

Commentary: Regulatory means for coping with medicinal adherence-issues in Israel

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One of the major goals of governmental health ministries is to focus on the patients' needs; their right for high standard care and empowering their knowledge. The Pharmaceutical Division (PD) in the Israeli Ministry of Health (MoH) is the governing authority for the pharmacy profession in Israel and the regulating body of the pharmaceutical industry. The PD's goal is to improve patients' adherence - the process by which patients take their medications as prescribed¹. Adherence is composed of several elements: filling the prescription, collecting the prescribed medication, taking the medications according to the instructions, and discontinuation of treatment when needed². However, approximately 50% of the population does not comply to the physician's orders, according to the world health organization (WHO)¹. This worldwide challenge, called "non-adherence", may stem from lack of understanding of the treatment importance, as well as the lack of reliable medicine information. Non-adherence has direct negative outcomes on patients' health, as well as on the utilization of the health system resources.

There are several strategies to address the challenge of non-adherence, including: disease awareness campaigns (DAC) to raise the public awareness to specific diseases, direct-to-consumer advertisement (DTCA) to raise the public awareness to prescription medicines, specific treatments and over-the-counter (OTC) medications to improve the accessibility of patients to specific medicines. In addition, improved access to highly reliable and scientific pharmaceutical information may also contribute to better adherence³.

Direct-to-consumer advertisement (DTCA).

It was shown that DTCA can influence the public and promote the sales of specific medications^{4,5}. This may lead the patients to request medication that may not benefit, and might even damage their health

This may influence patients to persuade their physicians to prescribe inappropriate, ineffective and even life-threatening medications. Therefore, DTCA is strictly forbidden in the European Union⁶, UK⁷, Australia⁸ and Canada⁹. DTCA of pharmaceutical products that require prescriptions is strictly illegal in Israel, unless approved by the director general of the MoH. In comparison, DTCA and promotion of prescription drugs are currently permitted in the USA and New-Zealand^{10,11}.

Disease awareness campaigns (DAC)

DAC can also have the potential to influence patients' behavior to

prefer a specific medicine, and also influence physicians to prescribe specific medications. Some patients may legitimately suffer from a particular disorder that require medicine treatment, however others might be mistakenly diagnosed with a disorder they do not actually have, or start taking medications that might not benefit them and even harm their health^{12,13}. However, DAC may also contribute to the improvement of the public health, for example DAC to promote the use of artemisinin-based combination therapy (ACT) to treat Malaria in rural areas of East Africa, contributed to the increased usage of ACT in children aged 0-5 years¹⁴. DAC is allowed in the USA, the European Union, UK, Australia and Canada^{7,8,9,15,16}.

The Israeli MoH has recently established regulations regarding DAC so that consumers can be empowered with information about the availability of treatments for diseases (medications or preventive treatments) in a manner that does not involve promotion of a particular commercial product¹⁷. For example, campaigns and information regarding cancer that are provided and run by the Israeli Cancer Association.

Promotion of adherence for patients with prescribed medications

In 2015, the PD established a procedure that regulates how pharmaceutical companies are allowed to encourage compliance among patients who have been prescribed medications, after the prescription is issued. The patient destined to receive the prescribed drug can receive non-commercial, reliable scientific information in various ways as specified in this procedure, in order to maximize the treatment's efficiency and to protect the patient's health. A "medical-information/adherence" center (approved by the MoH and the pharmaceutical company) calls patients (after they gave their consent). This center provides a call center service to supply information regarding the disease and the treatment, and offers in addition home visits for personalized training on appropriate usage of treatment¹⁹.

Over the counter (OTC) medications

DTCA of OTC may aid to patient empowerment. It enables the patient to purchase medications, in an informed manner, without the need to visit or consult their physician. OTC-DTCA medication is common in most of the western countries, including the European Union²⁰, and Israel.

Improved access to reliable scientific pharmaceutical information

- A recent initiative to improve the adherence in Israel -which has diverse populations speaking in different languages- was labeling the outer package of every pharmaceutical product in four languages: Hebrew, Arabic, English and Russian. The patient's leaflets

in Israel must be written in three languages as well (Hebrew, Arabic and English).

- Most of the western countries have official websites that provide information regarding the medications registered in these countries, the leaflet, and other relevant information. Similarly to the British website²¹ and the US website (that is held by the FDA)²², the Israeli drug registry website provides comprehensive data on all the registered medicines in Israel, including the commercial name, manufacturer, active ingredients, dose, indications, a scanned version of the physician leaflet, the patient's leaflet, a picture of the packaging and an updated medication price²³.
- A software application ("Trufa To Go") launched by the PD aims to promote rational and safe use of OTC medications. The application enables the patient to search the database by product trade name or symptoms experienced, and scan the package barcode for product information. The information available for patients includes: product picture, product information leaflet, indication, package size and price²⁴.
- During 2016, the MoH has established a program of financial support to encourage the health maintenance organizations (HMOs) to enable patient-pharmaceutical counseling, in particular for polypharmacy patients. The counseling can be requested by either the treating physician or the patient himself, and takes place in a designated counseling room within the pharmacy. The program finished the year with significant success and the MoH director has decided to continue the program in the upcoming years.

Conclusions

A major challenge of the MoH is to improve the patients' health, focus on their needs and ensure their access to scientific, evidence based and reliable relevant information. Similarly to initiatives enforced world-wide, the MoH uses various approaches to enhance adherence, both on the pre- and post-prescribing phases. These guidelines issued by the MoH, will benefit both the patient and the industry by allowing them to keep investing in marketing and at the same time to empower the patients. The Israeli experience shows that the pharmaceutical industry has quickly and efficiently adopted the regulations and implemented them successfully.

We believe that the personal patient-pharmaceutical counseling may significantly contribute to a better adherence. Much like the advancing means of communication with the treating physician - now available

through online application chat or video calls as well as in face-to-face meetings - we find that the patient-pharmaceutical counseling should expand its border into the online world, and offer the patients easy access for professional assistance.

In order to further cope with non-adherence, more research is needed. National surveys and collaborations with the HMOs may aid in revealing the rates of non-adherence and its causes. In addition, the MoH must continue monitoring, and collecting feedbacks regarding the new procedures as well as to keep on developing the adherence enhancement tools and policies.

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Competing interest

The authors declare that they have no competing interests.

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