

# The safe use of drugs on the example of qualitative analysis of opinions of Internet users about drugs containing the recalled valsartan - an exploratory study

DOI:10.7365/JHPOR.2020.1.1

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## Keywords:

*Internet; Valsartan; Falsified drugs;  
Falsified Medicines Directive; Internet forum*

#### How to cite this article?

Świeczkowski D., Merks P., Jaguszewski M., *The safe use of drugs on the example of qualitative analysis of opinions of Internet users about drugs containing the recalled valsartan - an exploratory study*. 2020 [cited YYYY Mon DD];2. Available from: <https://jhpore.com/article/2236-the-safe-use-of-drugs-on-the-example-of-qualitative-analysis-of-opinions-of-internet-users-about-drugs-containing-the-recalled-valsartan--an-exploratory-study> DOI: 10.7365/JHPOR.2020.1.1

contributed: 2020-01-11 final review: 2020-03-23

published: 2020-05-09

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## Abstract

### Background

The recall of medicines from the pharmaceutical market is one of the most important responsibilities for pharmacists working in community pharmacies ensuring that patients receive medicines of the highest quality and safety. The aim of the study was to evaluate how Internet users in Poland perceived recall of valsartan. The study was conducted as a qualitative analysis of opinions posted on Internet forums. The study is an exploratory in its nature.

### Methods

The study was conducted as a qualitative analysis of opinions posted on Internet forums. Thematic analysis was used and the data was coded to generate codes and categories, and subsequently to identify patterns between above-mentioned elements. The initial categories were organized and aggregated in themes. Posts were coded until theoretical saturation was achieved. All selected Internet forums were dedicated to laypeople and professionally-oriented platforms were excluded from our investigation. Moreover, to achieve full anonymity, we do not provide any additional details about investigated platforms, e.g. website name.

### Results

Three themes were identified:

- i) impact of falsified medicines on the health status (abbreviated as 'health status'),
- ii) responsibility of the pharmaceutical industry and government agencies ('responsibility'),
- iii) legal issues, e.g. consequences and repercussions of introducing poor-quality medicines into routine clinical usage ('legal issues'). In general, posts were highly emotional. Health and responsibility were motives mostly highlighted in posts.

## Conclusions

Recall of medicines from the market has been widely described on the Internet forums. Patients expressed doubts about the impact of recalled medicines on health, raised the issue of the responsibility of persons and institutions involved in pharmaceutical distribution, and finally mentioned legal repercussions of undesirable actions on the pharmaceutical market. Further, more representative studies are warranted.

## Introduction

The recall of medicines from the pharmaceutical market is one of the most important responsibilities for pharmacists working in community pharmacies ensuring that patients receive medicines of the highest quality and safety, and unwanted medicines are eliminated from pharmaceutical distribution in a reasonable time.<sup>[1]</sup> Patients should be convinced that they use medicines produced aligned with well-accepted standards. On the other hand, the recall of medicines, particularly when it concerns a significant part of stock available on the market and is conducted urgently, may affect patients' trust for treatment, physicians and pharmacists. Community pharmacy is the place in the chain of pharmaceutical distribution, which is the most crucial in the recall of medicines, at least from the patients' perspective.<sup>[2]</sup> Due to the fact that patients have unrestricted access to pharmacists, in many cases, pharmacists are the first health care providers who need to answer to patients' fears.

Valsartan, angiotensin II receptor antagonist widely used for the treatment of high blood pressure and heart failure, has been commonly used among Polish patients diagnosed with cardiovascular diseases. Since July 2018, the vast majority of brand products has been recalled from the Polish market due to contaminated ingredients, mostly produced in China.<sup>[3]</sup> This situation was widely discussed in nationwide media.<sup>[4,5,6]</sup> Medicines containing valsartan have been recalled not only from the Polish market, but also from the United Kingdom, and from the United States of America and was confirmed by an official statement issued by the European Medicines Agency.<sup>[7,8,9]</sup>

Despite the fact that patients have access to valsartan provided by other producers under varied brand names, this recall might have affected patients' attitude to pharmacotherapy, subsequently leading to lower adherence. With the advent of new technology, patients can share their opinions and feelings on the Internet extensively. Although opinions posted on the Internet belong to this part of society which is able to use new media actively, we cannot underestimate the Internet as a valuable source of information about patients' feelings in general.<sup>[10,11]</sup>

Considering that patients' belief might affect adherence to recommended therapies, Internet forums contain useful information, which scientists and healthcare providers can use to design more effective interventions aimed at improving adherence. From a scientific perspective, studies based on opinions expressed by Internet users have been more and more frequently conducted recently. In the light of above-mentioned issues, the aim of this study was to evaluate how Internet users in Poland perceived recall of valsartan. The study was conducted as a qualitative analysis of opinions posted on Internet forums. The study is an exploratory in its nature.

## Materials and methods

Since in social studies data used in qualitative research can be defined in various ways, and include a relatively broad spectrum of data, to fulfill the aim of this study, and to adopt a proper methodological approach, we classified posts posted in the Internet forums as a primary unit of investigation. We believe that these kinds of 'documents' can tell us insightful information about social setting and reflects the way in which people perceive a particular problem, in this case, the drug recall from the market. We decided to use a thematic analysis as a method which reduces the amount of data in a systematic and flexible way and is mostly focused on the description of the content, rather than generating new theories or concepts. The researchers investigated forums to find rich cases providing new insights and widen researchers' perspectives on the aim of the study. Only posts that were classified as 'rich' were copied and analyzed. At the initial stage, extracted posts (60 posts) were coded in order to generate codes and categories, and subsequently to identify patterns between the above-mentioned elements. In order to generate codes and categories correctly and immerse deeply in collected materials, our search was based on the 'semantically meaningful units', predominantly words, phrases, and sentences underlying the aim of our study. Moreover, we analyzed almost solely contextual context. Textual (linguistics) context is highlighted only if it is necessary to understand more nuanced messages. The initial categories were organized and aggregated in themes. Codes and categories were identified separately by the members of the research team (DŚ, PM) and discussed collectively until consensus regarding themes was achieved. A constant comparison approach was used during the whole procedure. As it is widely used in a qualitative study, we collected posts until new categories were not generated (theoretical saturation).<sup>[12,13]</sup> Categorization was immersed in an inductive approach and we based purely on topics revealed from analyzed material. To maintain high ethical standards, we decided to collect posts only from Internet forums which are accessible without obligatory registration, both from users' and

readers' perspective. Taking into consideration current ethical standards in social media research, forums unprotected by passwords with the possibility of open discussion, should be considered as public Internet space. Since the matter of our study was not sensitive and we provided an English translation of originally Polish pieces of texts, fragments were left untouched without paraphrasing.<sup>[14]</sup> All selected Internet forums were dedicated to laypeople, and professionally-oriented platforms were excluded from our investigation, a primary exclusion criterion. Internet forums were selected after an initial screening based on the Google search engine; moreover, the research team agreed to include in the final analysis all initially selected platforms. In summary, we analyzed five Internet forums. The data was extracted in the first two weeks of May 2019. Several combinations of search terms were used; although, valsartan recall should be considered as the most important one (including various brand names instead of the general term). Moreover, to achieve full anonymity, we did not provide any additional details about investigated platforms, e.g. website name. The extracts were provided without users' login; moreover, due to the fact that the lexical form of verbs in the Polish language makes it possible to distinguish gender, in order to achieve full anonymity we decided to unify the gender and not to distinguish it in the translations into English. To describe our findings, we decided to use the term 'patient' not 'respondent' or 'participant' in order to emphasize the clinical significance and to emphasize humanistic approach so important in qualitative inquiries. When necessary, the vulgarisms and obscene expressions were removed from the extracts. All trade names and producers were deleted from extracts. Extracts were translated by a bilingual person, American Native Speaker (L1 English, L2 Polish), with medical background and both clinical and scientific experience. The study used the term recall/recalled, the strictly correct term, describing recall based on temporary safety, which can be contrasted with the full withdrawal, as in the case of Rofecoxib withdrawn from the market due to serious cardiovascular adverse events.<sup>[15]</sup>

## Results

In general, posts were highly emotional. Patients had a lot of doubts about further treatment, quality of care, and further pharmacotherapy. Some posts highlighted a lack of drug quality, both from the perspective of insufficient legal regulations ensuring the suitable quality of medicines, as well as standards used during manufacturing and proper supervision provided by external institutions, e.g. pharmaceutical supervision guaranteed by an authorized national agency. Three themes were identified: i) impact of falsified medicines on the health status (abbreviated as 'health status'),

ii) responsibility of the pharmaceutical industry and government agencies ('responsibility'),  
iii) legal issues, e.g. consequences and repercussions of introducing poor quality medicines into routine clinical usage ('legal issues'). Health and responsibility were motives mostly highlighted in posts. In [Table 1](#), we attached appropriate extracts from data.

Patients emphasized the relationship between long-term use of falsified medicines with potential health-related consequences. In some posts, we can find information about a different class of medicines, e.g. statins. Patients connected recall of medicines containing valsartan with the overall lack of evidence-based recommendations regarding pharmacotherapy. In patients' opinion, recall leads to decrease in confidence, even substantial erosion of trust, particularly for 'big pharma', the synonym widely used to describe not only the pharmaceutical industry, but also a connection between pharmaceutical manufacturers and government, or in wider perspective authorities involved in the drug supervision. However, some patients were more neutral in their opinions. They suggested that there was no detailed information about the reason for recall, even more; there was no established relationship between taking 'falsified' medicines and health-related consequences. What is interesting and may have further scientific and educational consequences, patients linked almost automatically recall of medicines from the market with falsified medicines, which is not correct according to the current legal framework existing in European Union. The recall of medicines due to the lack of quality and incompatibilities between legal portfolio and production was associated with the recall of medicines because of the potential risk of falsification, i.e. introducing to the market illegal medicines of unknown origin. Moreover, patients considered generic substitution as one of the reasons for drug recall. The results are summarized in [Table 1, extracts from 1 to 7](#).

The second theme identified during our investigation is associated with the potential liability of the pharmaceutical industry. Both themes 'health status' and 'responsibility' are interconnected. For some patients, the consequence of taking poor quality medicines may lead to the development of cancer. The legal liability, however, is not only limited to the pharmaceutical industry, which is not clearly described by patients, but should be addressed by individual accountability of persons directly involved in the control of drug quality, or those who are responsible for lawmaking. The relationship between taking recalled medicines and occurrence of serious clinical condition, e.g. cancer is noticed in analyzed material, frequently in terms of the credibility of the pharmaceutical industry. Finally, some patients indicated that community pharmacy is the place where recalled medicines should be returned, and financial compensation should be distributed among

patients, at least refund of medicines value. Pharmacists were considered as health care providers who should answer this need ([Table 1, extracts from 8 to 12](#)).

Finally, legal issues were one of the most important themes in analyzed data. Patients indicated that a lawsuit against pharmaceutical companies should be considered as a justified legal action in order to protect own rights, but also the rights of all patients who need to be sure that medicines used on the market are safe. Moreover, the bureaucracy was considered as a reason for the necessity of introducing medicines obtained manufactured outside Poland borders, in this case from China. In conclusion, in the patients' opinion, red tape impeded innovation in Poland. Once more time, the use of statins was expressly invoked by patients as an example of abuse against patients due to the 'big pharma' manipulation ([Table 1, extracts from 13 to 16](#)).

As it was mentioned before, identified themes are interconnected, and boundaries between them are sometimes slightly vague, as it may happen in studies immersed in a qualitative approach. Undoubtedly, fear of the negative effects of medicines on health is connected with a willingness to take more formal legal actions; this need was highly anticipated in analyzed material and even in one case patients informed about a real lawsuit against the pharmaceutical industry. It might seem that the common denominator is a willingness or, more precisely speaking, a deep need for searching people or institutions responsible for introducing medicines of questionable quality into routine clinical settings.

## Discussion

Our study revealed that massive recall of medicines containing valsartan from Polish market has been noticed by Internet users and is associated with substantial fear and doubts regarding further treatment and quality of medicines. The study is only exploratory in its nature and immersed in a qualitative approach, findings could be considered as a starting point for further research. Apart from building a more substantiated theoretical background, the study can lead to more practical implications. We can assume that massive drug recall should be accompanied by nationwide campaigns aimed at increasing public awareness about the potential consequences of unexpected actions on the pharmaceutical market. Whereas drawing up the range of educational campaigns is beyond the scope of this paper, we should, at least briefly, highlight that community pharmacies should be considered as the most suitable place for this kind of actions. Furthermore, among other roles of pharmaceutical care, education has been widely noticed as one of the most useful from patients' perspective due to unrestricted access to pharmacists in the vast majority of well-developed countries.<sup>[16]</sup>

The study revealed substantial lack of patients' trust not only in health care providers but also in the basis of clinical care – the efficacy and safety of medicines supported by evidence from clinical trials and post-marketing observation. Halepian et al confirmed that trust in physicians among patients diagnosed with diabetes influenced adherence to insulin regimen; patients who trusted physicians had a lower level of distress and a higher level of adherence score based on results obtained from the questionnaire Problem Areas in Diabetes Questionnaire (PAID).<sup>[17]</sup> Similar findings were observed in a study conducted by Linetzky et al who noticed that not only trust in physicians but the overall quality of the relationship between physicians and patients, particularly physicians' commitment, had significantly affected adherence and achieved outcomes, e.g. glycemic control.<sup>[18]</sup> Numerous studies are consistent with this observation, not only among diabetic patients but also among other chronically ill patients.<sup>[19,20,21]</sup> Slightly different findings were observed in the study conducted among HIV-positive patients. Though a lack of patients' trust was not associated with better outcomes, patients with a more positive attitude to health care team had been longer under specialized HIV care.<sup>[22]</sup> Further studies are needed to confirm the relationship between patients' trust and adherence. Our study, however, might be considered as a helpful voice in the current discussion.

Careful analysis of Internet forums can have substantial clinical implications. The analysis of posts published by sunbed users led to a more serious attitude towards critical comments from followers of extensive sunbathing and changed the directions of discussions among those who are involved in promoting pro-healthy life habits.<sup>[23]</sup> Some patients considered Internet forums as an important source of information about the disease and the place where those living with the disease can share experience in an anonymous way.<sup>[24]</sup> To some extent, we can also assume that Internet forums are the contemporary ways of exploring own dissatisfaction and distress.<sup>[25]</sup> In this case, we observed that patient were eager to share opinions on the legal consequences of unexpected drug recall, and poor quality of disseminated medicines.

Some study limitations should be briefly highlighted. As it was mentioned before, opinion expressed on the Internet forum might not be representative to the whole generation. Still, an important part of the population does not have access to the Internet and is not willing to share their opinions publicly. However, due to the fact that the study is exploratory, furthermore representative studies are needed in order to achieve higher generalization. Moreover, the study is immersed in a qualitative approach; thus, the primary aim of the study is not to collect a large sample of data, rather to collect rich data supported by 'thick' description. The aim of a qualitative

study is to generate a hypothesis, not to test pre-defined assumptions. Finally, some aspects of the methodology applied in our study are consistent with techniques typical for grounded theory, e.g. theoretical saturation. However, it is worth remembering that some features of grounded theory are used in different qualitative techniques, as in this case. In addition, comments were translated from Polish into English, which might be associated with some discrepancies, probably in the semantic context. We tried to achieve the highest possible quality of translation, which was conducted by bilingual American Native Speaker (L1 English, L2 Polish), who has lived a substantial amount of time in both cultures. Moreover, all authors of the current article are proficient non-native English speaker with clinical and scientific experience.

## Conclusions

Recall of medicines from the market has been widely described on the Internet forums. Patients expressed doubts about the impact of recalled medicines on health, raised the issue of the responsibility of persons and institutions involved in pharmaceutical distribution, and finally mentioned legal repercussions of undesirable actions on the pharmaceutical market. Further, more representative studies are warranted.

**CONFLICTS OF INTEREST** None.

**FUNDING** This study did not receive any funding.

### LIST of ABBREVIATIONS

HIV - Human Immunodeficiency Virus

PAID - Problem Areas in Diabetes Questionnaire

UK – United Kingdom

USA – United States of America

Table 1. Identified themes and extracts from data.

Theme	Nr	Extracts
Health status	1	I always felt bad after taking valsartan, but the informational leaflet insisted that it was a good medication. I have 3 cancers - in my reproductive organs, breasts and bone. I also used statins from X Company, also carcinogenic, they kept insisting cholesterol needs to be gotten rid of, while they made good money off of us.
	2	No risk to the patient, but since the results were out of proper metrics, now the product is disqualified. At the moment, there is no reason to worry, especially since the medications have put on hold from being sold and were not immediately recalled from the market.
	3	I've been using these medications for about 6 years. What now? Do you even know what you can actually take? It's a scandal!
	4	I have already used up two packets from the recalled series and I am still alive, so what - I should stop taking them now?
	5	As long as they are only stopped, not recalled, we do not know what is going on and how it happened. There is no reason to make a fuss. For 4 years, nothing happened, they were checked on a regular basis, now some faulty delivery of raw material happened, what can we do about it... it happens.
	6	I bought this terrible series of medication for my whole vacation time. At the pharmacy, they said not to take it and to go get a new prescription and now I am 500 kilometers from my family doctor because I went away for the summer. I will be treating myself with herbal remedies, which cannot hurt me.
	7	All patients who took medications with valsartan, I mean these cheap substitutes (proposed in pharmacies) should go for oncological consultations. Especially the stomach, the liver. Pharmacies must exchange the medicine for free, but people, be sure they are changing it for the original medication and not a fake, because this is how it ends later.
Responsibility	8	I have been taking this medication for many years. We are experimental rats. They're producing these medications for big money. Doctors are prescribing them to us, because they also get money from this. Only us - the patients, are the victims. Who will refund us for the medications purchased? Who will check the side effects of these Chinese drugs... While we believe in them and take them.
	9	I have a case with Company X for poisoning me with cholesterol-lowering drugs. I have had oncological surgeries. Scientists write that artificial cholesterol lowering is life-threatening, and now it has happened to me. Now, even high blood pressure drugs are carcinogenic.
	10	Absolutely, in each pharmacy there should be refunds of contaminated medications and a monetary refund. It's a disgrace that such a rich pharmaceutical industry is able to make such dirty tricks. Only money matters, not our health.
	11	I took drugs recalled from circulation for the past four years and now what? Who should I blame???? And what about those people who have already taken this for over two years, I mean, they basically poisoned them.
	12	It's a scandal. I took medicine X for several years. No one from GIF controls what is in these drugs? What ingredients, where they come from? And what? The matter is quiet, and the pharmaceutical concerns, what about them? And for us, patients? You can't return the medicine to the pharmacy, I asked today.
Legal issues	13	Patients should file charges in a group and not return the medications so that there will be samples for analysis without any coverup. Pharmaceutical companies are fattened up to the limits, they have money to pay for it [settlements].
	14	And why have all these regulations, when it ends up with such cases anyway? After all, it's this excess of bureaucracy that leads to the fact that companies prefer to import from China. Europe does not produce anything of value because there are too many restrictions here.
	15	Poles, start filing court cases for damages. I'm appealing also to those, who had their cholesterol lowered [with drugs], this is a crime. Cholesterol can not be killed, and statins according to Scientists should not be allowed as drugs at all, they are also a poison, but pharma schemers have now come up with the idea that statins will fight cancer.
	16	Compensation, for taking poison, I thought I was curing myself, and I have been poisoning myself for 4 years with this medication, we should file a collective lawsuit.

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