

UNITED ARAB EMIRATES  
MINISTRY OF HEALTH & PREVENTION



الإمارات العربية المتحدة  
وزارة الصحة ووقاية المجتمع

## GLOBAL REGULATORS CONCLAVE “INTERNATIONAL REGULATORY CONVERGENCE TO PROMOTE ACCESSIBILITY AND AFFORDABILITY OF QUALITY MEDICINES”

(21 – 23 SEPTEMBER 2022)

MINISTRY OF HEALTH AND PREVENTION - UAE  
PUBLIC HEALTH POLICY & LICENSING  
DRUG DEPARTMENT  
DR. FATMA RAHIM – DEPUTY DIRECTOR

Supported by



Organizer



Co-Organizer





# MOHAP STRATEGY

## Mission

To enhance community health by providing comprehensive, innovative, and fair healthcare services as per international standards, and performing its role as a regulator and supervisor of the healthcare sector through a modern and integrated health legislative system.



## Vision

An effective and sustainable Healthcare System for a happy society





# MOHAP STRATEGY

## OUR STRATEGIC OBJECTIVES

### 1st objective

Provide a comprehensive and integrated healthcare in innovative and sustainable ways to prevent the spread of diseases in the community.

### 2nd objective

Develop effective health information systems and apply global standards in the management of health facilities and infrastructure.

### 3rd objective

Build quality and safety for therapeutic, healthcare and pharmaceutical systems according to international standards.

### 4th objective

Provide a vital legislative framework and, governance, and distinctive regulatory and supervisory services for the healthcare sector

### 5th objective

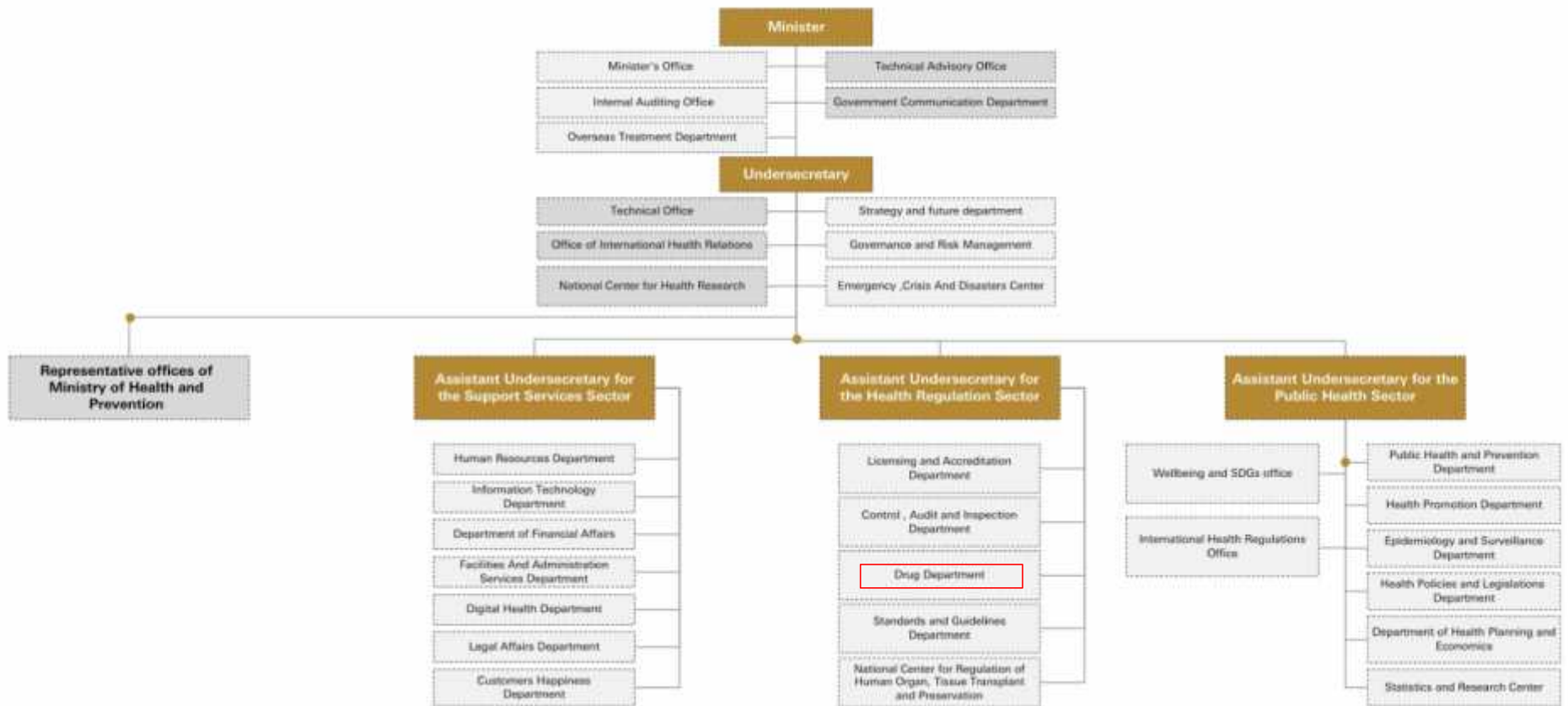
Ensure and guarantee the provision of all administrative services according to the standards of quality, efficiency and transparency

### 6th objective

Entrench a culture of innovation in the institutional work environment



## MOHAP ORGANIZATION STRUCTURE





# DRUG DEPARTMENT

1



Medical  
Products  
Regulation  
Section

2



Quality Control  
of Medical  
Products

3



Regulating  
Import and  
Export

4



Regulating,  
Controlled  
Products and  
Precursor  
Chemicals

5



Medical  
Products  
Vigilance  
Section

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# COVID-19 RELATED LEGISLATIONS REGULATORY ENABLERS FOR FAST TRACK APPROVALS



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## LAWS, LEGISLATION, POLICIES AND REGULATIONS



- When faced with the pandemic His Highness Sheikh Mohamed bin Zayed Al Nahyan, president of the UAE, Said 'latsheloon ham', which means 'do not worry'.
- The UAE's robust infrastructure of healthcare laws, legislation, policies and regulations meant the leadership was confident that the pandemic could be effectively managed.
- 52 laws, Circulars and Administrative decrees were issued or updated during the pandemic.



## UAE GOVERNMENT PARTNERSHIP WITH THE PHARMACEUTICAL INDUSTRY

- A great example was a partnership that multinational companies had with the Ministry of Health and Prevention to ensure that vaccines are available in UAE almost at the same time that they were available in the country of manufacturing.
- Moderna vaccine was approved within four hours.
- UAE was among the first countries started clinical trials with 54,000 volunteers of different nationalities for the Sinopharm vaccine.
- People of over 200 nationalities live in the UAE, adhered to the guidelines and rules which helped us an made us able to protect their health.



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**UAE THE FIRST COUNTRY IN THE WORLD TO USE THE MEDICINE 'SOTROVIMAB-VIR-783T' AGAINST COVID-19**

MoHAP approves the emergency use

After is approval by the US Food

Produced by: CSH Global Company

**Contributes to:**

- Limiting the number of cases that require hospitalisation
- Reducing the number of deaths
- Up to 85% when given to patients at an early treatment

It depends on monoclonal antibodies to treat patients aged 12 years and over

Sources MoHAP

UAE Farsan

EMERGENCY USE AUTHORIZATION CERTIFICATE

Certificate # 5076/2020/0005-C1

**Biological Medicines – Other Biotechnical**

It is certified that the following product was authorized for emergency use under the provisions of the regulations issued by the Ministry of Health and Prevention

Registration No:	5076/2020/0005	Exp. Date:	31 May 2021
Product Name:	Sotrovimab (SOT-19) (SGLAW)	Exp. Date:	31 May 2021
Indication:	For use in the treatment of COVID-19		
Strength:	100 mg/100 mL		
Manufacturer:	CSH Global Company		

Issued on: 27 May 2021

FDA Approval --> May 26, 2021  
 Approval of the Ministry of Health and Prevention --> May 27, 2021  
 First shipment of Sotrovimab arrives in the country --> June 16, 2021

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# UAE announces 2-week treatment results for Covid-19 medicine Sotrovimab

Led to the recovery of 97.3% of recipients



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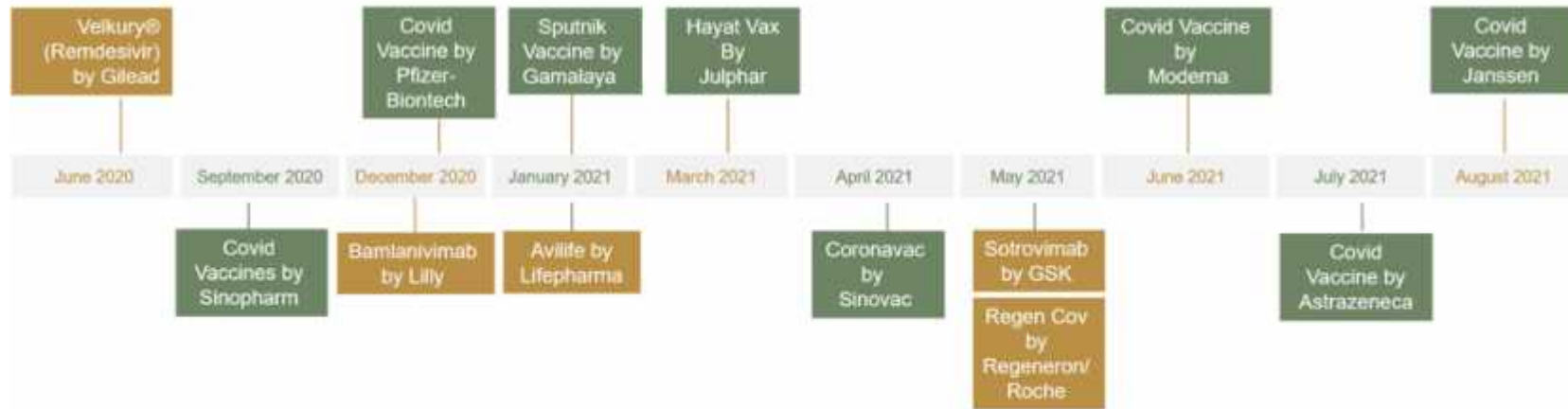
وزارة الصحة  
DEPARTMENT OF HEALTH



هيئة الصحة بدبي  
DUBAI HEALTH AUTHORITY



Innovative treatments and Vaccines launched in the UAE



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## INNOVATIVE SYSTEMS SUPPLY CHAIN RESILIENCY



## 2018 MOHAP E-SERVICES

In 2018 the Ministry of Health & Prevention launched number of enhanced E-Services in Drug Department, which contributed in improving the level of services provided to applicants and save time and effort.

- Product Classification.
- Product Registration.
- Import & Export Services.



## EVALUATION OF PRODUCT / REGISTRATION

### BEFORE



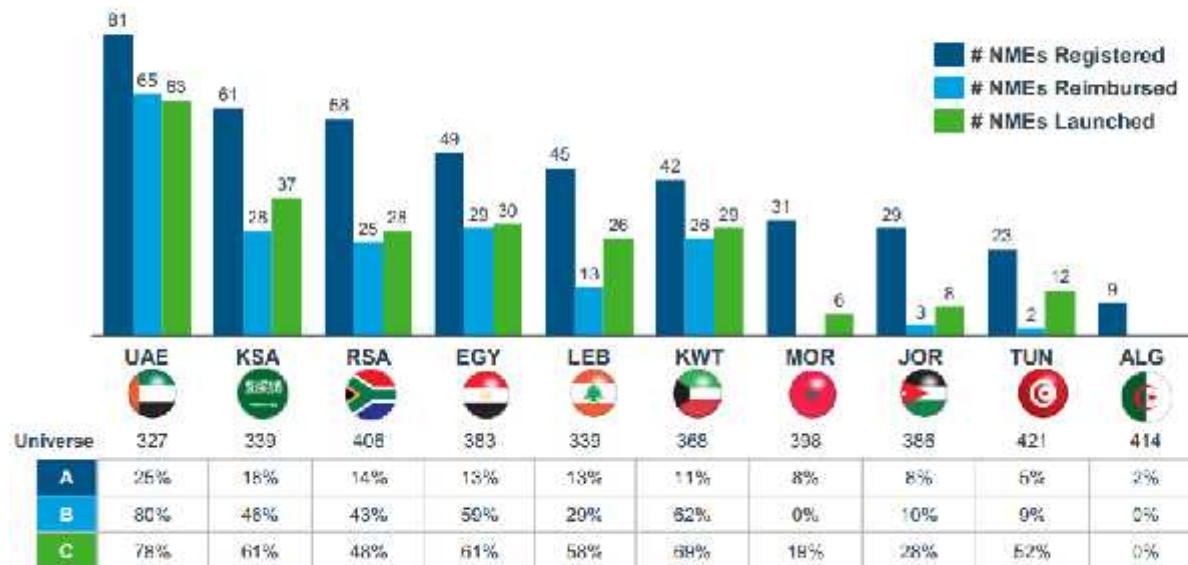
### Now





## UAE has the highest number of NMEs registered followed by Saudi Arabia and South Africa

Number of NMEs registered, launched and reimbursed per country since 2018 – To date



### Key Highlights

- The configuration of the market access landscape has a determinant impact on the number of available products per country
- The UAE has the maximum number of molecules registered (81) in MEA followed by KSA (61) and South Africa (58)
- Name-patient based programs are used more commonly in UAE, KSA and Kuwait as an early access mechanism
- The proportion of reimbursed NMEs is not correlated with the number of registered NMEs

A = % of NMEs registered out of the universe (total number of NMEs assessed in each country)

B = % of NMEs reimbursed out of total NMEs registered in each country

C = % of NMEs launched out of total NMEs registered in each country

Note: Number of NMEs launched is based on IQVIA available data; NMEs available only in tenders/hospital in Jordan and Morocco are not reflected in this analysis unless confirmed by the company

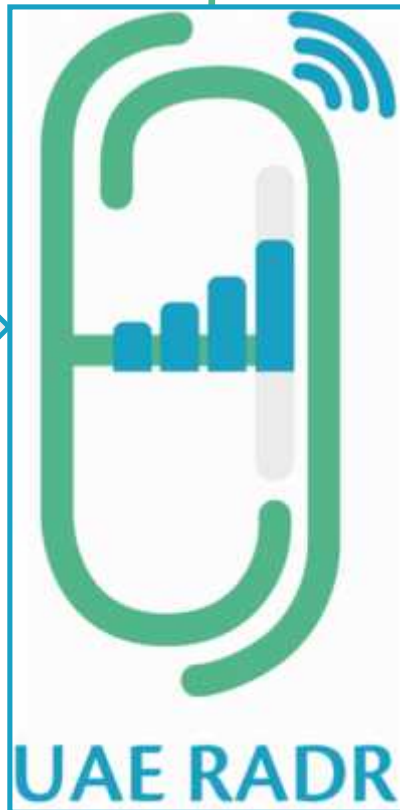
PhRMA | Assessment of access to medicines (including selected countries in Middle East and Africa - Wave 2) | Project Report | November 2021





Reporting of ADRs by any member of the UAE community, whether healthcare professional or general member of the community.

### Main Purpose



**UAE RADR** allows users to review statistics of reports of ADRs received at global level by the **UPPSALA** Monitoring center (medicine safety center collaborating with the **WHO**)

1<sup>st</sup>

### Stand-Alone

App. for side effect reporting outside of Europe, UAE is 4<sup>th</sup> globally to have this standalone app after the UK, Netherlands and Croatia.

### New Code Base

Deployed onto a new code base and other countries have then migrated onto this platform that gives increased functionality and stability.



It works in 2 ways (member of the community sends reports to WHO through MOHAP and receives a full statistical report from WHO)



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## REGULATORY PREPAREDNESS FOR HEALTHCARE EMERGENCIES



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Public Health Management Solutions

Public Health Management Solutions (PHMS)

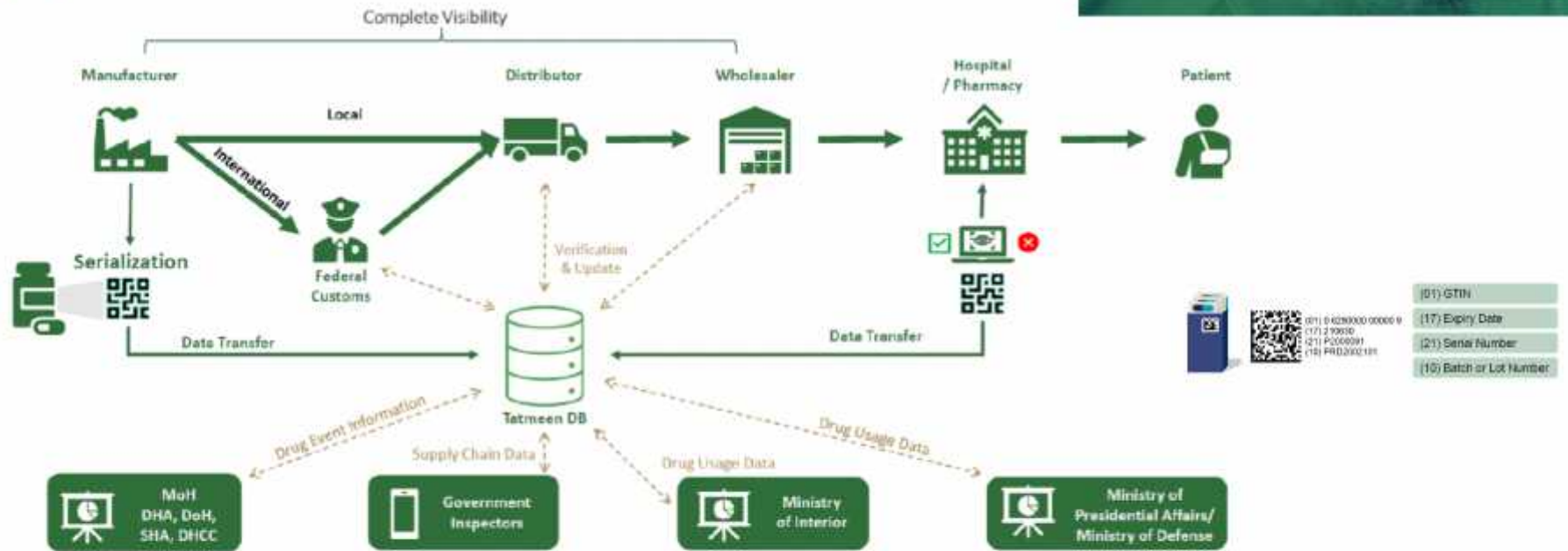
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An integrated system of early surveillance, investigation, follow-up and management of events affecting public health to promote health. This program is one of the most important integrated projects based on the latest technology, where the program will document the impact of health preventive interventions by monitoring epidemics, reducing their spread and pursuing immunizations in effective ways, and will contribute to the creation of a real-time data board at the state level, conduct epidemiological analysis and calculate indicators related to their use to make decisions based on evidence and evidence to maintain public health and community health. Target groups: health care staff, technicians and administrators of the government and private sector.



## COMPREHENSIVE PARTICIPATION



Tatmeen will ultimately ensure the right product, in the right place, at the right time, in the right condition!





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THE SUPREME COUNCIL FOR NATIONAL SECURITY  
National Emergency Crisis and Disasters  
Management Authority

لاستخدامها في حالات الطوارئ: مخزون طبي استراتيجي يعادل استهلاك من 3 أشهر إلى سنة

## محمد بن راشد يصدر قراراً بشأن المخزون الطبي الاستراتيجي

الإثنين، 11 يناير 2016

يستخدم للاستجابة لأي وضع استثنائي ناتج عن أزمة أو كارثة

**البيان :** أصدر صاحب السمو الشيخ محمد بن راشد آل مكتوم، نائب رئيس الدولة رئيس مجلس الوزراء حاكم دبي «رعاه الله»، قرار مجلس الوزراء رقم 39 لسنة 2015، في شأن المخزون الطبي الاستراتيجي، ووفقاً للقرار المنشور في العدد الأخير من الجريدة الرسمية لتلزم الجهة الصحية حسب النطاق الجغرافي لاختصاصها باتخاذ الإجراءات اللازمة لتوفير وإدارة مخزون طبي استراتيجي وتغطية النفقات المترتبة على ذلك وفقاً لأحكام هذا القرار. وأشار القرار إلى أن المخزون الطبي الاستراتيجي يستخدم للاستجابة

للاحتياجات الطبية والصحية لمواجهة أي وضع استثنائي ناتج عن حالة أو أزمة أو كارثة، ويجب أن تكون كمية وأصناف المخزون الطبي الاستراتيجي كافة لتغطية الاحتياجات الصحية للفترة الزمنية التي يحددها وزير الصحة، وذلك بالتنسيق مع الهيئة الوطنية لإدارة الطوارئ والأزمات والكوارث والجهات الصحية.



دائرة الصحة  
DEPARTMENT OF HEALTH



8001717 or 02-4493333 (UAE)

ABU DHABI PUBLIC HEALTH CENTRE  
مركز أبوظبي للصحة العامة



05-62312171 (UAE)

هيئة الصحة بدبي  
DUBAI HEALTH AUTHORITY



800342 or 04-2198888 (UAE)

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MINISTRY OF HEALTH & PREVENTION



80011111

وقاية  
WEQAYA



800-WEQAYA



## Ministry of Health and Prevention signs MoU with Tabuk Pharmaceuticals to ensure delivery of medical supplies during emergencies

Published Tuesday, 18 December 2018



Twitter Instagram LinkedIn

18 December 2018

## Ministry of Health and Prevention and Pfizer, joint efforts to establish the first NCDs Global Excellence Centres

Published Saturday, 23 April 2018

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## Ministry of Health and Prevention signs an agreement with GSK to ensure delivery of medical supplies during emergencies

Published Tuesday, 21 June 2018

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## Ministry of Health and Prevention partners with Julphar to help reinforce UAE's medicine supplies during emergencies

Published Wednesday, 07 February 2018

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10 May 2021

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الامارات العربية المتحدة  
المجلس الأعلى للأمن الوطني  
THE SUPREME COUNCIL FOR NATIONAL SECURITY  
الهيئة الوطنية للأمن الوطني  
National Emergency Crisis and Disaster Management Authority

## The distribution of Hayat-Vax began in UAE

which is expected to become a leading regional hub in this field

This is considered as a strategic step in raising the efficiency of the health sector infrastructure and developing local and national capacities in the field of biotechnology.



**Hayat-Vax** حياة-فاكس

SARS-CoV-2 Vaccine (New Cell), Inactivated  
لقاح فيروس كورونا (SARS-CoV-2) جديد

Group  
مجموعة

Manufacturer and Supplier  
المصنع والموردين

CNBG42

## MOHAP MOBILE APPLICATIONS

In the context of the importance of racial innovation and creativity in enabling organizations harmony with the developments and the enormous mutations taking place in our world today, especially in the field of technology and E-transformation to develop services to unprecedented heights, **MOHAP** has launched the following “**Mobile Applications**”:



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## UAE RADR



The UAE RADR Scheme is vital in helping the MOHAP monitor the safety of all healthcare products





## MOBILE APPLICATION –DRUG DIRECTORY



To ensure the safety and health of the people MOHAP maintains the approved drug and medicine list that are available in UAE. The consumers, health professionals and pharmaceutical companies can benefit from the approved drug directory and get the information on the availability.



**His Highness Sheikh Mohammad Bin Rashid Al Maktoum**, Vice-President and Prime Minister of the UAE and Ruler of Dubai, launched the app during the Arab Health event at Dubai World Trade Centre.

The announcement is in line with the Ministry of Health and Prevention organ donation program Initiative.

App for donors in UAE. Designed for registration of organ donors. User can edit his details, read news and important links.





## MOHAP WEBSITE



**What's new**

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MINISTRY OF HEALTH & PREVENTION

**Nursing Program**  
Nursing Program

Click Here

**Ministry Services**

Common Services Individual Services Business Services Government Services Social Services

**Common Services**

- Registration of a conventional pharm...
- Request Educational Material
- Classification of product
- Submit Medical Complaints on Governm...
- Change the medical activity of priva...
- Healthy restaurant accreditation req...
- Issuing permission to import medicin...
- Provide Health statistics to Public...
- Provide Blood Units and components
- Request Awareness of Educational Eve...
- Neonatal Intensive Care
- Request Treatment Abroad



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## MOHAMMED BIN RASHID LAUNCHES FIVE-DECADE GOVERNMENT PLAN 'UAE CENTENNIAL 2071'

The UAE Centennial 2071 project was launched by the Cabinet to make the UAE the best country in the world by 2071.

His Highness Shaikh Mohammad Bin Rashid Al Maktoum, Vice-President and Prime Minister of the UAE and Ruler of Dubai, made the announcement on Twitter regarding the

launch of the project during a Cabinet meeting held on Wednesday.



## THE UAE GOVERNMENT CHARTER FOR FUTURE SERVICES



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**THANK YOU**