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Short Communication

High Cost Drugs a worldwide Issue Resolved in Mexico by the IMSS: Catalog II a Model to Follow

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Historically, drugs are stigmatized in the history of medicine; where all civilization to date, makes use of superstition and the fable of diseases in their cure to divine causes. The great milestones of human history focuses on fighting disease and living longer in the best health conditions; that after centuries of efforts, successes and errors, medicine has experienced in recent decades an advance of such caliber that it has made it possible. The oldest form of pharmacology is documented in China Pentsao, attributed to the works ordered by Emperor Shemmeng 2,697 years BC. C. he codified more than 350 herbs that included medicinal plants like ginger, aconite, pomegranate root, rhubarb, opium, minerals like mercury, sulfur and arsenic [1]. The Ebers papyrus, 3,000 to 1,500 BC. C. describes a recipe mix for 700 substances, some in use today [2].

The elaboration of the medicines comes from the traditional extraction of active principles of medicinal plants, organic synthesis and the isolation of molecules with therapeutic effect. Towards the second half of the 20th century, industrial production takes off and the pharmaceutical sector experiences great development [3,4].

On the other hand, in Mexico, scientific and drug research activities are carried out with more bitterness in the Porfiriato (1876 - 1911), but already in 1917, companies dedicated to the production, importation and massive commercialization of drugs were established in our country. drugs, getting stronger until 1940; subsequently, European and US companies began to displace Mexican pharmaceutical

companies. Achieving a dependency with the foreigner, thanks to the fact that the State with no interest and the few Mexican researchers with no support, they were never able to create a pharmaceutical industry in the national territory to this day [4].

Medicines are a fundamental pillar of public policies in any country in the world, their affordability is an economic trigger for the user with excessive cost, as well as for any public health financial system. With real problems such as research, development, availability, which together with the precariousness of health services, are faced with limitations in the supply and affordability of supplies and medicines. All of the above impacts even more and exponentially in the so-called high-cost drugs (MAC), adding the following characteristics:

- Diseases with a high impact of social repercussion.
- High risk of death.
- Very scarce population to be treated.
- Very high financial cost for the patient and the Health Institution.
- Governments must visualize financial viability, with scientific evidence and evaluating the budgetary impact [5].

The definition of MAC, in a certain percentage is immersed among them in a stigmatized linguistic effigy as orphan drugs (HM), these are for the treatment of rare diseases, called as low prevalence conditions with high chronically debilitating and incapacitating consequences or life threatening [6-9], in addition MAC in a greater proportion includes other diseases with very high cost treatments. To cite some examples are Crohn's disease, Nonspecific Chronic Ulcerative Colitis, multiple sclerosis, colon and rectal cancer, lung cancer (others more oncological), rheumatological diseases, hematological diseases, etc.

There is a huge global problem that to date has not been resolved in relation to MACs, and puts in check the Governments, Secretaries or Ministries of Health, judicial systems, bonding companies, health insurance companies, group or labor insurance and the same patients; exposing themselves to a high degree of vulnerability [10,11]. The financial cost of MACs becomes the eye of the hurricane with regard to their accessibility and/or acquisition to the end user "the sick" [12,13]. That is why the objective of the following analysis of world problems.

The empires of power and influence of the pharmaceutical companies; whose objective is not clear and where, in addition, there is a certain lack of transparency, when determining the final cost of the drug, after its creation, production, distribution and/or marketing. They are also supported by patents and periods of exclusivity [7,14-17].

The so-called "missing links", (failed and/or useless experimental, preclinical and clinical studies) carried out from 1975 to date, which consist of the research and development of drugs; that show a very high cost and therefore its increase in price [10,18,19].

The large economic impact of MAC makes it impossible to use them in diseases with high-cost doses, since in most of the po public policies of nations around the world regarding health care; the inaccessibility of MACs results in legal requirements, which in the end exponentially triple the costs for the State [20,21].

The culture and influence of pharmaceutical empires on treating physicians, translates into an inclusive prescription making excessive use of MACs, which is defined as the provision of medical services that are more likely to harm than benefit a patient, or the considerable abuse of so-called polypharmacy [22,23].

The lack of research interest in verifying the effectiveness of MACs in the tropicalization of each country, with regard to their indication, prescription, complications, effectiveness, efficiency, their dosage and long-term follow-up, which in some Items may be greater

than 5 years, within the health systems applied around the world, it leaves an open door towards the optimization of the resource in rare diseases, cancer and other high cost in their control and treatment [24,25].

Other factors that must be considered no less important are financial difficulties in terms of productivity of companies, distribution; in the psychological responses of each patient, the administration and equity in the accessibility of the MAC, administrative procedures and survival or survival to cancer, with the cost and continuity of an accumulated expense [26,27].

For all the above, it is imperative to find a solution to this global problem that MACs represent. In France the reimbursement of the cost of the medicine is carried out by government decree issued in March 2016 by Haute Autorite, reporting catastrophic costs [28]. In Brazil, the Specialized Program for Pharmaceutical Assistance is created to measure the cost and high prevalence drugs, but with very limited coverage due to few patients and coverage for only some diseases [29]. On the other hand, the Department of Health and Human Services of the United States of North America (USA) constantly scrutinizes the formula that responds to the exponential spending of MACs in that country, such as reform, regular power or no, the prices through the Medicare program in its sections B and D, with a shared payment; and that influences the international context [30-33]. In Europe (England, Switzerland, Germany and France) they develop strategic negotiation scenarios to lower their prices, with research studies to achieve the health benefits in all countries of the use of MAC, for the management of cancer [3,4].

In the region of Southeast Asia, in the Mediterranean region, the western and eastern Pacific, an inequity is detected in the price (unit and adjusted) of MACs against cancer; proposing the development of policies and economics that achieve accessibility and affordability [35]. In Canada, the allocation of health resources for the accessibility of MACs, as well as the creation of policies that may challenge pharmaceutical companies, base their hope on a mosaic as diverse as group insurance, labor insurance, private insurers, etc. [11,27,36]. In Australia there is a Pharmaceutical Benefits Program against cancer (PBAC), its functionality is to scrutinize MACs in the inclusion process to grant the government subsidy; however, the rejection has been higher than 56%; and the most frequent reason for the rejection was "the inadequate profitability or the price of the medicines too high" that is to say, it is not efficiently economical in a real life scenario in this country [37].

In India for breast cancer they use generic MACs, achieving significant savings but not exceeding 25% of the total cost of the drug [38]. In other countries such as Portugal, Spain, France and Germany, the use of generics in rheumatological diseases is determined by comparing them with the original drugs; the MACs (generic) used do not modify the efficacy, safety and immunogenicity profile, and if they work they reduce costs by up to 26.4% [39-46].

Another strategy to reduce the costs of MACs that is identified is dose de-escalation that yields high savings, with a gradual decrease in the dose for a successful and long-lasting effect [47,48].

Finally, in Mexico there is a logistics strategy that is an innovative, implausible, insurmountable, economically effective and efficient program in the largest health institution in the country, the Mexican Institute of Social Security, which covers 70% of the population, allowing not only the access of MACs, but also an affordability of innovative therapies to the population, managing to equate with a material and human machinery, in the necessary treatment niches; with great equity, accessibility, efficiency, reasoned and specific prescription, distribution, profitability, homogenization, rationalization, unification of criteria, without discrimination, with long-term sustainability; And the best of all is that this administrative tool is translated into a potentializing link between health and life; in addition, it allows a gain in quality and life expectancy of the patient: this strategy is called Catalog II [49].

There are two strategies that are mentioned with great impact so far:

- The first one is the model to follow: Catalog II of the IMSS in Mexico, which becomes the spearhead for the solution of the catastrophic global problem of MACs, and which becomes a part of the global waters; by reducing costs by demonstrating its effectiveness under specific scenarios in diseases with high-cost dosages.
- The second is still speculation, where the authors project a certain viable future in the use of biotechnological and / or biosimilar therapies, as well as generic drugs; where it is seen as the tip of an iceberg, since it will be a future strategy that can solve a certain part of the global problem of MACs.

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