CORA Cork Open Research Archive
Cartlann Taighde Oscailte Chorcaí

Title	Pharmacists' views on the impact of the falsified medicines directive on community pharmacies: A cross-sectional survey
Authors	Dalton, Kieran;Connery, Ciarán;Murphy, Kevin D.;O'Neill, David
Publication date	2022-04-11
Original Citation	Dalton, K., Connery, C., Murphy, K.D., and O'Neill, D. (2022) 'Pharmacists' views on the impact of the Falsified Medicines Directive on community pharmacies: A cross-sectional survey', Exploratory Research in Clinical and Social Pharmacy, 5, 100127 (8 pp). https://doi.org/10.1016/j.rcsop.2022.100127.
Type of publication	Article (peer-reviewed)
Link to publisher's version	https://doi.org/10.1016/j.rcsop.2022.100127
Rights	© 2022 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license - http://creativecommons.org/licenses/by-nc-nd/4.0/
Download date	2026-11-05 09:31:26
Item downloaded from	https://hdl.handle.net/10468/13896



UCC
University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

Exploratory Research in Clinical and Social Pharmacy 5 (2022) 100127

Contents lists available at ScienceDirect

Exploratory Research in Clinical and Social Pharmacy

journal homepage: www.elsevier.com/locate/rcsop

Pharmacists' views on the impact of the Falsified Medicines Directive on community pharmacies: A cross-sectional survey

Kieran Dalton *, Ciarán Connery, Kevin D. Murphy, David O'Neill

Pharmaceutical Care Research Group, School of Pharmacy, University College Cork, Cork, Ireland

ARTICLE INFO

Keywords:
Community pharmacy
Falsified medicines
Legislation
Patient safety
Pharmacist
Survey

ABSTRACT

Background: The Falsified Medicines Directive (FMD) was implemented to minimise the circulation of falsified medicines in the legal pharmaceutical supply chain. Whilst pharmacists are involved in the final step of the FMD requirements with the decommissioning of medicines at the point of supply to patients, limited research has been conducted to investigate the impact of fulfilling these requirements on the relevant stakeholders.
Objective: To examine community pharmacists' views on how the FMD has affected their practice.
Methods: An online survey was disseminated via email in June 2020 to pharmacists in Ireland ($n = 4727$), who were invited to participate if practising full time or part time in community pharmacies. Quantitative data were captured through multiple option and Likert-scale questions, and analysed using descriptive and inferential statistics. Qualitative data were captured by use of a free-text box, with the open comments analysed thematically.
Results: In total, 618 valid responses were received (13.1% response rate). Most perceived that FMD requirements increased waiting times for patients (82%) and reduced time interacting with patients (65%). Only 28% agreed/strongly agreed that the *introduction of the FMD legislation improves patient safety*. In the open comments, the need for medicine authentication was acknowledged, but it was believed that this should be the wholesalers' responsibility, not pharmacists' responsibility. The additional step of medicines decommissioning was viewed as a time-consuming distraction to clinical checks that increased the risk for error. Pharmacists complained that they were not remunerated for the lost staff productivity or the additional software and equipment costs. Many pharmacists felt that the increased workload was disproportionate to the small risk of patients receiving falsified medicines.
Conclusions: Key stakeholder engagement is required to optimise the implementation and integration of the FMD procedures into community pharmacy practice with minimal impact on dispensing and without compromising patient care.

1. Introduction

Falsified medicines are those which deliberately or fraudulently misrepresent their identity, composition, or source.[1] Such falsified products can cause direct harm by denying patients active pharmaceutical ingredients or exposing them to toxic substances.[2] Whilst a systematic review found the prevalence of substandard and falsified medicines in low- and middle-income countries to be 13.6%, the European Commission estimated that the prevalence of falsified medicines in the European legal supply chain as approximately 0.005%. In Ireland for example, the only falsified medicines detected were bought from illegal websites and not through legitimate supply channels (e.g. through pharmacies),[3] but the true prevalence of such falsified medicines is unknown. These evidence gaps in the data appear to be a shortcoming globally, making the scale of the problem unclear.[4]

Several mechanisms exist internationally to help detect falsified medicines, including pharmacovigilance reporting systems, drug quality screening, training programmes for pharmacists, mobile phone applications for medicine authentication, and pharmaceutical track-and-trace systems (PTTSs).[2,5] In 2011, the Falsified Medicines Directive (FMD) was published by the European Commission with the goal to implement such a PTTS to minimise the circulation of falsified medicines across the European Union by tracking medicines from production to their dispensing to patients.[6] The FMD requires that most prescription-only medicines, as well as some over-the-counter products which have been falsified previously, must be protected with an anti-tamper seal and have a unique identifier (achieved with a 2D barcode).[6] Since February 2019, pharmacy staff supplying a medicine to a patient must check the integrity of the anti-tamper seal and scan the 2D barcode to verify its authenticity against a national database, which is regulated in each country by a National Medicines Verification Organisation (NMVO), and overseen by the European Medicines Verification

* Corresponding author at: School of Pharmacy, University College Cork, Cork, Ireland.
E-mail address: kieran.dalton@ucc.ie (K. Dalton).

http://dx.doi.org/10.1016/j.rcsop.2022.100127
Received 7 October 2021; Received in revised form 12 February 2022; Accepted 14 March 2022
2667-2766/© 2022 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Organisation (EMVO).[7] Once the database confirms that the medicine is not falsified, the medicine is '*decommissioned*' (i.e. rendering the serial number as no longer in use) and can be supplied to the patient. Therefore, any medicine using this same barcode in future is likely to be falsified.

While PTTSs targeting falsified medicines were common practice in countries such as Greece and Belgium prior to the FMD,[8] they are novel in most other European countries, such as Ireland. Previous evidence shows that PTTSs can require significant investment and can be challenging to implement.[5] Thus, it will be particularly important to investigate how the FMD has affected the key stakeholders involved in implementing the directive's procedures across Europe – particularly community pharmacists, who are responsible for the final step in the supply chain. From reviewing the literature, the FMD has been primarily framed as an important measure in further safeguarding patients, but was also predicted to be quite disruptive to community pharmacists' dispensing process (e.g. additional scanning increasing prescription turnaround time).[9–12] However, most of the literature was written before the FMD procedures were implemented and only hypothesised the impact of this legislation. With a paucity of evidence available, there is a clear need to establish community pharmacists' views on the FMD's effect on their practice to help inform the future of pharmacy operations and delivery of patient care. Therefore, the aim of this survey study was to obtain the views of community pharmacists in Ireland on the FMD and its impacts on their practice.

2. Methods

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement was used to guide reporting in this study.[13]

2.1. Study context for the FMD procedures in Irish community pharmacies

Community pharmacies in Ireland primarily obtain most medicines from two main wholesalers, with some exceptions including certain medicines that are very expensive and specialised ('*High Tech*') and unlicensed medicines. Medicines are dispensed to patients in a variety of ways; this may include dispensing in their original packs (full or part pack), in appropriate containers (e.g. bags, vials), or as part of dedicated unit-dose packages or blister packs. Whilst a registered pharmacist must be responsible for the review and dispensing of each prescription medicine in Ireland, the FMD's legal requirements of checking the anti-tamper seal and decommissioning can be performed by any member of pharmacy staff. This now means additional steps for the dispensing process before medicine supply, as each prescription medicine must have its 2D barcode scanned, then the staff member must check the scanning software on a pharmacy computer (which may or may not also be used for dispensing) to ensure that the medicine is authentic (i.e. not falsified) before continuing with the dispensing process. At the time of the study and at the time of writing, safety feature verification and decommissioning are legal requirements in Ireland but there is a national 'use and learn' period. This means that if a medicine is scanned and flagged as falsified during this time, it should be made known to the NMVO but could be dispensed if the pharmacist was confident of its authenticity. The 'use and learn' period is ongoing at the time of writing due to pressures on community pharmacies associated with the COVID-19 pandemic.

2.2. Survey design

This cross-sectional survey was constructed by the research team, fostered by a comprehensive review of the existing literature[9–12,14–17] and the research team's experience of working in community pharmacy. During the conduct of the study, KD and KM were pharmacists based primarily in academia, DON was a community pharmacist, and CC was a final year pharmacy student. To guard against the researchers bringing their personal biases on the topic, informal discussions took place with practising community pharmacists to inform the survey content, and reflexivity was encouraged throughout the study.

The research team minimised the number of questions to reduce the likelihood of incomplete surveys. The survey was reviewed for face and content validity by two practising community pharmacists; the survey was also piloted with these pharmacists (along with one additional practising community pharmacist). The pilot showed consistent comprehension of questions and responses among the pharmacists, with minor refinements made to phrasing based on their feedback. As seen in Appendix A, the survey used a combination of multiple-choice questions, yes/no questions, Likert-scale ratings, and open comment sections. After capturing participant demographics, the remainder of the survey focused on attaining pharmacist views on the FMD and its impact on community pharmacy practice; the topics included patient safety, the impact on dispensing, staff training and involvement with decommissioning, rates of compliance with decommissioning, and possible penalties with non-compliance. At the end of the survey, an open comment box was provided for pharmacists to provide any additional views on the impact of the FMD on their practice. The survey was anonymous by design, and was described as such to potential respondents to reduce hesitation due to fear of giving socially undesirable responses.

2.3. Survey distribution

Ethics approval was granted by the Social Research Ethics Committee of University College Cork. An email list was obtained from Ireland's pharmacy regulator, the Pharmaceutical Society of Ireland (PSI), which contained the email addresses for all pharmacists on the PSI's register of pharmacists who had either community pharmacy, hospital, industry, or academic settings as their area of practice ($n = 4727$). On the day the email list was obtained (10th June 2020), an email containing a link to the anonymised survey was sent out to these 4727 pharmacists and invited those who practise full time or part time as a pharmacist in a community pharmacy setting to participate. Participation was voluntary and participants could withdraw from the study up until the point of data submission. No reminder emails were sent, and the survey was closed on 3rd July 2020. The data were extracted from the survey platform (Microsoft® Forms) and reviewed so that any potentially identifiable information provided in the free text responses could be omitted.

2.4. Data analysis

A valid response was achieved when a participant clicked 'submit' at the end of the survey. Eight duplicate responses from one participant were identified, deemed invalid, and removed. It is unclear what caused this data duplication from the survey platform, but the remainder of the dataset was reviewed to ensure the integrity of the individualised responses. Thereafter, the percentage response rate was calculated by dividing the number of valid responses received by the number of pharmacists who were sent the survey via email, and then multiplying by 100. All respondents answered all closed-ended questions (i.e. there were no missing data). As the data acquired were mainly in text form, extensive data remediation was undertaken to give a discrete numerical data set, which could be more easily analysed using IBM® SPSS Version 26. Data remediation was performed both manually and using Microsoft® Excel functions to reduce the chance of human error, with a reconciliation step to ensure both steps corroborated. The open boxes for gender and who performed the decommissioning procedures were reviewed and the responses were categorised in three and nine categories respectively. A frequency analysis of each question was done (based on valid responses). Chi-squared analysis was performed to ascertain whether there were significant differences i) between the age and gender of the respondents versus pharmacists nationally and ii) in the responses based on the respondent demographics in the dataset (as shown in Appendix B). All statistically significant differences were reported, i.e. where $p < 0.05$.

The comments from the open text boxes (from question 7 where participants could outline any 'other' impact FMD had on their practice, as well as the final survey question) were imported into NVivo® Version 12 to

facilitate analysis. The answers to both questions were studied independently as part of thematic analysis to identify themes from the data (not identified in advance).[18] Three authors (DON, CC, and KD) read and re-read through all responses (phase 1). Each response was open coded by DON and CC (phase 2), whereby each response could receive multiple codes. Code categorisation by DON, CC, and KD followed this to form potential themes (phase 3). These were then reviewed to form initial descriptive themes, which helped shape the subsequent generation of the final themes and subthemes through discussion and iterative refinement by all authors (phase 4 to 6).

3. Results

In total, 618 valid responses were received (13.1% response rate), with the respondent demographics displayed in Table 1. There is a general consistency between the population of registered pharmacists in Ireland at the time of the survey (Appendix C) and the survey respondents (primarily based in community pharmacy). Compared to the population, the proportion of i) respondents ≥46 years was significantly higher (25.4% versus 35.7%; $p < 0.0001$) and ii) respondents <36 years was significantly lower (41.7% versus 28.2%; $p < 0.0001$).

Table 1
Respondent demographics.

Descriptor	Frequency
Gender:	
Female	352 (57%)
Male	261 (42.2%)
Other response	5 (0.8%)
Age range (in years):	
≤25	16 (2.6%)
26–35	158 (25.6%)
36–45	223 (36.1%)
46–55	148 (23.9%)
56–65	65 (10.5%)
≥66	8 (1.3%)
Sector primarily worked in:	
Community Pharmacy	593 (96%)
Academia	14 (2.3%)
Hospital Pharmacy	7 (1.1%)
Industry	2 (0.3%)
Other sector	2 (0.3%)
Role in community pharmacy:*	
Supervising pharmacist†	274 (44.3%)
Pharmacy owner	166 (26.9%)
Support pharmacist‡	155 (25.1%)
Superintendent pharmacistΔ	151 (24.4%)
Locum pharmacist	81 (13.1%)
Pharmacy manager	54 (8.7%)
Other	3 (0.5%)
Years post qualification:	
≤3	36 (5.8%)
4–9	117 (18.9%)
10–19	201 (32.5%)
20–29	182 (29.4%)
≥30	82 (13.3%)
Setting most commonly worked in:	
Single independent pharmacy	296 (47.9%)
Small chain (<10 pharmacies)	175 (28.3%)
Large chain (≥10 pharmacies)	147 (23.8%)

* Respondents could have chosen more than one option.

† The supervising pharmacist is the person responsible for the day-to-day management and operation of the pharmacy. A supervising pharmacist can only act in respect of one pharmacy premises and must have a minimum of three years' post-registration experience.[19]

‡ A support pharmacist works under the supervising pharmacist and may be responsible for the safe and effective running of the pharmacy in the supervising pharmacist's absence.

Δ The superintendent pharmacist is in overall control of the management of a pharmacy, including its professional and clinical management and management of the administration of the sale and supply of medicines. A superintendent pharmacist can act in respect of more than one pharmacy (i.e. all pharmacies within a company/chain), and must have a minimum of three years' post-registration experience.[20]

3.1. Impact on pharmacists' practice

When asked about the level of disruption that the FMD has caused on the dispensing process, nearly two-thirds (64.6%) conveyed that it caused a significant disruption. A further 33.8% marked that it caused some disruption, with 1.6% noting that it caused minimal disruption. Males, those ≥36 years old, superintendent pharmacists, and pharmacy owners were all significantly more likely to indicate that it caused a significant disruption ($p < 0.05$). Those with ≤3 years' experience were less likely ($p < 0.05$) to indicate a significant disruption (41.7%) compared to those with 4–9 years' experience (55.6%) and those with ≥10 years' experience (68.6%). Most of the participants (66.8%) indicated that they had seen no change in the number of near misses or dispensing errors, while 30.1% experienced an increased/greatly increased number. Males, those aged ≥36 years, those with ≥10 years' experience, and pharmacy owners were more likely to indicate an increase in the number of near misses or dispensing errors ($p < 0.05$).

Respondents were asked to choose any number of impacts on their practice from a given list (shown in Table 2) and could specify any "*other*" impact in a free text box. The most common responses were increased waiting time for patients (80.4%) and reduced time interacting with patients (64.6%).

Nearly one fifth of respondents ($n = 115$) provided a comment in this section on the "*other*" impacts on practice. Most of these impacts have been more comprehensively addressed in the themes identified from the survey's final open comment section below. However, some of the unique responses here included an increase in information technology issues and more contact with technical support for the FMD software. The packaging changes have meant that full pack dispensing is easier with the tamper-proof seal. However, some of these packaging changes caused problems for patients, and necessitated pharmacists to alleviate their concerns in this regard. Furthermore, it was pointed out that the increased packaging sizes have now introduced a larger negative environmental impact.

3.2. Impact on patient safety

Most of the respondents (85.7%) conveyed that they did not think falsified medicines were an important issue in Ireland prior to the introduction of the FMD. When asked broadly about their opinion of the FMD legislation with respect to patient safety, 47.4% disagreed (22% disagreed and 25.4% strongly disagreed) that the FMD improved patient safety, 27.7% agreed/strongly agreed, whilst 24.9% neither agreed nor disagreed. Superintendent pharmacists and pharmacy owners were more likely to disagree that the FMD legislation improves patient safety ($p = 0.0001$ and $p = 0.0005$ respectively), while locum pharmacists were more likely to agree that it

Table 2
Impact of FMD procedures on community pharmacy practice.

	Frequency	
Increased waiting time for patients to receive their medications	497	(80.4%)
Reduced time interacting with patients	399	(64.6%)
Reduction in quantity of medication stored in the pharmacy due to increased size of the packaging	237	(38.3%)
Medicine shortages	214	(34.6%)
Other (please specify)	115	(18.6%)
Less likely to loan products to another pharmacy	77	(12.5%)
Changes to the frequency of stock ordering	63	(10.2%)
Less likely to stock outside of the main channels	58	(9.4%)
Expiry date management	57	(9.2%)
More selective of where the pharmacy sources their products	28	(4.5%)
Not applicable	25	(4%)
Increased number of reporting options (e.g. can generate reports on the quantity of parallel imported [PI] versus non-PI products)	17	(2.8%)
Less likely to export products	12	(1.9%)

increases patient safety ($p = 0.0002$). Furthermore, participants were asked more specifically about the impact of FMD procedures in community pharmacy (such as "*scanning*") on patient safety. Nearly half (48.7%) marked that it had no impact, while 26.2% indicated that it increased the risk to patient safety and the remaining 25.1% believing the FMD increases patient safety.

3.3. Staff training and preparedness for implementation

When asked if the information provided by the regulatory authorities prepared them for FMD implementation, a similar proportion agreed/strongly agreed (39.6%) to those who disagreed/strongly disagreed (38.4%). Supervising pharmacists were more likely than others to strongly disagree with this statement ($p = 0.025$).

Over half the respondents (57.1%) indicated that training records and standard operating procedures (SOPs) were in place for best practice of the FMD procedures. However, 28.6% expressed that these records were not in place, while 14.2% did not know. Pharmacists who worked in pharmacies that were part of a chain were significantly more likely to indicate that they had training records and SOPs in place in comparison to those who worked in independent pharmacies.

Most pharmacists (62.5%) expressed that all members of the dispensary staff had received training on FMD procedures, while 25.4% said not all staff have received training and 12.1% did not know. Pharmacy owners, superintendent pharmacists, and supervising pharmacists were more likely to know that training records and SOPs were in place and to indicate all dispensary staff had received training on FMD procedures ($p < 0.05$). Locum pharmacists and support pharmacists were less likely to know if these training records were in place and if all dispensary staff had received training ($p < 0.05$).

3.4. Staff compliance with FMD procedures

Participants were asked who performs the decommissioning procedures in the pharmacy (Table 3).

Additionally, pharmacists were asked to estimate, as a percentage, how often they complied with the decommissioning step at the point of supply. The modal value in this case was the 85–99% range, to which 33.8% chose. Approximately two-thirds of respondents (67.7%) attested that they were compliant more than 60% of the time. A further question assessed whether the respondents were compliant with the decommissioning steps for phased prescriptions; compliance in this case dropped slightly, with 59.2% indicating they were compliant more than 60% of the time. Females were more likely than males to be compliant more than 30% of the time, both with respect to overall scanning compliance ($p = 0.0017$), and with scanning in the case of phased dispensing ($p = 0.00011$).

When assessed if compliance remained important during busy work periods, 18.7% of respondents attested that scanning was a key priority or remained important during busy work periods, while 16.5% expressed that it had not affected their compliance. Over a third (25.8%) signalled that they believed scanning to be less important while busy, while a further 29% noted that scanning was not important in these instances. Males were less likely to signal that scanning remains a priority when busy ($p = 0.0407$); similarly, pharmacy owners were more likely to think that scanning is not important during busy work periods ($p = 0.0007$).

Pharmacists were also asked about the 10-day rule (i.e. the 10-day limit to reverse the 'decommissioned' status of a medicine where required) and whether this had caused them problems, to which 86% responded that it had – 22% experienced 'a lot of problems', 42.2% had 'some problems', and 21.8% had 'minimal problems'. In this case, it was found that locum pharmacists were less likely to have problems ($p = 0.0011$). When asked about the degree of worry about penalties for non-compliance, over half indicated that they were worried (38% worried and 13.1% extremely worried), with the remainder (48.9%) indicating that they were not worried. Locum pharmacists were significantly less likely to be extremely worried about penalties for non-compliance compared to pharmacy owners, superintendent pharmacists, and supervising pharmacists (4.9% versus 16.3%, 19.9%, and 12.8% respectively; $p < 0.05$).

Table 3
Staff who perform decommissioning procedures.

Staff role	Frequency
Pharmacist	277 (44.8%)
All dispensary staff	132 (21.4%)
Pharmacist and/or pharmacy technician	89 (14.4%)
Pharmacy technician	71 (11.5%)
No response	29 (4.7%)
No one	14 (2.3%)
Pharmacist and/or pharmacy intern	3 (0.5%)
Pharmacy owner/manager	2 (0.3%)
Over-the-counter assistant	1 (0.2%)

3.5. Pharmacists' views of the FMD: themes generated from the final open comment section

Pharmacists were welcomed to share any other views they had about the FMD in the final question, of which 354 (57.3%) respondents left a comment, with no comments excluded from the analysis. For this section, males, pharmacy owners, superintendent pharmacists, those aged ≥36 years, and those with ≥20 years' experience were significantly more likely to leave a comment ($p < 0.05$). The main themes and subthemes are presented in Table 4, and are described in detail below with supporting quotes. Supplementary quotes are provided in Appendix D to corroborate the findings (which are presented under the initial descriptive themes that helped form the main themes and subthemes).

4. Discussion

This is the first study to have explored the views of pharmacists about the impact of the FMD on community pharmacy practice after its implementation. While the FMD was implemented with the aim of improving patient safety, only about a quarter of participants in this survey agreed that this directive and its requirements improve patient safety. This contrasts to a study done by Barrett et al prior to the directive's implementation, which found that 77.5% of English pharmacists surveyed believed the FMD might increase patient safety.[9] While one might hypothesise that this may be due to cultural differences in pharmacy practice, this is a notable contrast between pharmacists' pre-implementation perceptions and post-implementation experiences. In this study, 30.1% of pharmacists indicated that they experienced an increased/greatly increased number of near misses and dispensing errors with the FMD procedures; some pharmacists qualitatively attributed this as one of the reasons for an increased risk to patient safety. Accordingly, any increased risk of dispensing errors calls into question the requirement for the FMD procedures at the point of supply to patients in pharmacies. However, scanning at this point has a patient safety advantage of tracking medicines to individuals during batch recalls. Thus, if these procedures are to be retained in this setting, there must be careful consideration on what exact steps are required and when (e.g. on arrival or at the point of supply), so that there is a clear benefit to both community pharmacy staff and patients.

Pharmacists in this study also noted that a risk to patient safety arose due to the distracting nature of the FMD procedures and its disruption to the dispensing process. Furthermore, the hardware and software issues (e.g. scanning difficulties) add variation and unpredictability to the process. For many pharmacies, this dispensing process is a well-thought-out, well-established, and well-rehearsed operation. Therefore, while the FMD only adds two extra steps, approximately two-thirds of participants said that it had a '*significant disruption*'. As noted previously, those with more years of experience, over aged ≥36 years, superintendent pharmacists, and pharmacy owners were more likely to indicate this. This cohort is more likely than others to have long-established processes that they are comfortable with; therefore, change to these cohorts would be more significant and

Table 4
Main themes and subthemes from the final open comment section, with supporting quotes.

Theme 1: Obligation of the FMD	
Necessity The need to minimise the circulation of falsified medicines was acknowledged, particularly when obtaining unlicensed medicines or those not from the main suppliers. Pharmacists emphasised that the distribution of falsified medicines from pharmacies was not a problem otherwise in Ireland as most medicines obtained are from reliable and reputable sources, and suggested that the scanning in pharmacies was a "*disproportionate response*" to this "*negligible risk*".	"*While I understand the concerns of falsified medicines reaching patients, I feel this measure has impacted the workload in pharmacies to a disproportionate degree compared to the instances of known false products being identified in the state*" [**Pharmacist 532**]
Responsibility Many pharmacists indicated that they did not think that licensed medicines verification should be the duty of pharmacy staff and felt that authentication upstream with reputable manufacturers and/or wholesalers should be sufficient.	"*I believe that FMD scanning is not an appropriate use of time in the pharmacy. This work should be carried out at wholesaler level. Pharmacies are regulated to only buy prescription medicines from state licensed wholesalers…*" [**Pharmacist 64**]
Regulation Pharmacists felt strongly that compliance with scanning was a bureaucratic burden, which added "*more useless red tape*" to an already onerous administrative workload. It was perceived that the FMD regulations were "*forced on community pharmacists*", and that there had not been sufficient training or consultation with them. It was a "*good thing*" in theory, but there was insufficient consideration of the impacts on pharmacists. There was fear about possible repercussions with non-compliance but some were also unsure about how effective the FMD would be in minimising falsified medicines. It was pointed out by several pharmacists that this regulatory procedure was one that could easily be circumnavigated by intentionally not scanning falsified medicines.	"*I understand the logic of ensuring the authenticity of medications, but I feel that the implementation has not been planned adequately with regard to the practicalities of implementing the directive in the community pharmacy setting*" [**Pharmacist 406**] "*Anyone buying from dodgy sources won't scan their dodgy goods in any case*" [Pharmacist 575]
Theme 2: Technology – costs, challenges, and opportunities	
Cost of implementation Pharmacists noted the sizeable expenses incurred to satisfy the FMD requirements, such as the cost of software, hardware (including extra scanners and computer screens), and productive staffing time – which may have involved time training or hiring extra staff to deal with the additional procedures. It was viewed as a "*waste of time and money*" which placed a financial burden on pharmacies, and many sought appropriate remuneration for these costs.	"*Pharmacists have been expected to invest in hardware and software at their own expense, spend time training and learning about the process and then spent a significant amount of time implementing the system for ZERO payment.*" [**Pharmacist 271**]
Software issues Pharmacists complained about times where scanners did not work and that the reaction time lagged – which was slower than previously promised. Others indicated that the database was not entirely accurate or up to date, with some medicines not registering and others scanning as the wrong product. Pharmacists mentioned issues that were specific to certain software providers, which included the inconvenience of having to regularly switch between the dispensing software and scanning software.	"*Constant errors returned, programs freezing, scanners not functioning for periods of time…results of supply scans not matching contents of bag*" [**Pharmacist 252**]
Physical changes to pharmacy and packaging Pharmacists expressed frustration with scanning terminals that often took multiple attempts to scan one product. The scanner location also caused issues with space and constrained staff positioning in the dispensary. It was noted that many products drastically increased in size with the addition of the 2D barcode, meaning less could be stored, and that it sometimes meant the omission of medicine details from packaging, which negatively impacted on the checking of medicines. Whilst there was some praise for the tamper-proof seal in easing the checking of full packs, some products could not be safely re-sealed once opened – which created issues with storing on the shelf and when providing to patients.	"*The scanner is next to the computer and it is a difficult place to check medicines.*" [**Pharmacist 429**] "*The design of the new boxes pose a serious risk to patient safety once opened as they do not close again… Medication falling out in bag once dispensed and also for the patient at home.*" [**Pharmacist 383**]
Benefits and opportunities Pharmacists outlined potential benefits of using the FMD technology for expiry date checking, product recalls, stock control, and as a double-check when dispensing. However, many questioned the true benefit of the FMD to pharmacies and patients. Pharmacists perceived that audible cues when errors occurred with scanning would be advantageous, and that there was a missed opportunity whereby the dispensing software should be able to flag any mismatch with what was dispensed and what was scanned. It was pointed out that if more benefits to the technology were realised, this may encourage better compliance with scanning and its integration into pharmacies.	"*…it is disappointing that we have not capitalised on the opportunity for improved stock management, expiry dates…which may have justified or mitigated the added workload*" [**Pharmacist 192**] "*…huge amount of work for no real benefit*" [**Pharmacist 20**]
Theme 3: Impact on dispensing process and patient safety	
Workflow complexity FMD scanning was described as a significant workflow disruption in "*an already very complex dispensing process*", which "*distracts from clinical checking of prescriptions*". Many believed that scanning at the point of dispensing to a patient was ill-timed; if pharmacies had to scan, it was suggested that this should be done at another time (e.g. on arrival into the pharmacy). It was also flagged that scanning often requires staff crossing each other to access scanners, and the need for social distancing during the COVID-19 pandemic complicated this further; thus, many pharmacists stopped scanning "*to prevent congregation of staff*".	"*This is a robotic procedure that hugely complicates, delays and interrupts workflow. I really don't like it.*" [**Pharmacist 57**] "*Point of dispensing is totally the incorrect point to check for falsified medication.*" [**Pharmacist 368**]
Workload The FMD procedures were viewed as "*a cumbersome time-consuming burden*" which "*adds an unremunerated workload on pharmacies*". This extra workload added to the existing pressures, which lengthened dispensing times and waiting times, frustrating both pharmacy staff and patients (who may not have been aware of the FMD). Furthermore, the increased workload with COVID-19 meant that compliance with scanning was given less priority.	"*It has added extra work to our already overloaded schedule and I have no problem in saying that I do not decommission medicines during busy periods in the pharmacy*" [**Pharmacist 166**]
Patient safety Pharmacists found that more time spent scanning resulted in less time interacting with patients and performing other duties that are essential to the safe supply of medicines. While some respondents testified that the FMD does not contribute to the priority of ensuring patient safety or perceived that the scanning "*creates a real and genuine risk to patients*", others went a step further to state that it definitively reduced patient safety.	"*The number of near misses and the error count increased after the introduction of scanning…*" [**Pharmacist 595**] "*…a complete waste of time that can only potentially decrease patient safety rather than increase it!*" [**Pharmacist 322**]

perhaps a contributory reason to the older respondent demographic compared to the population. This idea of the FMD being disruptive is not universal across the literature, with studies agreeing and disagreeing.[10,12] Studies by Naughton et al proposed ways to lessen the impact on the dispensing process; this included robotic dispensing systems, as well as critiquing and re-structuring the dispensing process.[11,16] While these may be very expensive and time-consuming measures, it may reduce the overall number of errors in the dispensary. Moreover, the additional steps in this process have delayed dispensing times, and pharmacists in this study described placing extra stress on themselves to meet pre-existing patient waiting times, further increasing the risk of dispensing errors. It is therefore clear that this administrative task of scanning has further intensified pharmacists' workloads, which may have important negative consequences for community pharmacists in the future, such as increased stress, decreased levels of pharmacists' health, well-being, and job satisfaction.[21]

This survey has highlighted the impact that the FMD has had on community pharmacists' patient-focused care. Many pharmacists in the open comment sections admitted that the FMD procedures often distracted them from clinical checks of patients' pharmacotherapy, whilst most also indicated that they were spending less time interacting with their patients, an essential part of the pharmacist's role. During the COVID-19 pandemic, where patients were seeing their doctors less and less, contact with patients was essential.[22–24] Pharmacists also described how their time with patients was further hampered by technology issues. Although previous research has shown that usability was not often an issue with barcode scanning technology in pharmacy settings,[25] the present study identified several user issues with both the software and hardware – including scanners not working, medicines scanning as the incorrect product, or medicines not registering with the system. Respondents noted that the reaction time of the software was not sufficient; this contrasts with studies conducted by Naughton et al, which measured a database accuracy of 100% and deemed the software reaction time to be appropriate and quick.[10,17] It is unclear exactly how much time is spent by community pharmacy staff completing the FMD procedures, but there are studies from hospital pharmacies that demonstrate that an extra full-time technician was required to deal with the additional workload.[12,26] With many pharmacists in this study complaining about this lost staff productivity as well as the additional costs incurred with hardware and software, it brings into focus the question of whether pharmacies should be remunerated for their compliance with the FMD procedures.

The relevant regulatory bodies were criticised by respondents as many expressed that the FMD was "*forced on*" them, without enough consultation with community pharmacists. For multiple reasons, many believed that the FMD procedures should not be a major responsibility of community pharmacies. Firstly, most participants (85.7%) did not believe that falsified medicines were an important issue in Ireland before the FMD. Whilst falsified medicines are typically less prevalent in countries like Ireland compared to low- and middle-income countries,[27] it may be beneficial for the NMVO to show the extent of this problem by regularly publishing evidence on any falsified medicines identified in community pharmacies. Secondly, many pharmacists felt that changing their dispensing process to incorporate the FMD procedures for each medicine supplied – along with the knock-on effects of this – was a disproportionate response to the matter. Thirdly, many believed that the responsibility to ensure licensed medicines are authentic should rest with the wholesalers – to whom pharmacists trust and pay to source their medicines. Therefore, the present study's findings – particularly regarding patient safety concerns – should be reviewed by pharmacy regulators, to establish whether such procedures should be the responsibility of a community pharmacist to oversee, or how their use might be revised.

Even though many of the survey respondents did not feel it should be pharmacists' responsibility to decommission medicines, this study found that pharmacists were the most likely staff member to be performing this. With only 62.5% indicating that all staff had been trained on the FMD procedures, it may demonstrate the need for further training and more delegation of scanning to other staff members where possible. Furthermore, there was an equal proportion of pharmacists who felt prepared for FMD implementation by the information from regulatory bodies to those who felt unprepared (approximately two-fifths each), with respondents seeking additional training from the regulatory bodies in the open comments section. Worryingly, this study found that supervising pharmacists – who are responsible for pharmacy staff training – were one cohort who felt significantly less prepared in this regard, possibly affecting the extent of training provided. Therefore, it may be beneficial for regulatory bodies to provide additional training or information on best practice guidance on how to integrate the FMD requirements into community pharmacy practice.

While most respondents seemed to be quite negative toward the FMD procedures, about one-third of respondents affirmed that they were compliant with FMD procedures 85–99% of the time. It must be acknowledged that the survey was conducted during a national 'use and learn' period for the FMD,[28] the initial period whereby the system is operational and stakeholders begin using the system. Another limitation to this study's decommissioning rate is that it was conducted during the COVID-19 pandemic. Respondents flagged that social distancing had an impact on the decommissioning rate. Additionally, it has been reported that pharmacists' workload increased during this pandemic[29,30]; this aligns with our findings that only 18.7% of participants indicated that scanning was a key priority or remained important during busy periods. Pharmacy owners were one cohort who believed that decommissioning was significantly less important at busy times. This may be in part due to community pharmacies being a business – therefore, prioritising this alongside patient safety (which is paramount) – instead of decommissioning, which they may deem to have no positive bearing on either.

This study found that one of the other main motivators for compliance with decommissioning seemed to be the possible repercussions for non-compliance. Although the relevant regulatory bodies have not specified the nature of such penalties, over half of the participants indicated that they were worried or extremely worried about penalties for non-compliance. Previous research has shown less acceptance of barcode scanning for identifying falsified medicines than for scanning to verify dispensed items.[25] Thus, rather than simply reinforcing scanning compliance with possible punishments, there should be greater incentives for pharmacy staff to scan for falsified medicines. For example, a single scan could unify this with additional functions such as verifying that dispensed medicines were selected correctly, recording expiry dates, managing stock, and for medicines reimbursement.[25,31,32] The Technology Acceptance Model (TAM) would suggest that successful decommissioning will not be performed regularly where negative pharmacy staff perceptions are pervasive; by making scanning more relevant to staff with such incentives, this should have a positive effect on its perceived usefulness.[33] The TAM also outlines that decommissioning usefulness could be enhanced by improving the system's 'output quality' (e.g. minimising incorrect error messages) and 'result demonstrability' (e.g. tangible proof of reducing falsified medicines). However, another key TAM component to address is the 'perceived ease of use' whilst dispensing. Therefore, strategies to enhance acceptance of this scanning and its integration into pharmacy processes must be carefully considered if decommissioning is to continue in pharmacies going forward. Going forward, these findings can also importantly be applied to other countries planning to implement such technologies and in assessing the potential impact on community pharmacies and their patients.

5. Strengths and limitations

Although the FMD procedures have been implemented in many countries across Europe, this is the first national survey of pharmacists' views on the impact of this legislation on community pharmacy practice. Based on the authors' experiences of survey distribution using an email list from Ireland's pharmacy regulator, a response rate of 5–10% may typically be expected. Even with the COVID-19 pandemic at the time of survey distribution, this survey received a response rate of 13.1% – perhaps indicating the importance of this issue to pharmacists, which was further evidenced by the richness and vehemence of the open comments provided in the

results section and Appendix D. Although it is not possible to say that the opinions provided are truly representative of all pharmacists in Ireland, the respondents were diverse in terms of age, years of post-qualification experience, pharmacist role, and community pharmacy type. A limitation to this survey is the significant age difference between our sample and the population; while its importance is uncertain, it is not expected to alter the conclusions drawn by the authors.

It is unclear exactly how transferable these findings would be to other countries that have implemented the FMD procedures in community pharmacies, but many of the reported impacts on practice should be generalisable given that the requirements are standardised across the European Union. Another limitation of this survey was the time of dissemination; while it was an opportune point to study the impact of the FMD one year after the requirements for decommissioning were implemented, the participants responded in the earlier stages of the COVID-19 pandemic. This means that the rate of decommissioning compliance would likely have been different if conducted prior to this pandemic and warrants further exploration in future studies.

6. Conclusion

While these survey findings do not discredit the FMD as a tool for identifying falsified medicines, they depict pharmacists' opinions on how it has impacted their practice and ways in which it could be improved. This study emphasised that the FMD procedures have added complexity to the dispensing process, increased the number of near misses and dispensing errors, and created new software and hardware problems – ultimately, increasing pharmacists' workload and reducing their time with patients, and possibly increasing the risk to patient safety. Pharmacists have questioned if this responsibility should be shifted away from pharmacies, with many suggesting that this should be dealt with at wholesaler level. However, if these FMD procedures are to remain in community pharmacies, the regulatory bodies should cooperate with pharmacists to find creative and affordable means for them to implement the FMD procedures in practice so that any additional workload is offset against direct benefits for community pharmacies.

The present study findings have important implications for the future of patient care in pharmacies, and it is vital that more research is conducted to assess if these pharmacists' views depicted are pervasive in other European countries, or how these insights may change over time. However, further engagement is needed with the other relevant stakeholders from the pharmacy, wholesaler, manufacturing, regulatory, and legislative bodies at an international level to identify the best way to implement falsified medicines legislation so that it definitively minimises their circulation in the pharmaceutical supply chain with clear evidence of enhanced patient safety.

Funding

This research received no external funding.

CRediT authorship contribution statement

Kieran Dalton: Conceptualization, Data curation, Formal analysis, Investigation, Methodology, Project administration, Supervision, Visualization, Writing – original draft, Writing – review & editing. **Ciarán Connery:** Data curation, Formal analysis, Validation, Visualization, Writing – original draft, Writing – review & editing. **Kevin Murphy:** Conceptualization, Investigation, Methodology, Supervision, Visualization, Writing – review & editing. **David O'Neill:** Data curation, Formal analysis, Investigation, Methodology, Project administration, Visualization, Writing – original draft.

Declaration of Competing Interest

The authors declare no conflict of interest.

Acknowledgments

The authors would like to express sincere thanks to all the pharmacists who responded to this survey, and to the small group of pharmacists who helped inform the survey content.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.rcsop.2022.100127.

References

1. World Health Organization. Definitions of Substandard and Falsified (SF) Medical Products. Accessed September 18, 2021: https://www.who.int/teams/health-product-and-policy-standards/about/regulation-and-prequalification.
2. Hamilton WL, Doyle C, Halliwell-Ewen M, Lambert G. Public health interventions to protect against falsified medicines: a systematic review of international, national and local policies. Health Policy Plan 2016;31(10):1448–1466. https://doi.org/10.1093/heapol/czw062.
3. Irish Medicines Verification Organisation. Falsified medicines. Accessed January 14, 2022: https://www.imvo.ie/falsified-medicines/.
4. Hodges S, Garnett E. The ghost in the data: evidence gaps and the problem of fake drugs in global health research. Glob Public Health 2020;15(8):1103–1118. https://doi.org/10.1080/17441692.2020.1744678.
5. Kootstra J, Kleinhout-Vliek T. Implementing pharmaceutical track-and-trace systems: a realist review. BMJ Glob Health 2021;6(suppl 3), e003755. https://doi.org/10.1136/bmjgh-2020-003755.
6. Directive 2011/62/EU of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products. Accessed September 18, 2021: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0074:0087:EN:PDF.
7. European Medicines Verification Organisation. Accessed September 19, 2021: https://emvo-medicines.eu/.
8. Simoens S. Analysis of drug authentication at the point of dispensing in Belgian and Greek community pharmacies. Ann Pharmacother 2009;43(10):1701–1706. https://doi.org/10.1345/aph.1M215.
9. Barrett R. Evaluation of community pharmacists' readiness to implement the falsified medicines directive (directive 2011/62/EC): an English cross-sectional survey with geospatial analysis. BMJ Open 2020;10(1), e033405. https://doi.org/10.1136/bmjopen-2019-033405.
10. Naughton B, Roberts L, Dopson S, Brindley D, Chapman S. Medicine authentication technology as a counterfeit medicine-detection tool: a Delphi method study to establish expert opinion on manual medicine authentication technology in secondary care. BMJ Open 2017;7(5), e013838. https://doi.org/10.1136/bmjopen-2016-013838.
11. Naughton BD, Smith JA, Brindley DA. Establishing good authentication practice (GAP) in secondary care to protect against falsified medicines and improve patient safety. Eur J Hosp Pharm 2016;23(2):118–120. https://doi.org/10.1136/ejhpharm-2015-000750.
12. de Pinto C, Koshkouei M, Jeske M, Zeiler M, Brindley D. The impact of the falsified medicines directive in the dispensing operations of an Austrian hospital pharmacy. J Hosp Med Manage 2017;3(1).
13. von Elm E, Altman DG, Egger M, et al. The strengthening the reporting of observational studies in epidemiology (STROBE) statement: guidelines for reporting observational studies. Int J Surg 2014;12(12):1495–1499. https://doi.org/10.1016/j.ijsu.2014.07.013.
14. Naughton B, Roberts L, Dopson S, Chapman S, Brindley D. Effectiveness of medicines authentication technology to detect counterfeit, recalled and expired medicines: a two-stage quantitative secondary care study. BMJ Open 2016;6(12), e013837. https://doi.org/10.1136/bmjopen-2016-013837.
15. Merks P, Swieczkowski D, Byliniak M, et al. The European falsified medicines directive in Poland: background, implementation and potential recommendations for pharmacists. Eur J Hosp Pharm 2018;25(1):10–15. https://doi.org/10.1136/ejhpharm-2016-000970.
16. Naughton BD, The EU. Falsified medicines directive: key implications for dispensers. Medicine Access @ Point of Care, 1; 2017. https://doi.org/10.5301/maapoc.0000024.maapoc.0000024.
17. Naughton BD. Medicine authentication technology: a quantitative study of incorrect quarantine, average response times and offline issues in a hospital setting. BMJ Open 2019;9(2), e026619. https://doi.org/10.1136/bmjopen-2018-026619.
18. Braun V, Clarke V. Using thematic analysis in psychology. Null 2006;3(2):77-101. https://doi.org/10.1191/1478088706qp063oa.
19. The Pharmaceutical Society of Ireland. Supervising Pharmacists. Accessed January 4, 2021: https://www.thepsi.ie/gns/Pharmacy_Practice/practice-guidance/Guidance_for_pharmacists/Guidance_for_Supervising_Pharmacists.aspx.
20. The Pharmaceutical Society of Ireland. Superintendent Pharmacists. Accessed January 4, 2021: https://www.thepsi.ie/gns/Pharmacy_Practice/practice-guidance/Guidance_for_pharmacists/Guidance_for_Superintendent_Pharmacists.aspx.
21. Lea VM, Corlett SA, Rodgers RM. Workload and its impact on community pharmacists' job satisfaction and stress: a review of the literature. Int J Pharm Pract 2012;20(4):259–271. https://doi.org/10.1111/j.2042-7174.2012.00192.x.
22. Bragazzi NL, Mansour M, Bonsignore A, Ciliberti R. The role of hospital and community pharmacists in the management of COVID-19: towards an expanded definition of the

roles, responsibilities, and duties of the pharmacist. Pharmacy (Basel) 2020;8(3):140. https://doi.org/10.3390/pharmacy8030140.
23. Paul AK, Bogart T, Schaber AR, Cutchins DC, Robinson RF. Alaska pharmacists: first responders to the pandemic in the last frontier. J Am Pharm Assoc (2003) 2021;61(1):e35–e38. https://doi.org/10.1016/j.japh.2020.09.008.
24. Marwitz KK. The pharmacist's active role in combating COVID-19 medication misinformation. J Am Pharm Assoc (2003) 2021;61(2):e71–e74. https://doi.org/10.1016/j.japh.2020.10.022.
25. Weir NM, Preston K, Newham R, Bennie M. A mixed-method study of community pharmacy staff?S use, perceptions and acceptance of barcode scanning technology Pharmacy's experience of scanning technology. Health Policy Technol 2021;10(1):60–68. https://doi.org/10.1016/j.hlpt.2020.11.005.
26. Vajda P, Bodrogi Z, Richter K, Vida RG, Botz L, Fittler A. Hospital costs associated with the implementation of the falsified medicines directive in Hungary. Value Health 2019;22:S599. https://doi.org/10.1016/j.jval.2019.09.1031.
27. IME Bakker-t Hart, Ohana D, Venhuis BJ. Current challenges in the detection and analysis of falsified medicines. J Pharm Biomed Anal 2021;197:113948. https://doi.org/10.1016/j.jpba.2021.113948.
28. Irish Medicines Verification Organisation. Announcement of national approach to safety features implementation – initial 'use and learn' phase. Published February 5; 2019. Accessed September 19, 2021: https://www.imvo.ie/announcement-of-national-approach-to-safety-features-implementation-initial-use-and-learn-phase/.
29. Johnston K, O'Reilly CL, Scholz B, Georgousopoulou EN, Mitchell I. Burnout and the challenges facing pharmacists during COVID-19: results of a national survey. Int J Clin Pharm 2021;43(3):716–725. https://doi.org/10.1007/s11096-021-01268-5.
30. Collins CD, West N, Sudekum DM, Hecht JP. Perspectives from the frontline: a pharmacy department's response to the COVID-19 pandemic. Am J Health Syst Pharm 2020;77(17):1409–1416. https://doi.org/10.1093/ajhp/zxaa176.
31. Oldland AR, Golightly LK, May SK, Barber GR, Stolpman NM. Electronic inventory systems and barcode technology: impact on pharmacy technical accuracy and error liability. Hosp Pharm 2015;50(1):34–41. https://doi.org/10.1310/hjp5001-034.
32. Nold EG, Williams TC. Bar codes and their potential applications in hospital pharmacy. Am J Hosp Pharm 1985;42(12):2722–2732.
33. Venkatesh V, Bala H. Technology acceptance model 3 and a research agenda on interventions. Decis Sci 2008;39(2):273–315. https://doi.org/10.1111/j.1540-5915.2008.00192.x.