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Research Article

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Assessing the knowledge and practice of the Irish Community Pharmacists in reporting Adverse Drug Reactions and Falsified Medicines

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Abstract

Background: Pharmacovigilance is a critical aspect of healthcare, enabling the monitoring of adverse drug reactions (ADRs), eradication of falsified medicines (FMs), identification of medication errors, monitoring off-license drug use, addressing abuse and misuse, assessing lack of efficacy, tracking poisoning incidents, managing drug-drug/food interactions, ensuring the destruction of expired stock, and evaluating drug-related mortality. It is essential for healthcare professionals to be aware of their role in Pharmacovigilance.

Objective: This study aims to assess the current knowledge and reporting practices of ADRs and FMs among community pharmacists in Ireland, focusing on two important components of Pharmacovigilance.

Method: The research employed a cross-sectional, observational design, utilizing an online questionnaire survey to gain insights into the pharmacists' knowledge and practices related to Pharmacovigilance programs, ADR reporting, FMs, and their opinions on their role in these areas.

Results: The study found that Irish colleges and universities played a significant role in providing Pharmacovigilance education to pharmacy students. The majority of pharmacists demonstrated a good understanding of Pharmacovigilance, but only a third of them were aware of Irish legislation in this regard. Additionally, only 20.23% of pharmacists believed that Irish patients were aware of ADR reporting, although 92.49% were familiar with the Health Products Regulatory Authority's (HPRA) ADR reporting system. The findings suggest the need for pharmacists to educate their patients about ADR reporting, while recognizing the convenience of the HPRA reporting system.

Conclusion: Overall, the study revealed that most community pharmacists possess a solid understanding of the fundamental aspects of Pharmacovigilance, including ADRs and FMs. However, there are areas for improvement, such as raising awareness among patients about ADR reporting. The findings highlight the importance of continuous education and communication to enhance Pharmacovigilance practices among community pharmacists in Ireland.

Keywords: Community Pharmacists, Pharmacovigilance, Falsified Medicines, Ireland, Health Products Regulatory Authority (HPRA), Adverse Drug Reactions

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1. Introduction

Pharmacovigilance is a critical component of the healthcare industry, defined by the World Health Organization (WHO) as "The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems". (1) The scope of Pharmacovigilance extends beyond just detecting and reporting adverse drug reactions (ADRs) to include other drug-related issues such as medication errors, substandard and counterfeit medicines also called falsified medicines (FMs), low drug efficacy, drug abuse, and drug-drug interactions. Nevertheless, the primary focus of Pharmacovigilance remains the detection and reporting of ADRs. (2,3) This area is of paramount importance, as ADRs have been identified as a leading cause of morbidity and mortality, with approximately 5% of hospital admissions in Europe attributed to ADRs. (4)

Another critical issue in the healthcare industry is the proliferation of FMs. These are counterfeit medicines that deliberately misrepresent their identity, composition, or source, and are marketed as genuine, authorized medicines. (5) FMs pose a grave threat to public health and have become a global issue, making

Pharmacovigilance even more critical. (6) This research article delves into the vital aspects of Pharmacovigilance, with a particular focus on the detection and reporting of ADRs and the problem of FMs. By exploring these issues in-depth, the article seeks to increase awareness of the importance of Pharmacovigilance in ensuring the safety of medicines and protecting public health. (7-9)

2. Pharmacovigilance

2.1 Pharmacovigilance programme in Ireland

The European Union (EU) law mandates that each marketing authorization holder (MAH), national competent authority (NCA), and the European Medicines Agency (EMA) implement a Pharmacovigilance programme. (10) In the EU, Pharmacovigilance is a collaborative effort among the EU Member States, EMA, and the European Commission (EC). The collection, assessment, and monitoring of all ADRs are carried out by the NCA of the member state where the ADR was observed, as per this law. (11)

The Health Products Regulatory Authority (HPRA) is the NCA responsible for Pharmacovigilance operations in Ireland. (12) It is responsible for monitoring drug safety, including operation of the national ADR reporting system, and identifying signals for possible new ADRs to detect changes in the risk-benefit balance. (13) ADR monitoring, in collaboration with EU Pharmacovigilance partners, enables the HPRA to search for new forms of reactions or improvements in reporting patterns. The HPRA also plays a pivotal role in monitoring drug safety in the Irish market through vigilance evaluation and risk management activities. It contributes to the research of the EMA's Pharmacovigilance Risk Assessment Committee (PRAC). (14)

The below graph displays, the total number of ADRs reported to the HPRA by various stakeholders in Ireland (14-21):

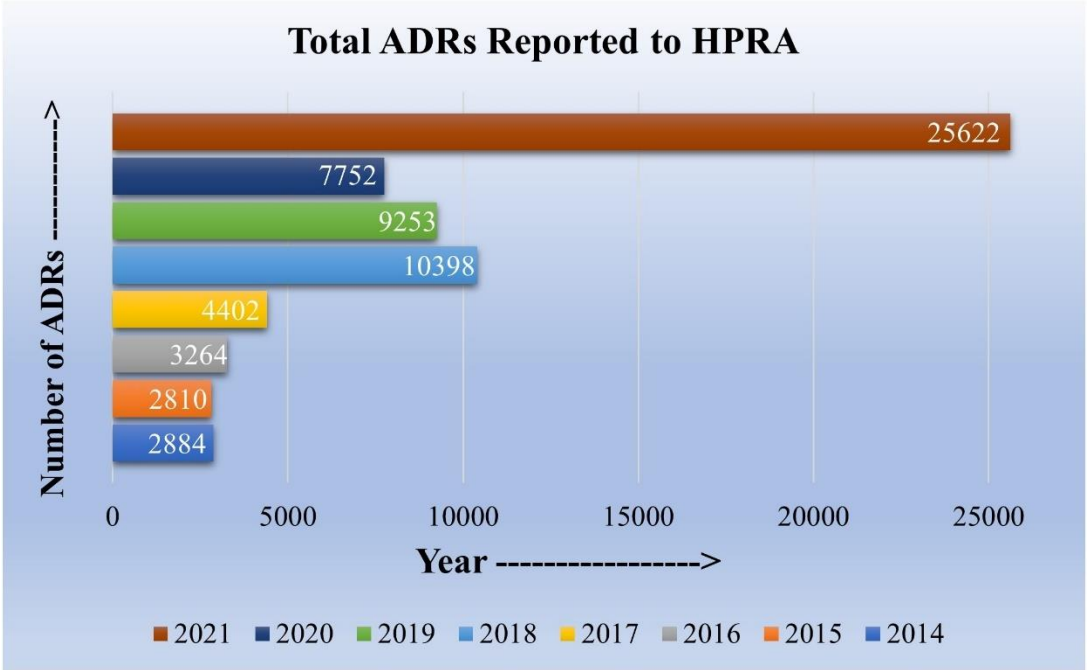

Figure 1. Total ADRs Reported to the HPRA

2.2 Legislation governing Pharmacovigilance in the EU and Ireland

In the EU, Pharmacovigilance follows Directive 2001/83/EC and Regulation (EC) No. 726/2004, with 2010 amendments (Directive 2010/84/EU, Regulation (EU) No. 1235/2010) enhancing ADR reporting and EudraVigilance. (10, 11) EudraVigilance enables MAHs to continuously monitor ADRs since 2017. (22,23) Ireland adopted this framework in 2012, integrating it into Irish law (24), encompassing regulations such as S.I. No. 272/2012, S.I. No. 273/2012, and S.I. No. 274/2012. (25)

2.3 Methods of Spontaneous Reporting of Adverse Drug Reactions (ADRs) in Ireland

The EMA recommends that ADRs should be reported to the NCA of the respective EU member state. In Ireland, ADRs can be reported through the following methods, as advised by the HPRA (26):

- Patients can inform their healthcare professionals about any suspected ADRs, who in turn will report it to the HPRA.
- Patients or their representatives, as well as healthcare professionals, can fill an online Adverse Reaction Report Form for Human Medicines available on the HPRA website. A downloadable copy of the form is also available, which can be completed manually and sent to the HPRA by email on medsafety@hpra.ie or via freepost.
- Alternatively, the ADR can be reported by calling the HPRA on +353 (01) 676 4971.

By reporting ADRs, patients and healthcare professionals play a crucial role in helping to ensure the safety of medicines in Ireland.

3. Falsified Medicines

3.1 Major concerns of Falsified Medicines in the EU and Ireland

Falsified medicines (FMs) pose a major concern in the EU and Ireland due to the potential harm they can cause to patients. According to the WHO, since 2013, there have been over 1500 reports of substandard or falsified products globally, with anti-malarial and antibiotics drugs being the most commonly reported. Of these reports, 21% came from Europe. (27) Customs officials in European countries have also reported an increase in the number of counterfeit medicines being seized. For instance, in 2007, over 40 million counterfeit medicines were seized, which was a 56% increase from the previous year. (27)

In Ireland, FMs can come from various sources. Theft or diversion of a product is not a reportable defect, but it can be associated with falsification, especially with certain types of susceptible goods. (28) FMs can also appear in online and social media advertisements, where a suspect product can misrepresent a prescription-only medicine. Without a sample, it can be challenging to prove the authenticity of a product advertised online. (28)

To combat the problem of FMs, various agencies in Ireland, including the HPRA, Revenue's Customs Service, An Garda Síochána, and Interpol, jointly conducted Operation Pangea XI in 2018. This operation resulted in the detention of approximately 90,000 dosage units of illegal prescription medicines, including anabolic steroids, sedatives, analgesics, erectile dysfunction drugs, and other miscellaneous drugs, with a total value of € 3,75,000. (14) The cooperation of these agencies underscores the importance of a collaborative effort in combating the problem of falsified medicines in Ireland.

3.2 Legislation addressing Falsified Medicines in the EU and Ireland

In the EU, the Falsified Medicines Directive 2011/62/EU prevents counterfeit medicines through safety features, stringent controls on ingredients, and wholesale distribution rules. A 2015 regulation (EU) 2016/161 added detailed provisions, ensuring verification of medicinal products' authenticity. In Ireland, this directive was implemented through amendments signed by the Health Minister in June 2011, officially published as S.I. No. 162/2013, S.I. No. 163/2013, and S.I. No. 164/2013. (29-31)

3.3 Methods of reporting of Falsified Medicines in Ireland

It is important to report all confirmed FMs to the HPRA as soon as possible so that necessary investigations and precautionary measures can be taken. It is recommended to obtain samples and information before reporting, if possible. (28)

Reporting of suspected FMs in Ireland falls under the category of quality defect reporting. MAH, suppliers, and wholesalers should use the Quality Defect Report Form to report suspected and/or apparent defects in the product to the HPRA via post, email, fax, or telephone. (32)

4. Role of Pharmacists in reporting of ADRs and FMs

A pharmacist has the potential to report the ADRs through their personal clinical experience that may differ from that of a general medicine practitioner. By communicating the appropriate risk data to health care workers, they will assist in improving the Pharmacovigilance process. (33) Through developing connections between patients and other healthcare professionals, they are able to prepare and distribute educational materials such as newsletters, pamphlets, and publications through drug information centres that provide information about drug warnings and drug safety. (33) A pharmacist may be involved in collecting data that are useful in initiating pharmacoepidemiologic longitudinal studies. During the one-on-one counselling session, pharmacists can minimize medication errors; improve patient safety and quality of life. (33)

Pharmacists are the healthcare professionals, who are responsible for the final custodian of medicines before they are dispensed to the patients and for ensuring the proper use and administration of medicines. (7) They also play an important role in managing the supply chain from the manufacture of medicines to their procurement. (7)

Because of the shortage and high cost of medicine, market opportunities for falsified products are increasing. (7) In this context, pharmacists have important roles to play in strengthening procurement processes, by educating and warning patients about the risk of buying medicines from online pharmacies or from unlicensed medicine shops or suppliers and in reporting the changes in the efficacy of drug product. (7)

5. Method and material

The research was designed as a cross-sectional, observational, questionnaire-based survey. In an aim to ascertain the current knowledge and attitude of ADR and FM reporting amongst the community pharmacists of Ireland.

An online survey was distributed to the community pharmacists in Ireland via email to gain an insight into their knowledge and practice of Pharmacovigilance program, ADR reporting, FM as well as their opinion on their role. Surveys are useful to identify the characteristics of a large population. No other research approach can have this large capacity, which means a more reliable sample to collect tailored results for conclusions to be drawn. The email ID of the community pharmacists were obtained by the Pharmaceutical Society of Ireland (PSI).

A quantitative investigation of the knowledge, attitudes, and experience of ADR reporting and FMs was conducted from February 2020 to April 2020 in the Institute of Technology Carlow, Ireland using an online

survey designed using an online platform called "SurveyPlanet". A monthly paid "Pro" plan was purchased in order to use premium features such as custom formatting and logic and analysis tools. The survey begins with an introductory note which includes the name of the researcher, name of the institute, title of the research study, aims of the study, information on voluntary participation and anonymity, approximate time taken to complete the survey which was determined by the premium feature of the survey platform. The participants were informed that they give their informed consent by participating in the survey. The reason for creating a survey questionnaire because they provide an unbiased means of data collection regarding the participant's knowledge, perception, and experiences.

The questions were inspired by the literature on the similar subjects. The questionnaire contained a total of 21 questions divided into two sections: 1. Pharmacovigilance & ADR reporting and 2. Falsified Medicines

The questionnaire first asks about the years of practise of the responders. The responder was asked about their basic knowledge of Pharmacovigilance and ADR, how they acquired the knowledge of Pharmacovigilance, the legislation covering Pharmacovigilance, reporting methods, whether they have reported any ADR, awareness amongst the patients and their opinion on the role played by a pharmacist in ADR reporting. Further, they were asked about their basic understanding of FMs, their encounter with it, legislation covering the FMs, whether they have reported any suspected FMs, awareness amongst the patients and their opinion on the role played by a pharmacist in addressing this issue. Most of the questions were close ended (optional and multiple choices) and some open-ended questions were included to gather the opinions on the roles of pharmacists in ADR reporting and FMs.

A total of 3680 e-mails, containing a web-link were sent to the potential subjects, i.e., Community Pharmacists. A total of 173 responses were received for the survey with a response rate of 4.7%. Out of 173 responses received from the Community Pharmacists from Ireland, all of the participants were registered with the Pharmaceutical Society of Ireland (PSI) as confirmed by the list of e-mail addresses received from the PSI.

The data collection was completed using the "SurveyPlanet" online tool because it is quick and accurate. The responses were also described by the frequency and percentages. The data obtained were analysed using the Microsoft Excel 2019 and IBM SSPS Statistics 23 software.

The present research study raised no ethical concerns. The study was reviewed by the ethics committee of the Institute of Technology Carlow, Ireland. The study posed no risk to the participants and care was taken to ensure that all the participants are fully aware of the nature of the research. They were also informed that their participation is completely voluntary, and they give their informed concern by taking part in surveys. No name of any participant is provided in this thesis ensuring complete anonymity.

6. Results

6.1 Pharmacovigilance & ADR reporting

This is the first part of the survey questionnaire and is divided into four sub-sections.

a. Demographic information of Pharmacists

The survey aimed to categorize the responses received into four groups based on the years of practical experience of the pharmacists. The groups were defined as follows:

Group A: Pharmacists with less than 5 years of experience.

Group B: Pharmacists with 5-10 years of experience.

Group C: Pharmacists with 11-20 years of experience.

Group D: Pharmacists with more than 20 years of experience.

This categorization allows for an analysis of the survey results based on the different levels of experience among the pharmacists, providing insights into any potential variations or trends in their responses based on their years of practical experience.

Table 1. Survey results showing demographic information of Pharmacists

Q. no.	Question	Data received				
1	How many years have you been registered as a pharmacist?	**< 5 years** % (n)	**5-10 years** % (n)	**11-20 years** % (n)	**> 20 years** % (n)	**Total** % (n)
		4.62 (8)	17.34 (30)	39.31 (68)	38.73 (67)	100 (173)

The survey results reveal the distribution of respondents across experience groups based on their practical years in the field. Group A, comprising pharmacists with less than 5 years of experience, accounted for 4.62%, potentially representing early-career professionals. Group B, encompassing those with 5-10 years of experience, constituted 17.34%, signifying mid-career development. The largest segment, Group C, included pharmacists with 11-20 years of experience (39.31%), reflecting seasoned expertise. Group D, comprising those with over 20 years (38.73%), showcased extensive experience. These insights offer a valuable depiction of the sample's experience composition, pertinent for research and decision-making across diverse pharmacist groups.

b. Knowledge of Pharmacovigilance

This section of the questionnaire aimed to evaluate community pharmacists' comprehension in several dimensions:

Understanding of Pharmacovigilance: The survey assessed familiarity with "Pharmacovigilance" and its components, such as adverse drug reactions (ADRs), falsified medicines, medication errors, off-label drug use, abuse/misuse, lack of efficacy, poisoning, drug interactions, expired stock management, and drug-related mortality.

Knowledge Acquisition: The questionnaire gathered insights into how pharmacists gained their Pharmacovigilance knowledge. This encompassed formal pharmacy education, ongoing learning programs, professional growth endeavours, and other resources contributing to their grasp of Pharmacovigilance.

Knowledge of Legislation: This section evaluated pharmacists' understanding of Irish legislation linked to Pharmacovigilance. It gauged familiarity with applicable laws, regulations, guidelines, and directives governing Pharmacovigilance practices in the country.

Knowledge of the Irish Pharmacovigilance System: The survey aimed to determine pharmacists' awareness and comprehension of Ireland's Pharmacovigilance system. This involved knowledge of reporting mechanisms and the regulatory bodies overseeing Pharmacovigilance, including entities like the HPRA.

Table 2. Survey results showing Pharmacist's knowledge of Pharmacovigilance

Q. no.	Question	Respondent with a 'Yes'% (n)
2	Do you possess a basic knowledge of the term "Pharmacovigilance"?	98.27 (170)
3	From where did you achieve basic knowledge of Pharmacovigilance?	
	College/University	90.17 (156)
	Refresher Courses hosted by PSI	4.05 (7)
	Uppsala Monitoring Centre Online courses	0.58 (1)
	Others	3.47 (6)
	Unanswered	1.73 (3)
4	Are you aware of the Pharmacovigilance legislation of Ireland?	35.20 (61)

On evaluating the results, the following observations were made:

Understanding of Pharmacovigilance: The survey indicated that a significant majority of pharmacists (98.27%) possessed a basic understanding of the term "Pharmacovigilance." This suggests that most pharmacists are familiar with the concept and its key components.

Sources of Pharmacovigilance Education: The survey revealed that the primary source of Pharmacovigilance education for pharmacists was their College/University education, as reported by 84.71% of respondents. Refresher courses hosted by the Pharmacy council/society, such as the PSI, were another significant source, with 4.71% of pharmacists acquiring Pharmacovigilance education through these courses. Other sources, such as continuing pharmacy education (CPE), training from the Irish Pharmacy Union, and work practice, accounted for 3.17% of pharmacists. Online courses hosted by the UMC were reported by 3.17% of respondents.

Knowledge of Irish Pharmacovigilance Legislation: The survey findings indicated that only 34.10% of the surveyed pharmacists possessed knowledge of the Irish Pharmacovigilance legislation. This implies that a significant proportion (65.90%) of pharmacists surveyed were unaware of the specific legislation governing Pharmacovigilance practices in Ireland.

In summary, the survey results highlighted that most pharmacists surveyed had a basic understanding of Pharmacovigilance. Irish colleges and universities played a crucial role in providing Pharmacovigilance education and training. However, there is room for improvement in terms of pharmacists' awareness and knowledge of the specific Pharmacovigilance legislation in Ireland.

c. Knowledge, attitude, and practise of ADR reporting

The objective of this section was to collect information regarding the awareness and attitude of pharmacists towards ADRs, including their awareness of ADRs among patients, their own awareness of the ADR reporting system, and whether they have reported any ADRs themselves.

By gathering this information, the questionnaire aimed to assess the pharmacists' level of awareness and engagement in ADR monitoring and reporting, as well as their perception of patient awareness in this regard.

Table 3. Survey Results Showing Pharmacist's knowledge, attitude, and practise of ADR reporting

Q. no.	Question	Respondent with a 'Yes'% (n)
5	Do you know what Adverse Drug Reactions (ADRs) are?	98.27 (170)
6	Do you think reporting of an ADR should be mandatory for safety surveillance of the drug product?	90.75 (157)
7	Do you think that the patients are aware of ADR reporting?	20.23 (35)
8	Are you aware of the ADR reporting system of HPRA	92.49 (160)

9	Which of the following ADRs reporting methods are you aware of?	
	ADR Reporting form for healthcare professionals	56.65 (98)
	Online ADR Reporting on HPRA website	31.21 (54)
	Freephone number	0.58 (1)
	Others	4.05 (7)
	Unanswered	7.51 (13)
10	Have you reported any ADR before?	54.34 (94)

Upon analyzing the results, the following observations were made:

Understanding of ADRs: The survey indicated that a significant majority of pharmacists (98.27%) possessed a basic understanding of the term "Adverse Drug Reactions," indicating a good level of knowledge regarding this important aspect of Pharmacovigilance.

Compulsory Reporting of ADRs: The evaluation revealed that 90.75% of pharmacists agreed that it is mandatory to report ADRs for safety analysis of medicines upon their approval. This suggests that most pharmacists recognize the importance of reporting ADRs to ensure the ongoing safety monitoring of medications.

Patient Awareness of ADR Reporting: The results indicated that only 20.23% of pharmacists believed that Irish patients were aware of ADR reporting. This low percentage may be attributed to a lack of Pharmacovigilance education initiatives targeting the general public. There seems to be a need for increased efforts to raise awareness among patients about the importance of reporting ADRs.

Awareness of ADR Reporting System: The analysis showed that 92.49% of pharmacists surveyed were aware of the ADR reporting system of the HPRA. This demonstrates a high level of awareness among pharmacists regarding the existence of a dedicated system for reporting ADRs.

Methods of ADR Reporting: The evaluation revealed that the highest number of pharmacists (56.65%) were aware of the ADR reporting form for healthcare professionals, followed by 31.21% who were aware of the online ADR reporting system on the HPRA website. Only a small percentage of pharmacists (0.58%) were aware of the freephone number provided by HPRA for ADR reporting.

In summary, the survey results showed that the majority of pharmacists had a good understanding of ADRs and recognized the importance of reporting them. However, there seems to be a need for increased patient awareness regarding ADR reporting. Pharmacists demonstrated a high level of awareness of the HPRA's ADR reporting system, with the majority being aware of the ADR reporting form and the online reporting system provided by HPRA.

d. Opinion on a Pharmacist's role in ADR reporting

The objective of this section of the questionnaire is to collect the opinions of community pharmacists regarding the convenience of the ADR reporting system and their perception of their role in ADR reporting. By gathering this information, the aim is to assess the pharmacists' views on the ease of reporting ADRs and their level of engagement in the reporting process.

Table 4. Survey results showing Pharmacist's opinion on their role in ADR reporting

Q. no.	Question	Respondent with a 'Yes'% (n)
11	How do you think a patient can achieve basic knowledge of ADR reporting?	80.92 (140)
12	Do you think that the current system of ADR reporting is effective?	58.96 (102)
13	Do you think a pharmacist plays a prominent role in ADR reporting?	79.19 (137)

On evaluating the results, it was found that 80.92% of pharmacists agreed that it is their responsibility to educate patients about ADR reporting.

Regarding the convenience of the ADR reporting system, 58.96% of pharmacists considered the HPRA's system to be convenient. This indicates that a significant portion of pharmacists find the system user-friendly and easy to use.

Furthermore, 79.19% of pharmacists expressed the opinion that they play an important role in ADR reporting, while the remaining respondents disagreed. This suggests that the majority of pharmacists recognize their significance in identifying and reporting ADRs, emphasizing their active involvement in the process.

Overall, the survey results highlight the willingness of pharmacists to educate patients about ADR reporting, their perception of the convenience of the reporting system, and their recognition of their crucial role in ADR reporting.

6.2 Falsified Medicines

a. Knowledge of falsified medicine and its regulation

The aim of this section of the questionnaire is to assess the level of knowledge and understanding among community pharmacists regarding FMs. It seeks to gather information about their familiarity with the threat posed by FMs, their awareness of the legislation related to FMs, their personal experiences with FMs, and their perspectives on the potential entry points of FMs in the

supply chain, as well as their role in addressing this issue.

Table 5. Survey results showing Pharmacist's knowledge of falsified medicine and its regulation

Q. no.	Question	Respondent with a 'Yes'% (n)
14	Do you know what a falsified medicine is?	100 (173)
15	Do you know that a falsified medicine can cause a serious threat to the health of the consumer?	100 (173)
16	Are you aware of the EU falsified medicines legislation: Directive 2011/62/EU to safeguard public health by protecting the pharmaceutical supply chain from infiltration by falsified medicines?	94.8 (164)

The analysis of the survey results indicates that all of the pharmacists surveyed demonstrated a fundamental understanding of the term "falsified medicine." The accompanying graph illustrates that as the level of experience increases, the number of respondents within each experience category also increases. This suggests that a majority of pharmacists in Ireland have knowledge of falsified medicines.

Additionally, the analysis reveals that all surveyed pharmacists appeared to be aware of the threat posed by falsified medicines, as indicated by the 100% response rate.

Furthermore, the results indicate that 94.80% of the total pharmacists surveyed possessed knowledge of the EU Falsified Medicines Directive. This implies that only a small percentage, specifically 5.20%, had limited or no knowledge of the directive.

b. Experience with falsified medicines

The objective of this section of the questionnaire is to assess the community pharmacists' knowledge and experience with FMs. It aims to gather information about their familiarity with the threat posed by FMs, their understanding of the legislation related to FMs, their personal experiences in encountering FMs, and whether they have reported such incidents or not. The purpose is to gain insights into the practical experiences and actions of community pharmacists regarding FMs.

Table 6. Survey results showing Pharmacist's experience with falsified medicine

Q. no.	Question	Respondent with a 'Yes'% (n)
17	Have you come across a falsified medicine?	2.89 (5)
18	Have you reported a suspected distribution of falsified medicines?	2.89 (5)

The analysis of the results indicates that a small percentage, specifically 2.89% of the surveyed pharmacists, reported encountering a FM in their practice. The majority of pharmacists, accounting for 95.95%, did not come across any FMs during their practice.

Among the pharmacists who encountered FMs, the analysis shows that the same percentage, 2.89%, reported these incidents to the competent authority. This suggests that a small proportion of pharmacists who encountered FMs took the step of reporting them to the appropriate regulatory body.

Overall, the findings reveal a relatively low incidence of pharmacists encountering FMs in their practice, and a similarly low proportion of those pharmacists reporting these incidents. This information highlights the need for further investigation and intervention to address the issue of FMs in the pharmaceutical supply chain.

c. Reporting of falsified medicines

The objective of this section of the questionnaire is to gather the opinions of community pharmacists regarding their perspective on the potential points of distribution of FMs and the adequacy of the legislation covering FMs. It aims to collect information on their views regarding where FMs may enter the supply chain and their assessment of the effectiveness of existing legislation in addressing the issue of FMs. By capturing the opinions of community pharmacists, this section seeks to gain insights into their perspectives on the distribution of FMs and the regulatory measures in place to combat them.

Table 7. Survey results showing Pharmacist's experience on reporting of falsified medicines

Q. no.	Question	Respondent with a 'Yes'% (n)
19	It is evident that some of the branded and generic medicines including life-style medicines are sold as falsified products (Rahman et al., 2010) (Sample, 2019). What according to you is the major point of distribution of these falsified medicines?	51.45 (89)
	Online Pharmacy	
	Unlicensed Supplier	1.73 (3)
	Black market vendors	32.95 (57)
	Pharmacy store	0 (0)

	Others	12.72 (22)
	Unanswered	1.16 (2)

The assessment of the results reveals several interesting findings regarding the perspectives of community pharmacists on the distribution points of FMs in Ireland and their opinions on the adequacy of existing legislation. Here is a summary of the key findings:

Distribution Points: The majority of pharmacists, comprising 51.45%, believed that the major point of distribution for FMs in Ireland is online pharmacies. This is followed by 32.95% of pharmacists who identified black market vendors, such as smugglers, as the primary distribution points for FMs. It is worth noting that 12.72% of pharmacists mentioned other sources, including online unlicensed sellers.

Unlicensed Suppliers: Small percentage of pharmacists highlighted a concern about the potential import of medicines from unlicensed suppliers.

Pharmacy Stores: Interestingly, none of the pharmacists surveyed believed that pharmacy stores are responsible for the distribution of FMs. This may be attributed to the stringent regulations outlined in the EU Falsified Medicines Directive, as well as the ethical practices followed by community pharmacists to prioritize patient health and safety.

Overall, the results provide valuable insights into the perspectives of community pharmacists regarding the points of distribution for FMs in Ireland. The findings suggest a particular concern with online pharmacies and black-market vendors, while also acknowledging the existence of other potential sources.

d. Opinion on a Pharmacist on the issue of falsified medicines

The objective of this section of the questionnaire is to collect the opinions of community pharmacists regarding the adequacy of legislation related to FMs and their perspectives on their own role in addressing the issue of FMs. It aims to gather insights into their views on the effectiveness of existing FM legislation and their perceptions of their responsibilities and contributions in combating the distribution and use of FMs. By capturing the opinions of community pharmacists, this section aims to assess their perspectives on the legislative framework and their role in addressing the challenges posed by FMs.

Table 8. Survey results showing Pharmacist's opinion on the issue of falsified medicines

Q. no.	Question	Respondent with a 'Yes'% (n)
20	Do you think the present regulation is adequate for combating the issue of falsified medicines?	75.14 (130)
21	Do you think a pharmacist plays a prominent role in addressing the issue of falsified medicines?	56.65 (98)

The analysis of the results indicates the following findings regarding the opinions of community pharmacists on the adequacy of legislation related to FM and their perception of their own role in addressing the issue:

Effectiveness of EU Falsified Medicines Directive: The majority, 75% of the pharmacists surveyed, expressed the opinion that the EU Falsified Medicines Directive is effective enough to combat the issue of falsification. This suggests a general confidence in the regulatory framework in place to address FMs. However, it is worth noting that 23.78% of the pharmacists surveyed did not believe that the directive is sufficiently effective, indicating a level of scepticism or concerns about its impact.

Pharmacists' Role in Addressing FMs: The analysis shows that 56.65% of the pharmacists surveyed believed that they play an important role in addressing the issue of FMs. This highlights a sense of responsibility and recognition among a significant portion of pharmacists regarding their involvement in combating FMs. However, 42.77% of the pharmacists surveyed did not agree on the importance of their role, suggesting a potential need for further engagement or awareness-raising efforts within this group.

Overall, the findings reveal a mixed perspective among community pharmacists regarding the effectiveness of the EU Falsified Medicines Directive and their own role in addressing the issue of FMs. While a majority expressed confidence in the regulatory framework and recognized their importance in combating FMs, there is also a notable proportion that had reservations or a different viewpoint. These findings indicate the need for ongoing evaluation, improvement, and communication to ensure an effective legislative framework and foster engagement among pharmacists in addressing the challenges associated with FMs.

7. Conclusion

In conclusion, this research assessed the knowledge of Pharmacovigilance, ADR reporting, and FMs among community pharmacists in Ireland, along with their opinions on reporting ADRs and FMs. The findings revealed that most pharmacists were aware of the key elements of Pharmacovigilance and ADR reporting, although knowledge of EU legislation was lacking. Pharmacists primarily acquired Pharmacovigilance education through college or university. All surveyed pharmacists were familiar with "falsified medicine" and its associated risks.

Regarding ADR and FM reporting, pharmacists had a positive attitude, favouring mandatory reporting. About

half of the pharmacists encountered ADRs and promptly reported them to the competent authority, often using online methods. Pharmacists observed a low level of patient knowledge about ADR reporting, and opinions varied on the convenience of the reporting system.

Overall, this research provides valuable insights into the understanding and attitudes of community pharmacists in Ireland regarding Pharmacovigilance and ADR reporting. Recommendations for future research include improving awareness of EU legislation, exploring interventions to enhance patient knowledge, and investigating factors affecting pharmacists' perceptions of the reporting system. These findings contribute to advancing the roles of pharmacists in Pharmacovigilance.

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Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of this article.

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