	56.202	61.709	67.715	74.347	81.475	89.245
Annual Expenditure Growth (%)	9.68	9.39	9.80	9.73	9.79	9.59	9.54
Individual expenditures (USD)	1,452.7	1,566.3	1,700.1	1,846.7	2,009.3	2,184.0	2,373.6
Annual expenditure GDP (%)	3.38	3.67	5.00	4.73	5.03	5.19	5.40

Fitch solutions Q4 2020 Report

The increasing growth of expenditures within the health sector in the United Arab Emirates: Reasons:

- The growing numbers of population in terms of size and life expectancy
- The Country's vision for the best-quality health services to be received
- Increase of non-communicable diseases and emerging diseases
- Greater expectations and more demands from members of society
- Rapid expansion in the field of medical tourism in the Country

The value of the pharmaceutical market in the Country (during the period 2018 to 2024)



Fitch solutions Q4 2020 Report

The federal budget for the fiscal year of 2020 reached **AED 61.35 billion**

health care and community prevention)

AED 4.84 billion

The budget for the fiscal year of 2020 reflects the strength of the national economy, where the social development and social ameni i:s sectors had received the larg st share thereof. AED 2 9 illion of the total budget was . development sector, he re a d community social prevention

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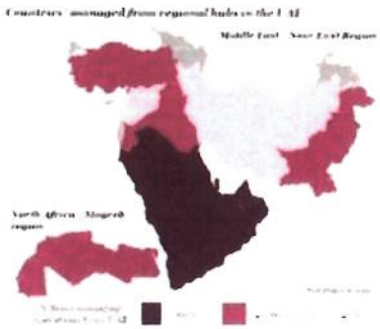
6.89% of the total budget	(31.13%) including health care and community prevention)

Achievements made in the pharmaceutical sector

The role played by the United Arab Emirates as a logistics center for international pharmaceutical companies

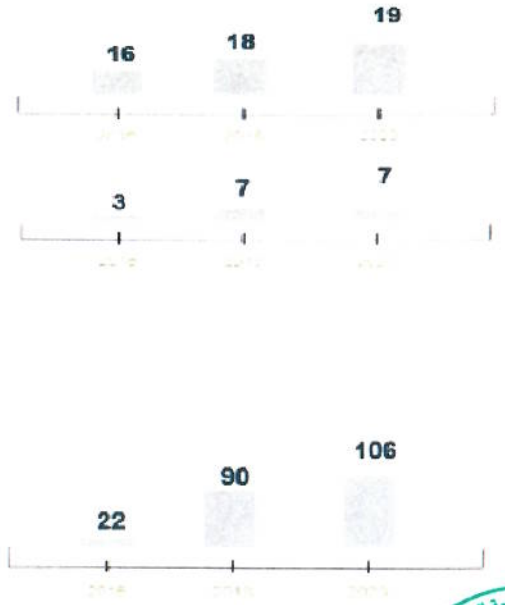
Activity of international pharmaceutical companies in the Country: Marketing offices and logistics centers serving the countries of the region



Marketing offices for global pharmaceutical companies 47 years 2014

83 years 2020

Constant cooperation in the field of pharmaceutical industries between international companies and national factories



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25 logistic centers distributing medicines and medical products to various countries in the region; some do cover about **41** countries

Percentage of increase in drug registration services

2017-2018-2019

9141 transactions finalized	9678 transactions finalized finalized	12594 transactions

RADR mobile application to enhance pharmacovigilance in the United Arab Emirates

Achievements made in the healthcare and pharmaceutical sectors

Expenditures on healthcare and pharmaceutical sector in the United Arab Emirates during the period 2018 to 2024

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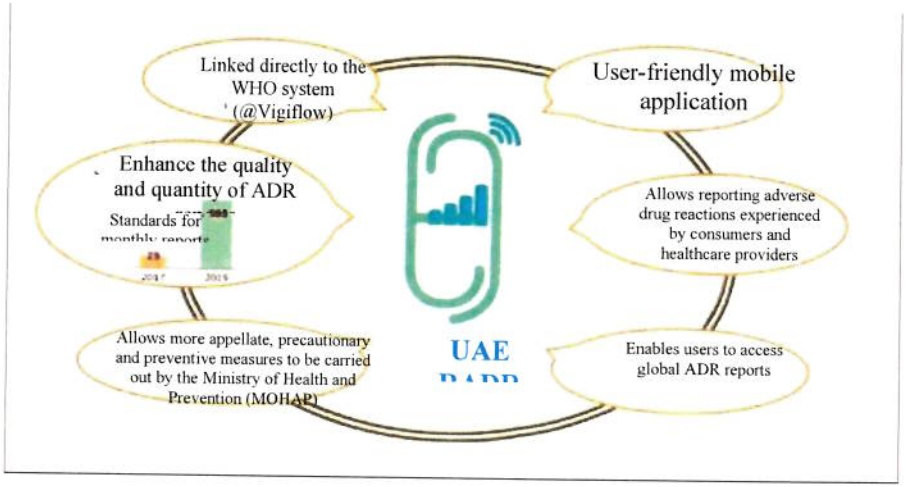
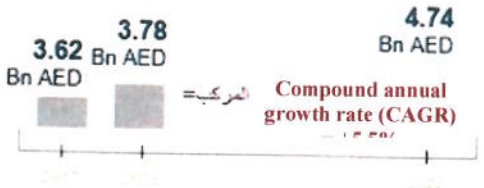


The value of the exported pharmaceutical products

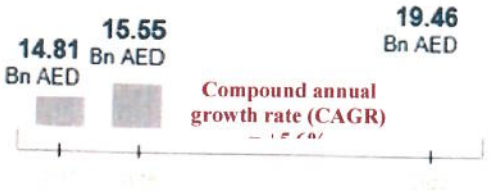


Based on locally manufactured medicines and re-exported medicines transactions

Import

Export

The value of the imported pharmaceutical products



Medicines come from 72 countries. 10 of such provide 80% of imports. Namely, Western Europe, the United States of America and Australia

BMI (Business Monitor International forecast, Q2 2019 Report

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Achievements in the field of smart projects and initiatives

UAE RADR smai

- UAE RADR is a smart application designed in collaboration with the UK Medicines and Healthcare products Regulatory Agency. It is the only application in the MENA region directly linked to the World Health Organization.
- The application is characterized by its ease of use and effectiveness in order to engage all members of society in the drug safety system by encouraging them all to report the side effects of the drug and by giving them the opportunity to review the data of the reported side effects of a certain product globally
- The smart application as well as the electronic system have led to a high rate of reporting of side effects of medicines from individuals and manufacturers that were monitored in the United Arab Emirates. These reports were sent to the Uppsala Center affiliated to the World Health Organization

A- Medicine Services

Finalized services increased from 19122 in 2018 to 26388 in 2019

As per the study conducted by the consulting studies company IQVIA,**the United Arab Emirates ranked first in the registration of innovative medicines for the year of 2018** in the Middle East

e-service	2018	2019
Issuing a permission to import personal medicines	6637	10412
Product rating	3604	4494
Issuing an amendment certificate for registered pharmaceutical products	2798	4241
Renewing the registration of a pharmaceutical product	1408	1274
Medical product analysis	914	1149
Registering a pharmaceutical product	950	1146
Issuing a certificate for a pharmaceutical product for the purpose of exporting	863	788
A request for pricing of a medical product	359	707
Drug stability study	575	538
Pharmacovigilance plan evaluation	291	497
Registering a manufacturer of medical products	270	287
A request for a Bio-equivalence study	162	272
Renewing the registration of a manufacturer of medical products	191	201

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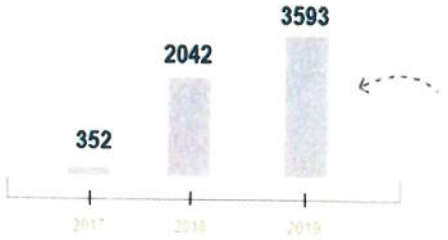
Number of side effects cases of the medicines that occurred in the United Arab Emirates were sent to the Uppsala Center to monitor the side effects of medicines



Re-pricing of a medical product	51	126
A minor amendment to the data of a registered medical product manufacturer	35	56
Issuing a free-sale certificate for a medical product for the purpose of exporting	14	15

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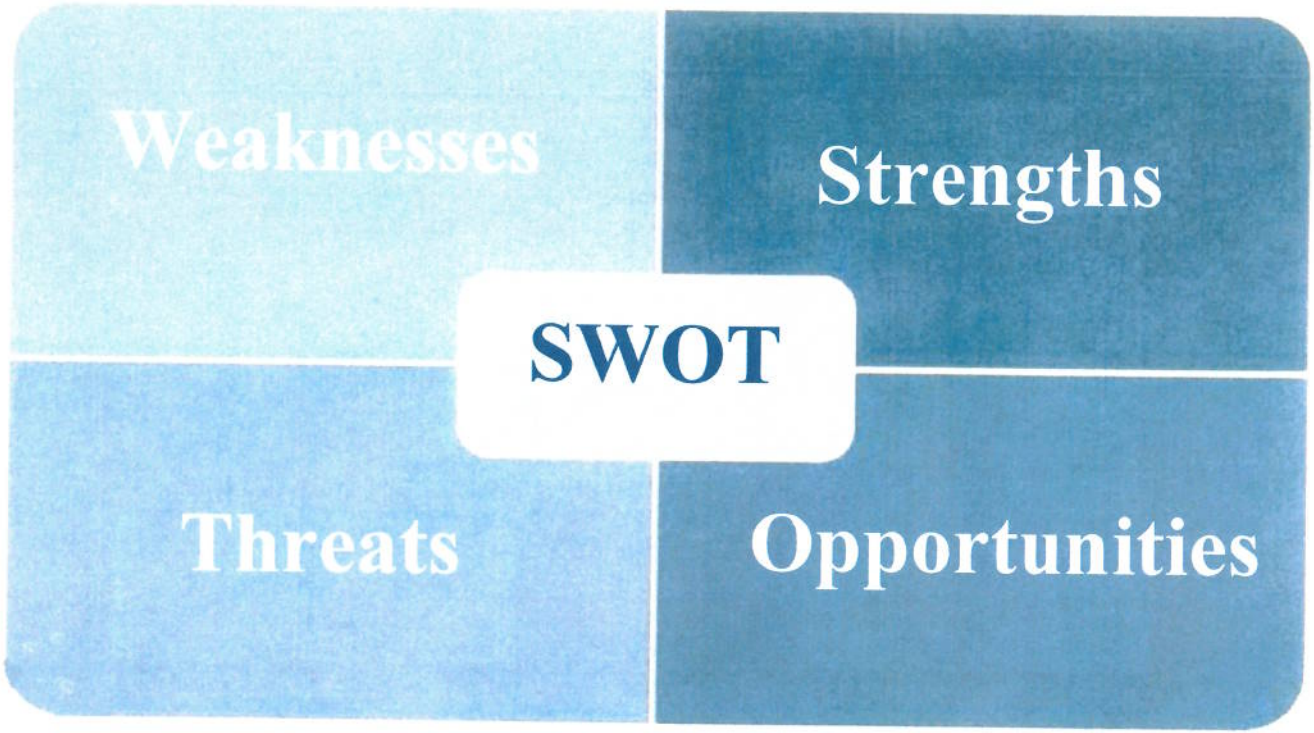
SWOT ANALYSIS Quadrant Analysis



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Strengths	Weaknesses
▪ Launching the UAE Vision 2021 with clear strategic objectives and a clear framework for implementation through concrete elements. ▪ The wise government's support for public health services in the Country through employing national capabilities in the health field. ▪ The existence of a solid legislative system that regulates the pharmaceutical sector. ▪ The Legislation and Laws Portal is an electronic gate that covers health legislation. ▪ Setting clear strategic objectives and a clear framework for implementation through the policy developed by the Ministry of Health and Prevention (MOHAP). ▪ The multi-sectoral cooperation: participation and support of concerned partners. ▪ The existence of cooperation with international competent authorities and organizations to support the strategic work of the Ministry of Health and Prevention (MOHAP). ▪ Choosing the United Arab Emirates to be a regional hub for pharmaceutical companies which is expected to have a positive impact on the supply, distribution and pricing of medicines to make such more convenient for patients.	▪ The absence of a unified national drug policy applied in the Country. ▪ The need for comprehensive and integrated coordination by and between various health authorities in the Country in such field. ▪ The shortage of human resources and qualified workforce required in the field of medicine to strengthen the pharmaceutical industry in the Country. ▪ The lack of a unified database in the Country to cover all pharmaceutical products and their rates of consumption (within the government sector as well as the private sector) in order to provide the data required for officials and decision makers to set policies and determine the budget and the workforce required for such field. ▪ The lack of scientific research works in the field of public health and pharmaceutical products in the Country as well as the services provided in such field. ▪ The need to increase programs of supervision and control over the enforcement of legislations in such field. ▪ The inadequacy of health education programs and awareness of initiatives and procedures conducted for pharmaceutical products. ▪ The inadequacy of local pharmaceutical products manufacturers ▪ The inadequacy of control procedures over unregistered drugs. ▪ The high cost of raw materials and production inputs required for pharmaceutical industries, which has its own negative impact on

▪ The presence of regional centers affiliated to numerous international pharmaceutical companies in the United Arab Emirates. ▪ The existence of health-related free zones in the Country. ▪ The existence of a mechanism to control pharmaceutical products. ▪ The existence of a clear mechanism for drug registration ▪ The existence of committees designed for medicine services	the production capacity of the pharmaceutical market in the Country.

▪ The Country's higher authorities following-up of indicators and objectives. ▪ The availability of most data and statistics. ▪ The coordination achieved by and between the United Arab Emirates and international health organizations in the field of health services. ▪ The partnerships with the private sector. ▪ The existence of a clear mechanism for monitoring the safety of registered medical products after marketing. ▪ The existence of factories with strong production capacity. ▪ The existence of a unified licensing system for health service providers in the Country that includes pharmaceutical professions. ▪ The noted increase in patents for innovative medicines.	▪ Many prominent drugs are imported at high cost. ▪ Many local companies are in need for experience and competition in the global pharmaceutical market. ▪ The inadequacy of regulations governing the relationship between agents and suppliers of medicines on one hand and health insurance companies on the other. ▪ Some medicines are not covered by health insurance. ▪ High drug prices in the Country compared to some other countries. ▪ Accumulation of expired medicines in some pharmaceutical facilities due to warehouses' failure to meet the deadlines set for handing expired medicines. ▪ Failure to define pharmacists at the Country level through the different specializations of pharmacy while settling for defining them as part of the technical staff (pharmacist and assistant pharmacist)

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Opportunities	Threats
▪ The increase of the total public expenditures in the health sector in the Country. ▪ The multi-sectoral collaboration: participation and support shown by concerned partners through **the preparation of a national drug policy to be applied in the Country**. ▪ The existence of cooperation with international competent authorities and organizations to support the strategic work of the Ministry of Health and Prevention (MOHAP). ▪ The political support and the Country's tendency towards prioritizing the health and public interest of society over any other interest. ▪ The specification of the strategies and tools by which the objectives of the drug policy can be achieved by various parties engaged. ▪ The excellent health infrastructure in the Country. ▪ The enhancement of the coordination and partnerships made by and between the public and private sectors. ▪ The promotion of effective communication with community members. ▪ The periodic implementation of a data quality assessment (DQA). ▪ Awareness for health service providers. ▪ The support shown for strategic partnerships. ▪ The existing support shown in the presence of the National Research Center.	▪ Addressing the weak cooperation of some stakeholders. ▪ The complexity of the procedures applied for issuing the policy and the multiplicity of the stages thereof. ▪ The multiplicity of parties engaged in the preparation of the policy as well as the issuance thereof. ▪ The efforts exerted to control the spread of non-communicable and communicable diseases in light of the Country's openness to the whole world. ▪ The shortage of human resources. ▪ The cost. ▪ The frail rational use of drugs. ▪ The heavy reliance on importing effective raw materials and inactive pharmaceutical ingredients from abroad. ▪ The unfair competition between some pharmaceutical dealers. ▪ The control shown by some foreign pharmaceutical companies over the drug market. ▪ The increase of dependence on imported medicines and their preference by the consumer. ▪ The reluctance of some pharmaceutical companies to supply medicines to the Country. ▪ The existence of anonymous global channels for the trade and promotion of fraudulent and counterfeit medicines.

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▪ The obvious development in the preventive pharmaceutical industries as well as the opportunity to develop industries in the preventive and curative field through the attraction of investments, world classified entities and health expertise. ▪ Attracting concerned experts. ▪ The support shown for the concepts of Smart e-government and data automation. ▪ The support shown by the wise government for innovation and flexibility to keep pace with global shifts. ▪ The rapid registration of modern and innovative medicines, including orphan medicines and vaccinations in the Fast Track system at the Ministry of Health and Prevention (MOHAP).	▪ The tendency to approach external channels for the provision of medicine from unofficial or uncontrolled bodies by those, who do not have health insurance. ▪ The presence of hindrances that affect the export of medicines out of the Country. ▪ The absence of a unified purchasing policy that obliges health authorities to prioritize the purchase of local products. ▪ The frail application of modern classifications of drugs. ▪ The inadequacy of mechanisms applied to regulate the circulation of conventional and herbal medicinal products. ▪

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▪ The generous support of the national industry while preserving such for being one of the pillars of the Country's economy ▪ The encouragement shown to investing in the manufacture of homeopathic pharmaceuticals and basic medicines. The priority of purchasing nationally manufactured pharmaceutical products provided by health authorities. ▪ The promotion of rational and effective use of medicines. ▪ The specification of objectives and priorities, setting plans based thereon and committing to the implementation thereof. ▪ The qualifying of the medical cadre while providing them with modern therapeutic guides to adjust the doses of medicines prescribed. ▪ The conduct of studies and research. ▪ The establishment of a drug sector or an agency in the Country. ▪ The consumer's easy access to information posted online. ▪ The compulsory health insurance. ▪ The growth of regional medical tourism. ▪ The huge growth in the homeopathic pharmaceuticals market. ▪ The regional increasing demand for pharmaceutical products (import and re-export). ▪ The interaction with colossal markets (the market of the Gulf countries and the Eastern Mediterranean ones). ▪ The availability of robust logistics companies in the field of medicine	▪ The region's lack of R&D infrastructure to produce innovative medicines. ▪ The instability in the surrounding area. ▪ The new and growing competitions. ▪ The great economic shifts around the world

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Global Best Practices

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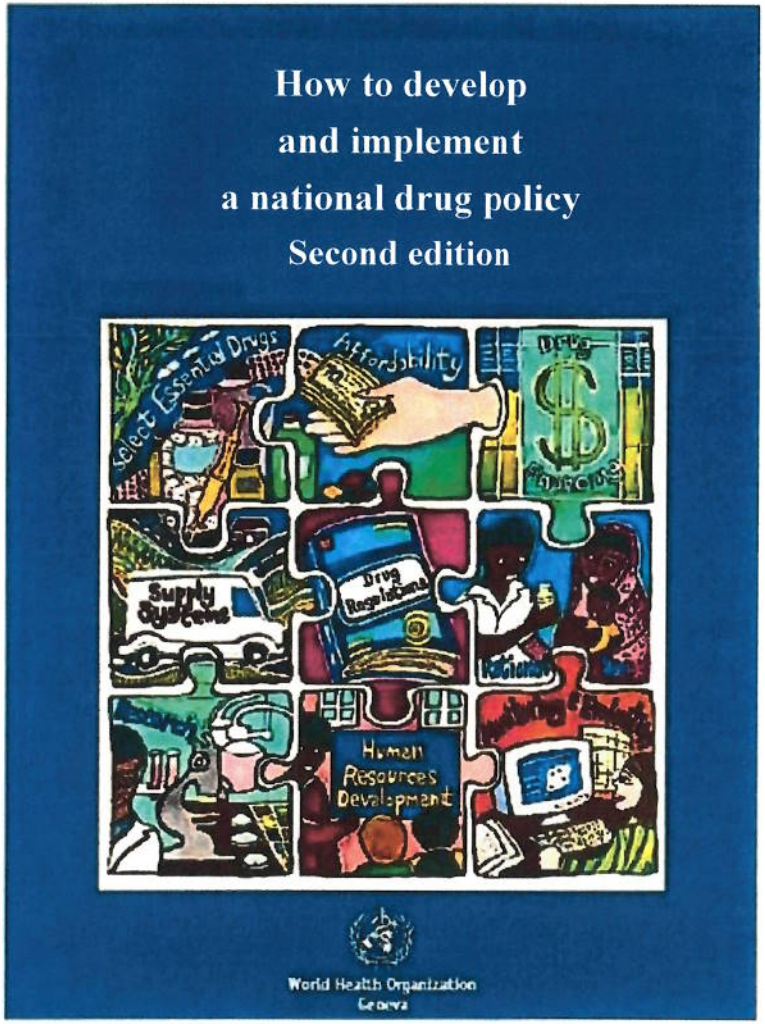

World Health Organization (WHO):

How to develop and implement a national drug policy

The World Health Organization defines the national drug policy as the government's commitment and the guide to action that prioritizes the medium to long-term objectives of the pharmaceutical sector. The policy also identifies the key strategies to be achieved and provides a framework within which the activities of the pharmaceutical sector can be systematic and coordinated to cover both the public and private sectors. The policy also includes all major players in the pharmaceutical field

The national drug policy is considered as a common framework for enhancing medicine services and for solving problems in the pharmaceutical sector. Experience in many countries has shown that policies built within a common framework can address problems optimally

The policy document must be prepared through a process of regular consultations with all parties concerned. In such process, objectives and priorities must be set, strategies must be developed and commitment must be established.

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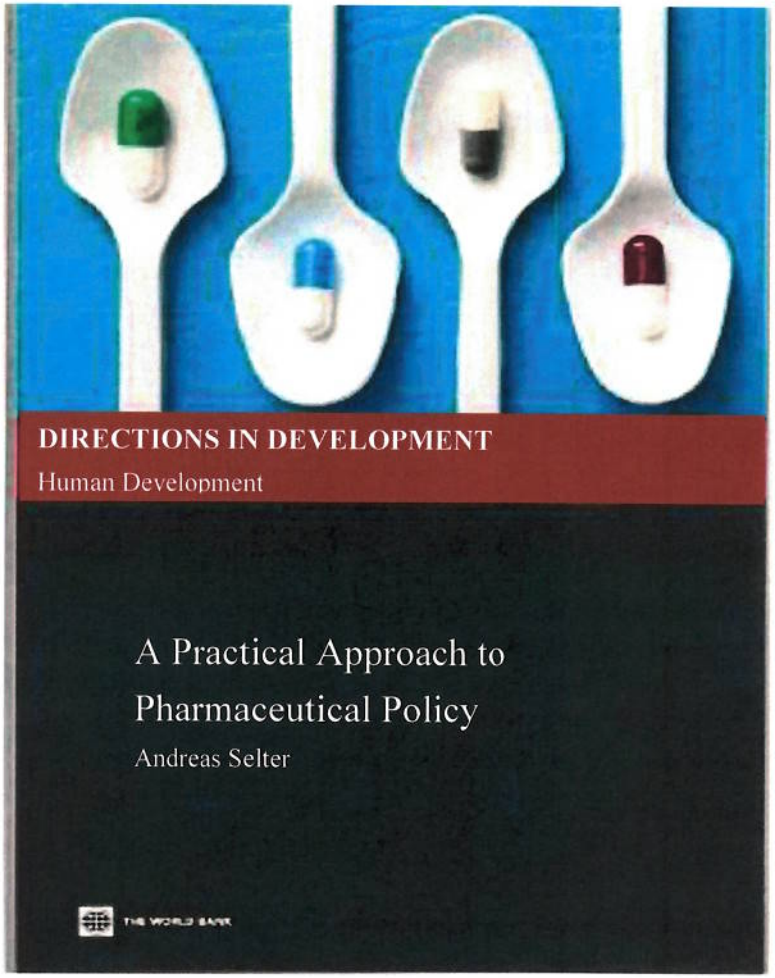

The World Bank:

A Practical Approach to Pharmaceutical Policy

For the purposes of the World Bank's document, "Policy" is defined as a mindful attempt made by authorized public health officials or executives in order to achieve certain objectives through a set of laws, rules, procedures and stimulus associated with strengthening the pharmaceutical sector of countries.

One way of describing the framework of the policy is to map the hierarchy that governs drug market and stakeholder interactions.

The document recommends that an expressive national drug policy or a national pharmaceutical policy should be developed; usually, such is formulated under the leadership of the Ministry of Health with inputs provided by stakeholders. The policy provides strategic direction and defines the general objectives of the sector.

The document outlines the high-level view of pharmaceutical policy necessary to identify techniques that policymakers can apply to address problems and to achieve policy objectives; such as facilitating access to medicines to improve the quality of health care in countries.

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European Commission:

Adopting a Pharmaceutical Strategy for Europe

The European Commission has developed a roadmap for the pharmaceutical strategy.

The key elements of such roadmap include: increasing funding for R&D; early drug development; promoting the development of European skills in the pharmaceutical sector and encouraging innovative manufacturing and development of research ecosystem (e.g. biobanks and data banks).

One of the key objectives of the strategy has been to reduce reliance on products manufactured outside the European Union while shifting the production of active pharmaceutical ingredients and other key operations towards Europe in addition to ensuring the efficient and fair distribution of medicines amongst the Union's Member States under fitter cooperation between industry, the European Union and the government; particularly in times of health crises.

Moreover, maintaining the absence of restrictions on exports has been another essential element of such strategy in order to facilitate free trade and to guarantee the smooth functioning of the internal market while addressing the deep-seated causes of supply shortfalls and supply chain risks. As for the improvement of the pharmaceutical regulatory environment, the document has recommended the need for greater clarity, adaptability and agility, which could be enhanced through the following:

- A firm intellectual property framework that protects patents;

Analysis of consultation activities directed towards the adoption of a Pharmaceutical Strategy for Europe

Factual Summary Report - Replies to the Roadmap

September 2020

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- Incentives to stimulate and expedite the research works and coordination of supplementary protection certificates (SPC);
- Input real world data (RWD) and real world evidence (RWE) into clinical development and regulatory decision making processes;
- Developing clinical trial networks for European countries;
- Building a European health data space.

Determination of options as based on global best practices:

The current situation of a drug in the Country has been studied, international best practices have been discussed with the concerned partners and options have been determined accordingly.

An approach that involves the application of a national framework to promote medicine in the Country has been chosen.

The strategy applied by the World Health Organization (WHO) in developing the drug policy has been adopted as it closely simulates the objective of the Country's policy in unifying and strengthening joint efforts to bolster the drug sector, which in turn contributes to combating diseases, advancing health services as a whole in the Country and achieves community happiness and Quality of Life (QOL). Other policies and strategies have been taken into account as well including the approach of the European Commission, which drew a roadmap for the drug strategy that aimed at improving the drug regulatory environment. In addition, the practical approach to the drug policy developed by the World Bank, which aims at facilitating access to drugs to improve the quality of health care in countries has also been considered in such regard.

All these frameworks added to others have been utilized to develop a supportive policy in order to enhance the pharmaceutical sector in the Country; as medicine is a key aspect of a healthy lifestyle and health system; provided that it is consistent with the current health situation in the Country.

The options have been identified to be in line with the framework of the "Governance" aspect in order to enhance the health sector in the Country by providing the best health care for members of society, which comes at the top of the wise government's priorities- and among the priorities of the UAE's National Agenda- to achieve a health system with international standards in a sustainable environment and Integrated infrastructure according to global health care quality indicators.

Vision:

The enchantment of the health of the individual and the Emirati society as a whole via the development of health and pharmaceutical services in the Country.

Mission- Purpose:

The preparation of a multi-sectoral national framework in order to bolster the pharmaceutical sector in the United Arab Emirates to ensure the use of all the capabilities of the national pharmaceutical sector, which relies on equitableness, accessibility and rational use of safe, effective, affordable and good-quality essential medicines to achieve the highest levels of health for community members in the United Arab Emirates.

The purpose of the national framework

There has been an increasing importance shown to following a more coordinated strategic approach for the effective success of efforts in order to promote the pharmaceutical sector in the Country, which falls on all the Country's concerned levels and sectors. Therefore, a multi-sectoral national approach can lead to a more effective and efficient use of national resources. There are significant benefits to a nationally coherent approach that compiles efforts to include all aspects of pharmaceutical sector promotion which in turn allows more focus on policy priorities and using resources optimally. The national framework can also achieve greater effectiveness due to the integration of efforts exerted thereunder without any changes to the responsibilities borne

by governments. In other words, it involves the commitment of all parties involved to work better together in areas of shared responsibility. It also includes a commitment to improve coordination of public health functions and drug sector services while coordinating planning and implementation to improve sharing of information and innovation. The national framework also provides a mechanism to engage the non-governmental sector and the wider community at the national level which in turn leads to the desired objective of developing the health system to prevent, monitor and control diseases in the UAE community. Moreover, it promote healthy lifestyles to reduce such diseases.

Aspects of Policy

Partnership

Leadership & Governance

Equality

Complete & Comprehensive Coverage

Safety & Quality

Innovation

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Objectives, scopes and actions of Policy

The objectives of the policy revolve around enhancing the provision of pharmaceutical services to members of society through a national system that functions efficiently and continuously with the framework of the comprehensive national drug policy to which all partners are committed and whose implementation is continuously monitored and evaluated while taking into account the recommendations made in the workshop held in cooperation with the various health and non-health authorities concerned in the Country as well as the meetings that have been organized with the various concerned authorities mentioned. Such objectives cover the following:

- Ensuring the availability of comprehensively consumed high-quality essential medicines within the Country at reasonable prices.
- Strengthening the local capacity to produce and export high-quality medicines at an efficient cost by promoting industry and trade in the pharmaceutical sector.
- Strengthening the quality control system on the production and distribution of pharmaceutical products to make quality an essential feature of the pharmaceutical industry and to promote the rational use of medicine.

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- Encouraging research and development within the pharmaceutical sector in a manner consistent with the needs of the Country while putting a peculiar focus on high-rate diseases by creating an enabling environment to direct a higher level of investment to research and development in the field of pharmaceuticals in the Country.
- Establishing an incentive framework for the pharmaceutical industry that encourages new investment in the pharmaceutical industry and encourages the introduction of new technologies and new drugs.

A table summarizing the aspects and scopes of work of the national drug policy

Aspects	Scopes
1 Governance - Advocating and supporting leadership and establishing partnerships	1-1 Building up and supporting the social, financial and administrative commitment towards the pharmaceutical sector.
	1-2 Strengthening leadership, management and coordination at all levels. Effective national partnerships, networks and global cooperation
	1-3 Developing legislations that support medicine services in the Country
2 Sustainability and availability of essential medicines	2-1 Achieving a high coverage of pharmaceutical products at the national level as well as in all the Emirates and the regions thereof
	2-2 Sufficient and appropriate funding and infrastructure to maintain sustainable coverage of all essential medicines in the Country
	2-3 Provision of medicines in cases of emergency, disasters and pandemics.
	2-4 Ensuring the availability of sufficient trained workforce within the pharmaceutical sector.
3 Strengthening the local capacity to produce and export medicines	3-1 Ensuring the existence of an effective and responsible local pharmaceutical industry.
	3-2 Expanding the scope of export markets for local pharmaceutical products
4 Strengthening the quality and safety control system for the production of pharmaceutical products	4-1 Protecting a timely access to quality-assured pharmaceutical products and ensuring functional drug-safety systems
	4-2 Establishing and strengthening comprehensive pharmaceutical product monitoring capabilities that are supported by robust and reliable systems based on drug laboratory testing
	4-3 Combating drug falsification.
	4-4 Strengthening the pharmacovigilance system, the drug control system as well as the quality systems affiliated thereto.
	4-5 Monitoring the professional practice.
	5-1 Generating data and statistics on medicine services for evidence-based decision making processes

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5 Information systems, innovation and research capacity	5-2 Strengthening research capacity, establishing systems and managing innovation in the field of various pharmaceutical products.
	5-3 Developing new technologies and improving pharmaceutical products and vaccines.
	5-4 Guaranteeing the intellectual property of inventors in the field of pharmaceutical products.
6 Rational use of the medicine	6-1 Developing supportive interventions and initiatives to raise awareness of the rational use of medicine

1- Aspect One: Governance - Endorsement and support of leadership and establishing partnerships

This aspect revolves around the establishment of partnerships with local and international ministries, federal and local authorities and bodies affiliated to the private sector in order to enhance the health status of the United Arab Emirates, enhance the pharmaceutical sector therein and contribute to achieving sustainable development in the Country by providing comprehensive and innovative health services characterized by their fairness and compliance to international standards. Such strategic partnerships include partnerships that work to meet the indicators of the National Agenda as well as the strategic objectives of the legislative committees, national initiatives and joint events. The pharmaceutical legislations including laws, regulations and resolutions form a key and mandatory tool to achieve the objectives of drug policies seeking to ensure drug effectiveness, safety, availability, quality and control of circulation to protect the health of members of society from the dangers of ineffective, unsafe and low-quality drugs. Moreover, such legislations empower the concerned federal and local drug control bodies to perform their supervisory duties and enforce the provisions of such legislation. Furthermore, such legislations enable the competent regulatory authority to issue rules, standards, regulations, guidelines and other binding requirements and to issue the decisions required in all scopes of pharmaceutical control. Such legislations also regulate the rules and principles for practicing the profession of pharmacy within various sectors. Accordingly, the legislation must be comprehensive in all of these areas and must keep pace with scientific developments and changes as well as with global and local advancements.

Aspect One -Work procedures:

1-1 Building up and supporting the social, financial and administrative commitment towards the pharmaceutical sector.

- Ensuring the addition of the aspects of the national drug policy to the government's directives and enablers as well as to the National Agenda from which all national strategies emanate in line with the UAE Vision 2021, the Smart Government Initiative, the National Innovation Strategy, Future Foresight 2050, the UAE Centennial 2071 and The Fifty-Year Charter - The Health Path.

- Ensuring that the competent authorities, decision makers and stakeholders do advocate for commitment to support medicine services including the sustainable local financing.

1-2 Strengthening leadership, management and coordination at all levels - effective national partnerships, networks and international cooperation

- Supporting the roles played by the Ministry, health authorities and the parties concerned while implementing medicine services supervision and control; each within the limits of the competences thereof. Providing the appropriate environment to enhance the pharmaceutical sector in the Country.

- Raising the efficiency of the pharmaceutical sector via establishing health partnerships with various international bodies and global organizations that cooperate with the Ministry under cooperation agreements, memoranda of understanding or with those in which the Ministry holds a member seat (if such are international or regional organizations); as international partnerships contribute significantly to encouraging competitiveness and improving the quality of pharmaceutical services provided to establish a more effective and efficient health sector in the region.

- Enhancing technical and economic cooperation with partners from the private sector (pharmaceutical companies and factories) and developing the works of the Medicine Board of Trustees in the Country via creating an integrative partnership between governmental bodies and private sector service providers within the pharmaceutical sector

- Developing proper mechanisms that ensure coordination between the concerned bodies in the pharmaceutical sector.
- Strengthening cooperation and coordination with partners within the field of veterinary medicine due to the significance of the role played thereby in reducing the risks of the spread of epidemic, infectious and common diseases between humans and animals in addition to the consequent increase of biosecurity rates.

1-3 Developing legislations that support medicine services in the Country

- Reviewing the legislations related to pharmacy and pharmaceutical products in addition to updating such to keep pace with local and global shifts and developments. Introducing new legislations in the pharmaceutical sector as needed
- Issuing regulatory resolutions based upon Federal Law No. 8/2019 regulating the profession of pharmacy, pharmaceutical facilities and medical products.

2- Aspect Two: Sustainability and availability of essential medicines

Providing medicines- especially essential ones- to all residents in both governmental and private sectors in a fair and reasonable manner is one of the key aspects of the drug policy in the Country. It is also deemed to be one of the significant governmental documents that regulate the pharmaceutical supply legally. The reasonable drug pricing is a key prerequisite for guaranteeing such point.

Aspect Two -Work procedures:

2-1 Achieving a high coverage of pharmaceutical products at the national level as well as in all the Emirates and the regions thereof

- Ensuring access to essential medicines by increasing affordability, reducing or canceling taxes and distributing margins.
- The existence of a unified list of essential medicines in the Country
- Monitoring pricing of multi-source products, promoting for competition, procurement and good practices and applying price negotiations for single source products
- Competing through price information, remedial substitution and parallel imports
- Controlling drug prices and setting profit margins for pharmacies and distributors.
- Adhering to good drug procurement and disposal practices for unwanted or expired drugs.
- Developing Fast Track procedures for essential medicines and prioritizing registration based on need.
- Establishing a mechanism for registering innovative and orphan drugs

2-2 Sufficient and appropriate infrastructure to maintain sustainable coverage of all essential medicines in the Country

- Attracting global investment directly into the pharmaceutical sector.
- Increasing the number of marketing offices and logistics centers for international pharmaceutical companies in the Country.
- Increasing the number of agreements of understanding concluded by and between the public and private sectors; especially with regard to the provision of medicines for orphan diseases and life-saving medicines
- Encouraging the registration of generic medicines to meet the needs of the community members for medicines at all price levels.
- Adhering to procedures that improve efficiency and reduce wastage.
- Enhancing the reimbursement of drug costs for patients as part of the health insurance umbrella; each according to the insurance plan available.

2-3 Provision of medicines in cases of emergency, disasters and pandemics

- Providing strategic medical stockpile of essential medicines and vaccinations as well as concluding related agreements with the private sector (drug suppliers and manufacturers).
- Taking the necessary measures and actions to support the essential items of the strategic medical stockpile. Such includes the importing of these items under a mechanism that ensures their arrival to the Country at the maximum speed and taking the necessary measures to expand storage warehouses and provide the items adequately and continuously in all cases.
- Increasing the manufacturing and operating capacity of local factories to reach maximum level in emergency cases.
- Founding a distinguished base of experts in the field of emergencies, crises and disasters and qualifying health cadres working in the field of medicine in the Country in order to support and enhance emergency response efforts.

- Electronic linkage of the concerned bodies in the Country to carry out the tasks of storing, recycling and distributing pharmaceutical products and vaccinations in cases of emergency.
- Ensuring the existence of a unified drug information system that enables the monitoring of the drug stockpile and the availability of essential drugs to be available in cases of emergency.
- Ensuring the existence of a unified list of essential medicines to be available in cases of emergency.
- Linking drug planning to forecasting the occurrence of epidemics and emergencies in the Country

2-4 Ensuring the availability of sufficient trained workforce within the pharmaceutical sector

- Developing the human resources needed for the pharmaceutical sector through appropriate education and training.
- Developing, attracting and retaining experts to enhance the pharmaceutical sector services.
- Ensuring the adequacy of trained and motivated employees available for implementation of works.
- The government's responsibility for planning and supervising development processes.
- Career planning for building the team necessary for pharmaceutical sector services.

3 Aspect Three: Strengthening the local capacity to produce and export medicines

The aspect includes the enhancing of the local capacity to produce and export medicines. It also includes developing an integrated policy in collaboration with the national pharmaceutical factories while focusing on increasing the share of pharmaceutical production to meet the needs of the medical sector in the Country and strengthening the capabilities of local factories to establish various partnerships among one another as well as with leading international companies to be able to produce medicines and vaccines. In addition, it focuses on the production of specialized medicines to expand the scale of pharmaceutical products and to provide the pharmaceutical manufacturing base with various technological and vital techniques. The aspect also tends to rely on artificial intelligence for the manufacture of medicines, which contributes to reducing the manufacturing cost and to increasing the quality of pharmaceutical products.

Aspect Three - Work procedures:

3-1 Ensuring the existence of an effective and responsible local pharmaceutical industry

- Working on the transfer of innovative and biological pharmaceutical industry Know-Hows and artificial intelligence techniques to the laboratories of local pharmaceutical companies,
- Supporting the supply of local factories with raw materials.
- Encouraging the manufacture of medicine at its three levels locally:
    - Level One: Production and primary manufacturing of raw materials, active pharmaceutical ingredients and intermediates.
    - Level Two: Production and preparation of dosage forms by mixing raw materials.
    - Level Three: Production that is limited to packaging of finished products or repackaging of finished liquids products.

- Strengthening the capabilities of local pharmaceutical factories and supporting such with technological and logistical capabilities,
- Maximum utilization of the existing capacity of the local pharmaceutical and medical industries.
- Raising the local market's share owned by local pharmaceutical factories.
- Developing technologies and manufacturing process of biopharmaceuticals.
- Supporting and encouraging the national industry within the field of essential medicines and vaccines.
- Encouraging local pharmaceutical industry of the enhanced-quality generic drugs.
- Investing in modernizing research in natural and conventional pharmaceutical products
- Promoting local manufacturing, encouraging the national consumer to use local products and encouraging the use thereof in the Country's hospitals.
- Creating job opportunities and attracting local national workforce in the field of manufacturing pharmaceutical products.
- Continuous training of the workforce in the pharmaceutical sector

3-2 Expanding the scope of export markets for local pharmaceutical products

- Expanding export markets in a manner that paves the way for new countries to be reached through modern legislations and regulations that encourage investment in the sector.
- Increasing export revenues for local pharmaceutical and medical supplies manufacturers.
- Accurate analysis of the situation and realistic evaluation of the local feasibility of exporting local pharmaceutical products

4 Aspect Four: Strengthening the quality and safety control system for the production of pharmaceutical products

The quality assurance of medicines covers all the measures taken to ensure that the pharmaceutical product is safe, effective, of good quality and useful for the patient as from the stage of development to the stage it is consumed by the patient. The aspect aims at ensuring the quality of pharmaceutical products and thus protects public health by promoting the implementation of quality standards related to the safety of pharmaceutical products. It includes the quality assurance of all stages of manufacturing, storing, registering, trading and importing the product. It also covers the provision of accurate information necessary for such product as well as distributing pharmaceutical products in line with quality standards and legal terms. The pharmacovigilance system contains a set of scientific principles and activities related to detecting, evaluating, understanding and preventing harmful effects or any problems related to medicines

Aspect Four - Work procedures:

4-1 Protecting a timely access to quality-assured pharmaceutical products and ensuring functional drug-safety systems

- Strengthening the regulation of the quality assurance process of medicinal products at every stage as from manufacture to distribution and consumption.
- Verifying that all pharmaceutical products have all the properties required for the intended use thereof and meet consumer expectations.
- Reviewing the product's quality, safety and efficacy as part of the registration process thereof.
- Drafting national rules and standards set for quality and drug safety.

- Developing Good Manufacturing Practices (GMP) and Good Storage Practices (GSP).
- Developing a mandatory system for licensing manufacturers, importing agents, distributors and drug stores to ensure that all products do conform to acceptable quality, safety and efficacy standards.
- Developing pharmaceutical quality control laboratories to test pharmaceutical products in the pre- and post-marketing phases through a smart electronic system in the presence of trained human cadres.
- Regulating the circulation of conventional and herbal medicines.

4-2 Establishing and strengthening comprehensive pharmaceutical product monitoring capabilities that are supported by robust and reliable systems based on drug laboratory testing

- Ensuring support and verifying that all persons concerned have been trained on a culture of quality; and that practices applied for registration, production, storage and distribution of medicines do comply with international standards and specifications.
- Developing the knowledge and skills of the bodies concerned with dealing with pharmaceutical products.
- Monitoring the pharmaceutical sector through regular indicator-based surveys.
- Establishing smart technical control platforms for pharmaceutical products.
- Commitment to the inspection and monitoring of good manufacturing practices and good storage practices while importing, exporting and distributing such to companies and pharmaceutical factories.
- Compliance with the regulation of advertising and promotion of pharmaceutical products; reviewing and approving product data and labels thereof.

4-3 Combating drug falsification

- Spreading communication, education and awareness amongst all members of society periodically to raise their awareness of the dangers of buying medicines from unknown sources.
- Strengthening cooperation with relevant government and private agencies by engaging them within various anti-fraud committees.
- Raising quality control capabilities and enhancing efficiency in the quality control laboratory and research for the control of pre- and post-marketing drugs
- Securing the supply chain for pharmaceutical products.
- Strengthening control and monitoring while increasing focus on the monitoring of the drug market in the Country to ensure that it is counterfeit drugs free and to combat the promotion thereof
- through unknown sources.
- Issuing warnings and withdrawing of products that do not meet the existing terms and conditions set according to the legislations in force in the Country.
- Using modern technology through the application of the latest techniques to detect counterfeit drugs in their various forms across the Country's air, sea and land borders

4-4 Strengthening the pharmacovigilance system, the drug control system as well as the quality systems affiliated thereto

- Establishing a national pharmacovigilance system for monitoring adverse drug reactions and monitoring harmful drug reactions
- Developing a system connected to the World Health Organization's collaborating center for international drug monitoring in Uppsala in order to collect and evaluate information on adverse drug reactions.

- Establishing early warning and recalling systems to act as additional methods to ensure safety.
- Developing unified electronic systems and platforms for prescribing and dispensing narcotic drugs and controlled and semi-controlled drugs (CD/SCD)

4-5 Monitoring the professional practice

- Developing medical and pharmaceutical Code of Professional Ethics document
- Licensing clinical trials by the concerned bodies in the Country
- Establishing a system for good marketing practices for medical products in the Country

5 Aspect Five: Information systems, innovation and research capacity

- Supporting need-based innovation, which is the ability to identify and manage innovation in the pharmaceutical sector including identifying, documenting, evaluating and implementing innovations; as well as supporting evidence-based research leading to development, improvement and expansion in the field of pharmaceutical products

Aspect Five - Work procedures:

5-1 Generating data and statistics on medicine services for evidence-based decision making processes

- Strengthening health information systems to enable decision-makers to use high-quality data and effectively manage medicine services, as well as ensuring their link to health care data systems in the Country.
- Establishing a system for exchanging reports on drug policy evaluation with highly efficient regulatory bodies in the field of promoting medicine services in other countries

5-2 Establishing and strengthening research capacity, establishing systems and managing innovation in the field of various pharmaceutical products

- Strengthening mechanisms for prioritizing research and innovation based on needs of community while ensuring that such do follow the innovations introduced within the field
- of various medicine products and services studies such as clinical research, preclinical studies, drug safety control studies, post-marketing studies, bioequivalence studies, stability studies and pharmacoeconomic studies.
- Computerizing the drug registration system and researching possible innovations to enhance such area.
- International exchange of information within the field of research and development for the innovation of new pharmaceutical molecules

- The use of innovative technologies such as virtual reality technology in the design of new drug therapies through the use of interactive simulations of molecular kinetics in the discovery of new drug products.
- Conducting studies to evaluate the quality and safety of conventional herbs and prove the effectiveness thereof.
- Cooperating with academic bodies and universities in research on pharmaceutical products.
- Cooperation with international private pharmaceutical companies and private research companies in the field of drug research and clinical research

5-3 Developing new technologies and improving existing pharmaceutical products and vaccines

- Supporting the development of new vaccines and technologies and improving pharmaceutical products while ensuring continued progress in the field of research for specific vaccines such as: HIV, novel coronavirus (Covid-19) as well as other priority epidemics and diseases

5-4 Guaranteeing the intellectual property of inventors in the field of pharmaceutical products

- Developing an intellectual property policy to be based within the health field to promote health, economic, scientific and cultural development in the Country by protecting intellectual property rights in the health field and using such as a tool to encourage and protect creativity, scientific research findings and local innovative capabilities while protecting society from the dangers of counterfeit and falsified medicines and medical supplies.

6 Aspect Six: Rational use of the medicine

The rational use of medicine is the process of promoting the proper and cost-effective therapeutic use of medicines by health professionals and consumers. Patients must receive medicines that are appropriate therefor, in doses that meet their individual requirements, adequately for a specified period of time and at the lowest cost for them as well as for their community.

Aspect Six - Work procedures:

6-1 Developing supportive interventions and initiatives to raise awareness of the rational use of medicine

- Promoting concepts of rational and healthy use of essential medicines.
- Developing regulatory and management strategies to promote rational use of medicines.
- Continuous training of health service providers in the Country to prescribe pharmaceutical products in an accurate and unbiased manner.
- Identifying problems related to prescribing and dispensing medication; and understanding the social and cultural aspects of drug use among groups of community members
- Increasing the awareness of community members regarding the dangers of using pharmaceutical products in an excessive and inappropriate manner without medical advice.
- Promoting the concept of reporting drug side effects when experienced by community members.
- Establishing a mechanism for dispensing medication by unifying the electronic medical file.
- Establishing a unified mechanism in the Country for the disposal of expired medication.
- Establishing a mechanism for exchanging data between the concerned authorities in the Country and health insurance companies to monitor the prescribed medicines in order to prevent unjustified repetition of the same prescription.

Key partners in the preparation of Policy

ai Health Authority

The Ministry of Health and Prevention (MOHAP)

Community

Public Health Sector

Health Regulation Sector (HRS)

Dhabi Department of Health (DOH)

arjah Health Authority

istry of Cabinet Affairs

rtment of Health Policies

rates Health Services (EHS)

Ministry of Climate ange and Environment

Ministry of Interior - Medical Services

Dubai Healthcare City

a Center for Treatment and Rehab

nistry of Economy

Jnited Arab Emirates University

Emirates Medical Association (EMA)

Private Sector

icine Board of Trustees

- *In case of any misinterpretation, the Arabic version of this policy prevails.*