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BADRI

The Vitals

An ounce of prevention is worth a pound of cure.

-Benjamin Franklin

Medical Newsletter

TOPIC 1

GENERIC VS BRANDED DRUGS - Page 2

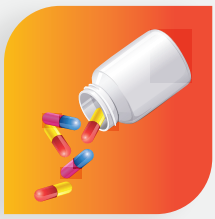
TOPIC 2

HEALTH UPDATES - Page 9

TOPIC 1: GENERIC VS BRANDED DRUGS

Generic medications are designed to be equivalent to branded drugs in terms of safety, quality, and efficacy while being more cost-effective. The dosage, therapeutic activity, administration, and formulation of the generic drug are the same as the branded drugs. [1]

Same Active Ingredients



Same Strength and route of Adminstration

Same Dosage Form

Same Indication

Inactive ingredients of the generic drug are safe and don't change how the drug works

The generic drug will work as intended for a reasonable amount of time before expiring

While the quality and performance of generic drugs are the same, It is noticed some minor visual differences. The major difference between the two is the cost of drugs and inert ingredients that give the drug its color, shape, or taste. [1]

Brand Name vs Generic Drugs

Brand		Generic
The same	**Active Ingredient**	The same
Higher in cost	**Price**	Lower in cost
Covered if no generic form exists	**Insurance Coverage**	Normaly always covered
Tested and approved by the FDA	**Inactive Ingredients**	May differ but proven and approved by FDA
The Same	**Strength/Dosage**	The Same
Standard in size, color, packaging, etc	**Appearance**	Packaging and the drug itself may look different

Upcoming Generic Drugs in 2023

According to FDA report published on 13 January 2023, between 2009 and 2019, the adoption of generic drugs resulted in significant cost savings for the U.S. healthcare system. In the United States, 90% of prescriptions are filled as generic drugs, on average generic prescription drugs can lead to substantial cost savings, with potential reductions of up to 85% compared to brand-name medications. A report from the Association for Accessible Medicines indicates that this difference in drug costs amounted to nearly $2.2 trillion over the decade. [2]

In 2023, several brand-name patented drugs will be available in generic forms. Some of the upcoming Generic drugs in 2023 are:

S.No	Brand Name	Generic Name	Dosage Form	Anticipated Launch
01	Lucentis	Ranibizumab	Injection and Solutions	2023
02	Onglyza	Saxagliptin	Tablet	2023
03	Humira	Adalimumab	Injection	2023
04	Ibrance	Palbociclib	Cap	2023

Generic Drugs Regulations and Reforms

Health authorities regulate both branded and generic drugs to guarantee their safety and efficacy. The decision between these options may hinge on factors like cost, insurance provisions, and individual preferences. However, both types can be equally proficient in addressing medical conditions. Worldwide, the regulations and legislation governing the approval of generic drugs exhibit a remarkable degree of uniformity, with only minor distinctions found in developing nations, mostly influenced by regulatory frameworks, healthcare system economics, and how generics are viewed by patients and healthcare providers. [3]

United States:

The U.S. pharmaceutical industry is strong, and it has clear regulations for approving generic drugs. The Hatch-Waxman Act of 1984 standardized this process, also known as the Drug Price Competition and Patent Term Restoration Act. This process allows for the availability of cost-effective alternatives. The Food and Drug Administration (FDA) within the U.S. Department of Health and Human Services regulates the drug approval system in the United States. [3]

In 2007, the FDA launched the Generic Initiative for Value and Efficiency, aimed at modernizing and streamlining the approval process for generic drugs while increasing their variety. This initiative introduced a new requirement called the "Abbreviated New Drug Application (ANDA)," which pharmaceutical companies must submit for regulatory approval of generic drugs. An ANDA must

provide information demonstrating that a proposed generic drug is equivalent to an already approved reference-listed drug (RLD) in terms of safety, efficacy, and quality. [3]

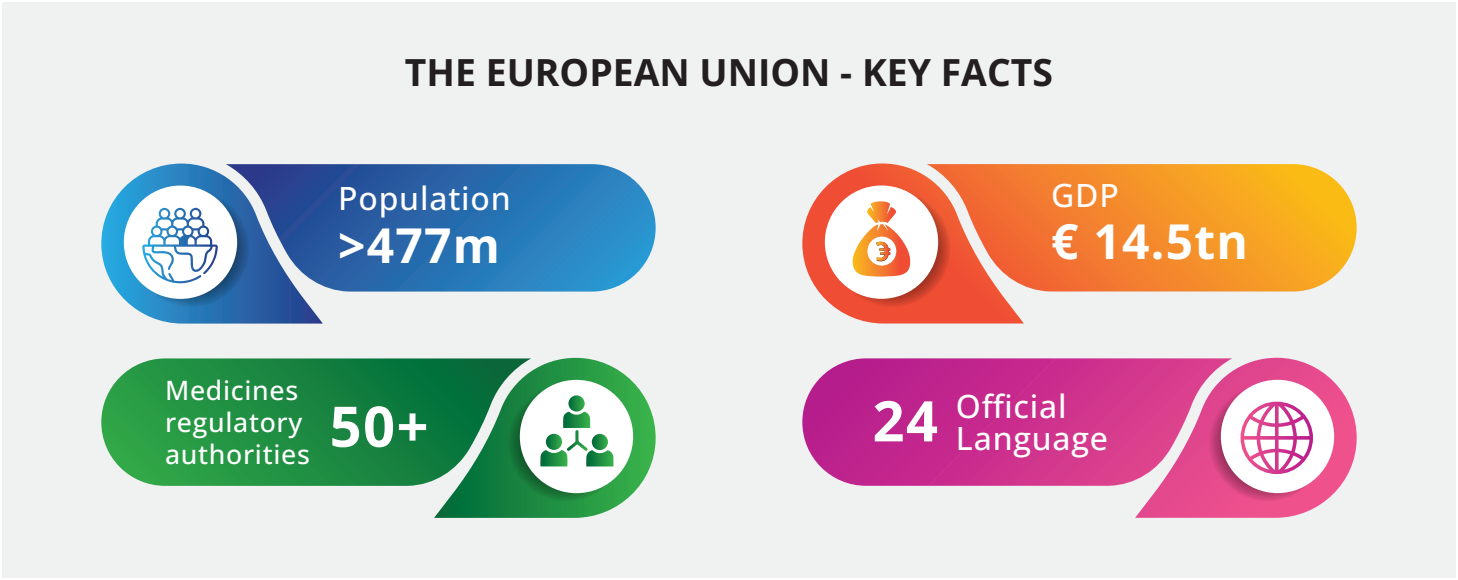
An ANDA has written a request to the U.S. Food and Drug Administration (FDA) to manufacture and market a generic drug in the United States.

- *The ANDA does not require the applicant to conduct clinical trials.*
- *An ANDA-approved drug must be bioequivalent to the brand-name drug.*
- *If an ANDA is approved, it is listed in the Orange Book as an FDA-approved medicine.* [4]

European Union (EU)

The system for regulating medicines in Europe is unique in the world. It is based on a closely-coordinated regulatory network of national competent authorities in the Member States of the European Economic Area (EEA) working together with the European Medicines Agency (EMA) and the European Commission.

The European medicines regulatory system is based on a network of around 50 regulatory authorities from the 30 EEA countries (27 EU Member States plus Iceland, Liechtenstein and Norway), the European Commission and EMA. This network is what makes the EU regulatory system unique. [5]



The European Medicines Agency (EMA) and national authorities rely on standardized processes and Information Technology (IT) systems to facilitate the exchange of critical information about medications among European countries and enable collaborative analysis.

Some of the data are supplied by the Member States and centrally managed by EMA. This supports an exchange of information on a number of issues, including:

- *suspected side effects reported with medicines;*
- *the oversight of clinical trials;*
- *inspections to check compliance with good practice in the clinical development, manufacturing and distribution, and safety monitoring of medicines.*

This helps to reduce duplication and supports efficient and effective regulation of medicines across the EU. [6]

United Kingdom:

The pharmaceutical system in the United Kingdom is robust, featuring a comprehensive regulatory body known as the Medicines and Healthcare Products Regulatory Agency (MHRA) established in 2003. This agency oversees a well-established framework that facilitates the timely approval of both branded and generic drugs. Meanwhile, the National Health Service (NHS) ensures broad public access to a wide range of medications across the country.

- *MHRA ensures pre-approval that the benefits of investigational drugs surpass their harms for marketing authorization.*
- *It has prioritized efforts to expedite the development, review, and approval of new drugs. These efforts are aligned with industrial policy objectives to reduce barriers to market entry.*
- *Reducing drug R&D (Research & Development) time limits clinical trial data, creating a conflict between MHRA's public health role and industrial goals.*
- *In the UK, uncertainty over drug benefits affects reimbursement choices, potentially diverting resources from proven, effective treatments in the NHS and impacting poplation health.* [7]

Canada:

Canada's strong pharmaceutical framework, overseen by Health Canada, handles drug approvals and regulations. The country's thorough process for generic drug approval ensures broad patient access and financial advantages. Drug firms perform clinical trials to compare bioavailability, ensuring equivalence. Generic drug submissions demonstrate bioequivalence through various tests, guided by legal provisions and guidance documents. [8]

In 2017, there was a prior authorization program that aims to manage costs while providing the plan to the members with coverage for accurate treatment. Prior authorization only applies to some drugs within selected categories, it can help manage the costs in a small number of cases where very expensive drugs are used.

It was projected that Canadians would allocate around $33.9 billion for prescription drugs, with the private sector expected to cover 57.3% of these expenses. This trend can be attributed not only to the sheer volume of claims but also to the fact that a small fraction of claims accounts for a significant portion of the costs. To illustrate, although specialty drugs make up only 2% of claims, they constitute 27% of the total drug expenditure. [9]

France:

In France, drug sales contribute to over 20% of healthcare expenses. The government is now proposing legislation to bring the sales of generics closer to the average level in other developed countries, in the hope of saving billions of francs a year.

The Social Security Authority, responsible for reimbursing patients for effective medications, is projected to face a deficit of 3.6 billion francs (£330 million; $480 million) in the current year.

To address this issue, the government will introduce legislation in October 2023 to improve France's ranking among the 22 developed countries surveyed. As per the Social Security Administration, if approximately 10% of the brand-name prescribed drugs were instead sold as generics, it would result in annual healthcare cost savings of 2.2 billion francs. [10]

India:

India is a major exporter of affordable generic medicines, due to lower production and research costs. This benefits countries like the US and the UK in reducing healthcare spending. Indian pharmaceutical firms are encouraged to expand access to generics, even setting up facilities in nations like Brazil, Mexico, and Argentina. The COVID-19 pandemic has boosted the export of generic medicines worldwide as both developed and developing countries seek cost-effective alternatives to pricey patented drugs to control healthcare costs. [11]

The "Patent Amendment Act" of 2005 made it illegal to reverse engineer or copy patented medications after January 1, 1995. The Act only permitted off-patent generic pharmaceuticals and generic copies of medications patented before 1995 to be sold in India. [3]

In 2008, the Indian government initiated "Jan Aushadhi," which translates to "Medicine for People." This program aims to provide quality medicines to citizens at affordable prices through specialized stores selling generic drugs. These generic medicines are both cost-effective and equivalent in quality and effectiveness to non-generic options. Additionally, in October 2016, the Medical Council of India proposed an amendment to the code of conduct for doctors, recommending that all practitioners prescribe medications using clear and understandable generic names.

UAE:

In the United Arab Emirates (UAE), the Ministry of Health and Prevention (MOHAP) oversees and regulates both generic and branded drugs. This regulatory process ensures that all medications, regardless of their branding, adhere to stringent standards of quality, safety, and effectiveness.

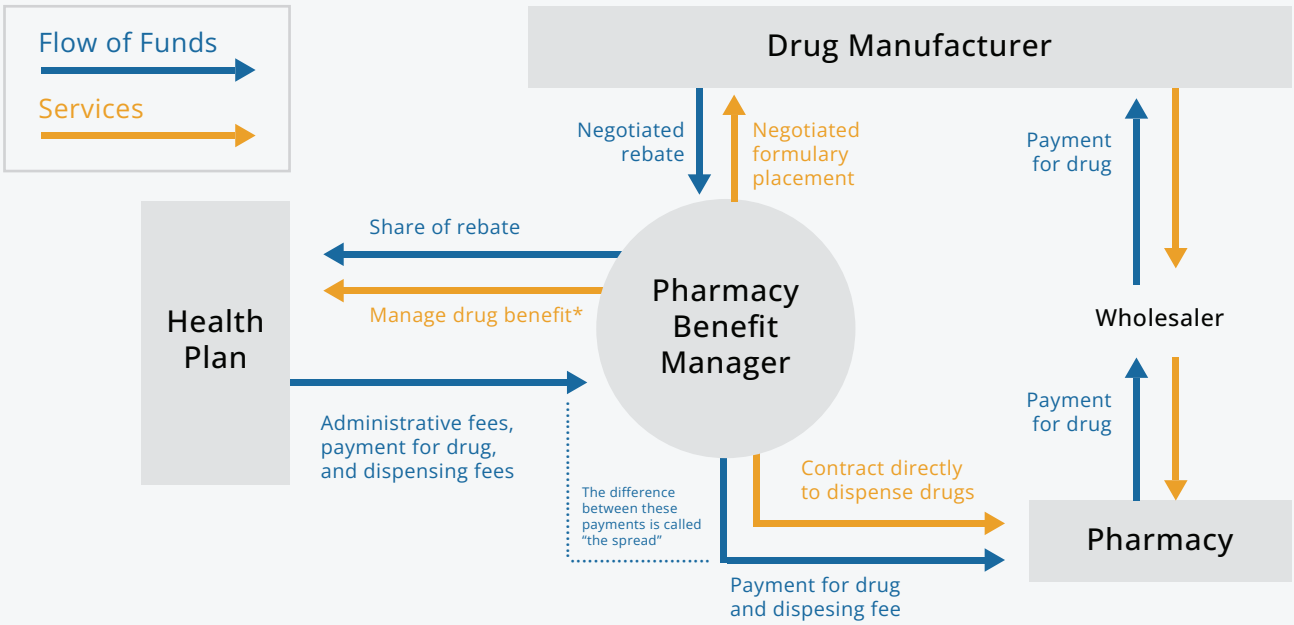
> *"In 2018, a new regulation for prescribing generics was introduced in Abu Dhabi which states that all pharmacies must dispense generic medicines as a first choice and those who prefer their branded counterparts must pay the difference, which can be up to 70 percent more."* [12]

Awareness and accessibility of generic medicines are positive steps toward boosting exports. More production of generic medicines is encouraged in several ways by the countries. These regulatory systems ensure that patients have access to safe and effective medications while also providing cost-effective options through generic drugs. It will also ensure substantial savings in health care especially for poor patients and those suffering from chronic ailments requiring long periods of medicine use.

Role Of Pharmacy Benefit Manager PBM:

Pharmacy Benefit Managers (PBMs) play a significant role in managing prescription medication benefits for health insurers. They exert substantial influence over factors such as drug pricing, drug distribution to patients, and pharmacy reimbursements. This influence is exercised through negotiations with pharmaceutical companies and pharmacies to control and optimize drug-related expenses. [13]

- *Develop and maintain lists, or formularies, of covered medications on behalf of health insurers, which influence which drugs individuals use and determine out-of-pocket costs.*
- *Use their purchasing power to negotiate rebates and discounts from drug manufacturers.*
- *Contract directly with individual pharmacies to reimburse for drugs dispensed to beneficiaries*



Insurance coverages for generic drugs:

In UAE, Insurance companies claim that doctors exclusively prescribing branded drugs is increasing healthcare costs, despite medicines accounting for only a third of the total premium. To address this, a system of approvals for each medicine through a 24-hour phone and web portal is proposed. This change is expected to benefit the insurance sector by lowering medication expenses.

Currently, diagnostic and radiology tests, along with medicines, are the primary cost drivers in healthcare insurance. By reducing medication costs, overheads can be reduced, making the healthcare sector more sustainable. [14]

An international insurance company that operates in multiple countries like Australia, the United Kingdom, UAE, the United States etc. offers coverage for most pharmaceutical items, including those under the Pharmaceutical Benefits Scheme (PBS) and certain High-Cost Drugs (HCD) approved by the Therapeutic Goods Administration (TGA) for specific conditions. [15]

Items not covered by the hospital include the following:

• Non-prescription medicine	• Any non-TGA approved items
• Any PBS listed items which have been supplied under the PBS (for out-patients)	• Any experimental drugs or compounded medications that are mixed from the individual ingredients to the strength and dosage required for an individual except in exceptional circumstances.
• Any items listed on the Company's Exclusions List	• Any item listed under the Alternate PBS arrangement list.
• Natural remedies	• Anabolic Steroids

TOPIC 2: HEALTH UPDATES

Dubai Health Authority Launches "Early Detection of Hepatitis C" Campaign

Each year, on July 28th, the world observes World Hepatitis Day (WHD) with a unified focus. The purpose is to increase awareness of the global impact of viral hepatitis and to drive tangible transformations. In 2023, the theme for WHD is "We're not delaying action." Awareness is needed among the public about hepatitis from early detection to prevention, diagnosis, and treatment to reduce the risk of liver cancer.

The Dubai Health Authority (DHA) has introduced a three-year Hepatitis C awareness campaign aimed at emphasizing the significance of early detection and prevention of hepatitis C. This initiative is an integral part of the "EKSHEF" screening program, which focuses on identifying various communicable and non-communicable diseases at an early stage. The "Early Detection of Hepatitis C" campaign plays a pivotal role in supporting Dubai and the United Arab Emirates' strategic objective of eradicating hepatitis C by the year 2030. [16]

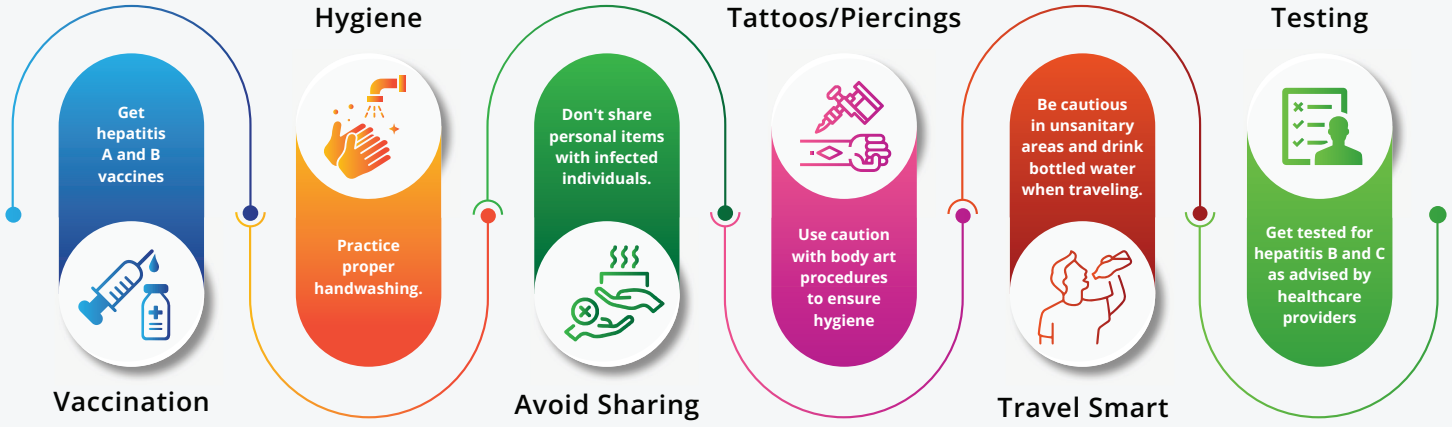
Globally, more than 350 million people have hepatitis B or C, both major causes of liver diseases and hepatitis-related deaths. [17]

While there's a vaccine for hepatitis B, there's none for hepatitis C. The World Health Organization has estimated that in 2019, approximately 290,000 people died from hepatitis C disease, mostly from cirrhosis and primary liver cancer. [16]

There are an estimated 170 million carriers of Hepatitis C around the world and the Middle East and North Africa regions have the highest regional infection rates. The virus causes approximately 399,000 fatalities each year worldwide, according to WHO. The prevalence in the UAE ranges from 0.24 to 1.64% of the population. But medics have said up to 70% of patients remain undiagnosed. [18]

Safety Measures for Hepatitis:

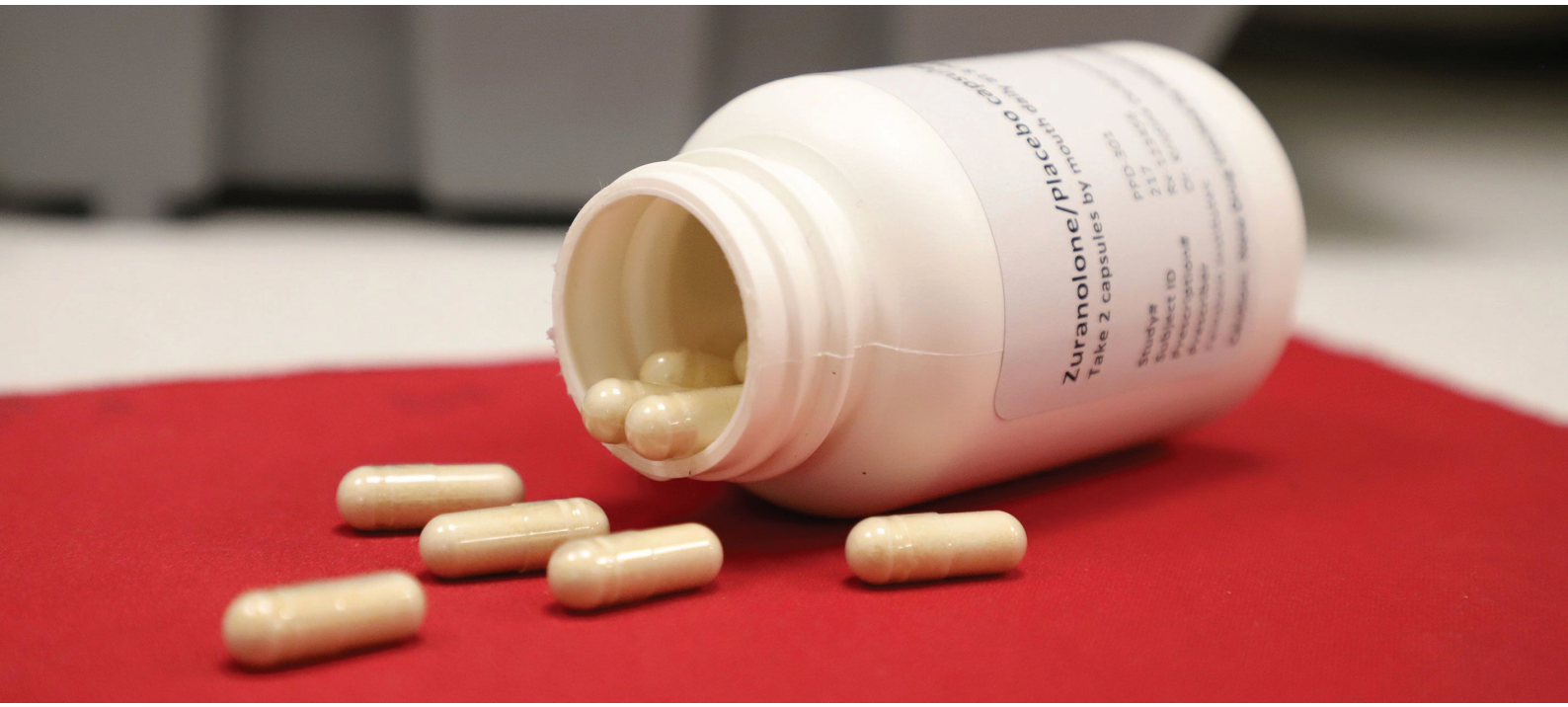
To minimize your risk of hepatitis: There are several ways you can reduce your chances of getting hepatitis:



The first pill for postpartum depression approved in the US

The US Food and Drug Administration approved for the first time an antidepressant drug, called zuranolone, the first oral medication indicated to treat postpartum depression (PPD) in adults. The PPD believed to affect around half a million women in the country every year. [19]

In the U.S., approximately 400,000 women experience PPD each year, as reported by the Centers for Disease Control and Prevention. [20]



Quick Postpartum Depression Facts and Statistics

- *Worldwide, about 1 in 8 women experience postpartum depression (PPD) after giving birth, and PPD prevalence among mothers globally ranges from 0.5% to 60.8%.*
- *Recent studies suggest that PPD may affect up to 30% of women after childbirth.* [21]
- *Postpartum depression generally lasts 3 to 6 months. However, this varies based on several factors.*
- *It is estimated that nearly 50% of mothers with postpartum depression are not*
- *diagnosed by a health professional.*
- *80% of women with postpartum depression will achieve a full recovery.* [20]

The prevalence of postpartum depression (PPD) among Middle Eastern mothers is 27%, which is notably higher than in Western countries like North America (10%–15%) and Australia (13%). According to research this difference in PPD rates could be due to factors like crises, cross-cultural variations, socio-economic conditions, including social support, stressful life events, poverty, and societal attitudes toward pregnancy and motherhood. Another contributing factor may be the lack of sufficient mental health care for postpartum women in these societies. [21]

According to the New York Times, the only other drug approved for postpartum depression is brexanolone, which was approved by the FDA in 2019 but requires a 60-hour intravenous infusion in a hospital, and costs $34,000. The cost of the new oral pill has not been disclosed or made public as of now.

UAE's new draft policy would mean women's health

To celebrate Emirati Women's Day, The Ministry of Health and Prevention (MoHAP) is currently in the process of preparing a National Policy aimed at improving women's health in the UAE. This policy seeks to enhance the well-being of women by offering customized healthcare services within a unified and comprehensive national framework. MoHAP is collaborating with strategic partners to achieve this goal. The upcoming policy will be constructed on fundamental principles, including backing from leadership, effective governance, promoting gender equality in healthcare, adopting a holistic approach to women's health throughout their lives, and a commitment to providing high-quality and inclusive women's healthcare services. [22]

National Framework includes:

- *Bolstering maternal and reproductive health*
- *Combating chronic diseases prevalent among women*
- *Mental health support for elderly women*
- *Initiatives for health education and awareness*

UAE to crack down on unlicensed health workers

The UAE Government approved the establishment of a national medical register for healthcare professionals at the Ministry of Health and Prevention. The law prohibits the submission of false documents or incorrect data to the health authority or employer, in addition to prohibiting the disclosure of the patient's secrets. Whoever practices the profession without holding a license and without meeting the conditions that allow him to obtain the license, or whoever submits incorrect documents or data or resorts to unlawful means that result in their wrongful licensing, will be punished by imprisonment and by a fine of not less than fifty thousand dirhams (AED 50,000) and not exceeding AED 100,000 (AED 100,000) or by either penalty. [23]

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How we can help

- **Pricing and Predictive Analysis**
- **Fraud Waste and Abuse**
- **Cost Containment Alternative**
- **Performance Monitoring and Analytics**
- **Profit Optimization**
- **Provide Network Structure**

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