

Original Research Article

On the Pharmacists' Attitudes toward the Off Label Use of Cosmeceutical Products in Taiwan

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Abstract: To assure the quality, safety and efficacy of a drug, a drug will be developed, tested, delivered, and used under strict regulatory legislations. Off-label prescribing refers to prescribing or use a registered medicine that not included in the product information. Off-label prescribing is legal, yet common around the world. Pharmacists in the hospitals, clinics, and community pharmacies are in the front line in protecting the general population from being hurt by such OLP. The current study investigated the pharmacist's attitudes toward OLP. 109 pharmacists were included in the investigation by answering the structured questionnaire. The survey indicated that the pharmacists were well trained to perform a good practice toward the off line use. The current study suggested integrating the efforts of all healthcare professionals to improve the national's knowledge on medication safety.

Keywords: Off-label use, Off -label prescription, Pharmacists, Community Pharmacy, Chain stores, Legislation, Taiwan

INTRODUCTION

Off-label (unlabeled or unapproved) prescribing refers to prescribing a registered medicine for a use that is not included or is disclaimed in the product information [1], can include altered doses, dosage forms or indications for use. Although, some reported that a physician may innovatively off-label use of a current drug for certain therapies, off-label use of medicine is illegal [2]. Off-label prescribing is legal, yet common around the world, its use is subject to the contradictory expectations of various stakeholders, including the pharmaceutical industry, physicians, pharmacists, and in growing numbers of consumers [3].

To assure the quality, safety and efficacy of a drug, developing and launching a new drug in the pharmaceutical manufacturing industry are enforced by regulatory legislations [4]. To register a pharmaceutical product, including cosmetics and beauty care products, are produced to abide with the internationally recognized standards of Good Manufacturing Practices. The medication professionals, such as clinical physicians (prescribers), pharmacists, and nurses, are then required to perform their duties strictly by following the guidelines that was established and described in the label. However, off label use of drugs are not uncommon around the world, and the most common off label use were dosage/frequency (50% of prescriptions) [5, 6] as well as alternative use of such as

antibacterial, antiasthmatics and analgesics. The OLP practice is so common around the world, with a rate may up to 40% for adult patients, and may up to 90% in pediatric patients [6]. In Taiwan, a study reported that there are around 50% of the physicians admitted having OLP [7].

Along with the rapid growth of beauty care products and cosmetics, a wide variety of so called Cosmeceutical (cosmetic and pharmaceutical) were introduced to the markets. Products that claimed for skin whitening were one of the most demanded in Taiwan based on its aesthetics culture, 'A white cover thousands of ugly' (i.e. White is everything of beauty). Whitening beauty care associated products are highly easily accessible through intensive-populated chain stores, such as Cosmed, Watson's, and many other supermarkets who equipped with registered pharmacists as required by the law.

Off label use could be risky to consumers, especially for those consumers seeking whitening cosmetics through easily accessible sales outlets. Any adverse or negative chemical effects could be a disaster to the consumer. Pharmacists in the front line is the major and might be the only gate keeper who can provide correct and sufficient information when dispensing or providing medicines to consumers. Accordingly, pharmacists' attitudes toward such kind of

off-label use will be critical to gauge the safety, security, and efficacy of medication. It is then to assume the pharmacists will be liable for dispensing off label prescriptions [8]. However, pharmacist's attitudes toward off-label prescribing are little known [9].

MATERIALS AND METHODS

The current study was conducted in the Hualien of Taiwan, a beautiful country face to the Pacific Ocean. Member pharmacists who attend the Annual Assembly Meeting and conference in the January of 2017 were invited to participate, from which 109 valid responses were gathered for analysis.

Instrument: Drawn from questions in the Auffret and colleagues [9], the authors developed a questionnaire to inquire the pharmacist's attitudes toward the off label prescriptions (OLP). Some personal information regarding the respondents were also included for analysis.

RESULTS

There are 63.05% of respondents had experience of accepting off label prescription, among which 28.11% are pharmacists from chine medicine hospitals, 13.25% from general clinics, 18.88% from community pharmacies, and 2.81% from chain stores (shown as figure1).

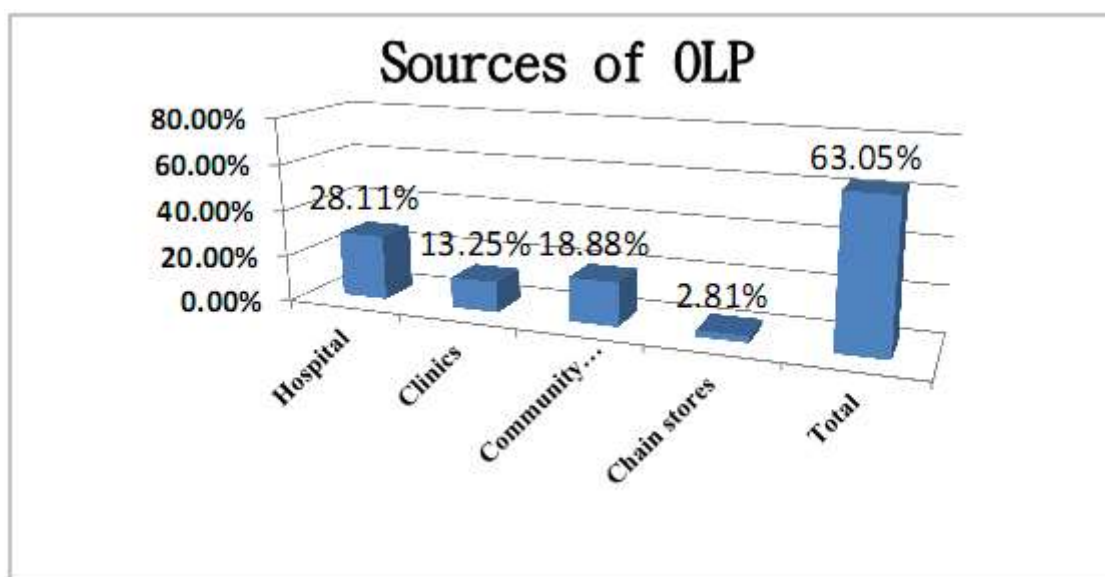


Fig-1: Pharmacists experienced beauty care OLP

As to the consumers who seek to purchase prescribed or non-prescription cosmeceutical is not rare as well in Taiwan. The current study indicates that 34.8% of the total responding pharmacists reported having received requests of this kind. The highest percentage is found in the community pharmacies, and followed by general pharmacy stores, hospital and clinics. As the respondents indicated, most consumers seek to obtain this kind of medicine were (1) referred by their friends who had used (2) referred by a pharmacist, (3) had experience of using this medicine, and (4) advised from web browsing. The data delivers an

important message that consumers are not aware of the seriousness of adverse effects of off label use. This can be a critical issue for the safety of proper medication.

High potency Vitamin C and Tranexamic acid are the top two items prescribed and used for skin whitening, 46.55% and 45 % are found in the prescription respectively. In addition, some others such as progesterone, Silymarin, and High potency B-complex are also frequently yet less than 205 of the prescription, as shown in figure 2.

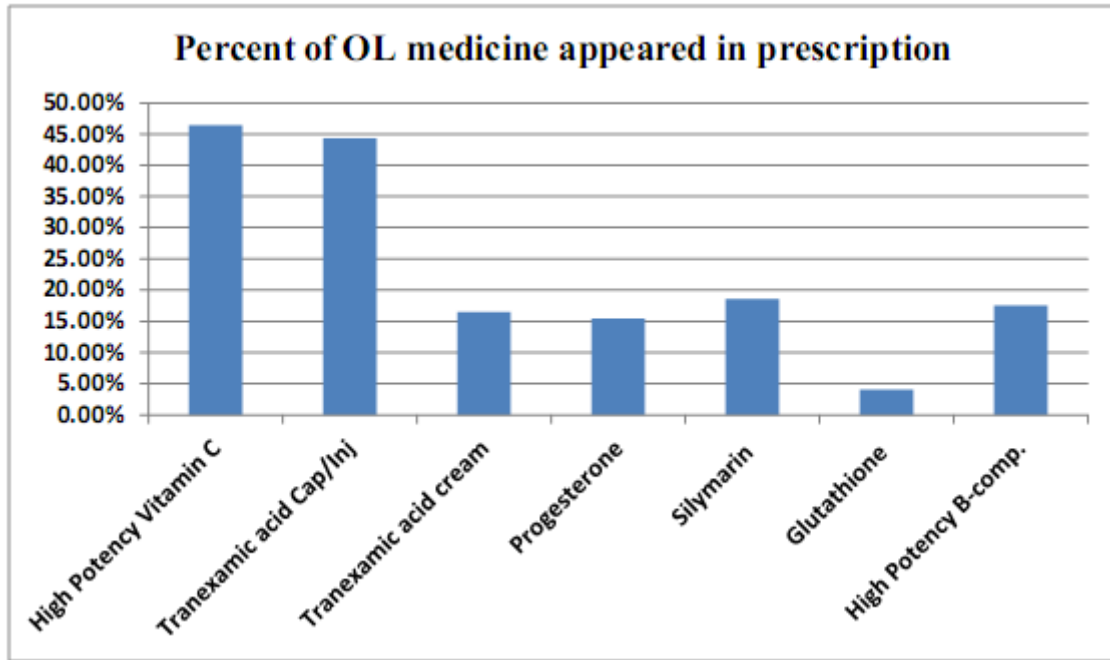


Fig-2: OL medicines in prescription

Close cooperation between medical professionals, such as physician and pharmacists are important for medication safety and is an important measure to escort the patient's health. Pharmacists were particularly trained to master in the nature and use of varied kinds of pharmaceutical components. Therefore, it is wise to examine the content of physician's prescription, including the items, quantities, doses, usages etc. before dispensing and then delivering to the patients. According to the current study, there are only 10 percent of the respondents will follow the

prescription without corresponding the physician for a suspicious OLP. This means the majority of pharmacists' attitudes toward off label use of medicine are cautious. Noteworthy is when OLP in present, the OPT pharmacists will reconfirm with the prescriber the correctness of the prescription, as well as the patients of such OLP, no matter how the dosage is. This shows that the pharmacists are well-trained and conduct a good practice toward the OLP. Details of this response are shown as figure 3.

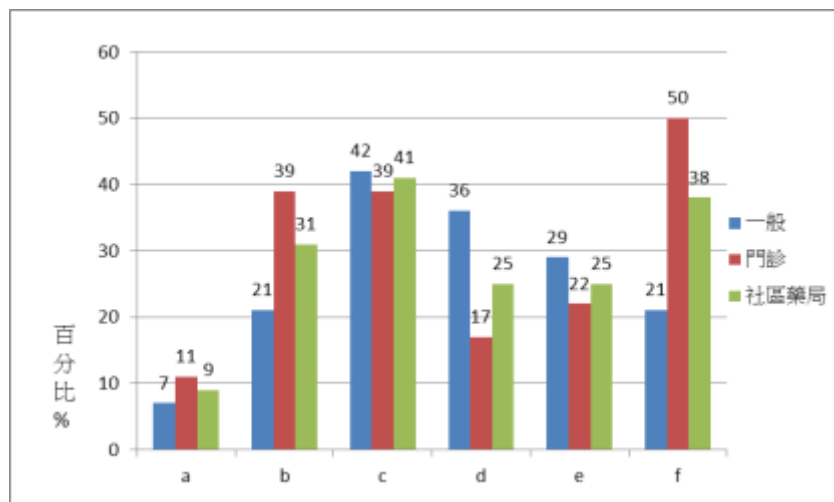


Fig-3: Actions taken by the pharmacists toward OLP

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|--|---|
| a. Dispensing with the prescription without contacting prescribers | doses |
| b. Confirming with the prescribers for any doses | d. Confirming with the prescribers when negative effects is possible for a particular patient |
| c. Confirming with the prescribers for the suspicious | e. Confirm with the patients for possible side effects |

and gain the patients' agreement for indemnification

- f. Confirming that the patients realized the risks and purposes of off label use of certain medicine

CONCLUSIONS

Despite the physician may play a role in identifying an innovative use of a current drug for certain therapies, it is illegal in terms of protecting the patient's safety. Off label use was high everywhere in the world. Immediate action for more rational drug use is necessary and requires not only regulatory intervention but also a more evidence-based, therapeutic approach

The current report provide evidence that the pharmacists in varied positions in the hospital, clinics and community pharmacies has favorable attitudes toward taking proper behavior in front of off label prescription. Additional attempts have to be made by the cooperation of the governmental agencies, pharmaceutical industries, physicians, and pharmacists to improve the nationals' knowledge concerning diseases and healthcare treatments.

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