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Perception on Adverse Drug Reaction Reporting by Physicians Working in Southern Romania

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ABSTRACT

Aim: *The purpose of our study was to investigate and to assess the perceptions of Romanian doctors towards adverse drug reactions (ADRs) reporting.*

Method: *A questionnaire with 20 items accompanied by a letter presenting the study was circulated using Internet and face to face interviews to 532 doctors in Bucharest and two neighboring regions from Romania (Muntenia and Oltenia).*

Results: *204 (56.2%) of the total number of responders expressed their opinion that the daily number of ADRs observed to be under 5 309 (58%) of responders were never informed about ADRs reporting, 439 (82.52%) did not know that the Romanian College of Physicians is scoring this activity under the "Continuous medical education program". Factors that might encourage voluntary reporting of adverse reactions were identified to be: the easiness of reporting, their periodic information and the training about all adverse reactions reported by doctors and the measures taken. Factors discouraging voluntary reporting of an adverse drug reaction were: the lack of information on where, when and how to report ADRs, the uncertain causality.*

Conclusion: *Currently, the pharmacovigilance activities including reporting of ADRs in Romania are more of an accidental nature, doctors are less or not at all informed about this activity. Doctors have a favorable attitude towards reporting ADRs – as the majority believes that the reporting should be either voluntary or mandatory as opposed to a small number that would expect to be paid for this activity.*

INTRODUCTION

The reporting of adverse drug reactions (ADRs) is a key component for ensuring the safety of the patients and the surveillance of the risk-benefit ratio of medicines during their life cycle. According to WHO definitions, an adverse drug reaction is "a response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function" and pharmacovigilance is "the science and activity relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine related problems" (1).

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Although ADRs are studied for many years, they have entered the worldwide public agenda only after the medical catastrophe of thalidomide, a drug that caused more than 10000 cases of phocomelia (2). As a response to this drama, today more than 130 countries have their national pharmacovigilance systems for reporting ADRs, all of them reporting the collected data to WHO Collaborating Center since 1978; this center, also called the Uppsala Monitoring Center, is part of the WHO Program for International Drug Monitoring, and Romania has joined the Program in 1974 (3).

A medicine's side effect is deemed as rare if its frequency of occurrence is less than 0.01% – or 1 in 10000. Unfortunately, such side effects often cannot be captured by the Phase I, II and III clinical studies, studies that include thousands of patients but rarely get to reach 10000. Such side effects can be captured only after the drug will enter the market and will be used by a large number of patients.

The main sources for investigating the occurrence of ADRs during post marketing surveillance are as follows: (i) spontaneous reporting systems, (ii) prospective cohort or case control studies, (iii) analyses of regional or national health insurance data, (iv) record linkage databases, and (v) registries (4). As the preregistration drug trials are able to demonstrate the efficacy and safety, in ideal conditions of treatment and selected groups of patients, identification of adverse reactions to drugs used in normal conditions is based mainly on "adverse reaction reporting system." The new ADRs detected through the surveillance systems are used to create hypotheses to be tested in subsequent studies (5).

The literature was reviewed for a number of factors affecting the spontaneous reporting or reacting system of ADRs. According to Inman, the so-called "sins" affecting the spontaneous reporting or reacting system are lack of financial incentives, uncertainty about the precise cause of adverse reactions, the belief that reporting an ADR would only be done if there was certainty that it was related to the use of a particular drug, the desire to publish the newly discovered adverse reaction, fear of legal disputes, indifference and belief that a simple signal coming from a physician will not make any difference, lack of time, and lack of information (6). We tried to find out how those "sins" are reflected among physicians in Romania.

In Romania, pharmacovigilance is regulated by Law 95/2006, and the National Pharmacovigilance Center is located in the National Agency for Medicines and Medical Devices (NAMMD). Unfortunately, pharmacovigilance activity seems to be far below the possibilities compared with other countries: as an example, in a report about the pharmacovigilance activity published on our competent authority's site, a number of 363 ADRs reported to NAMMD in 2009 are described (7). In our research, we tried to capture the perceptions of the usefulness of pharmacovigilance among family physicians compared with other specialty physicians in three neighboring areas from the south part of the country. ❑

METHODS

We designed a questionnaire with 20 items accompanied by a letter of presentation of the study. A pilot questionnaire was used on 25 physicians and readjusted after the investigated subject objections were analyzed. The questionnaire was completed in an anonymous manner. With the exception of five questions that allowed multiple choices, the questionnaire allowed only one answer per question.

The data were collected via Internet, by creating an online survey on the Bucharest College of Physicians website (only 8% of the valid questionnaires were completed this way) and also by face to face interview by means of the service of operators. The operators were all students of the Faculty of Medicine, "Titu Maiorescu" University, Bucharest, and the questionnaires were completed between October and December 2011. A total of 17% of the physicians interviewed face to face refused to complete the questionnaire despite their initial agreement to answer all the questions.

The questionnaire included questions regarding the following: physician demographics, specialty and place of work, average number of drugs prescribed daily, average number of suspected ADRs encountered daily, class of drugs that most often encounter adverse reactions, assessment of the category of side effects that should be reported, statement if they ever reported suspected adverse reactions or if they have ever received training in voluntary reporting of ADRs, opinion whether reporting ADRs must be done voluntarily, the type of drugs that should undergo reporting of adverse reactions,

who should report adverse reactions, what is the effectiveness of ADRs reporting and pharmacovigilance, the reasons which discourage ADR reporting, the factors that could help increase the number of reported ADRs, whether they know how to report an ADR, and if they know the benefits of reporting an ADRs (offered by the Romanian College of Physicians in its own continuous medical education system).

The data were presented as absolute values and percentages for categorical variables and analyzed using Excel with XLSTAT for chi-square tests; the observed significance level of the test was taken at 5% level or less. ❑

RESULTS

The questionnaire was completed by 532 health-care professionals from Oltenia and Muntenia regions of Romania and Bucharest. Of these, 118 (22.1%) were female subjects, and 414 (77.8%) were male subjects; 225 (42.3%) were younger than 40 years, 157 (29.5%) between 40 and 50 years old, and 150 (28.2%) older than 50 years. A number of 169 (31.77%) physicians were general practitioners (GPs), and 363 (68.23%) were specialists in other specialties (non-GP). Of all non-GP physicians, 133 (36.64%) work in hospitals and 230 (63.36%) in ambulatory offices; 359 (67.48%) of the investigated physicians work in Bucharest and 173 (32.52%) in two neighboring regions (Muntenia and Oltenia).

Response rates did not differ significantly between female (346; 65.04%) and male 186 (34.96%) physicians. ❑

REPORTING HISTORY

In terms of drug prescription behavior, we found significant statistical differences between physicians of specialties other than GP, which appear to use fewer drugs and GPs.

Most of the physicians stated that the daily number of ADRs observed is less than 5 (59.7% of GPs and 56.2% of other specialties), with no statistical differences between specialties; 234 (43.98%) of physicians did not differentiate between generic drugs and the recently licensed in terms of number of side effects, with no statistical difference observed between the various specialties examined (Table 1).

A large number of physicians, 388 (79.93%), admitted that in the last 5 years, they have not sent any report of ADRs (Table 2). A statistical difference has been revealed between the physicians who claimed to have reported an ADR and those who did not, in regard to their opinion on mandatory reporting ($p < 0.007$).

The number of responders who have sent a notification to a pharmaceutical company (84-15.79%) is higher than those who have sent a report to NAMMD (48-9.02%). When taking into account the age of the physicians, we have found significant statistical differences on reporting ADRs among physicians younger and older than 50 years.

The majority opinion of those interviewed is that OTC drugs require most often ADRs reporting. More physicians believe that they should have reported adverse reactions for generic drugs rather than the ones who believe that recent market entrants should receive special attention in this regard.

Most physicians appreciate that the main reason that discourages the reporting of ADRs is the lack of adequate information (Table 3). There were no statistically significant differences between GPs and physicians of other specialties in this regard, but statistical differences were found to exist between physicians younger than 50 years in comparison with those older than 50 years. Only 92 (17.29%) of the responders considered that the underreporting of ADRs is due to the lack of remuneration for this activity. These figures correlate with the percentage of people who believe that this activity must be rewarded - 63 (11.84%) (Table 4), whereas a larger number of respondents believed that reporting ADRs should be mandatory – 256 (49.81%).

The 63 responders who believed that reporting of ADRs should be optional and paid for, opted for different levels of payment, as follows: 13 (20.63%) for the equivalent payment for outpatient consultation; 3 (4.76%) for half the pay given to an outpatient appointment, one (1.59%) for a quarter in payment paid for outpatient consultation, 17 (26.98%) said they may not set a specific amount, and 29 (46.03%) opted for a fixed amount specified but limited to a monthly cap.

Of the 143 physicians (26.88%) who were reporting ADRs, 50 (34.98%) think that this activity should be done voluntarily, and 86 (60.14%) think that this activity should be mandatory; 7 physicians (4.9%) have not answered this question. When asked to indicate what factors would encourage voluntary reporting of

adverse reactions, most have opted for ease of reporting.

It is noteworthy that 309 (58%) of responders were never informed about ADRs reporting!

Most physicians 329 (61.84%) have found that ADRs must be reported by all pharmaceutical professionals, including nurses, although the practice contradicts this view! Approximately 376 (70.68%) of the physicians believe that the ADR reporting will reduce occurrence of ADR incidents. ❑

DISCUSSION

With the development of surveillance systems, it has become increasingly clear that ADRs are a true public health problem.

Number of medicines (counted by INN) prescribed daily by GPs and specialists other than general practitioners.	**Total (532) no (%)**	**GP (169) no (%)**	**non-GP (363) * no (%)**
1 to 10	195 (36.65)	41 (24.40)	152 (41.99)
11 to 20	118 (22.18)	29 (17.26)	89 (24.59)
21 to 30	62 (11.65)	23 (13.69)	39 (10.77)
31 to 40	57 (10.71)	22 (13.10)	35 (9.67)
41 to 50	26 (4.89)	17 (10.12)	9 (2.49)
above 50	74 (13.91)	36 (21.43)	38 (10.50)
Number of adverse reactions observed/ suspected daily.	**Total (532) no (%)**	**GP (169) no (%)**	**non-GP (363)** no (%)**
Between 1 and 5	305 (57.33)	101 (59.76)	204 (56.20)
Between 6 and 10	18 (3.38)	7 (4.14)	11 (3.03)
Between 11and 20	1 (0.19)	0 (0.00)	1 (0.28)
Between 21 and 30	0 (0.00)	0 (0.00)	0 (0.00)
I do not know, cannot specify.	208 (39.10)	61 (36.09)	147 (40.50)
Category of drug observed/suspected to be involved in an ADR	**Total (532) no (%)**	**GP (169) no (%)**	**non-GP (363) *** no (%)**
More frequent with original drugs or recently licensed	53 (9.96)	16 (9.47)	37 (10.19)
More frequent with generic drugs	121 (22.74)	36 (21.30)	85 (23.42)
Equal distributed for all drugs	234 (43.98)	86 (50.89)	148 (40.77)
Did not know to categorize	122 (22.93)	31 (18.34)	91 (25.07)
No answer	2 (0.38)	0 (0)	2 (0.55)
What kind of events related to a drug you think should be reported?	**Total (532) no (%)**	**GP (169) no (%)**	**non-GP (363) **** no (%)**
Only serious adverse reactions	275 (51.69)	75 (44.38)	200 (55.10)
Any side effects	308 (57.89)	103 (60.95)	205 (56.47)
Reactions to drugs occurring only in recently licensed drugs	32 (6.02)	13 (7.69)	19 (5.23)
Side effects – other than those already mentioned in the prospectus	218 (40.98)	69 (40.83)	149 (41.05)
Only side effects that occur repeatedly in most patients	89 (16.73)	30 (17.75)	59 (16.25)
Adverse reactions due to drug interactions	174 (32.71)	51 (30.18)	123 (33.88)
Lack of effect	101 (18.98)	35 (20.71)	66 (18.18)
Opinion on type of drug for which ADR reporting should take place (one or multiple choice):	**Total (532) no (%)**	**GP (169) no (%)**	**non-GP (363)***** no (%)**
OTC drugs	383 (71.99)	132 (78.11)	251 (69.15)
Prescription only medicines	340 (63.91)	117 (69.23)	223 (61.43)
Newly licensed medicines	212 (39.85)	70 (41.42)	142 (39.12)
Generic drugs	300 (56.39)	93 (55.03)	207 (57.02)
Blood and blood derivatives	243 (45.68)	81 (47.93)	162 (44.63)
Medical devices	216 (40.60)	68 (40.24)	148 (40.77)
Vaccines	350 (65.79)	121 (71.60)	229 (63.09)
Herbal medicines and food supplements	256 (48.12)	99 (58.58)	157 (43.25)

TABLE 1. Number of medicines prescribed daily, number of ADRs observed, and the category of drugs involved, events related to a drug you think should be reported, and opinion on type of drug for which ADR reporting should take place.

x2 = 38; df = 5; p < 0.0001; ** x2 = 2.15; df = 4 (one row excluded for null values); p = 0.541; ***x2 = 5.23; df = 3; p = 0.156; ****x2 = 5.10; df = 6; p = 0.53; *****x2 = 4.56; df = 7; p = 0.714

	Yes, I sent it to NMMDA	Yes, I sent it to pharmaceutical manufacturing company	Yes, I reported it in a magazine article	No, I haven't reported yet any	No response	Total	x2	p
GP	7 (4.14%)	24 (14.20%)	2 (1.18%)	136 (80.47%)	0 (0.00%)	169 (31.76%)	10.268	0.036
Non-GP	41 (11.29%)	60 (16.53%)	9 (2.48%)	252 (69.42%)	1 (0.28%)	363 (68.23%)		
Younger than 50 years	29 (7.59%)	51 (13.35%)	6 (1.57%)	295 (77.23%)	1 (0.26%)	382 (71.80%)	13.612	<0.009
Older than 50 years	19 (12.67%)	33 (22.00%)	5 (3.33%)	93 (62.00%)	0 (0.00%)	150 (28.19%)		
Total	48 (9.02%)	84 (15.79%)	11 (2.07%)	388 (72.93%)	1 (0.19%)	532 (100%)		

TABLE 2. Have you reported an ADR in the last 5 years? (comparison between physicians younger than 50 years or older).

However, according to estimates made in other studies, 5% to 6.7% of hospital admissions are due to ADRs, and approximately 3.7% percent of patients admitted for ADRs died (8-10). In Romania, the overall incidence of serious ADRs in hospitalized patients was reported at 4.7% (11).

The main objective of this study was to identify factors that influence spontaneous reporting of adverse reactions in Romania. Our study confirms that spontaneous reporting of ADRs, as part of pharmacovigilance, is very little known and used in Romania, as 72.93% of surveyed physicians admitted that they have never sent any report. In other European countries, the number of physicians who have not filed any report is much lower - for example, 38.7% in Germany (12).

In our study, we found no statistical significant differences between prescription patterns among health experts, most of the physicians affirming that they have captured at least 1 to 5 ADRs daily. From the total of 532 physicians, a total of 143 (26.88%) reported at least one adverse drug reaction in the last 5 years: 33 (19.52%) of 169 GPs and 110 (29.39%) of 363 non-GP physicians.

Analysis of attitudes on reporting adverse reactions

Physician's attitude toward ADRs reporting has been described as dependent on the professional attitude and the existing information about the reporting system (13). Our data confirms that opinion.

Professional attitude of physicians toward a reporting system

Evidence shows that Romanian physicians have a favorable attitude toward reporting, as 49.81% of them consider that this activity should be mandatory; 61.84% of physicians felt that all medical personnel should be entitled to file such reports, including nurses and pharmacists. However, Romanian legislation stipulates that the reports must be filed by physicians and by the marketing authorization

Answer	Younger than 50 years	Older than 50* years	Total n (%)
Absence of information on where, when, and how to report ADRs.	249 (65.18%)	82 (54.67%)	331 (62.22)
Uncertain causality	218 (57.07%)	52 (34.67%)	270 (50.75)
Difficulty in determining exactly which drug is responsible for the suspected adverse reaction;	172 (45.03%)	42 (28.00%)	214 (40.23)
Nobody have asked him/her expressly to report	134 (35.08%)	50 (33.33%)	184 (34.59)
Lack of time	114 (29.84%)	39 (26.00%)	153 (28.76)
Belief that his/her reporting of an ADR has no influence on the global use of a drug	73 (19.11%)	37 (24.67%)	110 (20.68)
Lack of pay for this activity	71 (18.59%)	21 (14.00%)	92 (17.29)
Fear of legal litigations	43 (11.26%)	2 (1.33%)	45 (8.46)
Too many side effects to be reported	36 (9.42%)	7 (4.67%)	43 (8.08)
Other	4 (1.05%)	1 (0.67%)	5 (0.94)

TABLE 3. Factors discouraging voluntary reporting of an adverse drug reaction (multiple choices).

*x2 = 23.332; df = 9, One-tailed p-value 0.005.

The usefulness of pharmacovigilance activities is to:	Total (532) no (%)	GP (169) no (%)	Non-GP (363)* no (%)
Measure the incidence of adverse effects;	313 (58.83)	94 (55.62)	219 (60.33)
Identify diseases for which the most commonly prescribed is a particular drug;	75 (14.10)	17 (10.06)	58 (15.98)
Identify factors that predispose to the occurrence of reactions (e.g., dose, age);	303 (56.95)	99 (58.58)	204 (56.20)
Identify new, unknown, rare, or bizarre adverse drug reactions;	328 (61.65)	91 (53.85)	237 (65.29)
Allow comparison of ADRs in the same therapeutic class;	199 (37.41)	56 (33.14)	143 (39.39)
Reduce the incidents occurring because of adverse drug reactions	376 (70.68)	121 (71.60)	255 (70.25)
Factors that might encourage voluntary reporting of adverse reactions (one or multiple choices)	**Total (532) no (%)**	**GP (169) no (%)**	**non-GP (363)** no (%)**
For each report feedback provided from NAMMD and/or marketing authorization holder;	201 (37.78)	69 (40.83)	132 (36.36)
Periodic inform physician about all adverse reactions reported and the measures taken;	321 (60.34)	114 (67.46)	207 (57.02)
Ease of reporting (e.g., online reporting);	364 (68.42)	110 (65.09)	254 (69.97)
Periodic training of medical staff on reporting utility	256 (48.12)	66 (39.05)	190 (52.34)
Monthly discussion of rare ADRs received by NMMDA.	124 (23.31)	37 (21.89)	87 (23.97)
Opinion about ADRs reporting:	Total (532) no (%)	GP (169) no (%)	non-GP (363)*** no (%)
Should be mandatory;	265 (49.81)	77 (45.56)	188 (51.79)
Should be voluntarily;	168 (31.58)	60 (35.50)	108 (29.75)
Should be optional and paid;	63 (11.84)	24 (14.20)	39 (10.74)
I do not know	25 (4.70)	6 (3.55)	19 (5.23)
No answer	6 (1.13)	1 (0.59)	5 (1.38)
Is useless;	5 (0.94)	1 (0.59)	4 (1.10)

TABLE 4. Views with respect to pharmacovigilance, ADRs reporting, and factors that could improve ADRs reporting (one or multiple choices).

x2 = 4.93; df = 5; p = 0.425; ** x2 = 7,46; df = 4; p = 0.114; *** x2 = 4,92; df = 5; p = 0.426

holder (MAH); the former also can receive complaints from all medical personnel.

The main beneficiaries of the ADRs reports were MAHs and not the designated legal authority. It is likely that the medical representatives encourage physicians to notify the MAHs about the adverse reactions related to the product they promote. However, manufacturer's efforts did not cause an increase in the general awareness related to the usefulness of reporting adverse drug reactions.

In other European countries, the main cause of underreporting was attributed to the lack of time and work overload (14). Our study indicates "lack of time" to be only the fifth cause of underreporting (28.76%).

We found that physicians are more worried and interested about finding an explanation for the ADRs suspected, as 214 (40.23%) reported the difficulty in determining exactly which drug is responsible to an suspected adverse reaction as the factor that impedes reporting.

Lack of information

Only 22.56% of physicians were informed about ADRs reporting. This rate is alarmingly low, but the data obtained in studies conducted in other countries are approximately on a same level (15). Approximately 33.57% of the physicians who reported an ADR said that they have never been officially informed about the existence of a national reporting system. The Romanian College of Physicians attempted to promote the national reporting system, including it in the continuous medical education program. Its effort was not successful; only 93 (17.48%) physicians knew about this initiative (Table 5).

A survey of the reasons that influence voluntary reporting of ADRs in Romania was made

Awareness on the 10 CME points offered by the Romanian College of Physicians for each ADR reported	Total (532) no (%)	GP (169) no (%)	Non-GP (363)* no (%)
Yes, but I haven't benefited because I hadn't reported any	31 (5.83)	8 (4.73)	23 (6.34)
Yes, but I received no points for that I didn't needed,	15 (2.82)	6 (3.55)	9 (2.48)
Yes, and I have been awarded points for Romanian College of Physicians	13 (2.44)	5 (2.96)	8 (2.20)
Did not know about the scoring system	439 (82.52)	137 (81.07)	302 (83.20)
Do not care.	34 (6.39)	13 (7.69)	21 (5.79)
Time elapsed from receiving Information/training on reporting voluntary ADRs:	Total (532) no (%)	GP (169)	
no (%)	Non-GP (363)**		
no (%)			
A month ago	64 (12.03)	21 (12.43)	43 (11.85)
A quarter ago	40 (7.52)	18 (10.65)	22 (6.06)
A year ago	58 (10.90)	18 (10.65)	40 (11.02)
3 years ago	59 (11.09)	14 (8.28)	45 (12.40)
I was never informed about this activity	309 (58.08)	98 (57.99)	211 (58.13)
No answer	2 (0.38)	0 (0.00)	2 (0.55)

TABLE 5. Awareness on the national system of ADR reporting.

x2 = 1.97 ; df = 4; p = 0.742; ** x2 = 5.02; df = 4; p = 0.285.

by Farcas et al in 2008, but their attention was limited to hospitals and physicians from a single city – Cluj (University hospital). Our data are largely similar to theirs, which show that in Cluj, 68% of physicians were not familiar with this system (11,16).

Physicians younger than 50 years are more open to use the reporting system. One explanation for this observation is that until 1989, the pharmacovigilance newsletter was edited in Romania on a quarterly basis, and since then, its appearance was interrupted.

A lack of accurate information on adverse reactions results from the second indicated cause of underreporting, namely, "the lack of certainty of causality between the reaction and the drug that produced it", 270 of the physicians (50.75%) consider that it is difficult to discover a cause-effect relationship when multiple drugs are administrated to the patient. The spontaneous reporting system was created to facilitate analysis and remove uncertainty regarding ADRs. Based on these reports, the manufacturer has to issue variations of the initial prospectus/summary of product characteristics resulted from Phase III studies or to conduct new studies focused on the detected reaction.

Physicians in Romania display a strong confidence toward innovative drugs, pointing them out as the drugs, which need the least reporting of ADRs. Paradoxically, Romanian physicians believe that the most frequent ADR reporting should be focused on OTC drugs, although these drugs have gained their status precisely because of the lack of dangerous side effects and also because of the long term they have been in use.

Too few physicians believe that unexpected ADRs originate from new medicines (9.96%), whereas 22.74% consider that generic medicines should be the main target of ADRs reporting; thus, the lack of information regarding ADRs is proved once more. This opinion is surprising as any generic drug is in medical practice for 10 years at least, time long enough for most adverse reactions to be already identified.

Situations where drugs are withdrawn from the market as a result of an unexpected ADR, which have occurred long time after the administration, are very rare but possible; such an example could be troglitazone withdrawn from market in March 2000 because of severe cases of liver toxicity/liver failure and for which the underreporting of the acute liver failure cases was considered as extensive (17). In an analysis performed on the reports submitted to FDA between 1969 and 2002, the most frequent ADR was identified as "drug ineffectiveness" (18). In our opinion, the main solution to remove the lack of trust in the efficacy of generic drugs is to increase reports of inefficiency and to inform the physicians on the number of such cases, especially on the result of the analysis and actions taken.

What can be done to improve the reporting system:

Most physicians have identified online reporting as the main method of improving reporting. Although physicians in other countries have indicated bureaucratic difficulties as a barrier to reporting (19), for physicians in Romania, this barrier is only a misconception. However, NAMMD has published a reporting form on their Web site, and this is not an online form. A significant number of physicians periodically identified staff information on adverse events (60.34%) and periodic training on reporting (48.12%) as the solution for improving ADRs reporting. Most physicians are interested in reporting and ask for feedback on actions taken as a result of their reporting; also, they would like to meet and discuss about ADRs with representatives from NAMMD on a monthly basis. ❑

CONCLUSIONS

Currently, pharmacovigilance activities and reporting of ADRs in Romania are more of an accidental nature, physicians being less or not at all informed about this activity. In our country, the current rate of reporting is a result of the obligations imposed by law and also of the education received in the past by physicians older than 50 years, which seemed apparently better informed.

Given our findings, we believe that there is a long jam of communication. Physicians have a favorable attitude toward reporting ADRs – as the majority believes that reporting should be either voluntary or mandatory as opposed to a small number that would expect to be paid for this activity. Even more, one of the main incentives of increasing reporting activity is considered to be getting feedback on the reports submitted and permanent information. We do support the current provisions of the law that encourage physicians to report ADRs but not in a mandatory manner (because pharmacovigilance is not the science of punitive actions but a science that rewards the efforts made to identify ADRs with saved lives), and based on the results of our study, we believe that the authorities could improve the effectiveness of the pharmacovigilance activities by including the pharmacovigilance in the curriculum of training for resident physicians, rewarding the activity of reporting serious adverse drug reactions but with a higher number of continuous medical education points, and developing programs devoted to the subject. If we take into account the very low cost of such simple measures and we compare it with the cost paid for treating patients with ADRs, we can get a picture about the attention that must be given to the ADRs system and we again understand why pharmacovigilance represents not only a concern but also a responsibility of all health-care professionals and patients. ❑

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