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Risks in Dietary Supplements

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The use of natural substances for treatment and healthcare dates back 5000 years, and has become popular in the last two decades. The rise in the use of these treatments has been driven by the increasing use of traditional medicine by the poor in developing economies as well as from the expansion of the use of alternative medicine to complement convention medicine in developed economies.

Natural substances can be used in different forms for treatment. They can be used in their natural state, e.g. the ingestion of garlic cloves to manage hypertension or high cholesterol. However, the widest use of natural substances is in the form of dietary supplements, which include vitamins, minerals, herbs and other botanicals, amino acids, enzymes, organ tissues, glandulars, and metabolites. Even many of the drugs available on the market are derived from plants, e.g. atropine, belladonna, colchicine, digoxin, Taxol, tubocurarine, vinblastine etc.

With the increasing popularity of dietary supplements, the safety of these treatments has become one of the major concerns of local and international health authorities and regulators. Although most countries have regulations for these products, since they are not classified as drugs, they are easy to reach and can be used without supervision.

The World Health Organization (WHO) reports that most people assume that dietary supplements are completely safe, just because they are herbal or natural. Gardnier et al. (2008) showed that even some children's hospitals in the USA are not concerned with the risks involved in unconsulted use of dietary supplements.

Although the warnings and studies by the United States Food and Drug Administration (FDA) (FDA 2008) and WHO (2005) to increase awareness on this issue seem to have resulted in progress, (e.g. Philadelphia Children's Hospital is reported to have removed unproven dietary supplements from its list of approved medications) there is still a long road to success. The focus of this study is to summarise the regulations on dietary supplements in Turkey and the inpatient policies and practices in VKF American Hospital.

Regulation of Herbal and Dietary Supplements in Turkey

Regulation in Turkey separates pharmaceutical products from dietary and herbal supplements. Pharmaceutical products are supervised and governed by the Directorate-General of Pharmaceuticals and Pharmacy (IEGM), which is a subsidiary establishment of the Ministry of Health. The dietary and herbal supplements are regulated and supervised by the Ministry of Food, Agriculture and Livestock.

The pharmaceutical products are classified into groups by the regulation dated 17 February 2005 (http://www.resmigazete.gov.tr/eskiler/2005/02/20050217-4.htm (in Turkish):

- Medication that can only be obtained on prescription: the types of prescription for specific medicines are also defined by the regulation, namely: renewable or nonrenewable prescriptions, special prescriptions and restricted prescriptions.
- Medication that doesn't require any prescription.

The basic components of Turkish medicine legislation, such as licensing, renewal, marketing and pharmacovigilance procedures have been changed to make them consistent with European Union Directives. The procedures for on-prescription medication and off-prescription medication

are the same. The documents and the application folders for licensing, labelling, price controls, marketing restrictions and procedures are the same for both groups. The off-prescription medicines are very restricted, and most of them are vitamins and minerals with medical purposes. All pharmaceutical products are required to be sold only in pharmacies.

On the other hand, the dietary supplements market, supervised by the Ministry of Food, Agriculture and Livestock, has fewer restrictions and regulations (Dietary Supplements Regulation published in the Official Gazette dated 16 August 2013 and numbered 28737). Dietary supplements can be sold anywhere and are easy to reach. The legislation on dietary supplements defines the production techniques consistent with hygienic conditions, preparation, transportation and the storage conditions of the product. A major part of the legislation is about the labelling of the product. According to the legislation:

- There can't be any declarations on the label, presentation or the advertisement of the supplementary product, stating or implying that it has disease prevention capabilities or curative effects.
- There can't be any declarations on the label, presentation or the advertisement of the supplementary product, stating or implying that micronutrients provided by the supplementary product cannot be met with an adequate and balanced diet.
- The amount of the nutrients, botanical and other substances in the supplementary products and their reference daily portion values are numerically stated on the label of the product. The units of the vitamins and minerals are also defined by the legislation. The amount of vitamins and minerals should be stated as the percentage of the daily recommended value listed by the legislation.
- Supplementary products cannot be produced and marketed for infants under four years old. Dietary supplements produced for children between 4 and 10 years old should state that "it is suitable for children between 4 and 10 years old" along with the name of the product. The products that are not suitable for this age range cannot have any picture or shape that might imply that the product is suitable for children on its label.
- For the products recommended for different gender and age groups, the label of the product might include statements that the product is produced for the recommended group.
- The label of the supplementary products should include the following statements:

    - The name of the product that expresses the classification or the nature of the main ingredients that characterise the product.
    - Recommended daily intake along with a statement "do not exceed the daily recommended intake".
    - A declaration stating "Supplementary products can't substitute a normal diet".
    - A declaration stating "Keep medicine out of reach and sight of children."
    - A declaration stating "Seek the advice of a health professional if you are pregnant or nursing a baby".
    - A declaration "It is not a medicine." The minimum size of this statement is also determined by the legislation.

Dietary Supplement Policies in VKF Amerikan Hospital

The inpatients in VKF American Hospital are not allowed to use patient-owned medication (POM), including dietary supplements, without supervision during their treatment in the hospital. Inpatients are questioned about the medication, including dietary supplements, that they have used, and this is recorded in the evaluation forms filled in by the nursing staff during the admission process.

In case of home supply dietary supplements that are brought by the inpatient, these are stored and administered by the hospital pharmacy. If the physician decides to use home supply medicine, he/she writes this on a prescription. Based on the prescription of the physician, the hospital pharmacy first identifies the POM by controlling the package for the name of the product, expiration date etc. Then, the suitability of the POM is checked by questioning the first-use date and storage conditions before arrival to the hospital, if necessary. In case of a foreign inpatient, the label of POM is translated by an interpreter for necessary controls. If POM isn't suitable then it is not stored by the hospital pharmacy, and the companions of the inpatient are asked to take the POM out of the hospital to prevent any unsupervised use of it.

POM, which is compatible with the storage and stability criteria, is accepted and stored by the hospital pharmacy. The medication management procedures of the hospital require the review of the medication order by a pharmacist or an authorised technician for completeness and appropriateness before dispensing. The ordered home supply dietary supplement's probable allergic reactions, indication suitability, treatment side effects and warnings and interaction with other treatments are checked, and the pharmacist's assessments and recommendations are put on the order to inform the nurse and the physician of the patient.

In addition, oncology patients request information about herbal supplements, such as turmeric and maitake mushrooms. The pharmacist pays special attention to oncology patients, informing the patients about the possible side effects, complications and interactions with their continuing medication, and warning them not to use these herbal supplements during their cytotoxic treatment.

Conclusion

As discussed above, patients are not well-informed about the effects of dietary supplements, and they are assumed to be safe to use. The regulations on these supplements do not involve strict review processes and are lighter compared to medicine application procedures. The legislation and regulations generally focus on the information required to be stated on the labels of the products. Since there are no pre-marketing safety tests, the side effects and interactions of some of these dietary supplements are still unknown. The use of these supplements without supervision might be very risky, especially taken along with other medication. Therefore, hospitals should have written policies about patient use of dietary supplements.

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