Universidade de Lisboa
Faculdade de Farmácia

Collection of Real-world Data at the Community Pharmacy

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Trabalho de Campo orientado pela Professora Doutora Carla de Matos Torre, Professora Auxiliar da Faculdade de Farmácia da Universidade de Lisboa

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Declaration

The work presented below was produced under the supervision of Professor Carla de Matos Torre, Assistant Professor at the Faculty of Pharmacy of the University of Lisbon.

This project was conducted with the help of the Pharmaceutical Group of the European Union (PGEU), where Gabriel Branco was interning in representation of the European Pharmaceutical Students' Association (EPSA).

Full acknowledgements have been made where the work of others has been cited or used.

Resumo

Introdução: A utilização de dados de vida real (*real-world data* – RWD) na produção de evidência científica tem vindo a ser cada vez mais explorado. A prestação de serviços farmacêuticos, nomeadamente a dispensa de medicamentos, é uma fonte de RWD de elevado potencial, mas para que este potencial possa ser atingido é necessário ultrapassar desafios como a falta de plataformas únicas de recolha de dados e a dificuldade em recolher RWD de maneira que possam ser processados.

Objetivos: Este estudo visa compreender o contributo das farmácias e dos farmacêuticos comunitários na recolha de RWD e explorar o contributo da expansão da prática profissional farmacêutica neste âmbito.

Métodos: Foi efetuado um inquérito às organizações membro do grupo farmacêutico da União Europeia (*Pharmaceutical Group of the European Union* – PGEU) sobre o estado da arte no que diz respeito à recolha e à utilização de RWD em farmácias comunitárias na Europa.

Resultados: Foi possível compreender o estado atual da recolha de RWD nas farmácias comunitárias, bem como identificar os pontos que facilitam ou impedem o seu desenvolvimento.

Conclusão: Os farmacêuticos comunitários são profissionais capazes e estrategicamente localizados para contribuir para a recolha de RWD em saúde. É necessário construir alicerces informáticos e legais que permitam a recolha de dados em registos preparados para a sua derivação, que estabeleçam a ligação entre os diversos pontos de contacto com o utente sem prejuízo do seu direito ao controlo dos próprios dados.

Palavras-chave: Real-world data; Farmácia Comunitária; Farmacovigilância; Adesão à Terapêutica; Efetividade.

Abstract

Introduction: The use of real-world data (RWD) to generate evidence to assess the benefit-risk of medicines has been increasingly explored. Pharmacy services, namely medicine dispensing, have a great potential as a source of RWD, but for that potential to be reached, some challenges need to be overcome, such as the lack of common data collection platforms and the difficulties in collecting raw data in a way that can be easily treated.

Objectives: This study aims at understanding the role that community pharmacists play in the collection of RWD and look into how pharmacy practice can expand in this regard.

Methods: A survey was sent to the member organizations of the Pharmaceutical Group of the European Union (PGEU) to collect data about the current state-of-play in regard to the collection and use of RWD in community pharmacies in Europe.

Results: It was possible to understand the current situation state of play regarding the collection of RWD at the community pharmacy, as well as identify the factors that either facilitate or hinder its development.

Conclusion: Community pharmacists are healthcare professionals (HCPs) able and strategically placed to contribute to the collection of RWD in healthcare. It is necessary to build the informatic and legal foundations that allow for this collection into registries prepared to derive the data into scientifical evidence, which establish a connexion between the several points of contact with the patients without compromising their rights to ownership of their own data.

Keywords: Real-world data; Community Pharmacy; Pharmacovigilance; Medicines Adherence; Effectiveness.

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Abbreviations

ADR – Adverse Drug Reaction

BDSG -– Big Data Steering Group

DARWIN – Data Analytics and Real-World Interrogation Network

DG SANTE - Directorate-General for Health and Food Safety

EC – European Commission

EHDS – European Health Data Space

EHRs – Electronic Health Records

EMA – European Medicines Agency

EPSA – European Pharmaceutical Students' Association

EU – European Union

FDA – Food and Drug Administration

GPs – General Physicians

HCP – Healthcare Professionals

HERA – European Health Emergency preparedness and Response Authority

HTA – Health Technology Assessment

ILI – Influenza-like-illness

MAH – Marketing Authorization Holder

ME – Medication Error

NCA – National Competent Authority

OECD - Organisation for Economic Co-operation and Development

PASS – Post Authorisation Safety Studies

PBS – Pharmaceutical Benefits Scheme

PCT – Pragmatic Controlled Trial

PGEU – Pharmaceutical Group of European Union

PRAC – Pharmacovigilance Risk Assessment Committee

PSUR – Periodic Safety Update Report

QoL – Quality of Life

RCT – Randomized Controlled Trial

RPBS – Repatriation Pharmaceutical Benefits Scheme

RWD – Real-world data

RWE – Real-world evidence

SFDA – Saudi Food and Drug Authority

US – United States

WHA – World Health Assembly

WHO – World Health Organization

Table of Contents:

Declaration 3
Resumo 4
Abstract 5
Acknowledgements 6
Abbreviations 7
1 Introduction 10
1.1 Real world data and real-world evidence definitions 10
1.2 Sources of real-world data 11
1.3 Uses of real-world evidence 11
1.4 Data Quality 15
1.5 Real-world evidence in decision and policy making 15
1.6 Opportunities and challenges for Pharmacy Practice 20
2 Objectives 22
3 Methods 23
3.1 Study population 23
3.2 Survey Design 23
3.3 Data Collection 23
3.4 Data Analysis 24
4 Results 25
4.1 Respondent Information 25
4.2 Pharmacovigilance 25
4.3 Adherence 27
4.4 Shortages 29
4.5 Health Technology Assessment 32
4.6 Screenings 32
4.7 Pharmacy dispensing software and other registries 33
4.8 PGEU Members' views on the collection of real-world data at the community pharmacy 36
5 Discussion 39
5.1 Pharmacovigilance 39
5.2 Medicine Adherence 39
5.3 Shortages 40
5.4 Health Technology Assessment 40
5.5 Pharmacy dispensing software and Patient Registries 41
5.6 Training Healthcare Professionals 42
5.7 Perspectives for the future 42
5.8 Limitations of the survey 43
6 Conclusion 45
References 46
Annexes 54
A1. PGEU Survey on the Collection of RWD at the Community Pharmacy 54

Table of Contents - Figures

Figure 4.1 Proportion of ADR reports which is generated by Pharmacists 25
Figure 4.2 Collection of data on medicine use to perform drug utilisation studies 27
Figure 4.3 Organisation of patient registries in community pharmacies 34

1 Introduction

1.1 Real world data and real-world evidence definitions

The United States (US) Food and Drug Administration (FDA) defines real-world data (RWD) as “data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources” and real-world evidence (RWE) as “the clinical evidence about the usage and potential benefits or risks of a medical product derived from analysis of RWD” (1).

Although the concept of RWE consisting of evidence derived from RWD is widely accepted, the same cannot be said regarding the definition of RWD.

There is general agreement that the raw data present in electronic health records (EHRs) is undoubtedly considered RWD, as it is obtained without any intervention by the investigator. There is also general agreement that the data from randomized controlled trials (RCTs), which is obtained in a very controlled setting, is not considered RWD. However,(2) a review of definitions performed by Makady A. et al. found that there was not complete consensus on which type of data could be considered RWD, and concluded that the publicly available definitions of RWD could be divided into four main definitions: data collected in a non-RCT setting; data collected in a non-interventional/non-controlled setting; data collected in a non-experimental setting; and others (2).

At the European Union (EU) level, the European Medicines Agency (EMA) has somewhat informally defined RWD as “routinely collected data relating to a patient's health status or the delivery of healthcare from a variety of sources other than traditional clinical trials” while presenting their Data Analytics and Real-World Interrogation Network EU (DARWIN EU), but this definition is yet to be included in any piece of legislation. However, in the Pharmaceutical Strategy for Europe, published in November 2020, the European Commission (EC) proposed to revise the pharmaceutical legislation in order to include new methods of evidence generation and assessment, including the analysis of RWD, so there will be more legislative clarity on the topic in the near future (3), and possibly further clarification on the definition and use of RWD.

For the purpose of this paper, the broader definition of RWD (data collected in a non-RCT setting) was used.

1.2 Sources of real-world data

RWD can be extracted from various sources. Routinely collected health data can be found in registries, collections of EHRs, administrative and medical claims databases, patient generated health data, Health Data Aggregators, Specialty Data Providers and Networks, country program databases, linked or enriched data sets, etc (1,4–6).

Closer to community pharmacy practice, there can also be collection of RWD through dispensing software, national pharmacovigilance systems and as part of specific pilots or initiatives from pharmacies (5–7). The value of these data, namely the one collected through the dispensing software, is mentioned by the EC in its proposal for a European Health Data Space (EHDS) (8).

1.3 Uses of real-world evidence

1.3.1 Pharmacovigilance

Pharmacovigilance was, in a way, the first step into the realm of RWD. Through spontaneous notification of adverse drug reactions (ADRs), there is a possibility to collect large quantities of data, and that data could be analysed to contribute to the safety profile of medicines.

In 1966, during the 19th World Health Assembly (WHA), the first pilot project for the creation of an international pharmacovigilance system was presented. In 1968, this project started and with it came the creation of the first medicines monitoring centre and a database of its own (9).

The World Health Organization (WHO) defines Pharmacovigilance as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem", and an ADR as "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function" (10,11).

Medication errors (ME) are defined as "an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient" and can be

related to the prescribing, dispensing, storing, preparation and administration of a medicine. According to the EMA, these are "the most common preventable cause of undesired adverse events in medication practice and present a major public health burden" (12).

1.3.2 Medicine adherence

One if not the main determinant of treatment success in any given regimen is medicine adherence. A low adherence represents not only sub-optimal results for patients, but also higher costs for healthcare systems and sometimes even environmental issues (13,14).

Both EHRs and pharmacy records and dispensing data were proven to be useful in the evaluation of medicine adherence, both at an individual level, but also to produce RWE concerning the medicine adherence of a given population (14,15). However, there are still some challenges in the analysis of this data, such as differences in the definition of medication adherence, record-linkage of different data sources, data selection for analysis and handling missing, incorrect, or duplicate records (15).

In Portugal, an evidence generator was created based on a cohort of community pharmacy users, which allows for the conduction of studies with patients undergoing treatment with certain drugs of interest. This evidence generator was able to measure therapeutic adherence through RWD collected from patients taking oral anticoagulants (16).

1.3.3 Shortages

Medicine shortages have been one of the major concerns of health systems in the past years. In the PGEU Medicine Shortages Survey conducted in 2021, all 27 responding countries responded that they experienced shortages in the previous 12 months, and 77.73% of these respondents indicated either that the situation had stayed the same or gotten worse from previous years, with cardiovascular medicines leading the board with shortages in 85.19% of the countries (17). At the hospital level, the European Association of Hospital Pharmacists (EAHP) also conducted a similar survey in 2020 with their members, which found that over 80% of hospital pharmacists had

experienced a medicine shortage over 3 times in 2019 alone, and that antimicrobial agents and oncology medicines were the ones most commonly out of supply (18).

In the pharmaceutical strategy for Europe, the EC sets out to "secure the supply of medicines across the EU and avoid shortages" as one of its main goals (3). In October 2022, a working document was published with the main findings of the structured dialogue on the vulnerabilities of pharmaceutical supply chains, among which were the agreement that public authorities did not have access to sufficient data to determine vulnerabilities and the reminder that the European Health Emergency preparedness and Response Authority (HERA) was developing an intelligence gathering tool to support the detection of vulnerabilities and availability challenges (19).

A multitude of factors can influence both the supply and the demand of a certain medication which can lead to a shortage. In order to ensure the resilience of health systems, it is important to be able to predict these shortages, act swiftly in order to minimise their impact, and, if possible, avoid them.

Very recently, with the COVID-19 pandemic, several medicines and medical devices suffered shortages, namely in-vitro diagnostics, Class I medical devices (e.g., bandages, thermometers, and surgical face masks), and Class IIa medical devices (e.g., lancets, needles, and short-term contact lenses) (17). It was found that the data collected in community pharmacies through daily practice, i.e., RWD, was useful to predict said shortages (20).

1.3.4 Health Technology Assessment (HTA)

RWD and RWE have a great potential to be used in HTA. In order to estimate the cost-effectiveness of a medicine and make pricing and reimbursement decisions, the payer needs to understand the impact that it will actually have on a given population.

RWD can be used to estimate disease-specific costs, direct and indirect costs of treatment, and the clinical effectiveness of medicinal products (21,22). HTA agencies already use RWD for different purposes, and its use in economic evaluations can guide the decision-making process and help optimizing resources (22,23).

The Portuguese evidence generator mentioned in 1.3.2. was also used to produce RWE on the quality of life (QoL) of patients using antidiabetics or oral anticoagulants in Portugal (24).

1.3.4.1 Efficacy-effectiveness gap

According to the conclusions of the EU High Level Pharmaceutical Forum, "efficacy is the extent to which an intervention does more good than harm under ideal circumstances", while "effectiveness is the extent to which an intervention does more good than harm when provided under the usual circumstances of health care practice" (25).

RCTs are the gold standard to determine safety and efficacy of a drug in the pre-marketing phase and they do allow for the most common ADRs to be discovered. However, there are some limitations, as RCTs are not able to mimic the real-world use of the medicine at hand. These trials are done on limited populations and in very controlled circumstances, where issues with, for example, medicine adherence and medication schedules/errors tend to be minimized. Because of this, there is often a gap between the efficacy found through clinical trials and the effectiveness of a medicine in practice, which is usually lower (26).

The use of RWD can be especially important to fill this gap when there is little representation of a specific patient group in clinical trials, as lack of representation makes it so that certain biological variations, such as differences in pharmacokinetics or pharmacodynamics due to different genetic makeups are not taken into consideration, so the gap is bigger (27).

Other important factors that are often not taken into consideration during RCTs are the non-biological variations, such as the budget and resource constraints that are higher in certain parts of the globe and that result in different reimbursement decisions and, consequently, differences in clinical practice (27).

RWD is often collected on the effectiveness of medicines to determine the efficacy-effectiveness gap and re-evaluate the benefit-risk ratio of medicines. Albeit not many, some of these studies are conducted using data from pharmacy databases (28).

1.4 Data Quality

A lot of health data is collected outside of RCT settings. As explained in section 1.2, RWD can be extracted from EHRs, pharmacy dispensing software, insurance, or other types of medical or administrative claims, patient generated health data (e.g., mobile health apps), Health Data Aggregators, Specialty Data Providers and Networks, country program databases, linked or enriched data sets, etc (1,4–6). However, large quantities of collected data do not necessarily reflect large quantities of useable data. The main concern is how to ensure the quality of the RWD used in order to produce RWE that can indeed inform decision-making.

Khan et al. proposed a framework for a Harmonized Data Quality Assessment Terminology, suggesting that having such a terminology would be the first step towards structuring data quality assessments to evaluate the conformance, the completeness, and the plausibility of the data in a given pool (29).

The future appears to lie in the standardisation of data, the creation of datasets already developed to be easily converted in RWE, and in shifting some of the responsibility of ensuring quality RWD to the side of the healthcare professionals (HCPs) that are collecting data (30,31).

1.5 Real-world evidence in decision and policy making

This section contains an overview of the current use and future prospects of including RWE in regulatory decision-making in several countries/regions.

1.5.1 European Union

In the EU, each country has its national pharmacovigilance system, that must fulfil specific requirements (9). HCPs and patients/caregivers can report ADRs to these national pharmacovigilance systems, which in turn report to EudraVigilance, the system that processes all the data collected regarding the safety of medicines in the EU, namely reported ADRs (32).

EMA's Pharmacovigilance Risk Assessment Committee (PRAC) is responsible for assessing and monitoring the safety of human medicines (33). This is done through

analysing safety signals detected by EudraVigilance. The analysis by PRAC results in the issuance of advice or recommendations (32,34).

After a marketing authorization has been granted, the marketing authorization holder (MAH) needs to follow a specific set of procedures, such as producing Periodic Safety Update Reports (PSUR), to ensure that benefit-risk evaluation is carried out throughout the whole lifecycle of the medicinal product, and not just before its marketing authorization (35). An important tool to obtain further information on a medicine's safety and benefit-risk profile or to evaluate the effectiveness of risk-management measures are the Post Authorisation Safety Studies (PASS) which can be carried out voluntarily by MAHs or imposed on them by the regulatory authorities (36).

Naturally, RWD has a vital role in the post-authorization phase, but its use in the pre-authorization phase has also been shown to regulatory decision-making in the pre-authorization phase, particularly regarding conditional marketing authorizations of orphan medicines (37).

As RWD and RWE have gained importance in the last few years, the EC has strived to keep up with the developments. In February 2020, the European Data Strategy was announced (38). This strategy aims at building a single market for data comprising of nine data spaces, including one for health, with sector-specific rules that will allow different users to share data. The EHDS, which is being developed by the EC's Directorate-General for Health and Food Safety (DG SANTE) and is a part of the Pharmaceutical Strategy (3), aims to facilitate access to health data across Europe, for primary and secondary uses, whilst ensuring citizens have control over their own health data. The purpose of the EHDS is to achieve better healthcare, better policy-making and better research, and innovation, supporting evidence-based decisions.

On the side of EMA, steps are also being taken in order to increase the work done in this area, with the creation of a Big Data Steering Group (BDSG), whose workplan was adopted on 18 June 2021 and, among other objectives, included the creation of DARWIN EU, a network that will be interconnected with the EHDS and will conduct studies for decision making using RWD while ensuring data quality, representativeness and developing the capability to analyse data, among other priorities (39). EMA produced a list of metadata for describing RWD sources and studies and is currently

working on a catalogue to be released in the beginning of 2023, having already released a draft version of a good practice guide for the use of that catalogue (40,41).

1.5.2 Organisation for Economic Co-operation and Development (OECD)

The OECD released an Analytical Report on "Using Routinely Collected Data to Inform Pharmaceutical Policies", in 2019, following a survey conducted with 26 countries. Among the findings, we can see that most of the countries collected patient-level data, mostly through pharmacy records, EHRs, and insurance claims, however, not all of them had the same capability to harness this data in order to inform pharmaceutical policies and evaluate the effectiveness of medicines. Another point of divergence was in regard to who could access that data. While in some countries only government agencies and data custodians had access to the data, in others, universities and non-profit research units could also use them, and in a few other countries it is even available to other stakeholders (31).

In the same report, OECD concludes that although this data is collected, it is not systematically used to inform policies, being more often used "to monitor consumption and national level spending (22 countries), providers' compliance with guidelines (18 countries), and prescribing quality and behaviour (15 countries)". The majority of the responding countries also use RWD to evaluate the safety of medicines and inform changes in clinical practice, and about half of them consider RWD in cost-effectiveness studies and relative effectiveness evaluations (31).

This report confirms what was stated in the previous sections, stating that "regulatory agencies use routinely collected data in post-marketing safety surveillance and for ad-hoc risk-benefit re-assessment". It is further stated that "institutions in charge of HTA consider evidence derived from routinely collected data to revise their assessments of medicines". Furthermore, one can read in the document that "observational studies based on routinely collected data have sometimes influenced decisions on coverage conditions or prices", and even that "evidence from routinely collected data has also driven changes in clinical guidelines" (42).

Overall, countries recognized that they were not using RWD to its fullest potential, but they were focused on addressing the existing barriers (42).

1.5.3 Australia

In Australia, the Pharmaceutical Benefits Scheme (PBS) is one of the pillars of the health system. It is through PBS that Australian citizens have subsidised access to prescription medicines. There is also the Repatriation Pharmaceutical Benefits Scheme (RPBS) for veterans. Medicines are placed in the PBS and RPBS listings based on their clinical efficacy, safety, and cost-effectiveness in relation to other medicines (43).

Australia's National Prescribing Service launched the National Medicines Policy in 2000 (44).

Data from dispensing records generated when PBS or RPBS prescriptions are dispensed in pharmacies have been shown to be useful in quantifying population-level medicine use and associated outcomes (45,46). However, these records were not originally designed to produce this kind of evidence, so there are limitations. That is the case, for example, with the directions for use, as those data are not present in the records (43).

On the other end, EHRs have high quality records on all prescriptions written including directions for use. However, the quality of the data is variable, especially since Australia does not have one harmonized EHR, although efforts are being made in that direction (47). On top of that, quantifying and capturing changes in medicine use as people transition to different healthcare settings has proved to be challenging (43).

RWD is also used, still in the medication use area, by the Antimicrobial Use and Resistance in Australia Surveillance System to ensure the responsible use of antimicrobials (43).

1.5.4 Japan

The number of observational studies from Japanese academia has increased significantly in the past few years. There have also been a number of governance changes, such as the revision of the Good Post-marketing Study Practice in 2018 to include database studies as a type of post-marketing studies and the implementation of the Clinical Trials Act to tighten the standards to conduct interventional studies. Also in 2018, the Next-generation Healthcare Infrastructure Act came into force, making it possible for medical institutions to provide personal medical information to certified business operators which are now able to anonymize medical data and provide it to

users. This change greatly promoted the use of RWD, and pharmaceutical companies in Japan are investing more in observational research and establishing systems to conduct it (48).

There are, of course, challenges, just as in other countries, such as limited access to data, difficulty in linking databases, poor data quality, and unclear guidance on the acceptability of RWD/RWE by regulators. The lack of decision criteria, standards, and guidelines for RWE development also poses a challenge, and the fact that it is still not completely established which items are necessary for scientific decision-making and validation in a database study does as well. However, despite there being room for improvement, progress has been made toward the use of RWD in some cases (48).

1.5.5 Latin America

In Argentina, RWE is sporadically used in HTA decisions. Although data is indeed collected in daily practice, there is a lack of a framework to coordinate between databases, share findings or create links at regional or national levels. Because of this, the generalizability and transferability of RWE in Argentina is fairly limited (49).

In Brazil, the interest in RWE, namely in patient-reported outcomes and the cost-effectiveness of interventions is growing, just as the importance of health economics itself is, because of the need to manage resources. Although Brazil has a comprehensive national health information system, DATASUS, and both a national health surveillance system and a national pharmacovigilance system, there are inconsistencies in common indicators and variation in data quality and security, which results in limited access to RWE to inform policies (49).

In Chile, there are national data-collection systems, good quality registries, and a system to monitor patients' safety after treatment authorization, but there is a lack of longitudinal data, and the funding for research using the data in the registries is quite scarce. However, Chile's public and private institutions are likely to coordinate to activate funding for the development of RWE research in the future (49).

The Colombian registry system has been capturing national RWD for decades. RWE has been generated from epidemiological, clinical, and cost RWD by producing simulation models or budget impact analysis. There are insufficient human resources and capacity, but Colombia has access to longitudinal data and a history of evidence-

based health decision-making, unlike many of its neighbouring countries. One of the big advantages that Colombia has is the fact that the healthcare is universal, so virtually all citizens participate in the data collection. However, the lack of identifiers that allow for the linking of heterogenous data sources still poses a great challenge (49,50).

1.5.6 Saudi Arabia

In Saudi Arabia, the use of RWD has been fairly limited because of the lack of integrated systems and readily available data for research. However, the Saudi Food and Drug Authority (SFDA) initiated the integration of EHR data from several organizations in a pilot database that can be utilized to inform decision-making. The objective is for SFDA to establish a national comprehensive integrated database that covers the whole population and is able to generate RWE on drug safety and, eventually, effectiveness.

1.5.7 United States of America

In December 2018, the FDA published a framework for its real-world evidence program. In this document, the definitions of RWD and RWE are established, there is a sum up of how RWD is being used in the present, and a strategy for how it should be used in the future. It explains how trials or studies with RWD/RWE should be used for effectiveness decisions and defines what RWD needs in order to be fit for use in regulatory decisions. It also explores the potential for study designs using RWD to support effectiveness, exposes some regulatory considerations for study designs using RWD and clearly defines the standards that must be followed in order for data to be appropriate for Integration and Submission to the FDA, something that was not found in any other country (1).

1.6 Opportunities and challenges for Pharmacy Practice

PGEU's Pharmacy 2030 Vision for the Future where PGEU outlines that "integrating real-world data on pharmacovigilance, adherence and effectiveness of medicines into practice, to improve safeguarding and advice on the safe use of medicines for each individual patient, is widely welcomed by community pharmacists" (51).

As explained above, pharmacovigilance is one of the areas where RWD has been used to inform decision-making for the longest time. Community pharmacists, as HCPs, can report ADRs, however, in some countries it is found that reporting rates by community pharmacists remain low or could be improved (52,53), which is also backed by PGEU's best practice paper on pharmacovigilance and risk minimization, and the results of the pharmacovigilance and risk minimization survey presented therein (54).

If we step out of the already established reporting of ADRs and into a more global approach, community pharmacists, as the HCPs closest to the communities, have access to a wide variety of data. From the screenings performed in some pharmacies to the dispensing records, and even considering shortages prediction, these data represent a major opportunity for the collection of RWD or RWE generation.

However, there are also some challenges for community pharmacists when it comes to the collection of RWD. As discussed in the section about data quality, the conformity, the completeness, and the plausibility of the data are very important to produce quality evidence (29), and so is the harmonization of the data collected (30,31). The differences between dispensing software, patient registries and other platforms of data collection (e.g., for pilot studies), but also the fact that patients' data is collected and stored in multiple platforms used by different HCPs, are all hindering factors in regard to maintaining the data quality.

2 Objectives

This study aims to understand how community pharmacists are currently contributing to the collection of RWD and consequent production of RWE, namely in the countries represented by PGEU. The objective is also to analyse the trends that are starting to form in this area and explore how pharmacy practice can expand in the future to contribute more to the creation of RWE, be it for pharmacovigilance purposes, to fill the efficacy-effectiveness gap or to study adherence to therapy.

3 Methods

The findings laid out in this study arose from a survey to collect data about the current state-of-play in regard to the collection and use of RWD in community pharmacies in Europe.

3.1 Study population

PGEU member organisations were the target population of this study. Through PGEU's internal communication channels, 41 associations representing community pharmacists and/or pharmacies in 32 countries were contacted and an answer per country was requested. The sole inclusion criterium defined for the study was being a member of PGEU, and no exclusion criteria were applied.

3.2 Survey Design

After the initial literature review, the survey was designed based on the latest information regarding the collection of RWD in community pharmacies and by community pharmacists.

The survey was divided in 8 sections: Respondent information, pharmacovigilance, adherence, shortages, HTA, screenings, pharmacy dispensing software and other registries, and members' views. Sections 2 through 7 were designed to obtain information on the current practices around Europe, while the last section was designed to collect information from the population regarding their future perspectives and the obstacles they saw to progress in the area.

Before being circulated, the PGEU Secretariat was able to review the structure of the survey and provide comments based on their expertise, in order to better target the questions to the population and obtain better quality data.

3.3 Data Collection

The survey was sent on May 3, 2022, via email. A form was sent to fill out with May 24, 2022, as a deadline. On May 30, 2022, PGEU member organisations that had not

submitted a response were contacted individually in order to remind them to fill the survey. Responses were collected until June 4, 2022. PGEU's internal communication channels were used to draft, circulate, and obtain answers to the survey which can be found in the Annexes.

3.4 Data Analysis

A descriptive analysis was conducted to provide an overview of the answers given by the organizations. Data were analysed using Microsoft Excel.

4 Results

4.1 Respondent Information

There were responses from 22 countries (Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Netherlands, Norway, Poland, Portugal, Serbia, Spain, Sweden, and United Kingdom), which account for 68.75% of the countries represented by PGEU.

Among the respondents, 19 were ordinary members of PGEU, meaning that they are part of the EU. This represents 73.08% of PGEU's ordinary members, and 70.37% of the countries included in the EU.

4.2 Pharmacovigilance

4.2.1 The role of pharmacists in the total ADR report generation

Most of the responding countries did not have data on the proportion of ADRs reported by pharmacists from 2021 as requested, so the most recent data was presented when there was data available.

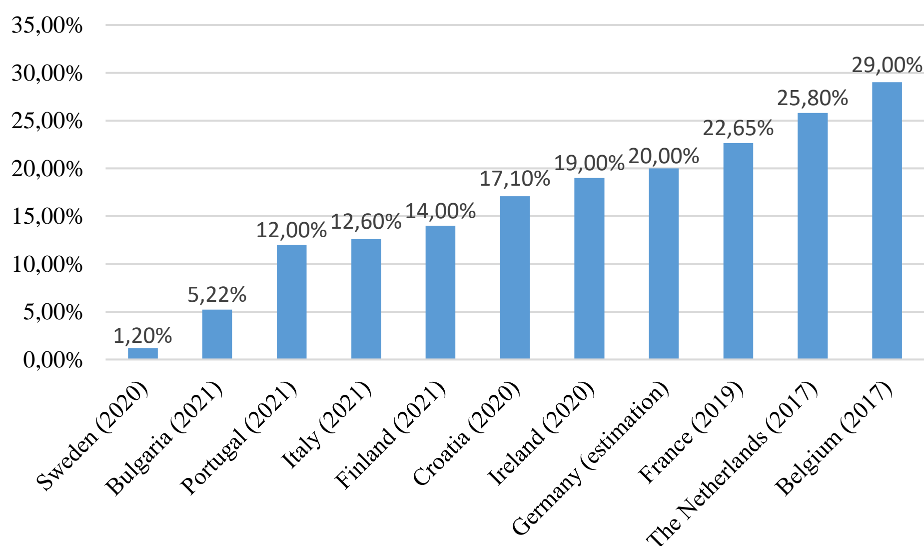

Figure 4.1 Proportion of ADR reports which is generated by Pharmacists

Most countries did not have data concerning specifically community pharmacists. In the Netherlands, in 2017, 89.14% of the pharmacist-generated ADR reports were done

by community pharmacists. In Sweden, data from 2020 indicated that this number was 59%. Portugal reported a lower ratio between ADR reports generated by community pharmacists and the total number of pharmacist-generated ADR reports, with 19% of pharmacist-generated reports being attributed to community pharmacists.

4.2.2 ADRs in the undergraduate curricula

16 out of 22 respondents stated that the act of reporting ADRs was covered by the undergraduate curricula (Belgium, Bulgaria, Croatia, Cyprus, Finland, France, Germany, Greece, Ireland, Latvia, The Netherlands, Norway, Portugal, Serbia, Spain, and United Kingdom). On the other end, 5 out of 22 respondents mentioned that it was not (Denmark, Estonia, Italy, Poland, and Sweden).

We did not receive a response from Czech Republic.

4.2.3 Post-graduate ADR trainings

18 out of 22 respondents indicated that there was some sort of training on ADR reporting (included in the continuous professional development programmes, given by academia, given by National Competent Authorities (NCAs), given by professional organizations or pharmacy chambers, etc.), albeit never in a mandatory format (Belgium, Bulgaria, Croatia, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Latvia, The Netherlands, Norway, Portugal, Serbia, Spain, and United Kingdom).

4 out of the 22 respondents answered that there was no post-graduate ADR training (Cyprus, Denmark, Poland, and Sweden).

4.2.4 Link between the pharmacy software and the national spontaneous reporting system

21 out of 22 respondents reported not having a link between the pharmacy software and the reporting system. Spain reported some kind of link between the two, but solely related to the so-called "Extreme Use Caution" medicines, which included pharmacovigilance warnings in the pharmacy software.

France reported that although there was no direct connection between the software of the pharmacy and the reporting systems, the link to the reporting portal was included in the useful links of the pharmacy software, so that pharmacists only needed to go to the list and click to open the specific tab in their Internet browser. Serbia indicated that at national level, a health digitalisation project was underway which included the link between the pharmacy software and the national spontaneous reporting system.

4.3 Adherence

4.3.1 Collection of data on medicine use to perform drug utilization studies

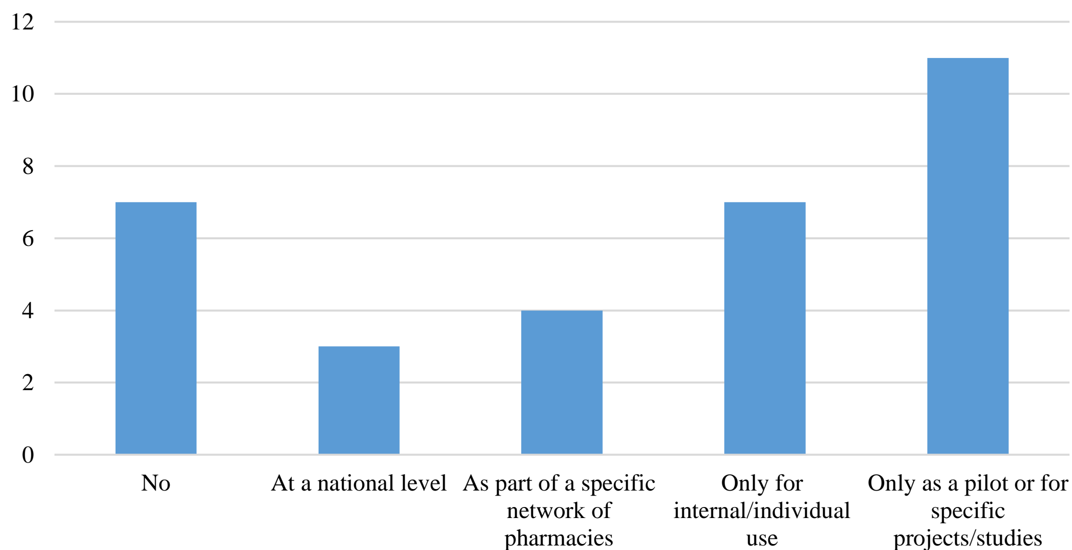

Figure 4.2 Collection of data on medicine use to perform drug utilisation studies

7 out of the 22 respondents answered that community pharmacies did not collect data on medicine use to perform drug utilisation studies (Bulgaria, Cyprus, Finland, Latvia, Norway, Sweden, and United Kingdom). Out of the remaining respondents, 7 answered "only for individual use" (Croatia, Denmark, Germany, Greece, Ireland, Portugal and Serbia), 11 answered "only as a pilot or for specific projects/studies" (Belgium, Croatia, Czech Republic, Demark, France, Germany, Ireland, Italy, Poland, Portugal, and Serbia), 4 answered "as part of a specific network of pharmacies" (France, Ireland, the Netherlands and Spain) and only 3 countries reported exploring this at a national level (Denmark, Estonia and the Netherlands).

In Belgium, there have been studies in different therapeutic domains (respiratory, osteoporosis, diabetes), where longitudinal dispensing data is captured in order to calculate adherence metrics.

In Denmark, dispensing data from all community pharmacies are sent to the Danish health data authority.

In Estonia, pharmacies add the data about dispensed medicines to the e-prescription system, and pharmacists can apply for the e-prescription data to perform nationwide utilization studies, but to the knowledge of the respondent they had not done such studies.

In France, private providers working for pharmaceutical companies sometimes collected adherence data through questionnaires performed by pharmacists, and statistical firms may have contracts with several pharmacies to collect data.

Although Italy reported not having a structured activity at national level, they reported that the creation of such activity was being considered in the discussions for a new remuneration scheme.

The Netherlands reported that data was collected at a national level, but as a part of a network of pharmacies that provide their data to the Dutch foundation for pharmaceutical statistics, which are over 97% of the total number of pharmacies in the country.

Poland reported that the recently created pilot program of Medicinal Drugs Review had started in 75 polish pharmacies, and its goal was to reduce the level of polypharmacy.

Portugal stated that community pharmacies collected data, through the pharmacy software, related to drug consumption, and in some specific projects, pharmacies could also study therapeutic adherence. An example was the fact that although detection and tracking of the flu primarily relied on physician diagnoses, sentinel influenza-like-illness (ILI) surveillance and virologic confirmation, such as other non-traditional data sources, namely community pharmacy dispenses, had been shown to provide accurate and more timely detection. Consequently, surveillance systems developed based on this data were able to anticipate the load on primary care services and hospitals. HiCorr-flu model, a surveillance system based on community pharmacy data, was able to anticipate the beginning and the peak of the flu epidemic in approximately two weeks, when compared with physician's diagnosis in primary care. The Portuguese delegation also

gave the example of PHOLLOW, which was a service provided by National Association of Pharmacies and consisted in a decision support tool for health technology assessment using real world data. The main objective of this tool was to obtain information of diseases, patients, and the use of medicines by the population, in complement to the information coming from clinical trials. This tool allowed pharmacists to know patients' therapeutic plan, to identify and intervene in situations where safety or effectiveness was compromised.

In Spain, some data was collected through the NodoFarma Asistencial tool, as part of a specific network of pharmacies.

4.4 Shortages

4.4.1 Organisation responsible for managing the medicine shortages reporting systems/databases

Most countries reported that it was their NCA that did this (Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Ireland, Italy, Norway, Portugal, and Sweden), but some of PGEU's members had their own reporting system to either complement (Ireland and Portugal) or compensate for the lack of a government-led initiative (the Netherlands and Spain). A response was not received from Latvia, Serbia declared that this was done through their insurance service, and the United Kingdom declared that it was the responsibility of the negotiator.

4.4.2 Functioning of the medicine shortages reporting systems

In most of the responding countries, only MAHs are obliged to report medicine shortages, and in 7 of them, Pharmacists and Pharmacies are not involved with reporting medicine shortages (Croatia, Cyprus, Czech Republic, Estonia, Finland, Germany, and Sweden). In the countries where pharmacists do report, the information collected by pharmacists varies slightly but generally includes date of the occurrence, identification of the Pharmacy, name, and dose of the medicine.

Belgium noted that their NCA evaluated and published the results of a report within the day on an official website. Cyprus stated that once a shortage was reported to the general health system organisation by importers, an announcement was sent through

their platform to community pharmacists. In Estonia, the shortage reports are sent to the State Agency of Medicines and published at the Medicinal Products Registry. In Ireland, both the Irish Pharmaceutical Union and the Health Products Regulatory Authority publish a Medicines Shortages Report online.

In Portugal, since April 2019, the regulatory authority, INFARMED, created and manages the Shortage Management System. Shortages can be communicated via email by any citizen or, if it is a community pharmacy or wholesaler, through the web service provided by INFARMED. At pharmacy level, the notification form is incorporated in the pharmacy software. It is mandatory to report shortages, according to the standards defined by the regulator. Community pharmacies have a voluntary reporting system, implemented by National Association of Pharmacies based on the pharmacy medicine orders that were totally or partially unfulfilled by the wholesale distributors. The system generates daily information regarding the medicine (name, dose, pharmaceutical form), package and price, name of the market authorization holder, name of the supplier pj(wholesaler) and number of units in shortage. The registry of shortages is undertaken during the verification of the orders received from the wholesalers in the Pharmacy. The pharmacy software generates a file which is sent by e-mails to the IT department of the National Association of Pharmacies, and their research centre produces a monthly report which is shared with the authorities.

In Spain, the Spanish Agency of Medicines and Medical Devices gets a direct notification of supply problems from pharma companies, which are then entered into its database, whilst another database run by the General Pharmaceutical Council of Spain gets notified by community pharmacies. Apart from those medicines that pharma companies have not reported to the regulatory agency, this database also makes it possible to detect in real-time different situations that may be affecting the supply of certain medicines.

4.4.3 Use of data collected by the medicine shortages systems

Most countries use the data collected in order to publish an up-to-date list of shortages publicly (Belgium, Croatia, Estonia, Finland, Germany, Ireland, Italy, The Netherlands, Poland, Portugal, Sweden). These lists are created mainly for HCPs, but in some countries, patients also have tools at their disposal to see, for example, which

pharmacies have the medicine they cannot find. Some countries also reported trying to predict the duration of the shortage to add to this list.

While not many countries reported the use of this data to inform regulatory action, Greece, and Poland both mentioned that exports are more strictly controlled during a shortage, while Portugal mentioned that during shortages exceptional use authorisations could be activated. Bulgaria and Italy both mentioned also using the data to inform regulatory action, but did not mention how, and Germany mentioned that the data was used to inform politicians as well as HCPs.

4.4.4 Additional national/regional evidence/information on the role community pharmacists play in mitigating shortages

Belgium highlighted that in the Flemish region of the country, a study had been conducted that calculated pharmacies spent on average of 25 minutes a week with drug supply problems.

Norway shared a mapping study published in 2022 that showed that 3.3% of patients did not bring home all the medicines they needed, but pharmacies were able to find a solution for most of these cases, reducing this percentage to between 0.3 and 0.7.

Portugal highlighted that in order to mitigate drug shortages, pharmacists could source the same medicine from alternative authorised sources (e.g., other pharmacies), perform generic substitution, or import the medicine from a country where it was available. They also stated that "the ability to perform therapeutic substitution and changing to the same medicine with a different dose are important instruments that Portuguese pharmacists can't use" and that "better communication between prescribing doctors and pharmacists, using new technologies, is essential to ease the difficulties imposed to patients by shortages".

Spain reported having a database which gave pharmacists immediate access to information on medicine supply incidents/shortages, allowing pharmacists to seek practical solutions such as the substitution of medicines or referring the patient to a nearby pharmacy where the medicine could be found (which could be done with the help of the evidence-based tool FarmaHelp).

Sweden stated that there were weekly meetings between the Swedish Pharmacy Association and the Medical Products Agency to discuss shortages and that the Swedish Pharmacy Association had developed a database that made it possible to see nearly all stocks at pharmacy level, which they used to answer questions from the Medical Products Agency regarding how many packs were available so that they could evaluate the risk for the patients when a shortage was reported.

4.5 Health Technology Assessment

4.5.1 Role of community pharmacists on the collection of data on the effectiveness/benefit of medicines

20 out of 22 countries did not collect this sort of data, with Belgium and the Netherlands being the only ones doing so through specific pilot projects.

4.5.2 Role of community pharmacists on the collection of data on patient reported outcomes and quality of life

17 out of 22 respondents reported that community pharmacists did not play a role on the collection of data on PROs and QoL (Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Norway, Serbia, Spain, Sweden, and United Kingdom).

All the remaining 5 countries did it only within the scope of pilot projects (Belgium, Denmark, the Netherlands, Portugal, and Poland). None of the respondents performed this collection at a national or even regional level.

Poland indicated that pharmacists providing pharmaceutical care within the pilot program of Medicinal Drugs Review were collecting data on PROs.

4.6 Screenings

4.6.1 Collection of patient data from screenings or other services

11 out of 22 respondents stated that data from screenings was collected. In some countries, namely Belgium, Germany, Greece, Italy and Portugal, this data collection

is done directly in the pharmacy software. Others, such as France, Poland, Serbia, and Spain, use a separate platform or app to register data from either all pharmacy services or specific ones (e.g., in France only data regarding COVID-19 tests is collected).

In Ireland, the data collected is shared with GPs (General Physicians) for them to record it in a nationwide platform shared with the Irish Health and Safety Executive, who then can perform, e.g., studies, medication reviews, etc.

In the Netherlands, this data collection is just done through pilot projects.

In Portugal, all vaccines administered in pharmacies are recorded in the e-Bulletin of vaccines of the Electronic Health Record, ensuring the integration of data between pharmacies with the National Health Service (NHS). During the 2021/2022 flu campaign, pharmacies were invited by the NHS to vaccinate chronic and immunocompromised patients, having access through their software to information on the eligibility provided by the NHS. Portuguese pharmacies have also contributed to an increased accessibility to testing by providing rapid antigen tests and dispensing self-tests, with direct communication of the results to health authorities.

4.7 Pharmacy dispensing software and other registries

4.7.1 Use of the data stored in pharmacy dispensing software to inform regulatory decision-making

A total of 11 out of 22 respondents reported that the data stored in the pharmacy dispensing software was used to inform regulatory decision-making (Belgium, Bulgaria, Czech Republic, Denmark, Greece, Italy, Latvia, Norway, Poland, Portugal, and Serbia). Belgium gave the example of the decision to stockpile paracetamol during the beginning of the COVID-19 pandemic.

10 out of 22 respondents reported the opposite (Croatia, Cyprus, Estonia, Finland, Germany, Ireland, The Netherlands, Spain, Sweden, and the United Kingdom).

We did not receive a response from France.

4.7.2 Record-linkage of the pharmacy dispensing software data

13 out of 22 respondents indicated that the data from pharmacy dispensing software was automatically integrated in a common database (i.e., there is record-linkage of the

data) a national level (Belgium, Bulgaria, Cyprus, Czech Republic, Estonia, Finland, Greece, Italy, Norway, Poland, Spain, Sweden and United Kingdom), Poland indicated that there was record-linkage but only within each software provider, and 8 either did not have record-linkage (Croatia, Denmark, Ireland and Serbia) or did not answer the question (France, Latvia and the Netherlands). In some countries, however, only the dispensing of reimbursed medicines is registered in the common database (e.g., Bulgaria).

4.7.3 Organisation of community pharmacies' patient registries

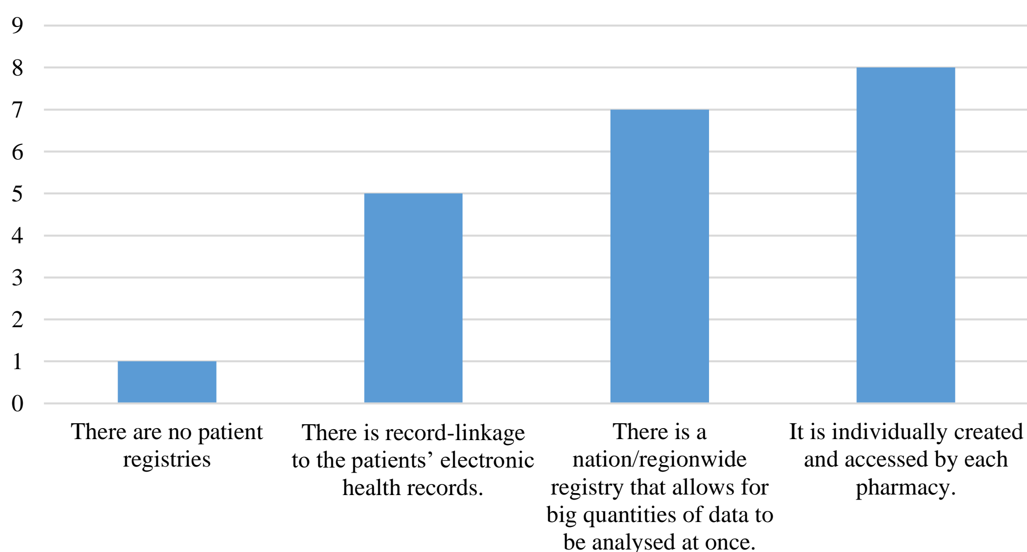

Figure 4.3 Organisation of patient registries in community pharmacies

5 out of 22 respondents reported that there was record-linkage to the patients' electronic health records (Denmark, Finland, Greece, Sweden, and the United Kingdom). 7 out of 22 respondents reported that there was a nation/regionwide registry that allowed for big quantities of data to be analysed at once (Belgium, Cyprus, Czech Republic, Greece, Italy, Latvia, and Spain), with Italy being the only one doing it at a regional level. 8 out of 22 respondents reported that the pharmacies' patient registry was individually created and accessed by each pharmacy (Croatia, Germany, Greece, Ireland, Latvia, Norway, Portugal, Serbia). Estonia reported not having patient registries in community pharmacies.

The answers from Bulgaria, the Netherlands and Poland could not be considered.

4.7.4 Data exchange or access of pharmacy-kept patient medication records, between pharmacies

10 out of 22 respondents indicated that there was a national platform where medication records were kept that all pharmacies could access during dispensing (Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, the Netherlands, Sweden, and the United Kingdom). In some of these countries, such as Denmark or Germany, the patient must grant the pharmacist access to the data in the moment of the dispensing. Although community pharmacists in most inquired countries did not have access to patient medication records, the trend seemed to be that more and more countries implemented something of the sort. Norway, for example, indicated that this feature was already set to be introduced until 2024.

4.7.5 Data exchange or access between the pharmacy and other healthcare professionals

10 out of 22 respondents stated that there was data exchange or access between the pharmacy and other HCPs (Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, the Netherlands, Sweden, and the United Kingdom). It is noteworthy that in Greece pharmacies data is shared with other HCPs and not within themselves, and that in Belgium it is shared within pharmacies but not with other HCPs.

In Ireland, although this is not current practice, communication does occur between prescribers and pharmacists, and between other HCPs via a Health and Safety Executive run clinically secure healthmail account.

4.7.6 Access to the patients' primary patient medication record

Only 5 out of 22 respondents indicated that pharmacists did have access to patients' medical records (Bulgaria, Czech Republic, Germany, France, and the United Kingdom), usually after the patient authorises this access, but many of the remaining 17 indicated that they were advocating for this practice to be introduced, and some were even already in the process of introducing it. In Ireland, for example, the health service was already starting the procurement exercise for electronic health records and shared

care records, and in the Netherlands, pharmacists had access to part of the medical data like contra indications and laboratory values in several regions of the country.

4.8 PGEU Members' views on the collection of real-world data at the community pharmacy

4.8.1 National perspectives for future evolutions of community pharmacists in real-world data collection and real-world data generation

The recurring answer was that pharmacists should have read/write access to patients' medical records. On top of that, respondents mentioned that data related to dispensing, pharmaceutical services, pharmacovigilance, medicine shortages, therapy outcomes, medication adherence and health threat monitoring should be collected at the community pharmacy level to derive into RWE. They highlighted the importance of using RWE for pharmacoepidemiology studies, HTA, and to improve pharmaceutical services, medication adherence and overall care.

There were also mentions on how the role of community pharmacists in post-marketing research could be expanded, and the Netherlands went one step further adding pre-marketing research to this perspective.

Germany stated that in the future there could be the option for patients to donate their data for research purposes.

Spain highlighted that "the definitions of RWD and/or RWE should be broad enough to include all relevant examples of added value from real practice data and experiences".

France stated that their Medicines Agency had just launched a specific initiative, which created a network of GP/pharmacist pairs over the territory. They would be tasked to answer short surveys meant to understand and consider their practices and expectations, as well as the challenges faced by them and by their patients. The pairs would also be able to feed the authorities with issues, ideas, or initiatives from their day-to-day practice (55). They also stated that French health authorities started a digital upgrade with the so-called "Ségur du numérique". At the time of answering the report, it was only about non-structured health data, which were only accessed for primary use, by the patient or by the health professionals they give access to in the context of care. However, the respondent believed that the future might bring additional features to

allow the collection of more structured data for secondary uses, in strict compliances with principles of consent and privacy, through the Health Data Hub. Finally, France suggested that an example of what could happen were official experiments, such as one that was currently being conducted with community pharmacists' involvement in collecting clinical data and data on QoL of patients after cataract surgery, for health authorities (56).

4.8.2 Hindering and facilitating factors for real world evidence generation in community pharmacy

The respondents identified the following facilitating factors:

- All operations in community pharmacy are now done electronically.
- The importance of the issue is already identified.
- Certain data are already integrated through software (including questionnaires and notes)
- The personal connection pharmacies have with patients.
- Community pharmacies are accessible 24/7, and have been the first line of advice, treatment, and referral for many people in Europe on common ailments.
- Pharmacies are equally spread throughout the national territory.

The respondents identified the following hindering factors:

- Not all HCPs have the same level of standardised electronic registries.
- The lack of reimbursement.
- The lack of time for collecting data.
- Low awareness of the importance of reporting ADRs.
- The lack of standardised protocols.
- The lack of system interoperability (including the fact that in some countries pharmacists do not have access to the health records, and when they do, they sometimes are not able to contribute to them).
- The General Data Protection Regulation.
- The slowness of the legislation updating processes.
- Difficulties with software development.

- The lack of consensus regarding how to organise the data collection and on who should be responsible for what.
- The collection of unstructured data.
- The lack of HCP training on RWD collection.
- Devolution of health matter to the regional competences creating disparities in medicines access and therefore in RWE projects.

5 Discussion

Although we did not obtain responses from all the countries represented by PGEU, the responses that we gathered allowed us to build a clear overview of the current panorama of RWD collection at the community pharmacy.

5.1 Pharmacovigilance

Due to its heterogeneity, the data collected do not allow us to understand the role that pharmacists in Europe as a whole are playing in reporting ADRs, nor to compare the part that community pharmacists play in the pharmacist-generated reports, also since there are more community pharmacists than clinical pharmacists, so we would have needed to know the number of professionals practicing in each area to really compare the level of reporting between the two.

There is no link between the pharmacy software and the reporting system in almost any responding country, which might pose an additional barrier to reporting for community pharmacists.

5.2 Medicine Adherence

Low levels of medicines adherence are a public health issue (57). The role that community pharmacists play in increasing these levels is well defined (58–60). However, the data collected suggests that the role that community pharmacies, and especially the pharmacy dispensing software could play in the assessment of medicines adherence and of the impact of campaigns and strategies that are put in place to increase medicines adherence.

Only 3 responding countries reported to collect data on medicine use to perform drug utilisation studies at a national level, but the trend seems to be positive with more countries moving towards that. The Spanish NodoFarma Asistencial tool, for example, albeit regional, has been expanding to more regions (61). Although the majority of the responding countries do collect data on medicine use to perform drug utilization studies, only 3 actually do it a national level, so there is a lot of room to grow in this regard.

5.3 Shortages

There has been a lot of discussion around medicine shortages at a European level, especially since the creation of HERA. Data on shortages will not be complete unless all parts of the chain can contribute, meaning MAHs, suppliers and HCPs. Pharmacists can play an important role in the management of medicine shortages, and in some pharmacies solving issues with drug supply actually takes up a considerable amount of time (56,57). However, pharmacists are not involved with reporting medicine shortages in 7 of the responding countries. This renders the monitoring of shortages incomplete, as data from the end of the chain is missing.

5.4 Health Technology Assessment

This is where the most untapped potential for the collection of RWD lies. Most countries still do not have the infrastructure needed to collect data on HTA, and additional training will be needed.

The vast majority of the responding countries does not collect data on the effectiveness/benefit of medicines (90.91%) or on PROs and QoL (77.27%), and those that do collect it do it only as part of pilot projects, which indicates that a lot of developments still need to be made on this. Taking into consideration how accessible community pharmacies are to patients both geographically and economically, and the fact that they are often the first place that patients go to for health-related matters, they are strategically placed to collect data on this. As we are in the implementation phase of this practice now, when we are aware of the importance of creating RWE-ready databases, efforts should be made towards a systematic approach.

Looking at screenings and other pharmacy services, only 11 respondents reported collecting data from screenings at the pharmacy, although data from 2020 indicates that pharmacies in 30 out of the 32 PGEU members do perform screenings (62). The amount of data that is being generated is greatly lower than the one that is being used, which would be counterintuitive for countries implementing remuneration for certain pharmacy services or discussing this implementation, as the lack of data collection does not allow them to produce evidence regarding the economic benefit that a pharmacy service brings.

5.5 Pharmacy dispensing software and Patient Registries

The pharmacy dispensing software and the patient registries are where pharmacies store most of the data collected on the previously mentioned categories, with pharmacovigilance being the only one where the collection of data is done outside of them in all responding countries. Taking this into account, these platforms are the main point to tackle when looking to further develop RWD collection at the community pharmacy.

This is where the issue of the lack of RWE ready databases comes into play. Only 13 respondents indicated that the data from the pharmacy-dispensing software was integrated into a common database, and only 5 indicated that these data were record-linked to the patients' EHRs, which implies that much of the data collected at the community pharmacy is lost by lack of integration.

From the data collected, we can see that the data stored in the pharmacy dispensing software is still not being used to inform regulatory decision-making in 10 out of 21 responding countries, indicating that the potential these data have is still untapped, perhaps because of the lack of structure aforementioned.

From a pharmacy practice point of view, low access to data is also a reality, with 12 respondents indicating that there is no national platform where medication records were kept, 12 also indicating that other HCPs did not have access to the dispensing records of the pharmacies, and 17 indicated that pharmacists did not have access to the patients' EHRs. The response from Ireland, although useful from a professional point of view, could not be considered as data exchange or access between the pharmacy and other HCPs, as the Health and Safety Executive run clinically secure healthmail account is only a communication platform (63).

Although it was not included in their response, it is worth mentioning that there is a database network in the Netherlands, the PHARMO Database Network, which gathers data from different sources throughout patients' journey in healthcare, including out-patient and in-patient community pharmacies. This database contains data on more than 10 million residents of the Netherlands for an average of 12 years. The access to this database network is restricted, therefore, HCPs contribute to each individual database without a view of the whole spectrum of data and how the data that they register can contribute to it in an RWE-ready format (64), but while we are still trying to understand

how to ensure that patients retain ownership over their own data and how exactly all HCP can contribute to the utopic RWE-ready, unified patient record, it is one of the most significant examples of RWD compilation we found.

5.6 Training Healthcare Professionals

There are 5 countries among the respondents that don't include the reporting of ADRs in the undergraduate curricula, which is definitely a barrier to the levels of reporting. On top of that, all postgraduate trainings on this topic are optional in the countries that do have them, which allows for the possibility that pharmacists might not be updated on this.

For the collection of RWD to be implemented to its full potential, a collaboration between all relevant parties will be crucial, as health data are collected in all different points of contact with the patient. For this to be a reality, both undergraduate and postgraduate training will be necessary to build HCPs' literacy on the matter and achieve optimal outcomes.

The European Union is already investing in initiatives focused on the training of HCPs with an interprofessional approach, such as the Train4Health project focused on improving students' education on behaviour change support to effectively promote self-care in people with chronic diseases, and after the software and legal backbone have been built in the creation of the EHDS, the next step will be to promote interprofessional education focused on the collection of RWD into RWE-ready databases (38,65).

5.7 Perspectives for the future

Although there is still a lot to be developed, the trend is for the collection of RWD at the community pharmacy to increase at both a National and European level, and several countries are working on strategies in this regard, such as Ireland, Finland, and Norway.

The hindering and facilitating factors pointed out by the respondents allowed us to understand that many of the factors that were limiting RWD collection at the community pharmacy were external ones, such as software development difficulties, the lack of a legal structure and standardised protocols, the consequent collection of unstructured data and the lack of system interoperability that is seen in many countries

between pharmacies and between pharmacies and other healthcare facilities. There is also a general lack of training on RWD collection for HCPs, which was also seen in the answers concerning the reporting of ADRs.

On the other end of the spectrum, respondents seem to agree with the fact that the operations at the community pharmacy are already done electronically, the proximity pharmacies have with patients, and the fact that the importance of collecting RWD is already identified can really drive development further.

All respondents agreed that the collection of RWD at the community pharmacy was something to invest in. Their main perspective was for pharmacists to gain read/write access to patients' medical records, which would allow for HCPs to all contribute to register the RWD collected in one common platform and make it easier to adapt the data collection in a uniform manner to be RWE-ready. However, for this to happen, all HCPs that would be contributing to this common platform would need appropriate training to do so.

5.8 Limitations of the survey

The most relevant limitation of the survey as a whole is the fact that not every PGEU member had data from 2021 as requested. This is especially relevant when comparing, e.g., the proportion of ADR reports that is attributed to pharmacists, because it does not allow for the interpretation of these numbers in a specific point of time.

Regarding the pharmacovigilance section, the Dutch respondent highlighted that data from 2021 would be distorted due to the large number of reports from patients about COVID-19 vaccines.

Regarding the section on Pharmacy dispensing software and other registries, upon the analysis of the answers, we realised that question 17 was not formulated the correct way, because it included the terms medical and medication records, as if they could be used interchangeably, which is not the case. This was a mistake in the redaction, which caused some of the respondents to answer about medication records only, although it was already covered by previous questions. However, we believe that it did not prevent us from gathering the data that we needed, as the countries where pharmacists had access to more than just medication data did highlight that in their answers.

6 Conclusion

One of the main obstacles to establishing the use of RWE in regulatory decision making is the persisting variability in stakeholder definitions of RWD, and it is necessary for regulatory agencies to establish what data can be considered RWD before deciding on how the evidence derived from RWD can be used in the decision process.

The amount of raw data that is and could be collected in community pharmacies could be of significant relevance for the improvement of pharmacovigilance, medicine shortages monitoring, medication adherence, HTA and patient outcomes. To take full advantage of the potential of this data, regional, national, or even European datasets need to be created that combine larger quantities of data to be analysed at the same time. These need to be designed as RWE-ready datasets, i.e., there needs to be a harmonization between the different software used by pharmacies within a country and even between countries.

For community pharmacists to be able to completely contribute to the collection of RWD, a connection should be created between the different platforms used to collect data in healthcare, and these should all be record-linked to RWE-ready databases so that RWD can be used to their full potential and health data can be mass analysed.

Community pharmacists can play a vital role in the collection of RWD from patients into these databases, as is shown by their contribution to the collection of pharmacovigilance data, but obstacles such as the lack off read/write access to EHRs, the legal hurdles that stand in the way of access to data and the fact that the existing software were not designed to collect data in a systematic way, are preventing them from contributing further. The focus should lie in the creation of a strong legal and informatic infrastructure that allows for the collection of health related RWD at all points of contact with the patient, including the community pharmacy, while also ensuring that the patients have ownership of their own data.

Finally, it is essential that pharmacists and other HCPs are trained to collect RWD so as to increase the quality of the routinely collected health data.

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Annexes

A1. PGEU Survey on the Collection of RWD at the Community Pharmacy

PGEU Survey

Collection of Real-World Data at the Community Pharmacy

Dear members,

Gabriel Branco, one of our EPSA Interns, is currently working on his final master's degree project in collaboration with PGEU and under the guidance of Carla Torre from the Faculty of Pharmacy of the University of Lisbon and Jorge Batista, our Professional Affairs Advisor.

The project aims to better understand the current role of Community Pharmacists in the collection of Real-World Data, a topic that is very high in the EU health agenda, especially with the new regulation for the European Health Data Space predicted to be released in the coming weeks. It is important for PGEU and its members to understand what community pharmacists' role in the collection of RWD is at the moment and how it can improve, so that we can establish a position on it.

After conducting a literature review, we are now releasing this survey to complement the information found and be able to discuss what steps need to be taken in order to better integrate RWD into pharmacy practice, as set out in PGEU's "Pharmacy 2030: A Vision for Community Pharmacy in Europe".

The survey will be open from 03 May – 24 May 2022. If you have any questions, please contact Gabriel at st2@pgeu.eu.

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PART 1: Respondent information

Country:
Organization:
Email:

PART 2: Pharmacovigilance

1. An Adverse Drug Reaction (ADR) is defined as "a response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function". Healthcare professionals play a big role in the reporting of ADRs. In your country, what percentage of the total ADR reports is generated by pharmacists in 2021?

If there is no data from 2021, please provide the most recent information and indicate the year when it was collected.

(Answer)

2. In your country, what percentage of the ADR reports performed by pharmacists is generated by community pharmacists in 2021?

If there is no data from 2021, please provide the most recent information and indicate the year when it was collected.

(Answer)

3. Do the pharmacy curricula cover reporting ADRs? (y/n)

(Answer)

4. After graduation, are community pharmacists trained regarding ADRs? (y/n)

If yes, please provide more details regarding who organises the training activities (nationwide / regionwide / individual pharmacies), the frequency of the training activities, whether it is mandatory, etc.

(Answer)

5. Is the pharmacy software linked with the national spontaneous reporting system? (y/n)

(Answer)

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PART 3: Adherence

6. Do community pharmacists in your country collect data on medicine use to perform drug utilization studies (e.g., drug utilization profile, adherence persistence, etc.)? (y/n)

(Answer)

If yes, please specify whether this happens **(select all that apply)**:

- At a national level
- As part of a specific network of pharmacies
- Only as a pilot or for specific projects/studies
- Only for internal/individual use (i.e., data is not shared with others)

Please provide any references or additional background information.

(Answer)

PART 4: Shortages

7. If your country has a medicine shortage reporting system that can be used by community pharmacists:

- Which organisation is responsible for managing the reporting system/database?

(Answer)

- How does the reporting system work?

(Answer)

- Which type of data can/must be reported by pharmacists?

(Answer)

- How is the data collected used (e.g., inform regulatory action)?

(Answer)

8. Do you have any national/regional evidence/information on the role community pharmacists play in mitigating shortages, besides the one provided in the PGEU Medicines Shortages Survey 2021? (y/n)
If yes, please provide any references or additional background information.

(Answer)

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PART 5: Health Technology Assessment

9. Do community pharmacists collect data on the effectiveness/benefit of medicines? (y/n)

If yes, please specify how this is done (e.g., nationwide/pilot/individual pharmacies/dedicated platform) and provide any references or additional background information.

(Answer)

10. Do community pharmacists collect data on Patient Reported Outcomes (PROs) and Quality of Life (QoL)?

If yes, please specify how this is done (e.g., nationwide/pilot/individual pharmacies/dedicated platform) and provide any references or additional background information.

(Answer)

PART 6: Screenings

11. Is patient data from screenings (e.g., diabetes, blood pressure, COVID-19, cardiovascular risk, etc.) or other services collected by community pharmacies? (y/n)

*data collection always implies consent by the patient (e.g., the patient signs a release form after being informed of how the data will be stored and used)

(Answer)

If yes, where do community pharmacists store the data collected through pharmacy services? **Select all that apply.**

- It is integrated in the Pharmacy dispensing software
- Patient registry
- Collected in a national/regional database where data can be analysed
- Other: -----(specify here)------

Please provide any references or additional background information.

(Answer)

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PART 7: Pharmacy dispensing software and other registries

12. Is the data stored in pharmacy dispensing software(s) in your country used to inform regulatory decision-making? (y/n)

If yes, please provide any references or additional background information.

(Answer)

13. In some countries, pharmacy dispensing software automatically integrate the data that is collected into a common database (record-linkage). Does the same happen in your country or are the databases used different and need to be integrated?

(Answer)

14. How are community pharmacies' patient registries organized? Select all that apply.

- There is record-linkage to the patients' electronic health records.
- There is a nation/regionwide registry that allows for big quantities of data to be analysed at once.
- It is individually created and accessed by each pharmacy.

Please provide any references or additional background information.

(Answer)

15. Are electronic Patient Medication Records shared between Pharmacies? This practice is defined as "exchange or access of pharmacy-kept patient medication records, between pharmacies within a country".

- Yes, it is provided in most pharmacies under contract, agreement, regulation.
- Yes, it is provided in some pharmacies as a pilot.
- Yes, it is provided individually by some pharmacies.
- No.

Please provide any references or additional background information.

(Answer)

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16. Are Electronic Patient Medication Records shared between Pharmacies and other healthcare professionals? This practice is defined as "data exchange or access between the pharmacy (primary point of data storage) and, for example, general practitioners or hospital physicians / hospital pharmacists".

- Yes, it is provided in most pharmacies under contract, agreement, regulation.
- Yes, it is provided in some pharmacies as a pilot.
- Yes, it is provided individually by some pharmacies.
- No.

Please provide any references or additional background information.

(Answer)

17. Do pharmacists have access to Patient Medical Records or Summaries? This practice is defined as "access to the patients' primary patient medication record" (for example, that managed by their general practitioner or other centrally managed record).

- Yes, it is provided in most pharmacies under contract, agreement, regulation.
- Yes, it is provided in some pharmacies as a pilot.
- Yes, it is provided individually by some pharmacies.
- No.

Please provide any references or additional background information.

(Answer)

PART 8: Members' Views

18. What are your national perspectives for future evolutions of community pharmacists in RWD collection and RWE generation?

(Answer)

19. What are the hindering and facilitating factors for real world evidence generation in community pharmacy (reimbursement for data collection, lack of standardized protocols, system interoperability, etc.)?

(Answer)

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