

The Scarcity Problematic of Breast Cancer Medicines in Algeria - (FULVESTRANT) – Study of the PCH "Hospitals Central Pharmacy" Case

إشكالية ندرة أدوية مرض سرطان الثدي في الجزائر دواء (FULVESTRANT) دراسة حالة الصيدلية المركزية للمستشفيات -PCH-

أسماء رجيل

جامعة جيجل – محمد الصديق بن يحيى -

Abstract: This article discusses the problematic of the scarcity of Breast Cancer Drugs in Algeria, including a very significant medicine called (FULVESTRANT), as this problematic has led us to discuss the causes of such phenomenon (scarcity of chronic disease medicines), through identifying the most important factors that increase the consumption of the chronic diseases medicines in general, and breast cancer medicines in particular. In addition to how it affects the pharmaceutical market size in Algeria. In this article, we wanted to shed the light to the high number of breast cancer patients and its economic and social effects, and to indicate the most significant conclusions and recommendations that would reduce these effects as well as their relation to the consumption of such medications and the expenses resulting from it.

Keywords: Chronic Diseases, Breast Cancer, Hospitals Central Pharmacy, Chronic Diseases Medicines Scarcity.

المخلص: يتناول هذا المقال إشكالية ندرة أدوية مرض سرطان الثدي في الجزائر، و من ضمنها دواء مهم جدا و هو دواء (FULVESTRANT) حيث هذه الإشكالية جعلتنا نناقش

مسببات هذه الظاهرة (ندرة أدوية الأمراض المزمنة)، من خلال معرفة أهم عوامل زيادة استهلاك أدوية الأمراض المزمنة بوجه عام ، و أدوية مرضى سرطان الثدي بوجه خاص. و كيف تؤثر على حجم سوق الأدوية في الجزائر . حيث أردنا من خلال هذا المقال تسليط الضوء على ارتفاع عدد مرضى سرطان الثدي و آثاره الاقتصادية و الاجتماعية و تبيان أهم الاستنتاجات و التوصيات التي من شأنها تقليل تلك الآثار و كذلك علاقتها باستهلاك الدواء و النفقات المترتبة عنه .

الكلمات المفتاحية : الأمراض المزمنة ، سرطان الثدي ، الصيدلية المركزية للمستشفيات ، ندرة أدوية الأمراض المزمنة.

Introduction: The problematic of Chronic Diseases and Health expenses recently drew the attention of both developing and developed countries, considering the rapid growth of health and pharmaceutical expenditures in light of changing the population need to medicines and age structure, In addition to changing the map of such disease and the expansion of the treatment supply. Whereas chronic diseases pose a great burden on the individual and society, it is also the leading cause of death in the industrialized world as well as in the developing world, such as Algeria, which is undergoing epidemiological transition that have made such chronic diseases a serious health problem, as Diabetes and Breast Cancer percentage reached epidemic proportions. Breast Cancer is considered the first cause of women death in Algeria and is one of the most prevalent cancers across the world as well, In this type of cancer, number of breast cells abnormally reproduced, which are divided in turn and faster than healthy cells. It can also begin to spread throughout the breast tissue, to the lymph nodes and other organs of the body. Every year around 11,000 new cases of breast cancer are registered

in Algeria, where several factors interact. Such continuous increase in the number of women suffers from breast cancer requires special awareness, especially prevention, to alleviate this disease. However, as the disease continues to rise, there is a serious shortage of essential medicines for breast cancer. This makes us wonder *about: "The impact of the scarcity of Breast Cancer medicine (FULVESTRANT) on the level of Public Hospital Pharmacies in Algeria?"* In this article, we will attempt to shed the light to the phenomenon of scarcity of the medicines for Breast Cancer patients, especially *FULVESTRANT*, through studying the level of stocks on the Hospitals Central Pharmacy level.

1-The concept of chronic diseases: The concept of chronic diseases nowadays is associated with any disease characterized by long time extension or pain associated with injuries or disability or diseases of aging.¹ Chronic disease differs from acute illness in that it is not fully cured and the necessity for continuous treatment and functional disability of the patient, in addition to the psychological burden, social and economic consequences. There are various types of chronic diseases including diabetes, blood pressure, cancer in general and breast cancer in particular.

1- خليل إسماعيل إبراهيم، الآثار الاقتصادية والاجتماعية لمعاناة ذوي الأمراض المزمنة في العراق، مركز بحوث السوق وحماية المستهلك، المجلة العراقية لبحوث السوق وحماية المستهلك ، المجلد 01، العدد رقم 02، (العراق، 2009) ، ص.131.

And this later is this article concern².

1.1 Definition of Cancer: Cancer is a group of diseases occur when the cells of the body converted into abnormal cells, and then divided without control or order. The Organ in the Human Body consists of different types of cells and such cells are usually divided in a systematic manner to produce other cells when needed in order to keep the body in a healthy state. If the cells are divided without the need for new cells, we will have excess tissues, this extra mass of tissues is called a Tumor, and the tumor is either Benign or Malignant.

- Tumors Benign: They are not cancerous tumors and can be removed, and in most cases, they do not reappeared . The most significant of these tumors that they do not spread to other places of the body, therefore they do not threaten human life.

- Tumors Malignant: They are called cancerous tumors because they can invade and destroy neighboring cells as well as the rest systems of the body. Therefore, such tumors can also be broken down and enter the bloodstream or lymphatic system. By this manner, the cancer spreads to form secondary tumors in other parts of the body; this process is called the process of cancer proliferation or Metastasis.

² - Institut national de santé publiques, épidémiologique et système de santé, Projet TAHINA*(Contracte N ica3-2002-10011), enquête national sante, novembre 2007, P 65.

2- Breast Cancer & its types: Breast Cancer is a cancer that grows in the breast; there are various types of Breast Cancer:³

- **Early Breast Cancer:** It is the cancer that is in the breast tissue, and may also be spread to the lymph nodes near the breast or in the armpit. It is also called early breast cancer, (Invasive Breast Cancer).

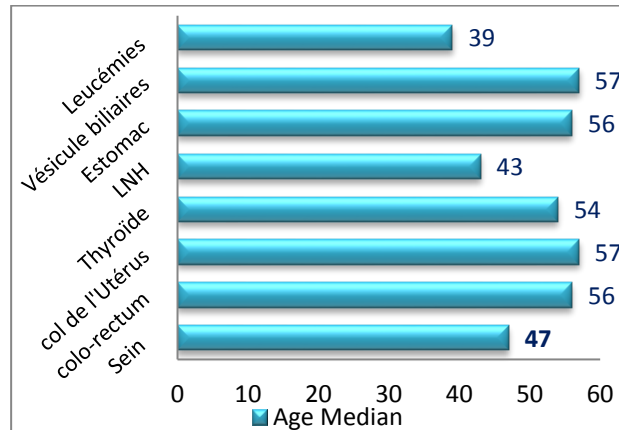
- **Ductal Carcinoma in Situ-DCIS:** It is a cancer in the ducts of milk in the breast; it is not spread out of the ducts to the breast tissue, sometimes called (Non-Invasive breast cancer).

- **Secondary Breast Cancer:** It is the breast cancer that has spread to other organs of the body such as bones, liver or lungs. It is also called Advanced or Metastatic Breast Cancer; it is not as common as other breast cancers.

3- Cancer type according to women age in Algeria: Various types of Cancer diseases related to different women affect different age groups of 39 years and above, and there is a great disparity among the residential and demographic areas, in the following figure, we will discuss them according to age groups. Women were more likely to have breast cancer at the age of 47.

Figure (01): Division of chronic diseases in Algeria related to women according to age groups

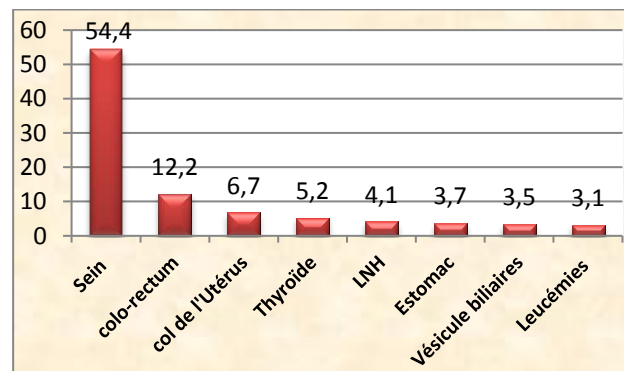
³ Guide for women with early breast cancer, Cancer Australia, 2012, P4.
www.canceraustralia.gov.au



Source: *Institut National de Santé Publique INSP Résultats du réseau national des registres du cancer, Alger, le 28/10/2014, P 08.*

4 - Women's Cancer Rates in Algeria: Breast Cancer is considered the first cause of women death in Algeria, it is one of the most prevalent cancers all over the world. The following figure shows the degree of its spread across the national territory.

Figure (02): Primary rate of cancer in women



Source: Prepared by students depending on:

1-Institut National de Santé Publique , INSP, Op.cit, p08.

In the previous figure, we see the most organ exposed to cancer in women body in Algeria, where there is a very high increase in breast cancer, which makes it the most frequent cancer with 54.4%, Colo-rectum 12.2%, followed by Cervix by 6.7%, then Thyroid by 5.2%, Then the rest types of cancers.

5 - The standard rate of the Breast Cancer spread in Algeria: The crude rate of breast cancer per 100,000 women is 54.4% in Algeria, in comparison to the standard rate per 100 000 women, which is 65.2%. This show us the increasing spread of such disease, estimated with 54.4% with a slight variance than the standard rate of 10.8%, this shows that there is an epidemiological phenomenon in Algeria, which is Breast Cancer, and should be alleviated through prevention and treatment, this table shows the spread of the disease.

Table (01): Prevalence Rate of Breast Cancer in Algeria.

<i>Localization</i>	<i>Gross Rate (100000)</i>	<i>Standard Rate (100000)</i>	<i>Median Age</i>
Breast	54.4	65.2	47

Source : *Institut National de Santé Publique INSP, Résultats du réseau national des registres du cancer, Alger, le 28/10/2014, P 08.*

The forgoing table shows the degree of breast cancer spread in Algeria, as well as age plays a significant role, as the most age recording cases of the disease at is 47 years.

6. Number of breast cancer cases in Algeria :
The increase in the breast cancer cases number is

back to several factors including: hereditary factor, smoking, alcohol, contraception pills, obesity, diet, and urban and city living, etc. the following table shows the number of breast cancer cases, whereas the number of cancer cases in 2015 was estimated with 10744 cases, and it increased in 2016 to 11,340, the number will continue increasing in the future during (2020 and 2025) to be (13812 and 18112 cases) respectively.

Table (02) : Number of Breast Cancer Cases in Algeria (2015-2025)

<i>Sites</i>	Number of cases 2015	Number of cases 2016	Number of cases 2020	Number of cases 2025
Breast	10744	11340	13812	18112

Source : 1-*Résultats du réseau national des registres du Cancer, INSP, Op.cit. P 10.*

2- **Institut National de Santé Publique (INSP), Direction des statistiques.*

The table shows that the number of breast cancer cases is continuously increasing, and this leads to higher health expenses and increased state funding pressures. There are also problems in the disease medicines supply, in particular (FULVESTRANT), that the hospitals central pharmacy (PCH) is responsible for its supply, storage and distribution.

7. Hospitals Central Pharmacy (PCH): is a national institution that emerged from the National Corporation for Pharmaceutical Products Supply (ENPHARM) and its most significant interests is to meet the needs of citizens of medicines, it is a non-independent related to the state. In addition, this commercial institution

imports, supplies various pharmaceutical materials and requirements and deals with various hospitals and health centers nationwide.⁴ In addition, it is a public institution of industrial and commercial form established by Executive Decree No. 11-457, 28 December 2011 amending and supplementing the executive Decree No. 94-293, 25 September 1994, which includes the creating the operation and progress of the Hospitals Central Pharmacy. It has a legal corporate personality, as well as financial independence, it is also relied on marketing in its relations with the other parties managed by the board of directors and headed by the Chairman of the Board.⁵ The main mission of the Directorate of Regulation, Distribution and Storage (DRDS) is receiving, storing and distributing all materials and supplies, medicines received by Hospitals Pharmacy Central to be provided throughout the country.

7.1 Determine the quantity to be ordered by predicting such order: represented in the management inventory for good materials in the regional and national stores, the quantity required for the next year is determined according to the safety stock reserve until the central administration follows up the operation progress of the regional units in order to know the quantity of orders through the quantity of requirements at the level of these units and then collect them to know the quantity to be ordered at the national level. The required quantities are determined according to a set of elements as follows:⁶

⁴ Hospitals Central Pharmacy (PCH), Directorate of Human Resources, Institution Definition appendix, p.5

⁵ Op. cit.

⁶ ibid.

- The status of the stocks considering the shelf life of the commodities; determining the average monthly consumption; the average quantity consumed per month; the duration of the supply; the time required to obtain the orders; the quantity and the duration of the current orders.

- **Regional directorates:** At the end of the year, the departments of the regional stocks management of the regional directorates in Algeria, the center of Oran- Biskra- Annaba determine the status of the stock based on its data elements mentioned above, identifying the average monthly consumption for the current year, the year preceding the target year and thus determining the quantity to be ordered is analyzed and compared with the previous two years. If there is a large discrepancy, the institution returns to the past two years in order to review the inputs and outputs and determine whether there is a defect or manipulation that led to a change in the quantity to be requested. So, the study is based on three past years. The monthly average consumption is calculated according to the following equation:

$$\text{Monthly average consumption} = \frac{\text{full year output}}{12}$$

Central Directorate: After determining the monthly average consumption of each commodity in all regional directorates, it is sent to the Department of Central Stock Management, which in turn collects the data of the four regional directorates and analyzes them in order to prepare the catering program for the next year by determining the quantity required for each commodity according to consumption rates for each Directorate taking into account the

current stock and current orders according to the following equation:

$$\text{Quantity required of PCH} = \text{monthly consumption rate} \times \text{PCH 18 months} - (\text{current stock} + \text{current orders})$$

Year (12 months) + 6 months: Reserve stocks shall be preserved for a period of 60 months in addition to the year to be covered for the vital commodities, as the period between the date of manufacture and the date of shipment shall not exceed two thirds $\frac{2}{3}$ of the validity period.

7.2 Analysis of the monthly rate of consumption of breast cancer medicine (Fulvestrant):

Before talking about the analysis, it is necessary to refer to the definition of the medicine (Fulvestrant): "It is an anti-estrogen receptors as "It is an anti-estrogen receptor, where Estrogen receptors are group of proteins existing inside the cells. They are the receptors activated by Estrogen hormone, and this medicine comes in the form of injections given to breast cancer patients with advanced conditions".⁷ Breast cancer consists of a large group of malignant cells, some of which have Estrogen and / or Progesterone receptors that are sensitive to the female hormones that help them to live and grow. Therefore, this cancer is treated by cutting the source of women's hormones or giving an anti-estrogen receptor drug (Fulvestrant)⁸ in this manner, we can kill the cancer cell or stop its growing for long periods of time during which it may die. The following table shows the level of monthly consumption of (Fulvestrant), which has

⁷ www.faslodexhcp.com ,le 11/19/2017.

⁸ www.akhbaralaan.net/health , le 11/21/2017.

a large demand at the level of public hospitals in Algeria, and we want to know the coverage of the stock available at the hospitals central pharmacy for, if we consider that the safety stock is not available in a necessary manner for this medicine and this is confirmed by the increasing demand for hospitals with no availability at the level of (PCH), the annual outputs (orders implemented) will become the standard of the extent to which the stock is covered for hospital orders during the order period.

Table (03): Monthly rate of consumption of the Fulvestrant for breast cancer (2015-2017)

<i>CL</i>	<i>DCI</i>	<i>U/ C</i>	<i>M/M PCH 2015</i>	<i>M/M PCH 2016</i>	<i>M/M PCH 2017</i>
5	FASLODEX Injection 500 mg (Fulvestrant)	B1	331	401	741

Source : La Pharmacie Centrale des hôpitaux (PCH), Direction des stocks.

The table shows how long Fulvestrant will be available during the period of order (2015-2016) as follows:

Analysis of the year 2015: Average monthly consumption of medicine (2015) = 331 pack / month. Annual output of the medicine = 331 x 12 = 3972 pack / year. The number of cases of breast cancer (2015) = 10744 per year

* The number of breast cancer cases in (2015) is 10744 annually met by orders of 3972 per year only with variance of 6772 annually which means the scarcity of this drug in 2015.

Analysis of the year 2016: Average monthly consumption of medicine (2016) = 401 pack / month. Annual output of the medicine = $401 \times 12 = 4812$ pack / year. The number of cases of breast cancer (2016) = 11340 per year.

* The number of breast cancer cases in (2016) is 11340 annually met by orders of 4812 per year only with variance of 6528 annually which means the scarcity of this drug in 2016. Despite the increase in quantity compared to 2015, but there is still scarcity in this medicine.

Conclusion: *Fulvestrant* is considered a very significant medicine for breast cancer patients, but despite this significance, it is already suffering from an excessive scarcity on the public hospitals level in Algeria. This problem is further exacerbated by the number increase of breast cancer patients on annual basis, as well as lack of coverage by Hospitals Central Pharmacy, Where this scarcity is negatively affect the situation of patients who are in dire need of such medicine because it is a necessary medication must be available at the level of the hospitals central pharmacy, and must be provided at the level of public hospitals also periodically, The increase in the number of breast cancer patients in Algeria leads to the growth of health expenditure in general and medicine in particular. If chronic diseases (breast cancer) cannot be avoided because they may occur at all times and in all societies and for reasons beyond human control, their economic and social effects can be reduced by providing medicines and other supplies and improving health care for those suffering from these diseases; and preventing chronic diseases

(Breast Cancer) leads to reduced health expenditure.

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9. * Institut National de Santé Publique (INSP), Direction des statistiques