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## *Full Length Research Paper*

# PATIENT SAFETY – REPORTING OF ADVERSE DRUG REACTIONS (ADRS)

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**Abstract**

**Abstract**: The issue of patient safety has been brought to the attention of the medical community in 1999 through a report of the US Institute for Medicine titled "To Err Is Human." In 2004, the World Health Organization launched the initiative "Patient safety – a Global Challenge" and established the World Alliance for Patient Safety. Owing to scientific progress, many new medications are being introduced in the market. In result of this "medicinal explosion," a need arises for the health specialists to inform their patients about any possible adverse drug reactions (ADRs) and to report about any suspected new ADRs.
**Objective:** This article intends to trace one aspect of patient's safety related to the use of medications, and this is the reporting of Adverse Drug Reactions (ADRs).
**Methods and materials:** We conducted an anonymous survey among the medical specialists (physicians and chemists) in the territory of Varna, Bulgaria with regard to the frequency of ADRs reported by them.
**Results:** All specialists take into consideration the risks inherent to the use of medications and all specialists share that they observe ADRs in their practice; however, all respondents unanimously shared that they did not report about observed ADRs neither on the page of the Bulgarian Drug Agency, nor though the Yellow Card.

**Keywords:** Patient safety, World Health Organization (WHO), Adverse Drug Reactions (ADRs), Bulgarian Drug Agency (BDA), Over the Counter Drugs (OTC).



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## INTRODUCTION

The pharmaceutical products are specific consumer goods related to the greatest of human values – human life and health. The trends and dynamic for the spread of OTC products puts an important highlight on the research of various aspects of their use. Such research is of significant importance for the adequate conduct of health specialists where the minimizing of risks are concerned and for the enhancement of the positive health-related and cost-saving effects on the healthcare system. The WHO's position is that through the option of OTC drugs the patients feel more satisfied, knowing that they themselves take the responsibility for their own health. On the other hand, medications represent an intricate system of which the majority of people have inadequate knowledge and cannot determine when, how and what quantity of medications they have to take, (Hersh *et al.,* 2007). This situation is further exacerbated by the drug market, which manufactures its goods in a situation of extremely intense competition and operates under a pattern, which contributes to the expansion of drug nomenclature and, at the same time, of the uncontrolled use of medications. In the European countries of developed market economy, the drug market is perhaps the market functioning under the most stringent legal regulation and post-marketing control. In 2004, the WHO started the initiative "Patient Safety – a Global Challenge" and organized the World Alliance for Patient Safety in response to Resolution 55.185, which appealed to the WHO and the member states to pay utmost attention to the issue of patient safety and medical staff safety. The World Alliance for Patient Safety (PS) at the WHO (2009) defined safety as reduction of the risk for the patient against unnecessary harm or potential harm in relation to the providing of health services. The reporting of ADRs is an aspect related to patient safety. In the new European legislation – Directive 2010/84/EC, a side effect is determined to be "any untoward and unwanted reaction to a medicinal product." (Directive 2010) The reporting of ADRs related to the use of medications was for the first time introduced in Great Britain in 1964 through the so-called "Yellow-card system." In Bulgaria, the beginning was set in 1971 through the establishment of a Coordination Centre for the Study of Side and Late Action of Drugs. At the beginning, the reporting system relied only on

the observations of physicians who, in their turn, sent informing notices that certain drug produced ADRs. For the purpose of obtaining more comprehensive information, the practice of reporting by all levels of medical specialists was introduced at a later stage.

Today, over 60 countries amongst which is Bulgaria, use this system of reporting. Historically, the problem dates from 1994 when the World Health Organization (WHO) in a Resolution of the World Health Assembly WHA47.13 (1994) defined the four key components which were intended to improve the access of the population to quality medications – ADRs, reasonable use of drugs, concept for the basic medications and support for the scientific exchange between the countries, scientific research and improvement of the knowledge and skills of the healthcare specialists, (World Health Organization, 2000). The tracing of ADRs in Bulgaria develops and improves continuously, in compliance with the international standards for efficiency assessment. According to the recent amendments introduced in the Act for Medicinal Products for Human Use in effect from 21.12.2012, the patients can, at any time, report adverse drug reactions to the medical specialists and to the Bulgarian Drug Agency (Act for Medicinal Products for Human Use, 2012) To facilitate the patients and to comply with the new European law, the Bulgarian Drug Agency provided an online blank form and electronic acceptance of patient notices about suspected ADRs. The patient plays the role of a source of primary information as regards the actual benefits or harms of the taken drugs and the physician is the one who assesses and forwards the original notice given by the patient. The notices given by medical specialists and recently by patients, too, are assessed and recorded in the ADRs database maintained by the Bulgarian Drug Agency.

If they provide sufficient evidence, the BDA can undertake immediate regulatory measures with respect of a particular medicine. In all cases, the information about these reactions is also forwarded to the international database maintained by the European Medicines Agency (EMA) and the World Health Organization (WHO). All messages received from patients and medical specialists from all EU member states are monthly reviewed by specialists and such reviewing might result in important regulatory changes such as the adding of new contra-indications in the product information, new drug interactions, new adverse drug reactions or suspension of the permit to use certain drug or, in certain cases, even withdrawal of the product from the drug market. According to the Bulgarian Association for Drug Information (BADI): Drug safety is a priority of the Bulgarian Drug Agency (BDA), which is the body applying the EU requirements in Bulgaria. The web-page of BDA uses the Yellow Card for ADR reporting, plus the uploaded "Methodological instructions on the manner and order of ADR reporting by the medical specialists (www.bda.bg), according to the requirements of the Act on Medicinal Products for Human Use. (Act for Medicinal Products for Human Use, 2012)

**Objective:** Our objective is to establish the frequency of reporting of ADRs arisen in result of OTC use in the territory of Varna notified by medical specialists – physicians and chemists.

## METHODS AND MATERIALS

We followed up the chronology of the patient-safety concept. We conducted an anonymous survey amongst 60 chemists and 68 physicians; we asked them about the frequency of ADRs reported by them on the BDA webpage and in particular the frequency of reporting about ADRs related to OTC drugs.

## RESULTS AND DISCUSSION

We observed an increase in the needs, requirements and expectations of the informed health-insured consumer playing on the pharmaceutical market. The process of OTC purchasing is accompanied with a higher risk level and frequently breaks the link between patient, physician and chemist. There are cases (which are not infrequent) when customers fall victim to a purely commercial policy on the part of the pharmacies, which is being conducted at the expense of customer's right to use humanistic pharmaceutical healthcare and services (Stoycheva *et al.,* 2012). The survey covered 80 chemists working in pharmacies in the territory of Varna. The average age of the participants in the sample is 52.65 and their average length of employment is 22.05 years. 58.75% of all respondents report an increased share of OTC in the pharmacy's nomenclature compared to the prescription drugs. We asked the chemists what share of the patients visiting the respective pharmacies use OTC products. About three fourths of the respondents share that over fifty percent of their customers use OTC. The most frequent purchases of OTC concern the treatment of acute conditions – this finding has been shared by 71.25% of the surveyed chemists.

Drugs have numerous specifics, which necessitate monitoring and documenting of their impact along the complete chain – from the drug manufacturer to the patient. Pharmacovigilance or monitoring of drug safety is determined by the WHO as the science and activities related to the finding, assessment, understanding and prevention of adverse drug reactions and any other problems related to the use of drugs (Monitoring *et al.*, 2002). In many cases the pharmacy keeps other drugs of the same INN, which are much more efficient and cost-saving than the advertised ones; however, the chemists are rarely successful in promoting such drugs because of aggressive publicity campaigns. This situation prevents the chemists from acting as qualified specialists who are knowledgeable about the reasonable use of medications. The patients are not always capable of correctly assessing and diagnosing their own condition. This leads to improper drug use and poses risks for the patients' health, (Danchev *et al.,* 2011). This statement is supported by the data of Fig. 1. 29% of the surveyed chemists share that in nearly all instances they succeed to convince the client to purchase the adequate OTC product which the chemist has recommended; 53% of the respondents consider that their opinion largely influences the patient's final decision to make a purchase, although this is not always the case. 16.25% of the respondents have no opinion on the matter and 2.50% share that their opinion does not influence the patient's decision to make a purchase. Over one half of the chemists consider that the use of OTC is risky overall; this opinion is shared by 57.50% of the respondents. 12.50% see the benefits from OTC

use and another 30% see potential complications related to the use of OTC although they do not express a definitive opinion.

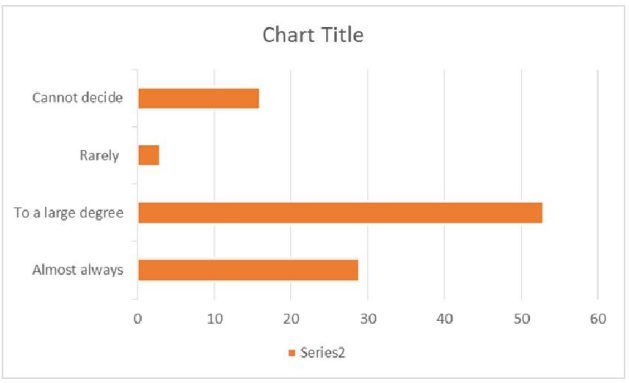


**Figure 1. Impact of the chemist's opinion on the patient's decision to make a purchase**

To the question whether they have reported ADRs on the BDA webpage, the responding chemists, regretfully, unanimously replied in the negative. The system for generating ADR signals in Bulgaria forms part of the European system and legislation and obliges all medical specialists to report any suspected side effects of the drugs launched on the market. The ADR reporting to the national drug agencies forms part of the modern pharmaceutical practice. In this way the chemists contribute to the patient safety and to the improvement of the quality of healthcare from the viewpoint of efficacy and safety. (WHO, 2009) According to data provided by the National Centre for Public Health and Analyses at 2012, the practising physicians in Bulgaria were 28 411, which makes 388 physicians per 100 000 residents. This value is higher than the values established in the majority of developed countries; however, factors are existent, which pose a huge risk to the manning of the Bulgarian healthcare system. Our survey addressed 68 physicians who practise their profession in the territory of Varna. Out of those, 40 physicians, or 58.82%, were general practitioners while the specialists were 28 (41.18%). Their average work experience was 15.04 years and their average age was 44.8 years. According to 48.53% of the physicians, half of the patients visiting their offices use OTC drugs. Their personal observations point at an increasing share of patients who use OTC. Most frequently OTC drugs are used for the treatment of chronic and acute illnesses, and 44.12% of the physicians point out this circumstance as motivation to use OTC. A large share of the physicians (72.06%) considers that the patients' free access to OTC intrudes in the physician's professional activities while 27.94% consider that OTC drugs make the medical practice easier.

Over one half of the responding physicians consider that the use of OTC bears risks exclusively for the patients; this opinion is shared by 61.76% of the respondents while 32.35% regard OTC as a source of complications; only 5.88% of the respondents report benefits from the use of OTC. 42.66% of the responding physicians who participated in our survey consider that the patients' attitude is an objective factor for the growing use of OTC; according to these respondents, such attitude is expressed as self-confidence in some of the patients or confusion in others, both patterns resulting from the informational invasion of the Internet, which influences the patients' choices. With regard to possible policy changes towards the safe use of OTC, the largest share of physicians (45.59%) consider that the large-scale implementation of collaborative healthcare services will be expedient. 33.82% of the respondents favour the improvement of patients' healthcare culture and improved awareness of patients' responsibility to their own health. According to 20.59%, the control and regime concerning the selling of OTC need to be changed. Bulgaria is amongst the EU countries of the lowest level of health prophylaxis and disease prevention. The residents do not practice cares for their health because of limited finances, bureaucratic obstructions or insufficient awareness. One out of ten people self-appoints their medical treatment because they do not trust the physicians or the way in which the healthcare system functions in this country. Owing to this reason and because of the low health awareness, the formidable 18.6%, i.e. every fifth Bulgarian acknowledges that they have never turned up for preventive medical examinations. The majority of physicians (77.94%) share that in their professional practice they have witnessed complications resulting from self-appointed treatment with OTC while 22.06% of the respondents answered in the negative. All respondents share that during their professional practice they did not report ADRs resulting from the use of OTC, neither on the BDA webpage nor through the Yellow Card system.

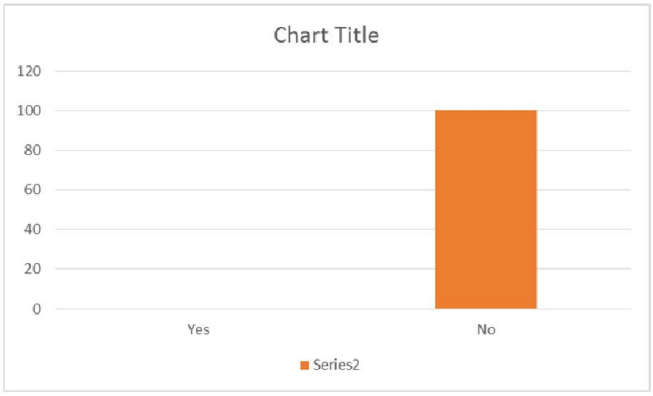


**Figure 2. Reporting of adverse drug reactions by physicians**

Regretfully, Bulgaria is amongst the EU countries of lowest frequency of ADR reporting by medical specialists. For 11 years, the average number of ADR reports has been 135 per year while in the European Agency's database, the number of reports submitted only in 2009 was 487 421. These statistics confirm the fact that our medical specialists who prescribe and provide medicines do not report occurrences of adverse reactions regardless of the fact that they have been provided with all convenient tools to do so. The replies to the preceding two questions bring the patient safety issue to the foreground. Actions have to be undertaken with regard to post-marketing control related to the safety and improved rate of ADR reporting by the medical specialists.

## Conclusion

According to the WHO, the patient safety in a number of countries has been assessed as a serious problem that, regretfully, remains invisible for the specialists and the society. The post-marketing control is a necessary tool for the medical specialists – it facilitates them to seek information from the patient concerning the use of OTC. The significance of this approach grows with the expansion in variety and number of

available medicinal products and their accessibility. ADR reporting should become part of the professional responsibilities of both physicians and chemists. Additional training programs should be introduced, intended to support the active participation of the medical specialists in the spontaneous reporting of ADRs. The relations between the separate participants and units along the chain represent a key element in the process of quality healthcare, especially when this is a comprehensive care implemented in a complex environment. The patients' needs should stand in the focus for the purpose of planning, understanding and making of correct decisions.

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