

Libya's Pharmaceutical Situation: A Professional Opinion

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Abstract: To improve the countries' pharmaceutical situation and to monitor the progress, the World Health Organization (WHO) and member states developed a system of indicators to measure the respective important aspects as a prerequisite step. Level I indicators to assess the country's pharmaceutical situation include the national drug policy; legislation and regulations; drug accessibility and affordability; essential drug list; quality control; pharmacovigilance; storage and distribution; information and rational use. This study is aimed to document the professional opinion of 20 pharmacy practice professionals on Libya's current pharmaceutical situation, utilizing WHO indicator-based approach. The core indicators measure the most important information needed to understand the pharmaceutical situation in a country. A closed-end questionnaire was distributed to ten practicing pharmacists and ten pharmacy teaching staff members who practice pharmacy. The questionnaires were handed over personally and collected on the same day. The responses were analyzed using simple statistics. The results were argued in the light of the first author's observation and view, being expert in this field, with reference to the other experts' views, relevant publications' findings and WHO reports' conclusions on these indicators. Suggestions and recommendations for a proper situation assessment, planning and action taking are presented. Primarily, government's commitment towards appropriate restructuring, management and monitoring of the pharmaceutical sector is crucial. That is to enhance the country's pharmaceutical situation, to provide and sustain efficient pharmaceutical services and to improve the overall health care system's performance.

Keywords: Pharmaceutical services, Pharmaceutical situation, Drug policy, Libya

1. INTRODUCTION

The World Health Assembly resolution of 2001 on the World Health Organization's (WHO) medicines strategy identified the four main objectives of WHO medicines (or drugs) strategy, namely, to frame and implement a national drug policy; to ensure access; to ensure quality, safety and efficacy; and to promote the rational use of drugs [1].

To monitor the progress of efforts to improve the global drug situation, WHO has developed a system of indicators that measure key aspects of a country's pharmaceutical situation [2]. Level I indicators is one of these tools, which measure the existence and performance of key national pharmaceutical structures and processes. These indicators assess progress in improving the pharmaceutical situation over time and enable comparison between the situation in countries by level of income. Level I indicators assess the structures and processes related to drugs' services in the

country. These include the national drug policy; legislation and regulations; drug accessibility and affordability; essential drug list; quality control and pharmacovigilance; storage and distribution; information and rational use. These are used to characterize the achievements and weaknesses of individual pharmaceutical systems and to illustrate common sectorial strategies and approaches. They also enable rapid assessment of the implementation of various components of the country's pharmaceutical system. Level II and level III indicators describe other data of relevant assessments as shown in Figure 1 [2]. Level II indicators measure the degree of attainment or outcome of the strategic pharmaceutical objectives. However, level III indicators assess in more depth specific components of the pharmaceutical sector, health system, and national drug policy.

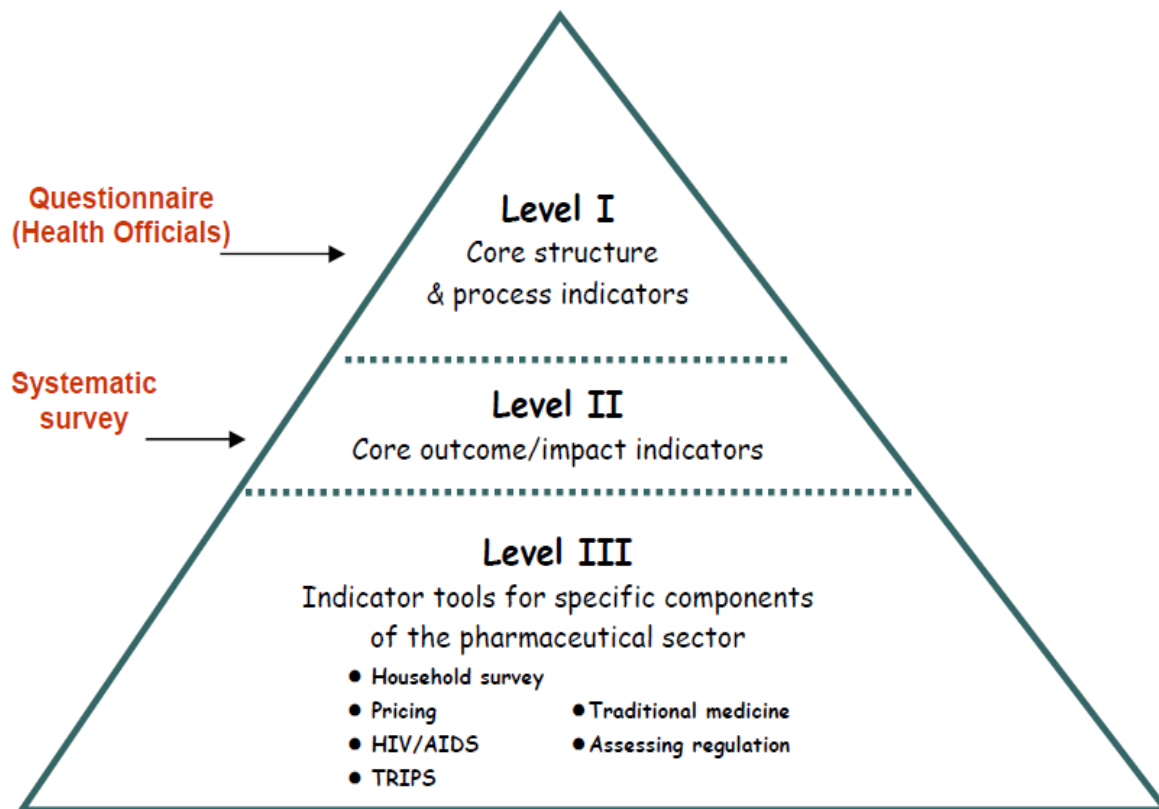


Figure 1. WHO strategy for monitoring country pharmaceutical situations

This study was to obtain a professional opinion on Libya's current pharmaceutical situation, covering the WHO developed Level I of indicators. It was not intended to give a detailed analysis of the national pharmaceutical situation, but to provide a professional overview, to help in current situation analysis and in the design of appropriate interventions. This study sought to answer the following questions:

Is there a national drug policy in Libya? Are drugs accessible and affordable in public and private dispensing facilities to treat common conditions? Are the government quality control procedures effective? Are the transport conditions of drug supply in the public sector trustable? Are drugs, supplying the public sector, adequately stored and handled in public health facility dispensaries and warehouses? Is there a national pharmacovigilance program, including a system for adverse drug reactions monitoring? Is there an independent drug information source for doctors and for pharmacists? Is there a national regulation for the pharmaceuticals' marketing, promotion or advertising; for national drug formularies; for hospitals' drug and therapeutics committees; for the standard treatment guidelines; for hospitals' antimicrobial resistance committees; for the lists of prescription-only and over-the counter drugs; or for the generics' prescribing? Is there a national obligatory continuing education program on pharmaceuticals for

doctors or for pharmacists? Are drugs rationally prescribed (by doctors), dispensed (by pharmacists) and used (by patients)?

2. MATERIALS AND METHODS

A closed-ended questionnaire was designed as per the WHO selected indicators for the measurement of a country's pharmaceutical situation. It included questions addressed to practicing pharmacists; half of them were Pharmacy Practice university teaching staff members as well.

The presented questions are shown at the Results section. Study's ethical approval was obtained from the Ministry of Health. The questionnaire was first piloted to 20% of the targeted participants. Then it was distributed to two groups of practicing pharmacists, ten in each group. The major job of the first group's participants was to practice pharmacy within a community pharmacy setting. The second group's participants were university teaching staff members, holding at least a PhD in Pharmacy Practice and teaching Pharmacy Practice, while they continue to practice pharmacy within a community pharmacy. The questionnaires were handed over personally, without interference with the participants, and were completed and collected on the same day. Response rate was 100%. The results were analyzed using simple statistics.

3. RESULTS

Seven (70%) of the first group participants and five (50%) of the second group participants were females.

Collected responses to the given questions were as following:

Question	Yes No.(%age)	No No.(%age)	I'm not sure No.(%age)
Do you think that there is a national drug policy in Libya?	3(15%)	13(65%)	4(20%)
Do you think that all key pharmaceutical products are accessible in the public sector by all people?	1(5%)	18(90%)	1(5%)
Do you think that all key pharmaceutical products are affordable in the private market to all people?	2(10%)	12(60%)	6(30%)
Do you trust the government quality control procedures?	2(10%)	16(80%)	2(10%)
Do you trust the transport conditions of drug supply in the public sector?	4(20%)	6(30%)	10(50%)
Do you trust the storage conditions of drug supply in the public sector?	2(10%)	6(30%)	12(60%)
Do you think that there is a national pharmacovigilance program, including a system for adverse drug reactions monitoring?	0(0%)	16(80%)	4(20%)
Do you think that there is an independent drug information source for doctors?	8(40%)	8(40%)	4(20%)
Do you think that there is an independent drug information source for pharmacists?	9(45%)	9(45%)	2(10%)
Do you think that there is a national regulation for the pharmaceuticals marketing, promotion or advertising?	2(10%)	12(60%)	6(30%)
Do you think that there is a national regulation for national drug formularies?	3(15%)	15(75%)	2(10%)
Do you think that there is a national regulation for hospitals' drug & therapeutics committees?	7(35%)	8(40%)	5(25%)
Do you think that there is a national regulation for the standard treatment guidelines?	3(15%)	3(15%)	14(70%)
Do you think that there is a national regulation for hospitals' antimicrobial resistance committees?	4(20%)	11(55%)	5(25%)
Do you think that there is a national regulation for the lists of prescription-only & over-the-counter drugs?	4(20%)	12(60%)	4(20%)
Do you think that there is a national regulation for the generics' prescribing?	3(13%)	13(65%)	4(20%)
Do you think that there is a national obligatory continuing education program on pharmaceuticals for doctors?	4(20%)	14(70%)	2(10%)
Do you think that there is a national obligatory continuing education program on pharmaceuticals for pharmacists?	9(45%)	11(55%)	0(0%)
Do you think that drug irrational prescribing (by doctors) exists?	13(65%)	2(10%)	5(25%)
Do you think that drug irrational dispensing (by pharmacists) exists?	14(70%)	3(15%)	3(15%)
Do you think that drug irrational use (by patients) exists?	12(60%)	4(20%)	4(20%)

4. DISCUSSION

Opinions of the majority of the study participants on Libya's pharmaceutical situation's presented indicators were negative, or at least they were unaware of the situation. These responses are in line with the authors' observation, with national experts' views, other related studies' findings and WHO's reports [3-13].

In Libya, it is well observed that there is a weak priority setting, lack of planning and bureaucratic budgetary processes. Moreover, there is a systemic weakness, with a lack of an adequate drug legislation and regulations; an institutional instability and a lack of reliable data. That led to improperly functioning drug regulatory authority with adequate resources and infrastructure to enforce the poorly developed legislation and regulations [4-5, 9-13]. National

drug policy was developed incomplete in 2003, never circulated, never implemented, never monitored and never updated. However, most world countries report the presence of extensive legal and regulatory framework, covering all aspects of the pharmaceutical sector. In 2011, 81% of the world countries had a national drug policy and 62.6% countries had an implementation plan integrated within the health strategy [14].

Currently, there is no documented/written national policy, regulation or system for the selection of items or specifications of the national specifications list or essential drug list at the Libyan Ministry of Health. No pharmacoeconomic analysis for the selection of new items was ever conducted. Furthermore, the existing list does not include several essential items that are recommended by the WHO [3-5, 8-11], while nearly all countries have a system of national specifications or essential drug list [15].

Continuous organizational drug supply difficulties and acute shortages exist, with an unguaranteed transportation, storage or distribution system [3-5, 10, 13]. Moreover, cold chain is not necessarily well maintained, especially in remote areas. Partial availability and inadequate public accessibility to essential drugs is reported at the public health facilities, with time and regional variations [4-5, 10]. Private market observes frequent drug shortages and large prices increases, with a lack of government control or monitoring, evidencing questions about drug affordability as well. The drug quality control administration is relatively weak and unstable, with no government serious official commitment or support. Quality control lacks necessary legislation, regulations, policy, system and special operation procedures, with insufficient equipment and a lack of enough trained personnel. No pharmacovigilance programs are taking place. Accordingly, counterfeit and substandard products are currently expected to circulate in the country freely, with estimates of rates equal to or higher than those in countries of high prevalence [5-7]. Nevertheless, on a personal communication, the Director of Drugs' Quality Control, the National Centre for Food and Drug Control, Tripoli, indicated that none of the referred samples to the centre of those illegally imported drug products has shown to be counterfeit.

Registration or licensing of pharmaceutical manufacturers and importers is implemented, with some weaknesses [5, 12-13]. Some private pharmacies and wholesalers operate with no licenses. Owners and dispensers at some of them are not pharmacists. Transportation, storage and distribution system is not guaranteed. Registration or marketing authorization of pharmaceutical products is not taking place in Libya.

No national standard treatment guidelines exist. Hospitals' drug and therapeutics committees are formulated in some hospitals with no country regulation or central guidelines. Moreover, there is no national policy to enforce or promote generics' prescribing or dispensing, while regulations around the world are in this direction. There is no country system for the lists of prescription and non-prescription drugs, whilst most of countries have three lists, including a list of the pharmacy or pharmacist drugs, which are regularly updated. Irrational drug use exists in doctors' prescribing, in pharmacists' dispensing and in patients' use. Drug promotion activities are not regulated in Libya, with frequent illegal, unethical and unprofessional practices [6].

A government's commitment towards appropriate restructuring, management and monitoring of the pharmaceutical sector is crucial, in order to enhance the country's pharmaceutical situation, to provide and sustain efficient pharmaceutical services, and to improve the overall national health care system's performance. Focus on the continuous professional development is a prerequisite. The developed national drug policy needs to be reviewed, updated and circulated. A standardized evidence-based process of drugs' selection that complies with the WHO recommendations is required. A properly structured stable

and professional drug procurement and supply system, with appropriate funding, needs to be established. The entire process of registration, quality control, pharmacovigilance and information requires further consideration and improvement. Additionally, strategies for the adherence to standard treatment guidelines and drug therapeutic committees; the promotion of good prescribing and dispensing practices, and the promotion of drug rational use need to be properly established. Private sector needs to be empowered and monitored, in order to represent a partner to the public sector, rather than a competitor.

In fact, the proper assessment of the country's pharmaceutical situation should be a governmental commitment and an institutional responsibility. That is recommended to be conducted using a standardized methodology. The outcome of the assessment is to be used to target different programs and resources related to the pharmaceutical legislation, policy, supply, quality control and rational use.

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