OPTIMISING PATIENT SELF-MEDICATION

THROUGH THE COMMUNITY PHARMACIST

A thesis submitted in partial fulfilment

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Dedicated to my family and Martina

Abstract

Self-care with 'Over-the-Counter' (OTC) medicines is a widespread practice. Patients consider OTC medicines to be safe and frequently ignore patient information leaflets. This may incur risks to patients' health. Facilitated self-medication addresses this issue, whereby the pharmacist is directly involved in providing advice on self-medication products. The aim of this research was to optimise patient self-medication through the pharmacist's intervention by investigating the nature and frequency of drug-related problems (DRPs) occurring in self-medication and documenting the interventions carried out by the pharmacist. The first phase of the study consisted of compiling and validating the tool required to run the research. During the second phase, 203 patients presenting at a community pharmacy asking for OTC medications were included in the study. The pharmacist recorded data on patient characteristics and the nature of the OTC request. Any identified DRPs were documented, together with the action taken by the pharmacist to resolve the identified DRPs. The time taken to resolve the problem was recorded. A total of 40 DRPs were detected in 18.7 % of patients presenting with requests for OTC medicines. The most common DRP (32.5%) was 'requested medicine is not optimal for symptoms presented', followed by 'requested medicine is contra-indicated' (27.5%) and 'duplication of medicines' (12.5%). The most frequent intervention by the pharmacist was to change to a more suitable drug (57.5%), followed by referral to a physician (22.5%). The results from this study highlight the importance of the pharmacist intervention when dispensing OTC medications, since a DRP was detected in nearly 1 in 5 encounters.

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Glossary

Drug-related problem: Issues involving drug therapy that can interfere with desired health outcomes. There are different classifications of drug-related problems, all of which cover aspects of overuse, underuse and duplication of treatment.

General sales list: Self-selection medicines that can be sold from pharmacies as well as other retail outlets. A pharmacist does not have to be present. This list is applicable in some countries depending on national legislation. This classification of medicines is not applicable to Malta.

Pharmacy medicine: Medicines that can only be purchased from a pharmacy and under the supervision of a pharmacist. No prescription required. This term may sometimes be used interchangeably with over-the-counter medication.

Over-the-counter: Medicines that are available to be purchased without a prescription, which can be purchased either from a pharmacy or other retail outlet. Normally both general sales list and pharmacy only products fall under this category.

Prescription only medicines: Medicines that can only be purchased with a valid doctor's prescription.

Abbreviations

ADR: Adverse drug reaction

DRP: Drug-related problem

EU: European Union

GSL: General sales list

OTC: Over-the-counter

MCC: Medicines classification committee

MI: Myocardial infarction

NRT: Nicotine replacement therapy

POM: Prescription only medicine

P: Pharmacy medicine

WHO: World Health Organisation

AESGP: Association of the European Self-medication industry

Chapter 1

Introduction

1.1 Development of the pharmacists' role

Community pharmacists are uniquely placed to provide support and advice to the general public. The combination of location and accessibility means that most patients have good access to a community pharmacy where free health professional advice is available on demand. Extended opening hours and no need for appointments further improve accessibility of pharmacists (Eades et al, 2011; Rutter, 2015).

Traditionally within a community health care setting, pharmacists have harnessed a role that involves the sale and distribution of medicines and a role that utilized all the clinical skills that the pharmacist amassed to manufacture medicines for medicinal use. The pharmacy profession was considered to be a thin line between a chemist and an advisor for the safe administration of medications (Guillaume et al, 2008).

In the middle of the 20th century, the pharmaceutical industry boomed and large scale manufacture of drugs and medicinal products started. A new legal status was also introduced which restricted the amount of drugs that the pharmacist was able to dispense without a prescription written by a medical practitioner. This limited the role of the pharmacist as a fabricator, compounder and a dispenser of drugs (Avery, 2005).

Between the 1960's and 1970's, pharmacists began to assume roles as direct patient health providers and developed a practice that involved less time in the preparation of pharmaceutical products and a closer interaction with patients and health care professionals. This shifted the practice to a more patient-oriented practice and

established the pharmacist as the distributor and primary advisor with regards to drugs and healthcare in general (Di Piro, 2003).

This change in role of the pharmacist led to the pharmaceutical care model being adopted to show that the role of the pharmacist involves responsible provision of drug treatment which results in significant and definite improvements that improve quality of life for the patient. Pharmacists are considered as drug experts across various spectrums, be it in a community pharmacy or in a clinical setting. As health providers, pharmacists work in harmony with medical practitioners and other health care professionals to ensure that the patient receives optimal health outcomes and manages medications appropriately (Pearson, 2007).

An important intervention of community pharmacists is to dispense medicines safely and to provide drug information with regards to appropriate drug usage, administration, dosage, side-effects, storage, drug–drug and drug–food interactions (Hammerlein et al, 2007). Lately, countries such as the United States of America, United Kingdom and Australia, have acknowledged new roles of community pharmacists in the multidisciplinary provision of healthcare. In these countries, community pharmacists provide an extensive range of healthcare interventions such as prescribing, counselling on therapy and diseases and patient monitoring including monitoring of blood glucose and blood pressure levels (Pradeep et al, 2010). Pharmacists also perform the important role of identifying, solving and preventing drug related problems (DRPs) for the purpose of improving patient outcomes and quality of life (Bennadi, 2014).

Patients place high levels of trust and confidence in the pharmacists' ability to advise on non-prescription medicines (Rutter, 2015). As indicated in a study carried out in Malta in 2010, the majority of patients (75%) visiting a community pharmacy would follow the pharmacist's advice when purchasing a non-prescription medication. Additionally, 80% of the patients also claimed that they would seek advice from the community pharmacist if they deemed that their condition was not serious enough to visit a physician (Wirth et al, 2010).

1.2 Patient self-care

Patient self-care is a concept whereby patients take responsibility over their own health and well-being. The World Health Organization defines self-care as *"the ability of individuals, families and communities to promote health, prevent disease, and maintain health and to cope with illness and disability with or without the support of a health-care provider*" (WHO, 2009).

Self-medication is considered as a particular component of self-care. Self-selection medicines are commonly referred to as "over-the-counter" (OTC) or "non-prescription" medicines. The availability of non-prescription medicines to the public varies from country to country, but all have been approved by regulatory bodies as safe and effective for the general public to be selected and consumed without the need for medical supervision or involvement (WMSI, 2004).

Drugs are classified in three legal categories namely prescription-only medicines, pharmacy medicines and GSL (general sales list) medicines. Drugs classified as

prescription only medicines (POM) can only be obtained by presenting a valid prescription which was prepared by a licensed prescriber. Normally, POM drugs are reserved for conditions which are diagnosed and treated by physicians. Examples of such drugs include antibiotics and drugs treating chronic conditions such as epilepsy and hypertension (Medicines and Healthcare products Regulatory Agency, 2014).

Pharmacy medicines (P) can be purchased without a prescription, but only from a pharmacy and under the supervision of a pharmacist. Medicines classified as pharmacy only are normally used for short-term treatment of conditions that can be diagnosed more easily and be treated quickly. Pharmacists' council patients on the safe use of the medicine and make sure the selected medicine is appropriate. General sales list (GSL) are medicines that can be purchased from outlets such as stores and supermarkets, without supervision of a pharmacist. These medicines treat simple and minor ailments. Pack sizes only contain a few doses. The term OTC covers all pharmacy only medicines as well as the GSL medicines (Medicines and Healthcare products Regulatory Agency, 2014). The Maltese classification of drugs is similar that mentioned above, with the difference being in that GSL medicines are non-existent in Malta. Therefore all non-prescription medicines must be obtained from a pharmacy and under the supervision of a pharmacist.

Self-medication is limited only to non-prescription drugs as irrational use of prescription drugs without a physician's prescription may cause other problems to manifest themselves rather than curing the disease they were utilized for (Rutter, 2015). Nowadays, patients wish to take a greater role in decision-making regarding the choice

of treatment and maintenance of their own health. They are understandably unwilling to go through the inconvenience of visiting the doctor for what they feel that they can manage for themselves, given adequate information (Bennadi, 2014). Self-medication is very common and a number of reasons could be accounted for its popularity (Solomon et al, 2003). Urge of self-care, wanting to help close relatives and friends in times of sickness, time constraints, lack of or inefficient health services, financial limitations, ignorance, mistrust in healthcare professionals, extensive drug advertisement and availability of drugs in places other than pharmacies are responsible for the growing trend of self-medication (Phalke et al, 2006). The use of non-prescription drugs has become an important part of the health care system which is evidenced by the continually increasing sales of these medicines (Krishnan et al, 2000). Self-care also depends on the patient's own awareness of his/her physical and mental health, as well as their present health state and how it is monitored (for example blood pressure, cholesterol and body mass index). Effective self-care also involves reduction of avoidable risk factors such as smoking cessation, limiting alcohol intake, following a healthy nutrition plan and regular engagement in physical activities (Bell et al, 2016).

Self-medication is practiced globally, with increased frequency in developing countries. Studies show that in European countries, self-medication is practiced by 68% of the population, whilst in developing countries such a Kuwait, 92% of the population utilize drugs without doctor's prescription (Abahussain et al, 2005).

A project aimed to create a framework for action to enhance self-care at EU level was started in 2014. A platform of 25 experts was created, composed of researchers, healthcare professionals, educators and policy-makers amongst others. The project

focuses primarily on self-care for five minor conditions, namely athlete's foot, heartburn, cold, cough and urinary tract infections. Guidelines for promotion of self-care, development of communication tools and a report on the actions and collaborations at EU level were created (PISCE, 2017).

1.3 Criteria for making drugs available without a prescription

Certain conditions have to be met for patients to be able to purchase and utilise drugs without a prescription. The patient should be knowledgeable enough to make a diagnosis or, following a professional opinion, be aware of what the diagnosis is. An example would be a case of hay fever, which is quickly diagnosed by the patient and various antihistamines are available OTC. The drug also has to be efficacious and should pose a very low risk to the safety of the consumer. All drugs may pose some sort of risk or side-effects but the risk versus benefit ratio should be considered when decisions concerning releasing a drug or withdrawing a drug from non-prescription status are taken.

Other logical reasons for non-prescription medicines would be improved and quicker accessibility for patients wishing to start treatment immediately and want to relieve symptoms rapidly, for example, anti-histamines or a nasal decongestant spray for a patient with a blocked nose who wants to get a good night's sleep and has no time to visit the general practitioner. Emergency contraception is also a time-critical product which has to be taken as early as possible for it to be effective. Another reason would be the shifting of cost from the government sector towards the patient (Aronson, 2004; Aronson, 2009; WSMI, 2009).

1.4 Prescription to non-prescription switch

The prescription to non-prescription switch is the transfer of prescription medicines to non-prescription status. Many new drugs are launched as POM medicines. After suitable amount time has passed, with the medicine being utilized by many patients and large-scale experience and scientific information has been gathered, a manufacturer may opt to submit an application to the appropriate authority for the medicine to be switched to non-prescription status. This transfer also helps to promote self-medication (WMSI, 2004; Bennadi, 2014). In recent years, perceived public demand for readier access to medicines has demanded a political response to increase the numbers of medicines to been reclassified from POM to P (Aronson, 2009). However, during the last decade, medicine reclassifications have slowed down in some major drivers such as the United States of America and the United Kingdom. Reasons which could be attributed to this include the increasing complexity of reclassifications as well as the reluctance of the pharmaceutical industry to fund reclassifications (Gauld et al, 2012).

Evidence of risks would lead to a P or OTC medicine having its non-prescription status withdrawn. Terfenadine, an antihistamine which was given P status, was reverted back to POM and later withdrawn after reports that it could prolong the QT interval, with a risk of torsade de pointes, an effect that was enhanced by inhibition of its metabolism by concurrent administration with other drugs or by ingestion of grapefruit juice (Committee on Safety of Medicines, 1997; Aronson, 2001).

For a POM to be reclassified as P, the Licensing Authority must ensure that the medicine would be safe to be supplied without a prescription. According to the UK MHRA, to be reclassified from POM to P, a medicine must:

> "• *be unlikely to be a direct or indirect danger to human health when used without the supervision of a doctor, even if used incorrectly*
>
> • *be generally used correctly (ie not frequently or to a wide extent used incorrectly)*
>
> • *not contain substances or preparations of substances where the activity of the product or its side effects require further investigation*
>
> • *not normally be prescribed by a doctor for injection (parenteral administration)*" (Medicines and Healthcare products Regulatory Agency, 2014)

A successful reclassification example is for topical calcipotriol, which was carried out in New Zealand in 2010. This reclassification was uncommon since it was driven by third parties and that calcipotriol is used to treat chronic conditions whilst reclassifications are normally carried out for drugs used for acute conditions. Considerations which were evaluated for this reclassification by the Medicines classification committee (MCC) were: The drug had to be on the market for three or more years, and had substantial use during those three years, together with a low adverse effect profile. Factors which were also considered were consumer convenience, potency of the preparation, availability of similar products for similar indications, therapeutic index of the drug, toxicity, potential for abuse, inappropriate use and public

risk (harm resulting from vast use of the medicine such as resistance) (Gauld et al, 2012). Challenges encountered in this reclassification are summarized in Table 1.1.

Table 1.1: Challenges encountered in the reclassification of calcipotriol in New Zealand

Challenges encountered	Solutions
OTC packaging/labelling was not available since the product is marketed internationally with same labelling	Product will be reclassified as pharmacy only, thus patients will receive professional counselling when purchasing. Patients will also be provided with an information sheet.
Risks of misdiagnosis or misuse	A prior physician diagnosis will be required before non-prescription dispensing, and the use will be limited to mild and moderate cases of psoriasis. Furthermore, a maximum weekly supply of 30grams was set. An algorithm for supply was also developed
Sponsor safety data was limited	Literature review was carried out, and a report put forward showed that topical absorption of calcipotriol was low at the proposed maximum weekly dose, leading to blood levels of calcium comparable to supplementation of oral vitamin D.
Hypercalcemia monitoring	Physician would be advised that the patient is using calcipotriol, and the patient was also advised to carry out blood tests if treatment duration exceeded three months. Algorithm excludes people with increased risk of hypercalcemia and those with severe psoriasis from treatment. Limited weekly dose.

Reproduced from: Gauld N, Emmerton L, Kelly F, Buetow S. New Model of Prescription to Nonprescription Reclassification: The Calcipotriol Case Study. *Clin Ther*. 2012; 34: 1324–1332.

1.4.1 Examples of notable drug switches worldwide

The majority of deaths are attributed to chronic diseases such as diabetes, heart disease, cancer, stroke and respiratory disease. In 2005, there were 58 million deaths, out of which 35 million were due to chronic diseases (WHO, 2005). However, many of chronic diseases have modifiable risk factors such as smoking, hyperlipidaemia and obesity that can be mitigated. Thus the switch for POM to non-prescription can result in a significant reduction of these risk factors (WSMI, 2009).

A few examples of drugs which were reclassified are described. **Nicotine replacement therapy (NRT):** Studies have shown that smoking is the leading preventable cause of death and disease in the developed world, accounting for 5.4 million worldwide deaths annually, and with projections of 8 million deaths worldwide by 2030 (Peto et al, 2001; WHO, 2009). Smoking cessation can reverse much of the risks incurred by smoking (U.S. Department of Health and Human Services, 1990). Quit rates are low; in Europe, 21% succeed in smoking cessation, whereas between 80,000-100,000 people become addicted to nicotine daily (WSMI, 2009). In the United States of America, only 5% manage to quit every year (CDC, 2000). NRT is able to double cessation rates (Silagy et al, 2004). In the case of NRT products, the POM to OTC switch in the United States of America and United Kingdom resulted to an increased access and utilization of the treatment. Studies have demonstrated that non-prescription NRT has been used safely and effectively, with minimal cases of misuse or abuse (Shiffman et al, 2008).

Simvastatin: In the United Kingdom, Simvastatin 10mg was switched to P status since it has been proven that it can reduce cholesterol levels (Law et al, 2003) and thus reduce

risk of major cardiovascular events such as myocardial infarction and stroke. The dose at 10mg is deemed very safe and accessibility is increased by making the drug available as P only. Studies have shown that 5 years on from the switch, there were no significant problems reported from use of the drug (Aronson, 2004; WSMI, 2009).

Orlistat: Obesity is a modifiable risk factor, which can be managed with the use of drugs and nutrition. Most weight loss drugs were limited to POM status. In 2009, orlistat was centrally switched to non-prescription status throughout Europe, in order to reduce the increasing incidence of heart disease (WSMI, 2009).

Azithromycin: Chlamydia infection is one of the most common sexually-transmitted diseases and is often symptom free. This leads to lack of diagnosis and implies long term complications such as infertility. Azithromycin has recently been transferred to P status in the United Kingdom, indicated for asymptomatic chlamydia infections. There were concerns about increased resistance following the switch, thus pharmacists are required to carry out a diagnostic urine test to confirm presence of chlamydia (Aronson, 2004; WSMI, 2009).

Levonorgestrel: Levonorgestrel products are now available in many countries as P medicine, including Malta. The basis of this classification rests on the fact that safety of levonorgestrel has been well documented and that timely access to the drug is vital for its effective use. When the drug was transferred to non-prescription status in the United Kingdom, no increase in unprotected sex or decrease in the use of other methods of contraception was noted (Marston et al, 2005; WSMI, 2009).

Table 1.2 shows recent reclassifications carried out in Malta, which resulted in increased availability of medicines to the patients.

Table 1.2: Recent reclassifications carried out in Malta

Allegratab 120mg film-coated tablets (fexofenadine hydrochloride)	Arfen suppositories 125mg,250mg, 500mg (paracetamol)	Zantac 75mg tablets (ranitidine hydrochloride)
Keral tablets 12.5mg, 25mg (dexketoprofen)	Regaine 5% topical solution (minoxidil)	Olfen Gel 1% (diclofenac hydrochloride)
Keral 25mg granules for oral solution (dexketoprofen)	Calpol Sugar Free Calpol Six plus Calpol Infant suspension (paracetamol)	Snip tablets (pseudoephedrine, paracetamol, chlorpheniramine)
Keral 12.5mg granules for oral solution (2,10 and 20 sachets) (dexketoprofen)	Actifed Syrup 30, 1.25mg/5ml Actifed DM 30,1.25 Actifed Expectorant (pseudoephedrine, triprolidine, dextromethorphan, guaifenesin)	Opticrom Aqueous Eye Drops 2.0%w/v (sodium chromoglicate)
Esomeprazol Actavis 20mg gastro-resistant tablets. (esomeprazole)	Medovir Cream 5% (aciclovir)	Candiplas H (2% +1%) w/w cream (miconazole hydrocortisone)
Muciclar prolonged release capsules 75mg (ambroxol)	Daflon 500mg film coated tablet (hesperidin, diosmin)	Candiplas cream 2% w/w (miconazole)
Lioton Gel 2.5 I.U/g (heparin)	Medofed Oral Solution 30mg/1.25mg per 5ml (pseudoephedrine, triprolidine)	Medovent Elixir Syrup 15mg/5ml (ambroxol hydrochloride)

Trade name, active ingredient and strength of product list.
Reproduced from: Malta Medicines Authority. Available from: http://www.medicinesauthority.gov.mt/reclassification

1.5 Economics of self-care

Responsible self-care has shown considerable potential to reduce costs of public health care systems and patients alike. Research carried out in European countries has shown that a switch of 5% from prescription-only to non-prescription medicines results in savings which exceed 16 billion euros (AESGP, 2004). These saving arise from various factors:

Self-medication leads to fewer medicines being prescribed, which corresponds in saving of public funds since patients are paying for the full price of medicines as opposed to getting free or reimbursed prescribed medicines. Self-medication will lead to less physician visits for minor ailments, which result in less income for physicians since patients are not paying any doctor's fee. However, the shift in volume will free up physician's time which could be spent in longer consultations and more complicated cases, as well as reducing waiting time (AESGP, 2004; Cohen et al, 2005).

Time lost is also a significant factor in the economics of self-medication. Physician visits result in absence from work when patients seek treatment during working hours. Patients who utilise self-medication normally return to work sooner than when they receive official endorsement from their physician that they are sick. Travelling to the physician also costs time and money. Patients spend less time travelling to the pharmacy as opposed to travelling to the doctor, then to the pharmacy. Travel expenses are also higher. One must also keep in mind that appointments with the pharmacy are not required and visits can be made after working hours (AESGP, 2004).

A case study carried out in Germany evaluated the economic benefits of self-medication of vaginal mycosis utilising recently reclassified azole antifungals. Total savings for both the public sector and national economy/employers were 65.5 million Euros in 2002. There were no reports of misuse of the products reclassified. Thus, the switch from POM to non-prescription was beneficial to both public and patients (AESGP, 2004).

1.6 Risks associated with self-care

Although medicines come with comprehensive labelling and information, patients consider non-prescription medicines to be safe (Ngo et al, 2010; Wawruch et al, 2013). Patient information leaflets are frequently ignored and the patients base their use of medicines on previous experience (Hughes et al, 2002; Cullen et al, 2006; Wirtz et al, 2009; Hanna and Hughes, 2011; Gavronski et al, 2014). Previous studies have confirmed that non-prescription medicines are purchased and utilized more often by elderly patients who often suffer from numerous comorbid diseases, and therefore may be using multiple drugs. As a result, drug-drug interactions between non-prescription and prescription drugs may occur (Sihvo et al, 2000; Gavronski et al, 2014). There are also some concerns that self-medication may delay or mask symptoms and diagnosis of serious illness, when professional medical help should have been sought in the first place (Wazaifi et al, 2008).

Other problems related to self-medication are wastage of resources, running risks of increased resistance of pathogens and other risks of serious health hazards such as adverse reactions and prolonged suffering. Antimicrobial resistance is presently a

problem worldwide, predominantly in developing countries where antimicrobials are available without any prescription and thus can be self-administered (Bennadi, 2014).

A study carried out in France by Berrenia et al investigated the main characteristics of ADRs associated with self-medication which were recorded in the Midi-Pyrenees Pharmacovigilance database between the years 2008 and 2014. Practice that was considered as self-medication consisted of firstly OTC drugs and secondly formerly prescribed drugs which were used again later without any medical consultation (reuse of previously prescribed drugs). Among the 12,365 notifications recorded, 160 (1.3%) were related to self-medication with 186 drugs. Around three-fourths of the ADRs were considered as 'serious'. The most frequent ADRs were gastrointestinal and neuropsychiatric and main drug classes involved NSAIDs, analgesics, and benzodiazepines. Homeopathy and herbal medicines accounted for 9.1% of drugs (Berrenia et al, 2015).

Simultaneous use of non-prescription and POM drugs is also a safety concern that has been investigated in a study carried out in Estonia between 2010 - 2012. The study examined the conditions for which non-prescription and POM drugs are used concurrently, frequency of use and to discuss possible risks associated with the combined use of such drugs. Seven hundred and twelve patients participated in the study, 50.4% of which stated simultaneous use of POM and non-prescription medicines throughout the survey. The study also gathered that simultaneous use of POM and non-prescription medicines increased with age and the number of chronic diseases. Greater use of non-prescription medicines, leads to more drug-drug interactions between prescription medicines (such as antihypertensives and anti-inflammatory medicines) and

non-prescription medicines (e.g. paracetamol, NSAIDS). The study revealed frequent concomitant use of prescription and non-prescription drugs, with the elderly and chronically ill patients being the most vulnerable (Gavronski et al, 2014).

1.7 Misuse of OTC medications

The increasing availability of OTC drugs has also resulted in the increase of misuse and abuse of such drugs. Abuse of OTC drugs can be placed in five different groups: codeine based drugs (such as compound analgesics), anti-tussive drugs (such as dextromethorphan), laxatives (bisacodyl, senna), decongestants (pseudoephedrine, xylometazoline) and sedating antihistamines (diphenhydramine) (Cooper, 2013).

A study carried out by Matheson et al on two pharmacists in Scotland (study undertaken in 1995 and 2000), reported the participating pharmacists' belief that OTC product misuse was occurring in their area as 67.8% and 68.5%, respectively. Another study by MacFadyen et al in 2001, also involving Scottish pharmacists, reported that 31% of pharmacists perceived there to be frequent misuse and 58% perceived occasional misuse. It was also estimated that an average of 5.6 patients were suspected of misuse every week (Cooper, 2013). Albsoul-Younes et al (2010) adopted similar methods to the studies carried out in the UK and found that 94.1% of pharmacists in Jordan suspected some abuse or misuse of OTC products.

A study carried out in Poland between October 2014 and June 2015 resulted that drug misuse is on the increase, with the use of preparations containing pseudoephedrine, codeine and dextromethorphan. The leading reasons for misuse were discovered to be the use of internet pharmacies and easy access to these drugs. The majority of polish

pharmacists included in the study (58.2%) believed that the drugs mentioned should be restricted. Such medicines could only be sold without a prescription by pharmacists with a higher level (Masters or Doctoral) with more than 5 years' experience. Social education may also contribute to reduce misuse (Zaprutkoa, 2014).

There are substantial possible harms associated with the abuse of OTC medicines. Firstly, there are the direct harms brought about by the pharmacological effects of the misused drug. Then there are physiological harms which manifest from the adverse effects of other active ingredients in a formulation which is being abused. Finally, there are harms associated with other factors such as effects on social and personal life, economic burden and development of abuse of other drugs (Cooper, 2013).

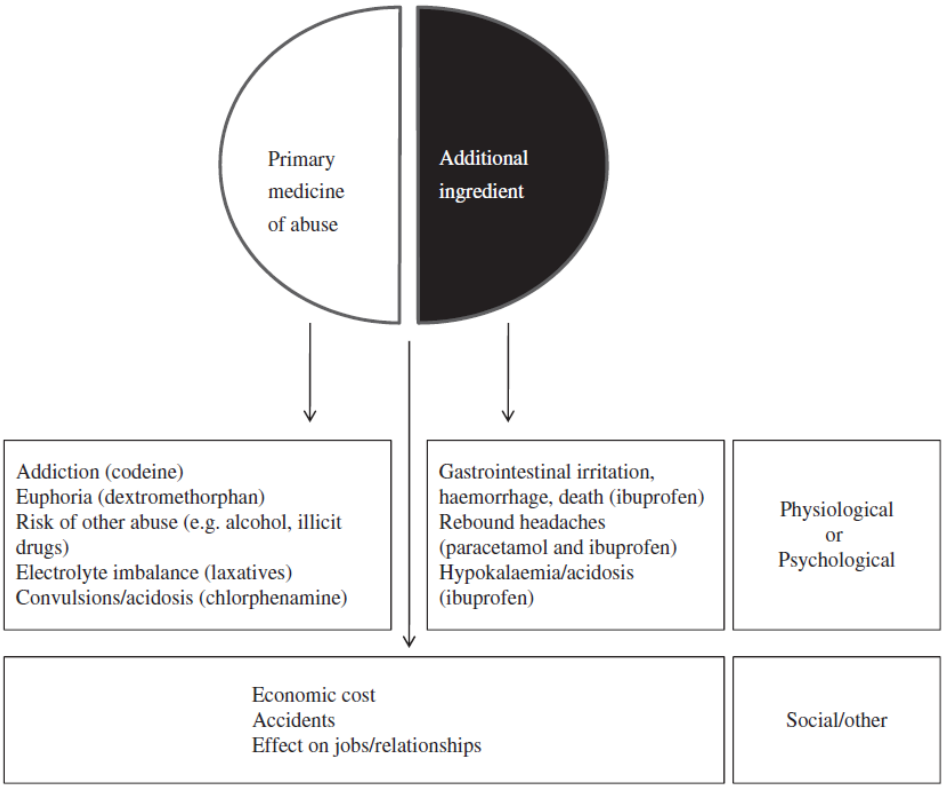

Figure 1.1: Medicines of abuse

Reproduced from: Cooper RJ. Over-the-counter medicine abuse – a review of the literature. *J Subst Use* 2013; 18(2): 82–107

1.8 Drug-related problems

Hepler and Strand defined a drug-related problem (DRPs) as "an event or circumstance involving drug treatment that actually or potentially interferes with the patient's experiencing an optimum outcome of medical care". They identified several categories of DRPs, including improper drug selection, untreated indications, sub-therapeutic dosage, over dosage, adverse drug reactions, drug interactions and drug usage without indication (Hepler, 1990). Identifying and resolving DRPs is an important aspect of pharmaceutical care (van Mil et al, 2004). DRPs may be caused by several issues such as prescribing errors, incorrect drug use by the patient or insufficient monitoring (Basger et al, 2014).

DRPs may have a negative effect on patient morbidity and mortality (Urbina et al, 2014). Studies suggest that they could be responsible for 28% of hospital emergency visits (Patel et al, 2002). Moreover, between 2% and 12.1% of hospitalizations may be attributed to DRPs, of which 50% or more can be prevented (Howard et al, 2007; Leendertse et al, 2008; Al Hamid et al. 2014; Urbina et al, 2014). The main culprit DRPs which lead to hospitalizations include adverse drug reactions and non-adherence to drugs (Howard et al, 2007; Al Hamid et al, 2014), with the most common drugs being those used in cardiovascular disease (Budnitz et al, 2011; Taché et al, 2011; Al Hamid et al, 2014).

Studies have been carried out with regards to DRPs with prescription drugs however; few studies have evaluated DRPs with OTC medicines and the role of community pharmacies in preventing or resolving these problems (Frøkjær et al, 2012).

1.9 Facilitated self-medication

A term which is innovative is the term facilitated self-medication or self care. The concept of facilitated self-medication relies on the pharmacist's direct role in providing advice and care with self-medication products. Facililated self-medication refers to scenarios when a patient enquires and seeks the advice of the pharmacist regarding an OTC product (Rutter, 2015). At this point, the pharmacist is in a strong position to influence the patient to take the best decision regarding their own care (Bennadi, 2014). Studies illustrated that patients altered their purchasing choices, aborted their purchase or were referred to the doctor after being approached in a pre-emptive way by pharmacy students (Nichol et al, 1992; Sclar et al, 1996). Such studies focus on how pharmacists are able to positively shape consumer decisions, improve healthcare outcomes and help guide patients to alternative and most probably better options (Rutter, 2015).

1.10 The strategic position of community pharmacists' in providing care

Although there is a global move towards liberalizing non-prescription markets and making the drugs available at any common retailer, pharmacies still remain the main providers of non-prescription drugs (Tisman et al, 2010). Pharmacists have to utilize the opportunity to promote their professional skills and demonstrate how they can improve outcomes of patient care.

A study carried out in the UK by Clifford et al in 2006 demonstrated the benefits of pharmacist counselling and advice on medicines soon after starting treatment. Non-adherence to treatment was significantly lower, drug-related problems were also lower

and the patients had more positive beliefs about their treatment. This study suggests that the service may be safe and useful to patients (Clifford et al, 2006). Another study carried out in Germany by Eickhoff et al in 2011 identified drug-related problems in patients utilizing self-care which were identified by community pharmacists. Most drug-related problems identified were self-medication inappropriate, requested product inappropriate, intended duration of drug use too high including abuse, and wrong dosage. All patients with identified drug-related problems were counselled accordingly. The most frequent interventions carried out by pharmacists were referral to a physician and switching to a more appropriate drug. In nearly one of five encounters, a direct pharmacist–patient interaction about self-medication exposed relevant drug-related problems. The availability of patient files as well as data on prescription and OTC drugs use may increase patient safety (Eikhoff et al, 2011).

Studies carried out in Sweden by Westerlund et al in 2003 and in Denmark by Thomsen et al in 2003 demonstrated the benefits of pharmacist counselling on OTC medicines. One study established that a counselling model which was designed to discover and resolve issues regarding symptoms and drug use seemed to have a positive impact on outcomes in patients with dyspepsia who were seeking non-prescription drug treatment in Swedish pharmacies (Westerlund et al, 2003). A similar study carried out in Denmark demonstrated similar results for dyspepsia and hay-fever patients (Thomsen et al, 2003). Another Swedish study by Westerlund et al in 2001 revealed the need for more professional attention and intervention by pharmacy staff in order to prevent and correct drug-related problems for patients requesting OTC medicines. The study highlighted that it was of particular importance to make sure that consumers receive the appropriate drugs for their current ailments (Westerlund et al, 2001). It was also discovered that

pharmacist counselling was a means to improve drug use, when it came to prescription-only medicines. In addition, more drug-related problems were found in patients who were sending a representative to pick up their medicines rather than patients visiting the pharmacy themselves (Ax et al, 2011).

A study carried out in Qatar investigated patient perceptions of pharmacists and the use of non-prescription medications in an ambulatory care setting. Patients presenting to a private clinic for prescription dispensing were asked to participate in a short verbal questionnaire. Patient awareness of the pharmacist's roles in directing OTC drug choice and attitudes towards pharmacist and nurse medication knowledge and comfort with dispensing were assessed. The majority of patients interviewed (85.3%) claimed that they would be interested in the pharmacist's role of guiding OTC therapy. In general, participants were also more comfortable with medication and related advice provided by pharmacists as opposed to nursing professionals (Wilbur et al, 2010).

1.11 Aims and objectives

The aim of this dissertation was to optimise patient safety and pharmacotherapy related to self-medication through the community pharmacist's clinical intervention.

The objectives of the research were to:

- Investigate quantitatively the nature and frequency of drug-related problems occuring in relation to self-medication.
- Document the interventions carried out by the pharmacist in relation to the identified drug-related problems.

Chapter 2

Methodology

2.1 Study design

The research study was aimed at obtaining descriptive statistical trends of DRPs with OTC drug use and pharmacist interventions towards detected DRPs in the local scenario. The approach towards the study was divided into two phases. The first phase consisted of compiling and validating the data collection tool required to run the research. During the second phase, patients were invited to participate in the study. The research was carried out between October and November 2016, in a community pharmacy.

2.2 Ethics Approval

Ethics approval was obtained from the University of Malta Research and Ethics Committee (UREC) on 21st July 2016. A study information sheet was developed in English and Maltese, together with a patient consent form (Appendix 1). These documents contained information related to the objectives of the study, patient involvement, animosity of data, freedom to refuse participation and the identity and contact details of the pharmacist.

2.3 Patient recruitment

An initial sample of 203 consecutive patients was included in the study to avoid bias during selection of patients. Patients agreeing to participate were asked to sign the consent form after reading and understanding the study information sheet. Patients were

eligible to participate in the research if they were aged 18 years and over, were able to understand English or Maltese and were not cognitively impaired.

2.4 Data collection tool

A data collection tool was adapted from a previous study carried out in Germany by Eickhoff et al in 2012. The tool was validated by a panel of experts comprised of three community pharmacists, a physician and a layperson. In order to facilitate completion of the tool in day-to-day work, the data collection form was limited to one page with checkboxes and minimal free text. The data collection tool recorded patient characteristics and DRPs (Appendix 2).

Patient characteristics (age and gender), nature of request (OTC request, first time request or repeat request, symptom presentation), patient medication list (prescription and non-prescription medicines), nature of any drug-related problems if detected (requested medicine unsuitable/not optimal for symptoms presented, requested medicine unsuitable/ duplication of medicines, requested medicine is contra-indicated, drug interaction, incorrect dose, drug regimen is too short, drug regimen too long, adverse drug reaction detected), the pharmacists intervention towards any drug-related problems detected (gave advice, changed to another drug, referred patient to doctor, stop treatment/withhold drug) and the time taken to solve any drug-related problems detected.

DRPs detected were classified as solved, partially solved or not solved. DRPs which were resolved during the patient's visit to the pharmacy were classified as solved, for example, a medicine which was not optimal for symptoms presented and was resolved by a product switch. DRPs classified as partially solved were those cases in which a DRP was detected but could not be tackled during the patient's visit to the pharmacy, example the patient was referred to the physician who was not present in the pharmacy or the patient was given advice to correct their habits in drug misuse. DRPs classified as not solved were those in which the patient would not take the pharmacist's advice and proceeded to request the drug regardless of the associated DRPs. Patient anonymity was preserved since no patient specific data apart from age range and gender was recorded.

2.5 The pharmaceutical care session

The pharmacist-researcher described the aims of the study and invited the patient to participate by filling out the consent form. Subsequently, the pharmacist proceeded with the one to one interaction with the patient. The data collection tool was filled out immediately after the interaction with the patient. The pharmacist-researcher recorded data on patient characteristics (e.g. estimated age, gender) and the nature of the OTC request (e.g. OTC medicine request, first-time or repeat request, symptom presentation). Identified drug-related problems, and the action taken by the pharmacist to resolve the identified drug-related problems was documented accordingly. Furthermore, the time needed for resolving the problem was also recorded.

The British National Formulary edition dated 2016 issue was used as reference material together with the summary of product characteristics where necessary. Drug interactions were also checked online through the Medscape drug interaction checker. [1]

2.6 Descriptive statistics

SPSS® version 20 was used in order to compile the data obtained from this study. The results were analysed to generate descriptive statistics including information regarding patient characteristics and data related to the incidence and nature of DRPs detected as well as interventions made by the pharmacist to solve the identified DRPs.

[1] Medscape drug interaction checker. Available from: available from: http://reference.medscape.com/drug-interactionchecker

Chapter 3

Results

3.1 Adaptation and validation of the data collection tool

The data collection tool which was used in this study was obtained and adapted from the study carried out in Germany by Eickhoff et al in 2012. Amendments which were carried out to make it more suitable for our local study were that the tool was translated to English from German, using Google Translate, the pharmacy identification number field was omitted as it was not required since the local study was carried out in a single pharmacy, the checkbox "Availability of patient file" was omitted since it is not applicable to our local setting, checkboxes for indications were removed and a space for writing was provided as it was deemed to be more efficient and flexible. Table 3.1 lists the amendments done following recommendations from the expert panel.

Table 3.1: Amendments to the data collection tool by the expert panel

Time required to solve intervention was moved to the top of the tool to improve the overall appearance
It was suggested to increase the visibility and size of the check boxes to ensure efficient data entry and avoid errors.
In section 1, checkboxes next to symptom presentation and name of medicine requested were removed as they were deemed unnecessary.
In section 1, the trade name and generic name checkboxes were removed since they were deemed unnecessary and to reduce needless steps.
In section 3, the checkbox: "Medication requested unsuitable. Prescription required" was removed as it was deemed to be outside the scope of the study.
In section 3, the checkbox: "Medication requested unsuitable. Duplication of medicines" was added.
In section 4, the checkbox: "Stop/withhold drug" was added.

3.2 Descriptive statistics

During the period of 6 weeks, 203 patients were included in the study, with 38 (18.71%) of the patients having one or more DRPs. The patients were included in a consecutive order to avoid selection bias.

The results obtained from this study were analysed to describe the characteristics of patients with DRPs related to self-medication and define the incidence and nature of the identified DRPs.

3.2.1 Age of patients with DRPs

The majority of patients presenting with DRPs were those in the 26-35 year ranges and those in the 46-60 year ranges (Figure 3.1). Patients with DRPs in 36-45 year range presented in 20% of the cases while patients between 18-25 and 61-74 presented in 10% of the cases, 5% of patients with DRPs were over 75 years of age.

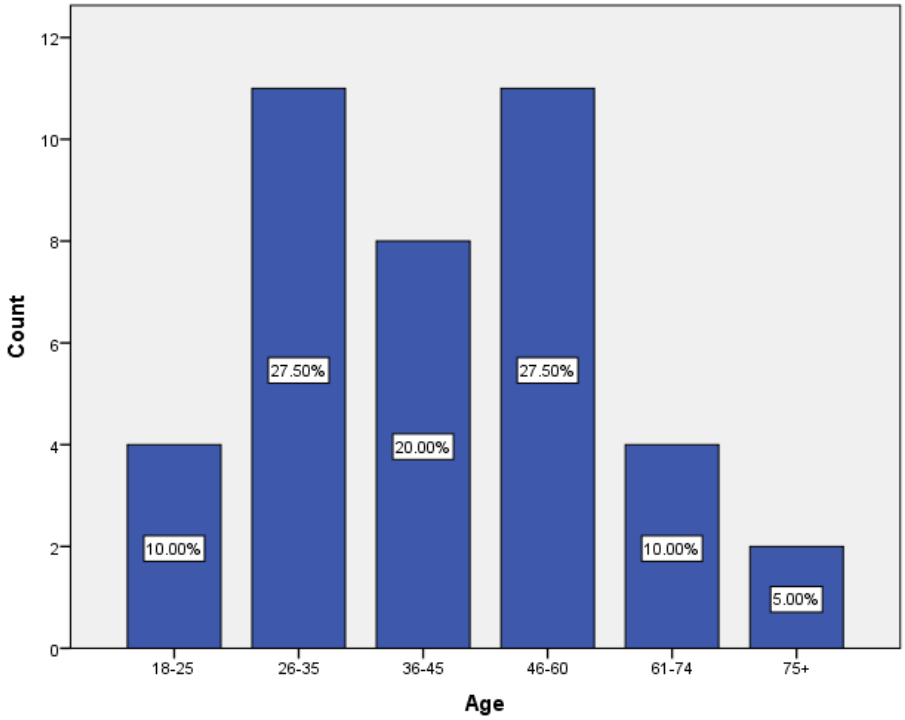

Figure 3.1: Age of patients with identified DRPs (n=38)

3.2.2: Gender of patients with DRPs

The majority of the patients who presented at the pharmacy with DRPs were female at 57.5%, whilst male patients presented in 42.5% of cases (Figure 3.2).

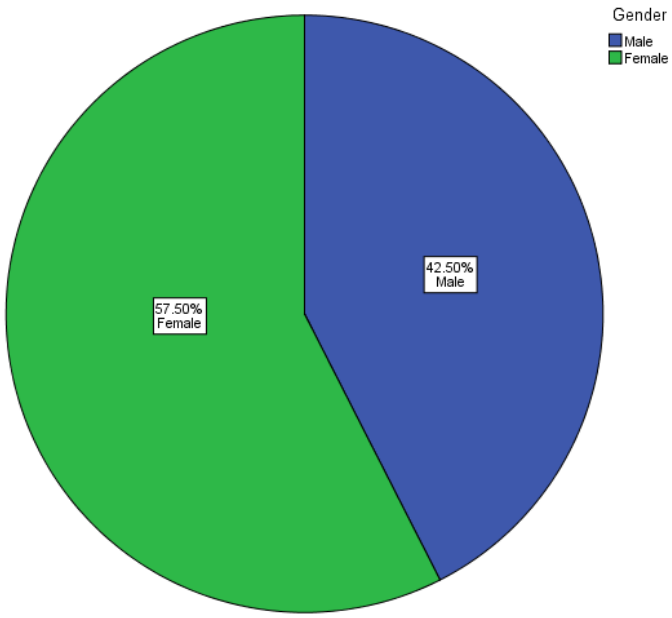

Figure 3.2: Gender of Patients with identified DRPs (n=38)

3.2.3 Requests of patients with DRPs

Figure 3.3 shows the requests that patients with identified DRPs presented with. 52.5% of all requests of patients with DRPs were classified as repeat requests, while 47.5% of requests were first-time requests.

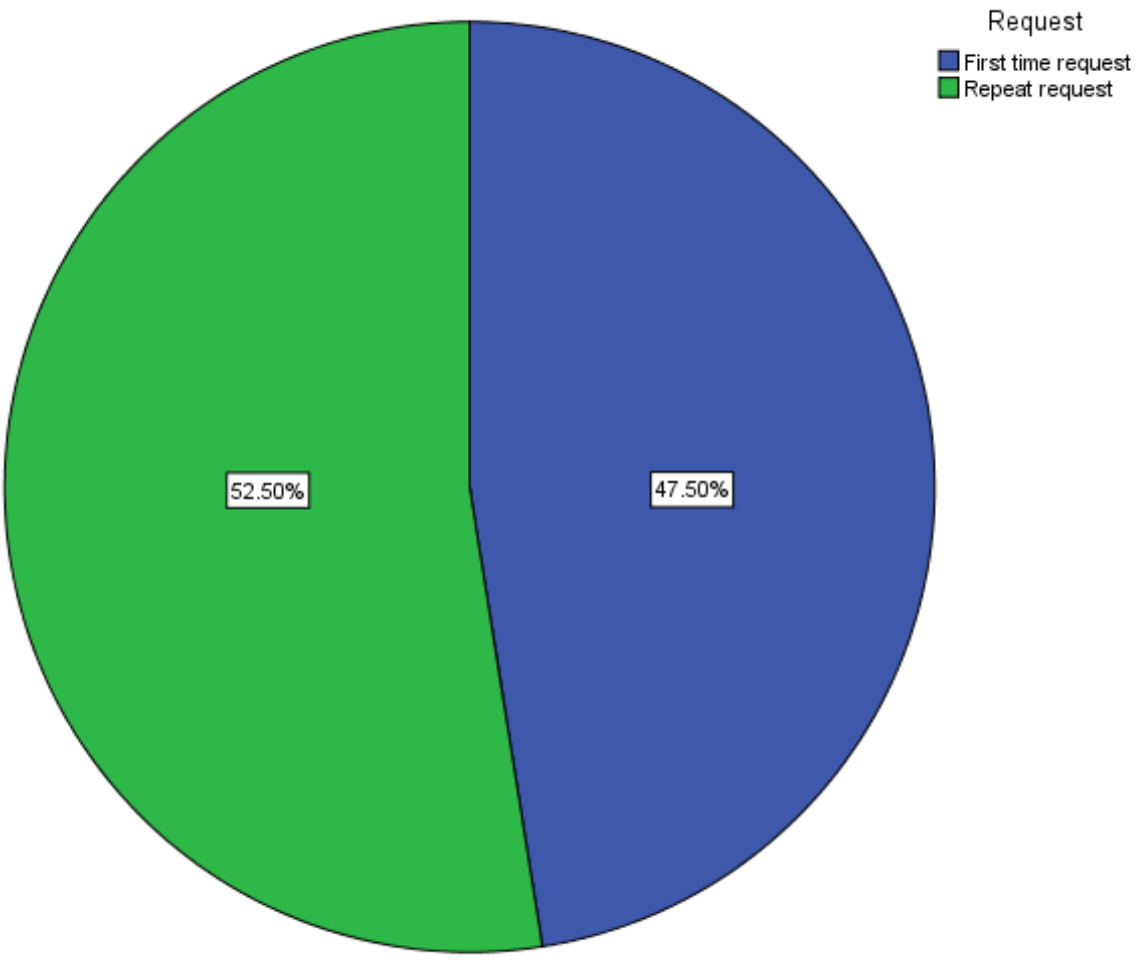

Figure 3.3: Request classification (n=40)

3.2.4 Symptoms presented in patients with DRPs

The most common symptoms which presented in patients with identified DRPs were respiratory disorders in 17 (42.5%) of the cases presented (Figure 3.4). Pain was the second most common symptom presented in patients with identified DRPs, in 9 (22.5%) of the cases. Both skin disorders and gastrointestinal disorders presented in 5 (12.5%) cases each.

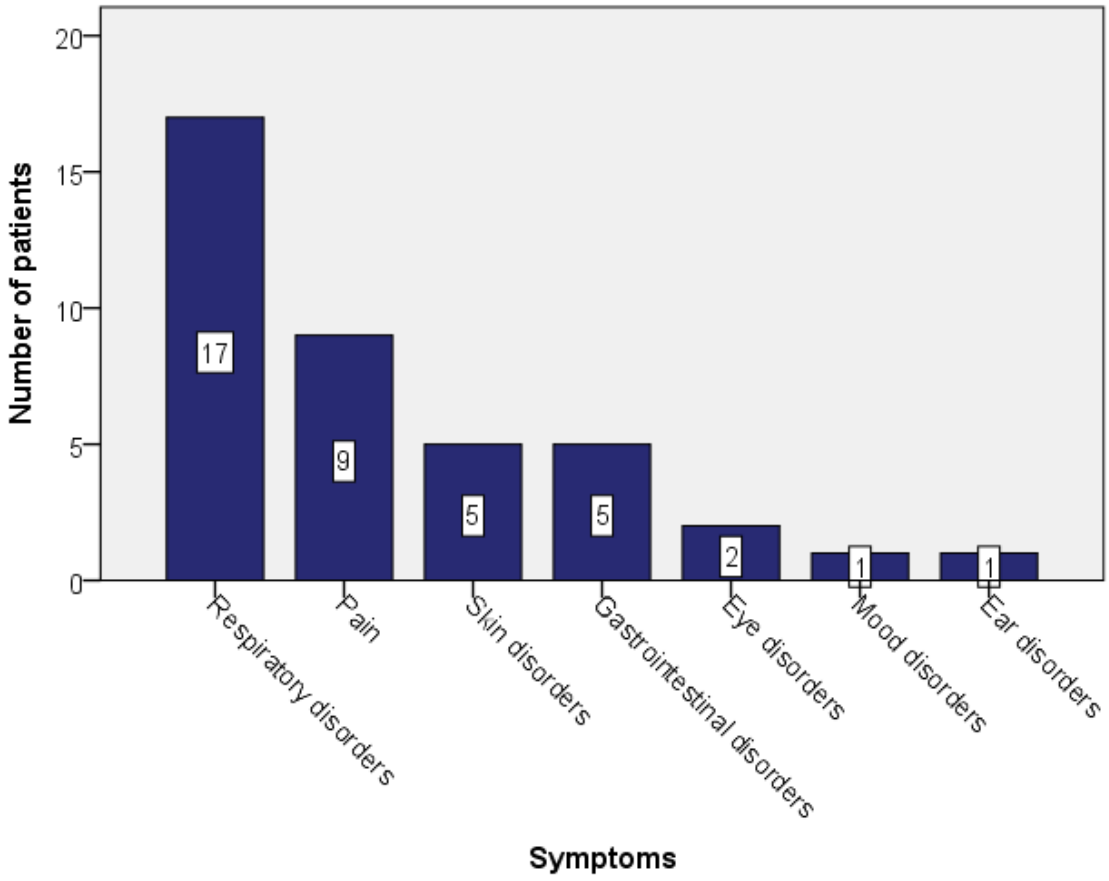

Figure 3.4: Symptoms presented in patients with DRPs (n=40)

The symptoms patients presented with during the study period were classified according to the organ system and sub-classified according to symptom presentation (Table 3.2). The most common symptoms related to the respiratory tract followed by pain.

Table 3.2: Classification of symptoms presented

Symptoms	Symptom Sub-category	Number
Respiratory Disorders (n=17)	Common cold/congestion	7
	Allergic Rhinitis	4
	Sore Throat	4
	Cough	2
Pain (n=9)	Headache	6
	Musculoskeletal Pain	3
Skin Disorders (n=5)	Skin infection	3
	Eczema	1
	Venous insufficiency	1
Gastrointestinal Disorders (n=5)	Heartburn/indigestion	2
	Nausea	2
	Constipation	1
Eye Disorders (n=2)	Eye irritation	1
	Eye infection	1
Ear Disorders (n=1)	Ear Blockage	1
Mood Disorders (n=1)	Depression	1

3.2.5 DRPs detected

The most common DRPs identified were requested medicine unsuitable/not optimal for symptoms presented in 13 (32.5%) of all identified cases, requested medicine is contra-indicated in 11 (27.5%) of the cases, and duplication of medicines in 5 (12.5%) of the cases (Figure 3.5).

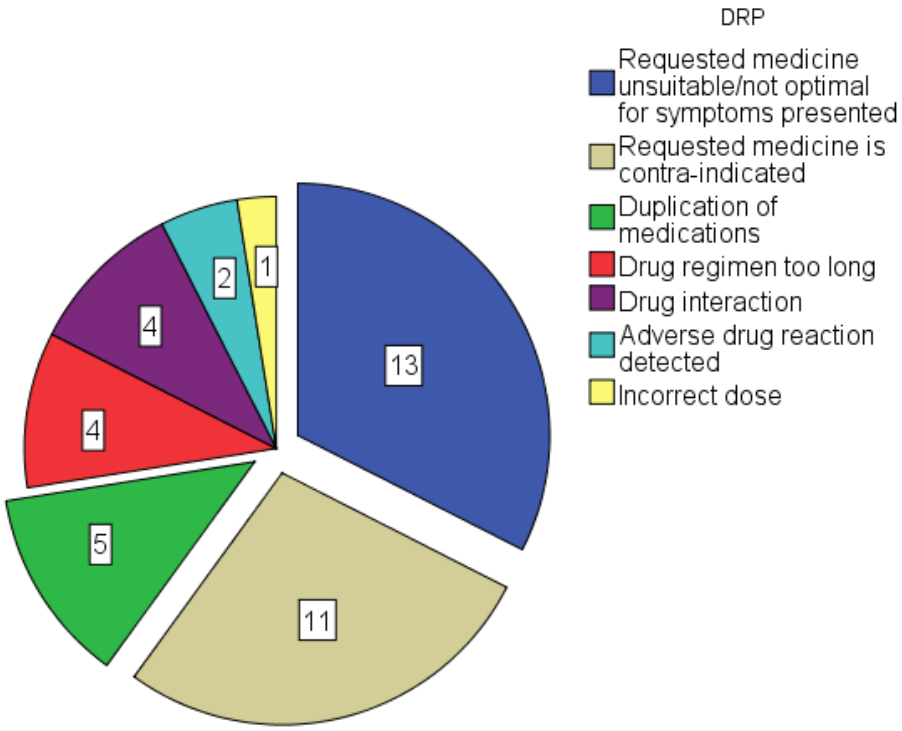

Figure 3.5: Classification of detected DRPs (n=40)

For each of the DRP classification detected, a summary of the patient cases is presented (Table 3.3).

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Table 3.3: Description of DRPs detected

DRP Detected	Case	Intervention
Requested medicine unsuitable / not optimal for symptoms presented	A patient asked for a preparation containing pseudoephedrine and triprolidine. The patient's work requires a lot of ladder work thus the preparation requested is not recommended due to sedation and risk of falls.	Changed to another drug
	A patient asked for milk of magnesia as he frequently suffers from heartburn. Upon further questioning he also said that suffers from loose stools. Thus magnesium containing antacids are not recommended.	Changed to another drug
	A patient asked for an anti-viral cream as she had a lesion on her lips. The pharmacist noticed that lesion did not look like a herpes infection. After questioning, the patient said the lesion was apparent for the past 6 months. This warranted referral to a physician.	Referred patient to physician
	A patient who was febrile and nauseated asked for probiotics, however the patient's condition warranted referral to a physician.	Referred patient to physician
	A patient who was suffering from migraine and was nauseated asked for a preparation containing ibuprofen as it was recommended by a friend. Patient had a history of heartburn, thus ibuprofen is not preferred.	Changed to another drug

Table 3.3: Description of DRPs detected (cont.)

DRP Detected	Case	Intervention
Requested medicine unsuitable / not optimal for symptoms presented	A patient suffering from nausea asked for a preparation containing loperamide. Loperamide has no effect on nausea.	Referred patient to physician
	A diabetic patient presented at the pharmacy asking for lozenges containing sucrose.	Changed to another drug
	A patient requested ear drops when he was suffering from nasal congestion.	Changed to another drug
	A patient with a persistent dry cough and fever requested a product indicated for chesty cough. The patient's condition warranted referral to a physician.	Referred patient to physician
	Patient complaining of a chesty cough asked for a cough preparation intended to treat dry cough.	Changed to another drug
	A patient asked for an antiseptic cream, when he had a fungal infection and needed an anti-fungal preparation.	Changed to another drug
	Patient presented at the pharmacy asking for antacid tablets, and she complained of heartburn with every meal for the previous 3 weeks. Referral was warranted.	Referred patient to physician
	A patient with an acute bacterial conjunctivitis came asking for an eye wash solution. Patient was referred to the physician for antibiotic eye drops.	Referred patient to physician

Table 3.3: Description of DRPs detected (cont.)

DRP Detected	Case	Intervention
Duplication of medicines	A patient asked for a preparation containing paracetamol and pseudoephedrine. After questioning, the patient said that she was already taking a preparation containing antihistamine and pseudoephedrine.	Changed to another drug
	Three cases of patients asking for a product containing an antihistamine for allergic rhinitis, but pharmacist recalled that the patients were already using a preparation containing anti-histamines.	Withhold treatment/Gave advice
	A patient requested a preparation containing pseudoephedrine but he was already taking pseudoephedrine in a prescribed drug.	Changed to another drug
Requested medicine is contra-indicated	A patient asked for a compound analgesic containing caffeine. The patient was suffering from hypertension and was on Enalapril, and did not know that the preparation requested may raise the blood pressure.	Changed to another drug
	A patient presented to the pharmacy asking for ibuprofen. The patient said that her doctor told her to avoid NSAIDS since she suffers from high blood pressure and heart failure (patient on diuretics and enalapril).	Changed to another drug
	Patient asked for a throat spray containing an NSAID. The patient said that he suffers from asthma. Thus NSAIDS are contra-indicated.	Changed to another drug
	Patient requested a preparation containing paracetamol and caffeine. Patient suffers from hypertension, thus caffeine is not suitable.	Changed to another drug

Table 3.3: Description of DRPs detected (cont.)

DRP Detected	Case	Intervention
Requested medicine is contra-indicated	Two patients asked for a preparation of paracetamol and pseudoephedrine, when they suffer from uncontrolled hypertension.	Changed to another drug
	A pregnant patient came to the pharmacy asking for an oral spray containing NSAIDs for sore throat. NSAIDs are contra-indicated in pregnancy.	Changed to another drug
	A patient who suffers from hypertension, diabetes and heart failure asked for a product containing pseudoephedrine.	Changed to another drug
	A patient requested a topical preparation containing capsaicin for a shingles infection. Capsaicin should not be used in acute infections, but only on post-herpetic lesions.	Stop/withhold drug
	An asthmatic patient suffering from a sore throat came asking for aspirin. Patient was febrile.	Referred patient to physician
	A pregnant patient came asking for dexketoprofen tablets.	Changed to another drug
Drug interaction	A patient asked for a preparation containing heparinoids, but pharmacist noted she was currently on warfarin therapy.	Stop treatment/gave advice
	Two cases of elderly patient on warfarin asking for an NSAID.	Changed to another drug
	A patient on a combined oral contraceptive asked for a preparation containing St John's wort.	Changed to another drug
Drug regimen is too long	Patient asked for an ointment containing hydrocortisone. The patient said that she has been applying it over her face and neck for the last month due to eczema without consulting a doctor.	Referred to physician
	A patient complaining of red eyes was using decongestant eye drops on a long-term basis.	Changed to another drug

Table 3.3: Description of DRPs detected (cont.)

DRP Detected	Case	Intervention
Drug regimen is too long	A patient asked for a preparation of co-codamol and admitted that she had been using them for a while. Co-codamol is not indicated for long-term use due to addictive potential.	Gave advice
	A patient asked for decongestant nasal spray. Patient claimed that he was using it long-term.	Gave advice
Adverse drug reaction detected	A patient using lactulose complained of flatulence, which may be a side-effect of lactulose.	Changed to another drug
	Patient asked for a strong painkiller for her persistent headaches over the past 3 weeks. Pharmacist noted that she started a combined oral contraceptive preparation recently and persistent headaches may be a side-effect of COC use. Referral was warranted.	Referred patient to physician
Incorrect dose (too low)	A patient complaining of allergic rhinitis was using a syrup containing pseudoephedrine and an anti-histamine at 5ml tds. Recommended dose for adults is 10ml up to 4 times daily.	Gave advice

3.2.6 Drug classes presented with DRPs

The drug classes implicated the most in DRPs were NSAIDs in 7 (17.5%) of the cases, decongestants in 6 (15%) of the cases and topical preparations and compound analgesics

both in 5 (12.5%) of the cases (Figure 3.6). Table 3.4 classifies the drug classes according to each DRP.

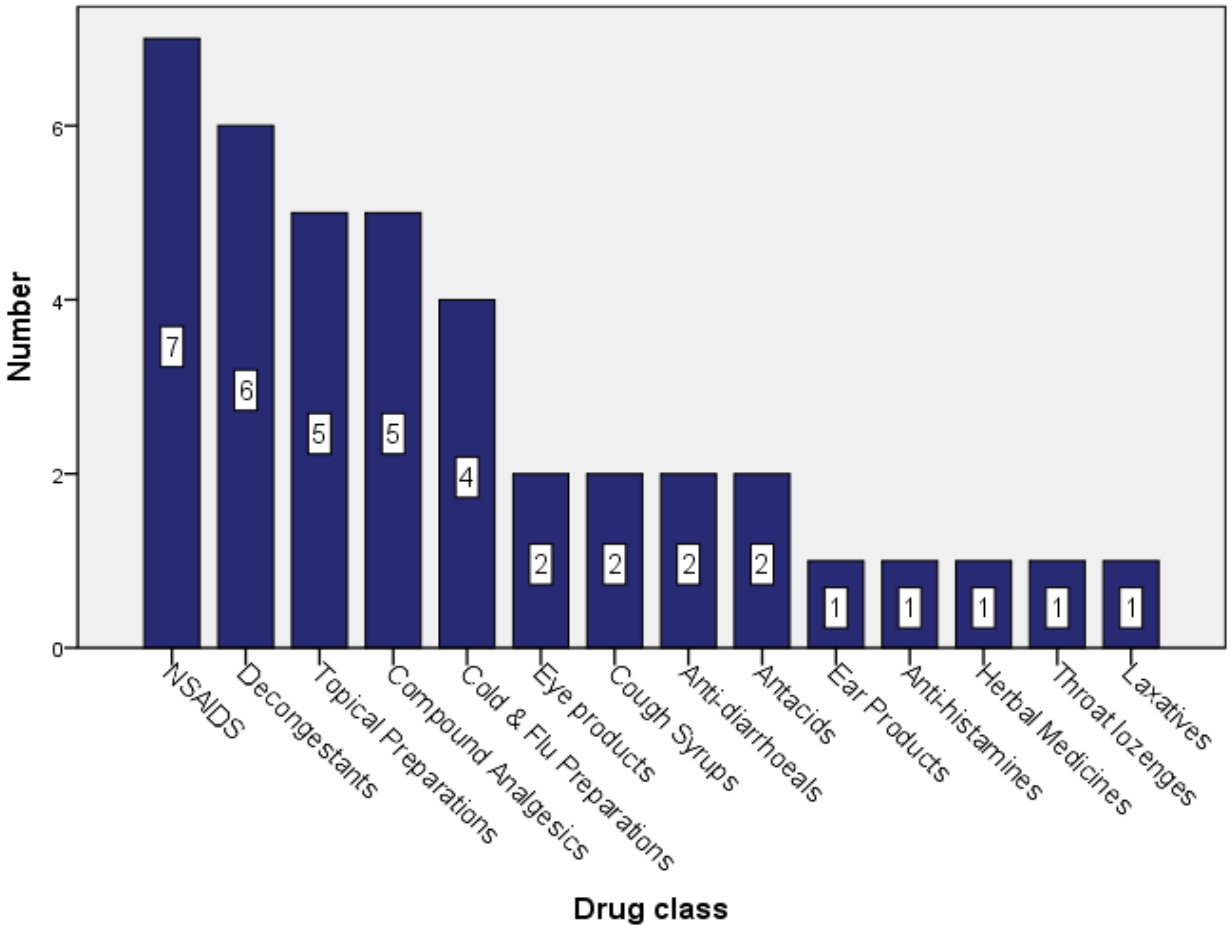

Figure 3.6: Drug classes associated with DRPs (n=40)

Table 3.4: Drug classes classified according to DRP

DRP	Drug class	Number
Requested medicine unsuitable/not optimal for symptoms presented (n=13)	Antacids	2
	Topical Preparations	2
	Cough Preparations	2
	Anti-diarrhoeal	2
	Decongestants	1
	NSAIDs	1
	Lozenges	1
	Eye Products	1
	Ear Products	1
Requested medicine is contra-indicated (n=11)	NSAIDs	4
	Compound Analgesics	3
	Cold & Flu Preparations	3
	Topical Preparations	1
Duplication of treatment (n=5)	Decongestants	3
	Anti-histamines	1
	Cold & Flu Preparations	1
Drug interactions (n=4)	NSAIDs	2
	Topical preparations	1
	Herbal Medicines	1
Drug Regimen too Long (n=4)	Compound Analgesics	1
	Decongestants	1
	Eye Products	1
	Topical Preparations	1
ADR detected (n=2)	Compound Analgesics	1
	Laxatives	1
Incorrect Dose (n=1)	Decongestants	1

3.2.7 Interventions carried out by the pharmacist

The interventions carried out by the pharmacist were namely changed to another drug in 23 (57.5%) of the cases, referred the patient to the doctor in 9 (22.5%) of the cases, halted treatment in 5 (12.5%) of the cases and gave advice in 3 (7.5%) of the cases (Figure 3.7).

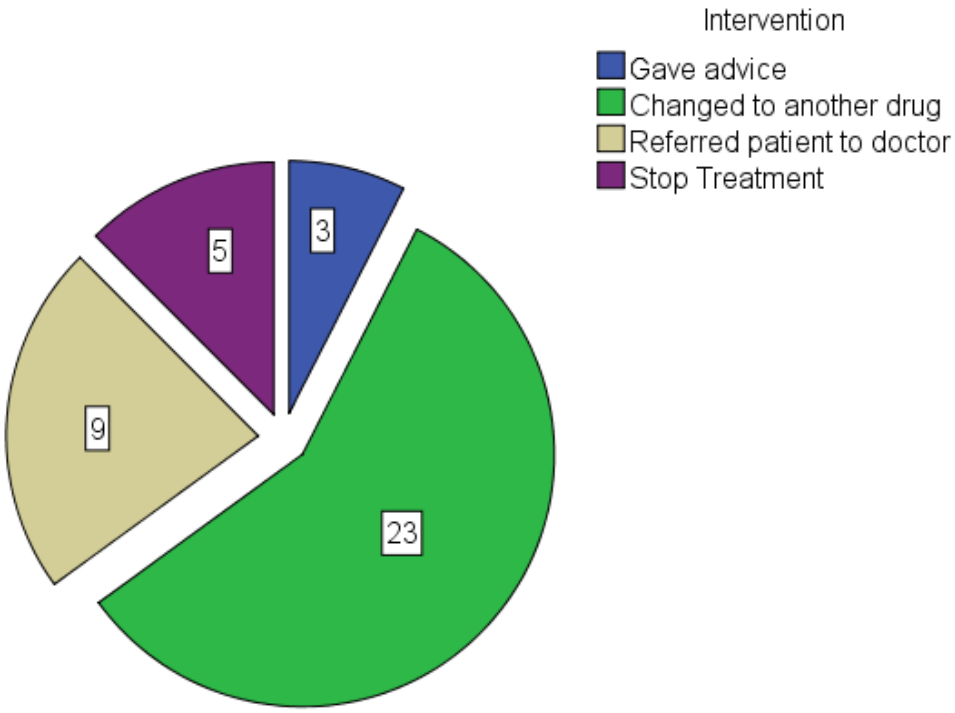

Figure 3.7: Pharmacist's interventions towards detected DRPs (n=40)

3.2.8 Outcomes of pharmacist interventions

Out of all the DRPs detected, 32 (80%) were classified as solved, 7 (17.5%) classified as partially solved and 1 (2.5%) was not solved. DRPs classified as solved were those in which the intervention was completed in the pharmacy (Figure 3.8). Partially solved were classified when the patients were referred to a doctor outside of the pharmacy or given advice. A case was classified as not solved because the patient did not heed the pharmacist's advice (patient advised not to use nasal decongestants for longer than 7 days, but purchased anyway).

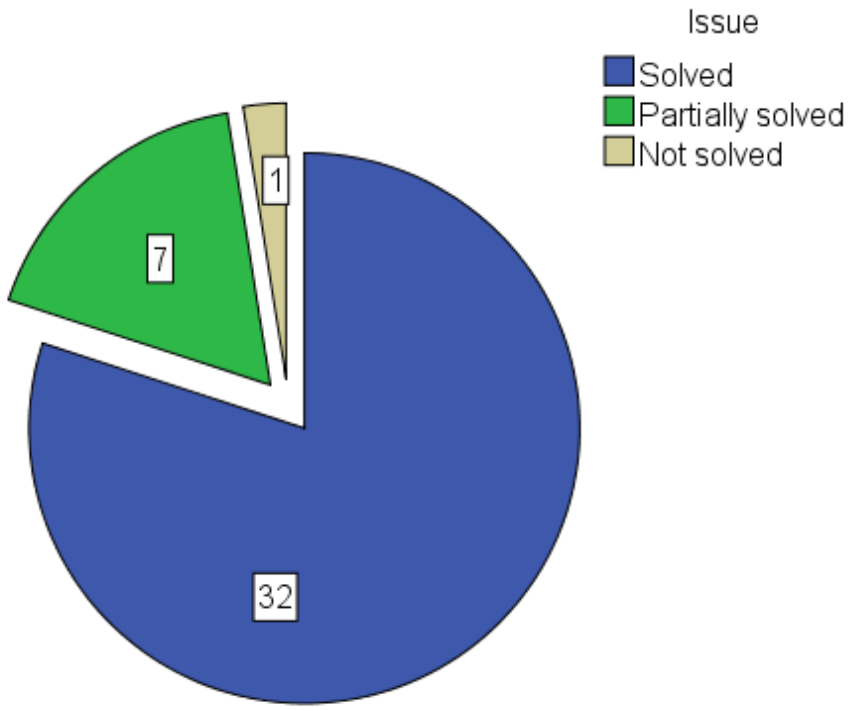

Figure 3.8: Outcomes of interventions carried out by the pharmacist (n=40)

3.2.9 Time required solving DRPs

The mean time taken to solve the DRPs was 4.35 minutes (SD 1.2) (Table 3.5).

Table 3.5: Time taken to solve the DRPs (n=40)

Number of DRP's identified	Minimum Time taken in Minutes	Maximum Time taken in Minutes	Mean Time taken in Minutes	Standard Deviation in Minutes
40	2.00	7.00	4.35	1.20469

Chapter 4

Discussion

4.1 Evaluation of DRPs in self-medication

The present study provided an insight on the incidence of DRPs in the local scenario with respect to OTC products. The study was carried out in a community pharmacy, where 203 customers presented with OTC requests and were included in the study. Forty DRPs were identified in 38 patients (18.71%). This result indicates that self-medication with OTC products can bring about risks.

The study showed that 75% of patients with DRPs were between 25 and 60 years old, most probably since most of the patients who presented at the pharmacy were in that age range. Patients in that age range may be more motivated to self-treat their own conditions when compared to patients over 75 years of age who comprised of only 5% of DRPs. This could be due to the increased literacy, as patients would feel more confident researching on OTC products and reading product information leaflets.

Female patients presented with more DRPs than males (57.5% and 42.5% respectively), most probably due to the fact that female patients presented at the pharmacy more frequently than male patients.

Fifty two point five percent of all patients with DRPs identified had utilised the drug requested in the past. This emphasises that the pharmacist should be alert at all times, even when a patient seems familiar with the OTC drugs requested, as the patient may have seen an advertisement or is following the advice of a friend or family member who had used that particular OTC medicine. This may also indicate that patients do not read

the product information leaflet before use, thus highlighting the importance of patient counselling in self-medication.

Out of all DRPs recorded, 32.5% were “requested medicine inappropriate/not optimal for symptoms presented”, 27.5% of DRPs were “requested product is contra-indicated” and 12.5% of DRPs were “duplication of medicines”. This shows that nearly three fourths of all DRPs were related to improper drug selection. In fact, 57.5% of the pharmacist’s interventions were “changed to another drug”. The high incidence of improper drug selection indicates that patients require counselling on self-medication with OTC products.

For ideal self-medication to be carried out, the patient must be capable to evaluate his/ her symptoms and diagnose the underlying condition appropriately, be able to judge whether the issue can be managed with self-medication or by a physician and select a suitable drug for treatment. This entails that the patient has to be able to read and comprehend the package information leaflets, in order to familiarize oneself with the proper doses, be able to recognise warnings and to know when not to use. Studies have shown that this practice may be lacking, especially in groups such as children, elderly patients, patients with chronic diseases and pregnant women (National Council on Patient information and Education, 2002). Therefore, counselling by the pharmacist is a necessity in order to mitigate potential DRPs that would otherwise be undetected and pose a safety risk.

Ten percent of the DRPs detected were classified as drug interactions. This also shows that the patients were unaware of the risks posed when taking multiple medications

simultaneously. One may assume that once again the patient did not take the time to read or did not understand the drug information leaflet provided. It should also be stated that the patient medication list was provided by the patients from memory thus results obtained may be underestimated. 10% of the DRPs were also classified as drug regimen taken for too long.

These results may show that there is a general opinion among patients that OTC medicines are not strong enough to cause actual harm. However, OTC medicines often contain powerful pharmacological active ingredients which are derived from the prescription only class of medicines, and studies show that they can cause serious harm which in the worst case, can lead to hospitalization (Farker et al, 2009).

The NSAIDs and compound analgesics were among the most commonly used drugs in patients with identified DRPs at 17.5% and 12.5% respectively. Their incorrect use may lead to severe adverse reactions such as cardiac and renal toxicity, gastrointestinal issues and hepatotoxicity (Ronnie et al, 2004). In fact, in identified DRPs where the requested drug was contra-indicated, NSAIDS were implicated in 36.3% of the requests, followed by compound analgesics in 27.2% of requests. Cold & flu preparations were also implicated in DRPs involving contra-indications, for example by being requested by patients who suffer from high blood pressure.

The most common symptoms reported were respiratory disorders, followed by pain and both gastrointestinal disorders and skin disorders (42.5%, 22.5%, 12.5% and 12.5% respectively). One should bear in mind that the study was carried out in November, thus common colds and allergic rhinitis symptoms were presenting quite often at the

pharmacy, with requests for decongestants and cold & flu preparations being the most common. Headaches were the most common type of pain reported in DRP patients, most of which asked for NSAIDS and compound analgesics.

Common pharmacist interventions were changed to another drug in 57.5% of cases, which, as explained previously indicated improper drug selection by the patients. 12.5% of DRPs required halting of treatment (for example in cases of duplication of medicines) and 7.5% consisted of giving advice on the use of the drugs. These DRPs were solved there and then by the pharmacist. The referral rate of 22.5% indicates that the pharmacist would refer if he perceived the need for more specialised treatment.

80% of all detected DRPs were solved and 17.5% were classified as partially solved. This result highlights the pharmacist's important role in guiding patients by identifying and managing DRPs for OTC medicines, thus ensuring that self-medication practice is safe and effective.

4.2 Comparison of local results with foreign studies

The results obtained for this Maltese study are similar to those obtained abroad, in Germany (Eickhoff et al, 2012) and in Denmark (Frøkjær et al, 2012). DRPs were detected in 17.6% of all self-medication requests in the German study and in 21% of OTC requests in the Danish study. The results of the local study are very similar at 18.7% DRPs detected in patients with OTC requests.

The types of DRPs detected in the foreign studies are also very similar to the ones obtained locally, with the most common DRPs in the German study being "self-medication inappropriate" (29.7%), "Requested product inappropriate" (20.5%), "Intended duration of drug use too high including drug abuse" (17.1%) and "Wrong dosage" (6.8%). Common Danish DRPs detected were "The choice of self-medication is not appropriate/ optimal for the condition" (44.8%), "Too little of the drug is being taken" (17%), "The drug is taken for too long (dependence)" (15%) and "Adverse drug events" (13.8%).

The results of the present study indicated a most commonly encountered DRP of "Requested product inappropriate/ not optimal for symptoms presented" in 32.5% of cases, very similar DRP to the most common ones observed abroad. This may show that self-medication traits are generally comparable across the three countries.

Symptoms presented with DRPs were also quite similar. The German study showed that in OTC requests with DRPs, the most common symptoms presented were pain (23.9%), Respiratory tract disorders (19.3%) and Gastro intestinal disorders (17.4%).
Pain was also the most common symptom in the Danish study in 57.6% of customers, with the second most common symptom being allergy or hay fever in 16.7% of customers. Their study indicated that patients with identified DRPs had similar symptoms to those without DRPs.

These symptoms are comparable to the ones observed in Malta. Our local study indicated that respiratory disorders were the most common, most probably due to the time of year (late October/November for local study, August/September for the German

study and June/July for the Danish study) when the study was carried out, resulting in more cold & flu symptoms. Pain and gastrointestinal disorders were also frequently observed symptoms. The similarity of the results show that patients are overall confident and willing to self-treat the aforementioned symptoms, but although the symptoms are commonly encountered, patient knowledge is still lacking and DRPs can occur.

There was a difference noted in the rate of DRPs solved when comparing the local study with the foreign ones. Our study showed that 80% of DRPs were solved, 17.5% partially and 2.5% not solved. This contrasts with the results from the overseas studies where the German study stated that 45% of DRPs detected were solved, 45% were partially solved and 9% were not solved. For the Danish study, 44.9% of DRPs detected were solved and 45.3% were partially solved.

The high success rate for the Maltese study may be due to the possibility that the pharmacist was familiar with the patients who presented at the pharmacy and their conditions, since Malta has a very low population when compared to the other countries. The German study also stated that the majority of DRPs which could not be solved were classified as “drug misuse or abuse”, of which only two were classified as such in the Maltese study (with one of them classified as not solved). In this study, the majority of patients who were referred to the doctor, visited the doctor who has his clinic at the pharmacy immediately after the interaction with the pharmacist, thus they were classified as solved since all issues detected were dealt with.

4.3 Assessment of current situation in Malta

From the results of this study, one can conclude that the incidence rate of drug-related problems with OTC products in Malta is relatively frequent and comparable to other results obtained abroad. In Malta, we have the advantage that OTC products can only be sold from community pharmacies, unlike the countries with which our study was compared to. According to the Danish study (Frøkjær et al, 2012), some OTC medicines are being sold from outlets other than pharmacies such as supermarkets. This practice can bring about risks as there may be insufficient information given about drugs by an employee outside of a pharmacy, or no information at all if the product is taken off the shelf. Most probably less attention is given towards DRPs outside of a pharmacy.

The results from the current study illustrate the benefits of having OTC products sales retained from pharmacies only. Nearly one out of every 5 patients would have purchased and utilised drugs which may have had the potential to cause them harm were it not for the intervention of the community pharmacist. In Malta, with a population of 434,403 (NSO, 2016) and with 229 licenced pharmacies (1897 inhabitants per pharmacy) one can find one at practically every corner. Additionally, a good portion of pharmacies have extended opening hours nowadays.

Locally, pharmacists are graduating with a Master's degree, which should result in improved knowledge and competence to detect DRPs. Recently, the Doctor of Pharmacy course was launched, which should also further improve the clinical knowledge and skills of pharmacists.

An issue that may inhibit detection of DRPs in the local scenario is the lack of patient files or patient medication history. One has to rely on the patient in order to obtain a history or current medication list. Patients do not always provide a clear overview of their current or previous medications, especially elderly patients and those who are mentally challenged. Access to patient files could potentially lead to more DRPs being detected. In fact in the German study by Eickhoff et al, the availability of a patient file was assessed and the study indicated that if drug history was available, significantly more cases with DRPs such as wrong doses and drug interactions were detected (Eickhoff et al, 2012).

Recently in Malta, the morning after pill (MAP) was introduced, amid numerous discussions and hype from the media. The MAP was ultimately licenced with a non-prescription status, which drew a lot of attention. One should always conduct a risk vs benefit assessment when faced with such options. It was concluded that with the pharmacist's skills in safe dispensing and due to the fact that MAP administration must not be delayed for maximal effectiveness, the rational choice was to licence the product as non-prescription and have the dispensing pharmacist use his/her professional judgement and skills to determine if the MAP is indicated and safe for use when the patient presents at the pharmacy asking for assistance.

Other medications such as azithromycin (licenced for asymptomatic chlamydia), chloramphenicol eye drops (licenced for acute bacterial conjunctivitis), simvastatin (prevention of coronary events), domperidone (relief of nausea) and zolmitriptan (acute relief of migraine attacks), to name a few, have been transferred to non-prescription status in the UK as of 2016 (Medicines and Healthcare products Regulatory Agency).

This study demonstrated that the competence of pharmacists in detecting DRPs is similar to pharmacists abroad. Thus one would pose the question of why should there be a variation in products that have been switched abroad which have not achieved non-prescription status in Malta. One would assume that more medicines in the pharmacist's "arsenal" would mean more effective and timely self-medication for patients. However there are differences in the classification switch processes amid individual member states. One would hope that the positive reclassification experience observed in other countries should diminish any apprehensions and assist policy makers in other member states including Malta. With the results from this study, it is being proposed that legislators take the lead to propose reclassification models that are implemented locally and which then are taken up in other member states within a `reference member state` model.

The AESGP are working towards harmonising faster access of self-care products in the EU, with proposals described in the Smart Regulation 2015. Proposals were based on four principles as follows: *Communication,* with package leaflets and labelling designed to provide adequate information to users as well as an attractive layout. Advertising is to be allowed for all non-prescription drugs and active ingredients switched to non-prescription status should be allowed to use original trade name of the prescription product. Free *pricing* for manufacturers of non-prescription products which are purchased directly by patients. *Safe medicines,* where the safety profile of non-prescription medicines should be taken into account and pharmacovigilance data should be compiled in one centrally accessible system. The regulation also highlighted various regulatory measures to enable speedy *market access* for non-prescription products around the EU (AESGP, 2010).

4.4 Limitations of the study

A limitation of this study was the limited sample size. Limited time with patients was also an issue since obtaining information such as drug history, an accurate account of symptoms and other issues was time consuming. The study was carried out within normal working hours and with normal working parameters so as to capture the real practice.

The unavailability of patient data was also a limitation to the study outcome since an accurate account of the patient's drug and medical history were sometimes difficult to obtain from the patient.

This study did not collect any information concerning the long-term outcomes coming out of the interventions and counselling carried out by the pharmacist. However, the outcomes may be quite difficult to measure. Economic impact was also not measured. Another limitation would be the possibility of researcher bias, as the data was collected by the same researcher.

4.5 Recommendations

For further studies, it is recommended that the study be extended to a greater number of community pharmacies recruiting a larger number of patients in order to gather more data and increase the generalisability of results. Patient outcomes may possibly be measured by contacting the participants a few weeks after the pharmacist intervention in order to enquire about the patient's perspective on the effectiveness of the treatment and

advice given by the pharmacist. This study did not measure the economic impact of self-medication practice in Malta, which would be a good initiative for further studies and may pique interest in self-medication by stakeholders.

4.6 Conclusion

This study was the first to indicate the traits of DRPs with OTC medicines in the local scenario, with results similar to those obtained abroad, in Germany and Denmark. The aims of the study were achieved, showing an incidence of DRPs in nearly one out of every 5 patients who ask for OTC medicines. The pharmacist was able to solve 80% of all DRPs detected. This study highlights the importance of the presence and advice of community pharmacists in order to reduce risks associated with patient self-medication. OTC drugs should not be trivialised, but should be treated with the same cautions and care as one would show towards prescription only drugs. Increased patient awareness is also needed, possibly in the form of education campaigns regarding self-medication and the importance of reading product literature.

Community pharmacists are the only group of healthcare professionals that patients interact with when it comes to obtaining non-prescription medications for self-medication. From this study on detection and resolution of DRPs of non-prescription products by pharmacists, it can be concluded that the community pharmacist is in a unique position to guide and advise patients on safe and effective use of self-medication products, thus as healthcare professionals, pharmacists should hold on to this key role, for the sake of patient safety. Hence more medications should be considered for non-prescription status within a facilitated self-care framework.

References

Abahussain EA, Matowe LK, Nicholls PJ. Self-reported medication use among adolescents in Kuwait. *Medical Principles and Practice*. 2005; 14(3):16 1-4.

AESGP. The Economic and Public Health Value Of Self-medication. Association of the European Self-Medication Industry; 2004.

AESGP. Smart Regulation 2015, The Future Regulation of Self-Care. Association of the European Self-Medication Industry; 2010.

Al Hamid A, Ghaleb M, Aljadhey H, Aslanpour Z. A systematic review of hospitalization resulting from medicine-related problems in adult patients. *Br J Clin Pharmacol*. 2014; 78(2): 202-17.

Aronson JK. Over-the-counter medicines. *Br J Clin Pharmacol.* 2004; 58: 231–234

Aronson JK. From prescription-only to over-the-counter medicines ('PoM to P'): time for an intermediate category. *British Medical Bulletin.* 2009; 90: 63–69.

Aronson JK. Forbidden fruit. *Nature Med.* 2001; 7: 7–8.

Avery AJ. Extended prescribing by UK nurses and pharmacists: with more evidence and strict safeguards, it could benefit patients. *BMJ.* 2005; 331(7526): 1154-1155.

Ax F, Brånstad JO, Westerlund T. Pharmacy counselling models: a means to improve drug use. *J Clin Pharm Ther*. 2010; 35(4):439-451.

Basger BJ, Moles RJ, Chen TF. Application of drug-related problem (DRP) classification systems: a review of the literature. *Eur J Clin Pharmacol*. 2014; 70: 799–815.

Bell J, Dziekan G, Pollack C, Mahachai V. Self-Care in the Twenty First Century: A Vital Role for the Pharmacist. *Adv Ther*. 2016 33:1691–1703.

Bennadi D. Self-medication: A current challenge. *J Basic Clin Pharma*. 2014; 5:19-23.

Berrenia A, Montastruca F, Bondon-Guittona E, Rousseaua V, Abadiea D, Durrieua G, *et al*. Adverse drug reactions to self-medication: a study in a pharmacovigilance database. *Fundam Clin Pharmacol*. 2015; 29: 517–520.

Budnitz DS, Lovegrove MC, Shehab N, Richards CL. Emergency Hospitalizations for Adverse Drug Events in Older Americans. *N Engl J Med*. 2011; 365: 2002-12.

Centers for Disease Control and Prevention. Cigarette smoking among adults—United States, 2000. Morbidity and Mortality Weekly Report. 2002; 51(29):642–5.

Clifford S, Barber N, Elliot R, Hartley E, Horne R. Patient-centred advice is effective in improving adherence to medicines. *Pharm World Sci.* 2006; 28(3): 165-170.

Cohen JP, Paquette C, Cairns CP. Switching prescription drugs to over the counter. *BMJ*. 2005; 330: 39–41.

Committee on Safety of Medicines, Medicines Control Agency. Terfenadine: now only available on prescription. *Curr Probl Pharmacovig*. 1997; 23:9.

Cooper RJ. Over-the-counter medicine abuse – a review of the literature. *J Subst Use.* 2013; 18(2): 82–107

Cuzzolin L, Benoni G. Safety of non-prescription medicines: knowledge and attitudes of Italian pharmacy customers. *Pharm World Sci.* 2010; 32: 97–102.

Cullen G, Kelly E, Murray FE. Patients' knowledge of adverse reactions to current medications. *Br J Clin Pharmacol*. 2006; 62(2):232–236.

Di Piro JT. Encyclopedia on Clinical Pharmacy. New York: Marcel Dekker Inc; 2003. p.188-190.

Eades CE, Ferguson JS, O'Carrol RE. Public health in community pharmacy: A systematic review of pharmacist and consumer views. *BMC Public Health*. 2011; 11:582.

Eickhoff C, Hammerlein A, Griese N, Schulz M. Nature and frequency of drug-related problems in self-medication (over-the-counter drugs) in daily community pharmacy practice in Germany. *Pharmacoepidemiol Drug Saf*. 2012; 21(3): 254–260.

Farker K, Rohenkolber M, Drewclow B, Hippius M, Siegmund W, Thurmann PA *et al*. Patient self-medication and serious adverse drug reactions (ADR's). *Br J Clin Pharmacol.* 2009; 68: 56.

Frøkjær B, Bolvig T, Griese N, Herborg H, Rossing C. Prevalence of drug-related problems in self-medication in Danish community pharmacies. *Inov Pharm.* 2012; 3(4), Article 95.

Gauld N, Emmerton L, Kelly F, Buetow S. New Model of Prescription to Nonprescription Reclassification: The Calcipotriol Case Study. *Clin Ther.* 2012; 34:

1324–1332.

Gavronski M, Volmer D. Safety concerns in simultaneous use of prescription and 'over-the-counter' medicines- results of patient survey in Estonia. *Springerplus.* 2014; 3:143.

Guillaume L, Cooper R, Avery A, Mitchell S, Ward P, Anderson C et al. Supplementary prescribing by community and primary care pharmacists: an analysis of PACT data, 2004–2006. *J Clin Pharm ther.* 2008; 33: 11-16.

Hammerlein A, Griese N, Schulz M. Survey of drug-related problems identified by community pharmacies. *Ann Pharmacother*. 2007; 41 (11): 1825–1832.

Hanna LA, Hughes CM. Public's views on making decisions about over-the counter medication and their attitudes towards evidence of effectiveness: a cross-sectional questionnaire study. *Patient Educ Couns.* 2011; 83(3): 345–351.

Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm*. 1990; 47(3): 533–43.

Howard RL, Avery AJ, Slavenburg S, Royal S, Pipe G, Lucassen P et al. Which drugs cause preventable admissions to hospital? A systematic review. *Br J Clin Pharmacol*. 2007; 63: 136-47.

Hughes L, Whittlesea C, Luscombe D. Patients' knowledge and perceptions of the side-effects of OTC medication. *J Clin Pharm Ther*. 2002; 27(4): 243–248.

Krishnan HS, Schaefer M. Evaluation of the impact of pharmacist's advice giving on the outcomes of self-medication in patients suffering from dyspepsia. *Pharm World Sci*. 2000; 22(3):102-108.

Law MR, Wald NJ, Rudnicka AR. Quantifying effect of statins on low density lipoprotein cholesterol, ischaemic heart disease, and stroke: systematic review and meta-analysis. *Br Med J*. 2003; 326:1423–6.

Leendertse AJ, Egberts AC, Stoker LJ, van Den Bemt PM, HARM Study Group. Frequency of and risk factors for preventable medication-related hospital admissions in the Netherlands. *Arch Intern Med.* 2008;168 (17): 1890-6.

MacFadyen L, Eadie D, McGowan T. Community pharmacists' experience of over-the-counter medicine misuse in Scotland. *Journal of the Royal Society for the Promotion of Health*. 2001, 121(3), 185–192.

Marston C. Meltzer H, Majeed A. Impact on contraceptive practice of making emergency hormonal contraception available over the counter in Great Britain: repeated cross-sectional surveys. *BMJ.* 2005, 30: 331.

Matheson, C, Bond, C. M, Pitcairn, J. Misuse of over-the-counter medicines from community pharmacies: A population survey of Scottish pharmacies. *Pharmaceutical Journal*. 2002; 269(7206): 66–68.

Medicines and Healthcare products Regulatory Agency. Medicines: reclassify your product Available from: https://www.gov.uk/guidance/medicines-reclassify-your-product (accessed 13th December 2016).

National Council on Patient Information and Education (NCPIE): Attitudes and Beliefs About the Use of Over-the-Counter Medicines: A Dose of Reality; 2002.

Ngo SN, Stupans I, Leong WS, Osman M. Appropriate use of non-prescription ibuprofen: a survey of patients' perceptions and understanding. *Int J Pharm Pract.* 2010; 18(1): 63–65.

Nichol MB, McCombs JS, Johnson KA, Spacapan S, Sclar DA. The effects of consultation on over-the-counter medication purchasing decisions. *Med Care*. 1992; 30(11):989–1003.

Patel P, Zed PJ. Drug-Related Visits to the Emergency Department: How Big Is the Problem? *Pharmacotherapy.* 2002; 22(7): 915-23.

Pearson GJ. Evolution in the practice of pharmacy-not a revolution! *CMAJ*. 2007; 176(9): 1295-1296.

Peto R, Lopez AD. Future worldwide health effects of current smoking patterns. In: Koop CE, Pearson CE, Schwarz MR, editors. Critical issues in global health. San Francisco: Jossey-Bass; 2001. p. 154–61

Pradeep P G, Molina J , Cheah J, Chan SC, Lim BP. Evolving Roles of the Community Pharmacist – A Literature Review—*Ann Acad Med Singapore*. 2010; 39 :861-867.

Phalke VD, Phalke DB, Durgawale PM. Self-medication practices in rural Maharashtra. Indian *J Community Med.* 2006; 31:34-35.

Ronnie CL, Griffin MR. Over-the-counter analgesics in older adults: a call for improved labelling and consumer education. *Drugs Aging.* 2004; 21(8): 706-707.

Rutter P. Role of community pharmacists in patients' self-care and self-medication. *Integr Pharm Res Pract.* 2015; 4: 57-65.

Sclar DA, Robison LM, Skaer TL. Pharmacy consultation and over-the-counter medication purchasing outcomes. Over-the-Counter Medication Intervention Project Team. *J Clin Pharm Ther*. 1996; 21(3): 177–184.

Shiffman S, Sweeney CT. Ten years after the Rx-to-OTC switch of nicotine replacement therapy: What have we learned about the benefits and risks of non-prescription availability? *Health Policy.* 2008; 86: 17–26

Sihvo S, Klaukka T, Martikainen J, Hemminki E. Frequency of daily over-the-counter drug use and potential clinically significant over-the-counter prescription drug interactions in the Finnish adult population. *Eur J Clin Pharmacol.* 2000; 56(6–7): 495–499.

Silagy C, Lancaster T, Stead L, Mant D, Fowler G. Nicotine replacement therapy for smoking cessation. Cochrane Database Of Systematic Reviews 2004;(3):CD000146

Solomon W, Abede GM. Practice of self-medication in Jimma Town. *Ethiop J Health Dev*. 2003;17:111-116.

Taché SV, Sönnichsen A, Ashcroft DM. Prevalence of adverse drug events in ambulatory care: a systematic review. *Ann Pharmacother*. 2011; 45(7-8): 977-89.

Tisman A. The Rising Tide of OTC in Europe: Trends, Challenges and New Potential in a Rapidly Evolving Market. Norwalk, CT: *IMS Health*; 2010.

Tomsen DV, Søndergaard B, Herborg H, Klinke BO. Improved self-medication and self-care - a controlled intervention study. København: Forskningscenter for Kvalitetssikret Lægemiddelanvendelse; 2004.

Urbina O, Ferrández O, Grau S, Luque S, Mojal S, Marin-Casino M et al. Design of a score to identify hospitalized patients at risk of drug-related problems. *Pharmacoepidemiol Drug Saf*. 2014; 23: 923–32.

U.S. Department of Health and Human Services. The health benefits of smoking cessation. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 1990 [DHHS publication No. (CDC) 90-8416]

Van Mil JWF, Westerlund T, Hersberger T, Schaefer MA. Drug-related problem classification systems. *Ann Pharmacother*. 2004; 38: 859–67.

Wawruch M, Kuzelova M, Foltanova T, Ondriasova E, Luha J, Dukat A, Murin J, Shah R. Characteristics of elderly patients who consider over-the-counter medications as safe. *Int J Clin Pharm*. 2013; 35(1):121–128.

Wazaify M, Al-Bsoul Younes A, Abu-Gharbieh E, Tahaineh L. Societal Perspectives on the role of community pharmacists and over-the-counter drugs in Jordan. *Pharm World Sci*. 2008; 30: 884-891.

Wester K, Jönsson AK, Spigset O, Druid H, Hägg S. Incidence of fatal adverse drug reactions: a population based study. *Br J Clin Pharmacol*. 2008; 65(4): 573-9.

Westerlund T, Allebeck P, Marklund B et al. Evaluation of a model for counseling patients with dyspepsia in Swedish community pharmacies. *Am J Health-Syst Pharm*. 2003; 60(13):1336-1341.

Westerlund T, Marklund BRG, Handl WHA et al. Non-prescription Drug-Related Problems and Pharmacy Interventions. *Ann Pharmacother*. 2001; 35(11):1343-1349.

World Health Organization (WHO). Preventing Chronic Diseases. A vital investment. 2005.

Wilbur K, El Salam S, Mohammadi E. Patient perceptions of pharmacist roles in guiding self-medication of over-the-counter therapy in Qatar. *Patient Prefer Adherence* 2010;4: 87–93.

Wirth F, Tabone F, Azzopardi LM, Gauci M, Zarb-Adami M, Serracino-Inglott A. Consumer perception of the community pharmacist and community pharmacy services in Malta. *J Pharm Health Serv Res*. 2010; 1(4): 189-194.

Wirtz VJ, Taxis K, Dreser A. Pharmacy customers' knowledge of side effects of purchased medicines in Mexico. *Trop Med Int Health.* 2009; 14(1): 93–100.

World Health Organization (WHO) Regional Office for South-East Asia. Self-care in the Context of Primary Health Care: Report of the Regional Consultation Bangkok, Thailand, 7–9 January 2009. New Delhi: WHO Regional Office for South-East Asia; 2009.

World Health Organization (WHO). Proposal for Inclusion of Nicotine Replacement Therapy in the WHO Model List of Essential Medicines. 17th Expert Committee on the Selection and Use of Essential Medicines Geneva, 2009 Available from: http://www.who.int/selection_medicines/committees/expert/17/application/NRT_inclusion.pdf

World Self-Medication Industry (WSMI). Responsible Self-Care and Self-Medication: A Worldwide Review of Consumer Surveys. Ferney-Voltaire WSMI, 2004.

World Self-Medication Industry (WSMI). Switch: Prescription to Non-Prescription Medicines Switch. Ferney-Voltaire: WSMI; 2009. Available from: http://www.wsmi.org/wp-content/data/pdf/wsmi_switchbrochure.pdf. Accessed December 14, 2016

Zaprutkoa T, Koligata D, Michalakc M, Wieczorekb M, Józiakb M, Ratajczakb M, Szydłowskab K, Miazekb J, Kus a K, Nowakowska EB. Misuse of OTC drugs in Poland. *Health Policy* 2016; 120: 875–881.

Appendix

Appendix 1

Ethics Approval

L-UNIVERSITÀ TA' MALTA
Msida – Malta
Skola Medika
Sptar Mater Dei

UNIVERSITY OF MALTA
Msida – Malta
Medical School
Mater Dei Hospital

Ref No: **42/2016**

Tuesday 13th September 2016

Dr Andrew Fenech
Hermes
Felica Abela Street
Zejtun

Dear Dr Andrew Fenech,

Please refer to your application submitted to the Research Ethics Committee in connection with your research entitled:

Optimising Patient Self-Medication through the Community Pharmacist

The University Research Ethics Committee granted ethical approval for the above mentioned protocol.

Yours sincerely,

Dr. Mario Vassallo
Chairman
Research Ethics Committee

38, 'Hermes',
Triq Felica Abela,
Zejtun ZTN 3385

10th March 2016

Dear Sir/Madam,

I am a pharmacist currently reading for a Doctor of Pharmacy degree at the University of Malta. As part of my studies, I am carrying out a thesis entitled 'Optimising Patient Self-Medication through the Community Pharmacist'

The study involves asking a series of questions to patients who present at the pharmacy complaining of symptoms or asking for a particular over-the-counter medication. The researcher will then proceed with his usual service with the patient. The encounter is expected to last approximately 5 minutes.

The aim of this research is to optimise patient safety and treatment related to self-medication through the community pharmacist's intervention, thus, upon completion of the study, patients are expected to benefit due to of improvement of service. Additionally, whilst disclosing the requested information to the researcher, patients shall receive a free review of their medicine use in the attempt to identify drug-related-problems. If any problem/s are detected, the identified problem/s shall be solved for the benefit of the patient.

I am writing to request your permission to include you as part of my study.

Some information will be included in the study report, however your identity will not be revealed at any time and all information will remain confidential throughout the study. Your participation is purely voluntary and you are free to quit the study at any point.

Thanking you in advance.

Yours truly,

Andrew Fenech

38, ‘Hermes’,
Triq Felica Abela,
Zejtun ZTN 3385

10 ta Marzu 2016

Għażiż sinjur/sinjura,

Jiena spiżjar li qieghed nistudja ghal Dottorat fil-Farmacija fl-Universita’ ta’ Malta. Bhala parti mil-istudji tieghi qed naghmel riċerka biex nevalwa kif l-ispiżjar jista jgħin lil pazjenti biex jagħżlu u jużaw il-medicini bl-ahjar mod fil-komunita.

L-istudju jinvolvi li jinstaqsu sensiela ta' mistoqsijiet lill-pazjenti li jippreżentaw fl-ispizerija jilmentaw b’ xi sintomi jew jistaqsu għal medikazzjoni bla riċetta partikolari. Ir-riċerkatur mbagħad jipproċedi bis-servizz normali tiegħu mal-pazjent. Id-diskussjoni għandha ddum madwar 5 minuti

L-għan ta 'din ir-riċerka huwa li ttejjeb is-saħħa u t-trattamenti medicinali tal-pazjent billi tghinhom jaghzlu medicina bla ricetta ahjar permezz tal-intervent ta l-ispiżjar, u b'hekk, mal-konkluzjoni ta l-istudju, il-pazjenti huma mistennija li jibbenefikaw minħabba ta 'titjib tas-servizz. Filwaqt li jghaddu l-informazzjoni mitluba lill-riċerkatur, il-pazjenti għandhom jirċievu reviżjoni b’xejn tal-użu mediċina tagħhom fit-tentattiv biex jiġu identifikati problemi fil-medicini taghhom. Jekk jinstabu xi problemi, il-problemi identifikati għandhom jigu solvuti għall-benefiċċju tal-pazjent.

Qieghed nikteb biex nitlob il-permess tieghek biex ninkludik bhala parti mil-istudju.

Xi informazzjoni se tkun inkluża fir-rapport dwar l-istudju, madankollu l-identità tiegħek mhux se tigi żvelata fi kwalunkwe ħin u informazzjoni kollha se jibqa' kunfidenzjali matul l-istudju. Il-parteċipazzjoni tiegħek hija purament volontarja u inti liberu li tieqaf mill-istudju fi kwalunkwe punt.

Nirringrazzjak bil-quddiem.

Dejjem Tieghek,

Andrew Fenech

CONSENT FORM

I am a Maltese citizen and am over eighteen (18) years of age.

I have been asked to participate in a research study entitled:

"Optimising Patient Self-Care through the Community Pharmacist".

The purpose and details of the study have been explained to me by Andrew Fenech and any difficulties which I raised have been adequately clarified.

I give my consent to the Principal Investigator to make the appropriate observations and tests. I am aware of the inconveniences which this will cause.

I understand that the results of this study may be used for medical or scientific purposes and that the results achieved from the study in which I am participating may be reported or published: however, I shall not be personally identified in any way, either individually or collectively, without my express written permission.

I am under no obligation to participate in this study and am doing so voluntarily.

I may withdraw from the study at any time, without giving any reason. This will not influence in any way the care and attention normally given to me.

I understand that any complications and/or adverse effects which may arise during or as a consequence of the study will be recorded and any treatment which this may entail will be given within the Government Health Services.

I am not receiving any remuneration for participating in this study.

In case of queries during the study I may contact Andrew Fenech on 79603932.

Signature of participant _____

Name of participant _____

ID of participant _____

Signature of Chief Investigator _____

Name of Chief Investigator _____

ID of Chief Investigator _____

PROPOSTA GĦALL-FORMULA TAL-KUNSENS

Jien/a ċittadin/a Malti/ja u għalaqt tmintax (18)-il sena.

Talbuni biex nieħu sehem fi studju riċerka bl-isem ta':

"Optimising Patient Self-Medication through the Community Pharmacist"

Il-għan u d-dettalji ta' l-istudju spejgahomli Andrew Fenech li wkoll iċċarli xi mistoqsijiet li għamilt.

Nagħti l-kunsens tiegħi lill-persuna responsabbli għal-din ir-riċerka u l-assistenti tagħha biex jagħmlu l-osservazjonijiet li hemm bżonn jew inkella jieħdu l-kampjuni u nifhem li dan jista' jkun ta' skomdu għalija.

Jiena nifhem li r-riżultati ta' dan l-istudju jistgħu jintużaw għal skopijiet xjentifiċi u jista' jiġi ppubblikat rapport bil-miktub: jekk isir hekk b'ebda mod ma nista' nkun identifikat/a, individwalment jew bħala parti minn grupp, mingħajr il-kunsens tiehħi bil-miktub.

Jiena ma għandi l-ebda dmir li niehu sehem f'dan l-istudju u dan qed nagħmlu minn rajja.

Jiena nista', meta rrid, ma nkomplix niehu sehem fl-istudju, u mingħajr ma' nagħti raġuni. Jekk nagħmel hekk xorta nibqa' nieħu l-kura li ssoltu tingħatali (tapplika biss għal pazjenti li qed jieħdu kura).

Jiena nifhem li jekk ikun hemm xi kumplikazzjoniji jew effetti mhux mistennija waqt l-istudju, dawn jiġu mniżżla bil-miktub u jekk ikun hemm bżonn xi kura, tiġi mgħotija fis-Servizz Nazjonali tas-Saħħa.

Jiena qed nitħallas/mhux qed nitħallas *biex nieħu sehem f'dan l-istudju.

Jekk ikolli xi diffikulta' waqt l-istudju, nista' nistaqsi għal: Andrew Fenech fuq 79603932

Firma tal-parteċipant _____

Isem tal-parteċipant _____

Numru ta' l-identita _____

Firma tal-persuna responsabbli għal din ir-riċerka _____

Isem tal-persuna responsabbli għal din ir-riċerka _____

Numru ta' l-identita _____

Data _____

Hompesch Pharmacy
207/211, Hompesch Road
Fgura

27th February, 2016

To whom it may concern,

I hereby confirm and approve that Andrew Fenech (545488M), a 2nd year Pharm. D student at the Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, will be carrying out a research study at Hompesch Pharmacy.

James Grech

Appendix 2

Data Collection Tool

Patient No: ☐ **Time Required:** ☐

Age: ☐ 18-25 ☐ 26-35 ☐ 36-45 ☐ 46-60 ☐ 61-74 ☐ 75+

Gender: ☐ Male ☐ Female

1. **Nature of request:**

   Medicine Request: ☐ First Time Request ☐ Repeat Request

   Name of medicine:_____

   Symptom Presentation: _____

   Other:_____

2. **Patient Medication List**

Prescription Medicines	Non-prescription Medicines

3. Please tick any of the following if any drug-related problems are detected	
☐ Requested medication is unsuitable/not optimal for symptoms presented	☐ Incorrect dose
☐ Medication requested unsuitable. Duplication of medicines	☐ Drug regimen is too short (ineffective)
☐ Requested medication is contra-indicated	☐ Drug regimen is too long (abuse)
☐ Requested medicine interacts with:_____	☐ Adverse drug reaction detected
More information/other:	

4. Information about Pharmacist's Intervention	
☐ Gave Advice	☐ Referred patient to doctor
☐ Changed to another drug	☐ Stop/withhold drug
Other:	

Solved ☐ Partially solved ☐ Not solved ☐

Appendix 3

Publication

Abstract for the 2017 77th FIP word congress on pharmacy and pharmaceutical sciences

Abstract Submission Number: FIP-1073
Abstract topic: Community Pharmacy
Abstract title: Optimising patient self-medication through the community pharmacist

Dear Mr. Fenech,

Thank you for having submitted the abstract listed above for the 77th FIP World Congress of Pharmacy and Pharmaceutical Sciences 2017, to be held in Seoul, South Korea from 10-14 September 2017.
On behalf of the Scientific Committee, it is our great pleasure to inform you that this abstract **has been accepted** for **POSTER presentation.**
Further information regarding the display dates of your poster and the poster guidelines will be communicated at a later stage.

Please note that the presenting author needs to register **before 15 May 2017** to keep your abstract in the Congress programme. If you have not yet registered, we kindly invite you to register as soon as possible. For registration and more information on the various fees and deadlines, please visit the Congress website: http://www.fip.org/seoul2017/registration.

Please also note that residents from some countries require a visa. An official support letter can be requested during online registration. We recommend that you start the visa process as soon as possible. Do not hesitate to contact us if you encounter any difficulty.

For questions regarding your presentation or registration, please contact fip@mci-group.com.

We look forward to meeting you in Seoul, South Korea and remain at your disposal for any further information you may require.

Sincerely yours,

Ymke Pol
FIP Congress Secretariat
c.o. MCI Amsterdam

Optimising patient self-medication through the community pharmacist

Fenech A, Azzopardi LM, Grech L.

Self-care with 'Over-the-Counter' (OTC) medicines is a widespread practice. Patients consider OTC medicines to be safe and frequently ignore patient information leaflets. This incurs certain risks on patients' health. Facilitated self-medication addresses this issue, whereby the pharmacist is directly involved in providing advice on self-medication products.

The aim was to optimise patient self-medication through the pharmacist's intervention by investigating the nature and frequency of drug-related problems (DRPs) occurring in self-medication and documenting the interventions carried out by the pharmacist.

The first phase of the study consisted of compiling and validating the tool required to run the research. During the second phase, 203 patients presenting at a community pharmacy asking for OTC medications were included in the study. The pharmacist recorded data on patient characteristics and the nature of the OTC request. Any identified DRPs were documented, together with the action taken by the pharmacist to resolve the identified DRPs. The time needed for resolving the problem was recorded.

A total of 40 DRPs were detected in 18.71 % of patients presenting with requests for OTC medicines. The most common DRP (32.5%) was 'requested medicine is not optimal for symptoms presented', followed by 'requested medicine is contra-indicated' (27.5%) and 'duplication of medicines' (12.5%). The most frequent intervention (57.50%) was to change to a more suitable drug, followed by referral to a physician (22.5%).

The results from this study highlight the importance of the presence of a pharmacist when dispensing OTC medications, since a DRP was detected in nearly 1 of 5 encounters.

Optimising Patient Self-Medication Through the Community Pharmacist

Andrew Fenech, Louise Grech, Lilian M. Azzopardi
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email: andrew.fenech88@gmail.com

Department of Pharmacy University of Malta

INTRODUCTION

Self-care with 'Over-the-Counter' (OTC) medicines is a widespread practice. Patients consider OTC medicines to be safe and frequently ignore patient information leaflets. This incurs certain risks on patients' health. Facilitated self-medication addresses this issue, whereby the pharmacist is directly involved in providing advice on self-medication products.

AIM

To optimise patient safety and pharmacotherapy related to self-medication through the community pharmacist's intervention.

The objectives were to investigate the nature and frequency of drug-related problems (DRPs) occurring in self-medication and to document the interventions carried out by the pharmacist in relation to the DRPs.

METHOD

A data collection tool required to run the research was compiled and validated. Ethics approval was sought and granted from the University of Malta Research and Ethics Committee (UREC).

203 patients presenting at a community pharmacy asking for OTC medications, who were over 18 years of age and able to understand English and Maltese were included in the study.

The pharmacist-researcher recorded data on patient characteristics and the nature of the OTC medicine request.

Any identified DRPs were documented, together with the action taken by the pharmacist to resolve the identified DRPs. The time needed for resolving the problem was recorded.

RESULTS

- A total of 40 DRPs were detected in 18.71 % of patients presenting with requests for OTC medicines.
- The most common DRP was 'requested medicine is not optimal for symptoms presented' (32.5%) , followed by 'requested medicine is contra-indicated' (27.5%) and 'duplication of medicines' (12.5%) (Figure 1).
- The most common drugs implicated with DRPs were the NSAIDs followed by decongestants and both topical preparations and compound analgesics (Figure 2).
- The most frequent intervention (57.5%) was to change to a more suitable drug, followed by referral to a physician (22.5%).
- The pharmacist solved 32 DRPs (80%). 7 DRPs (17.5%) were partially solved and 1 DRP (2.5%) was not solved.

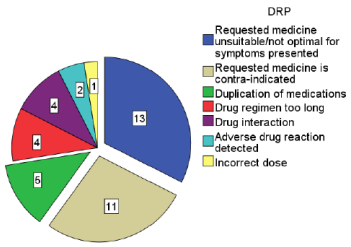

Figure 1: DRPs detected (n=40)

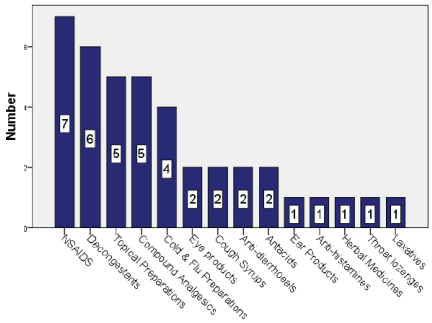

Figure 2: Drug classes involved in DRPs (n=40)

CONCLUSION

The results from this study highlight the importance of the presence of a pharmacist when dispensing OTC medications, since a DRP was detected in nearly one of five encounters. Self-medication should follow the facilitated model, with the contribution of the community pharmacist to guide and advise patients on self-medication products.