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DOCUMENTATION AND ANALYSIS OF AFTER-HOURS DRUG INFORMATION REQUESTS IN A GENERAL HOSPITAL

IMPACT OF PHARMACIST ADVICE ON METABOLIC SYNDROME

USE OF INTERNET PHARMACIES BY THE PUBLIC

Historical books donated to the Department of Pharmacy

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Editorial Mission:
JEMP publishes original research manuscripts, subject reviews and other contributions related to all aspects of research within the field of pharmacy. JEMP is dedicated to improve the dissemination and interpretation of results of scientific investigation and evaluation of pharmacy processes, pharmaceutical services and interventions and economic outcomes of pharmacy services.

DRUG INFORMATION

Drug information services provided by pharmacists answer clinical questions about medications and contribute towards merging evidence-based practice and personalised patient management. Drug information is often considered an early example of clinical pharmacy activities which developed in hospitals in the United States of America.

Drug information specialised skills are one of the areas of focus in the post-graduate Doctorate in Pharmacy degree programme offered by the Department of Pharmacy of the University of Malta in collaboration with the College of Pharmacy of the University of Illinois in Chicago, USA. Literature evaluation skills for providing evidence-based recommendations for the use of medications and in the evaluation of innovative medicinal products are developed during this course.

On the occasion of World Pharmacists Day 2015, Professor John Rizzo Naudi donated 50 historical books to the Department of Pharmacy. These books are now part of the historical collection within the Department and represent reference sources used in Malta over the last one hundred years.

The editorial board would like to recognise the contribution of Actavis, who are supporting this journal through a collaborative agreement with the Department of Pharmacy.

CONTENTS

EDITORIAL

THE JOURNEY TO EXCELLENCE IN RESEARCH FOR DOCTORATE IN PHARMACY CANDIDATES

This issue of the Journal of Euromed Pharmacy (JEMP) gives some reflections by pharmacists currently following the Doctorate in Pharmacy (Pharm.D.) course which is now in its second year. The Pharm.D. is an innovative level 8 degree (Ph.D equivalent) which bridges the professional aspects of pharmacy with research. The Pharm.D candidates have now embarked on their research projects in earnest and have all submitted their proposal to the Doctoral Committee of the Faculty of Medicine and Surgery. The research topics cover areas of interest to the student and the faculty and reflect some of the needs of pharmacy practice in Malta and internationally.

Medication errors can occur at any time during drug provision and community pharmacists are in a very good position to prevent occurrence of drug-related medication errors. Clifton Curmi is investigating this subject including the use of technology such as e-prescribing. Danika Agius Decelis is working towards proposing an innovative approach to improve outcomes in the use of glucagon in paediatric Type I diabetic patients. Khaled Abdelmaula is also working on a topic concerning diabetes by investigating the self-management of insulin in Type I diabetic patients. Optimising the practice of self-medication in a safe and appropriate manner is then studied as a general concept through the community pharmacist as the subject of research by Andrew Fenech. Patient-centred studies are music to the ears to those promoting pharmacy ensuring the provision of high quality, safe and effective medicinal products. Martina Muscat centres her studies on chronic disease management around patients in community pharmacy, while Elena Mifsud looks at a pharmacist-led approach to safer anticoagulation management in the community.

The introduction of innovative medicines showed impact on pharmacy practice from several aspects. Roberta Agius is investigating the evolvement of EU regulations regarding innovative medicines while Alison Attard is researching the pharmacotherapeutic and pharmacoeconomic implications of stem cell therapy. Another innovative therapy issue is the efficacy and safety of biosimilar therapeutic products. Mark Cilia is establishing the pharmaceutical issues involved in the use of biosimilars. A number of innovative medicines are also being introduced in cardiovascular disease. Mark Cardona is comparing the novel oral anticoagulants to warfarin considering costs of drug acquisition, INR monitoring, events and other direct or indirect costs. Regulatory implications are considered in a number of projects mentioned. Another thesis related to regulatory implications is that by Amy Tanti on the detection of signals in electrocardiogram QT prolongation or shortening.

Shared care of patients leading to personalised care is key to pharmacists working as part of the healthcare team. One is assuring that the Doctorate in Pharmacy Course equips pharmacists with the tools required for a successful and rewarding participation in direct personalised care. Topics related to this area of personalised care forming part of the proposals submitted by these students include the implication of monitoring tumour markers: A personalised medicine approach (Charyl Fava), shared care guidelines for patient medicines management in breast and colon cancer (Rebecca Theuma), a sustainable pharmaceutical care approach to prevention and management of digoxin therapy (John Vella) and risk assessment in pharmacotherapeutic practice (Richard Despott).

On a different pharmaceutical note, Noelia Helgado Sanchez is presenting the impact on clinical practice of culturing the bacterium *Clostridium difficile* and the relevant pharmacotherapy involved in the treatment. Another impact assessment is that on the quality and safety of herbal medicinal products and the way that these products are classified (Alexandra Curmi).

The success of this extensive research is highly dependent on the dedication of our Pharm.D. candidates. This would not be possible without the contribution of the seasoned supervisors and the many advisors and collaborators from all areas, especially in the Faculty of Medicine and Surgery. The Pharmacy Department is blessed with talent and the contribution of the three fresh Ph.D graduates cannot be overestimated. Louise Grech working on rheumatoid arthritis, Janis Vella on antibiotics in peripheral artery disease, and Francesca Wirth on the pharmacogenetics of antiplatelet drugs have made the Department of Pharmacy proud of its research teams. These new Ph.D graduates are now also supporting the Pharm.D. candidates in their quest for excellence. Our best wishes go to all the Doctorate of Pharmacy students for a rewarding and fruitful research journey towards success.

Professor Anthony Serracino-Inglott

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What is the Pharm D course?

The Pharm D programme is a new post-graduate course being offered by the Department of Pharmacy of the **University of Malta** in collaboration with the College of Pharmacy at the **University of Illinois at Chicago in Chicago**, USA. This course was developed to provide for the rapidly growing niche in pharmacy related to a professional doctorate. It is a means to develop professionals with a research-oriented approach and with skills in advanced clinical pharmacy practice with a focus on patient safety.

Pharmacists who would like to take up the area of Clinical Pharmacy as their specialisation will be able to develop the skills and attributes of undertaking research in the field while reading for a level 8 Doctorate level degree.

Course Details

- The programme is delivered using a blended learning model that includes lectures, distance-learning and practice based learning
- Taught elements integrate learning experience with the assessment and contextualization in professional practice
- The course includes a number of taught modules as well as clinical experience and research modules
- Course activities involve journal clubs, reflective portfolios, literature assessments and patient care discussions
- Over three years of study
- Successful completion of 90 ECTS will entitle students to a 'Masters in Advanced Clinical Pharmacy' should they opt to not proceed with the course

Career Prospects

The programme will empower pharmacists practising in the professional areas to take up leadership roles that will drive policies, developments in clinical practice and service provision which draw on a scientific and evidence base.

Skills Developed

- Co-operate and collaborate with healthcare professionals and patients to provide individualised treatment and support patient care
- Manage medication knowledge, mitigate errors and support decision-making based on evidence-based sources including information technology
- Efficiently collect, analyse and apply required literature sources for the appropriate clinical management of patients
- Evaluate, analyse and synthesise information and knowledge available to undertake and propose rational decisions
- Identify opportunities for improvement of a medication-use system
- Collect and critically assess clinically relevant data to facilitate monitoring and management of drug therapy plans
- Contribute significantly to development of practice research

Scholarship opportunities are available. For more information contact the Department of Pharmacy, University of Malta on pharmacy.ms@um.edu.mt

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DOCTORATE IN PHARMACY STUDENT REFLECTIONS

Currently there are 34 pharmacists following the post-graduate Doctorate in Pharmacy (Pharm.D.) degree programme which is offered by the Department of Pharmacy of the University of Malta in collaboration with the College of Pharmacy of the University of Illinois in Chicago, USA. Students come from 8 countries from different parts of the world. Seventeen students have completed their first year of studies and are now working on their research dissertation and following rotations. Another group of 17 students joined the first year last October.

Danika Agius Decelis

As a recently-graduated pharmacist, I enrolled in the Pharm.D. programme as clinical pharmacy has always been one of the areas which interested me, especially after undertaking a dissertation in clinical pharmacy. I particularly enjoy the course as it expands upon the knowledge we have and goes beyond the local and European clinical scenario, adding richness to the course by discussing other approaches applied in the USA. Having students from various backgrounds, each with their own experiences in pharmacy, brings out the beauty of sharing experiences and knowledge we each have gained. I would recommend the course to pharmacists pursuing a career in clinical pharmacy or those who simply want to broaden their knowledge on the area.

Jessica Attard

Clinical pharmacy is an area of interest to me so I opted to continue my studies straight after completing the Master of Pharmacy course. The Doctorate in Pharmacy is an intense programme with high academic standards. It provides students with an in-depth overview of various health and disease topics and their application in various clinical pharmacy scenarios. During the course, students are not only given the opportunity to learn through theoretical and online lectures, but also through rotations which provide students with hands-on experience. The course is well-organised with both local and foreign staff willing to help out and contribute to making this three-year journey a positive one.

Dania al-Haddad

I graduated from the University of Jordan with a Bachelor of Pharmacy degree in 2012. I worked as a patient counsellor at the Drug Information Centre and as a medical claims auditor at an insurance company in Jordan. I decided to enrol in the Pharm.D. course in Malta to become a professional clinical pharmacist. The pharmacotherapeutics unit was the most enjoyable since I wish to practice in a hospital within a clinical pharmacy setting. The rotation at Karin Grech Rehabilitation Hospital was very challenging and motivating as it was my first practice rotation in Malta. I would recommend the course to pharmacists interested in clinical pharmacy.

Denise Borg

The Doctorate in Pharmacy programme has proven to be an invaluable opportunity to further my education. With the emerging innovations within the pharmacy sector, it may be challenging for pharmacists to keep up-to-date. The course is based on developing clinical skills and competencies in practical aspects of current practice. One can benefit greatly from the flexibility of the course and the strong organisational structure to review course material according to one's personal schedule. I would strongly recommend this course to any pharmacist wishing to further develop research-based skills and delve into pharmacotherapy and other clinical aspects.

The pharmacotherapeutics unit was the most enjoyable since I wish to practice in a hospital within a clinical pharmacy setting

Neil Bugeja

As a newly-graduated pharmacist, the Doctorate in Pharmacy was the next step for my education since this programme provides the ideal balance between taught and research learning in clinical pharmacy. Lectures are engaging and provide further in-depth knowledge on the most important aspects of clinical pharmacy. Tutorials via videoconferencing, which were a novel experience for me, give the course an interactive facet. While it is challenging to balance work with studies, learning new information is always motivational, especially so when looking in detail at possible future careers within clinical pharmacy. I would recommend the course to pharmacists wishing to further their career in clinical pharmacy as well as those interested in other approaches to healthcare and treatment protocols.

Shaista Sadaf

I completed my Bachelor of Pharmacy degree last year in India. I opted for the Doctorate in Pharmacy course with the University of Malta since I wish to practice and serve as a clinical pharmacist in the hospital. This is a professional post-graduate pharmacy course dealing with patients and the healthcare system. Clinical rotations at the hospital and solving actual case studies in class are the most challenging yet exciting as we learn to apply knowledge gained to real-life scenarios. I would recommend this course to all pharmacists who are passionate about serving patients in a hospital setting. The University of Malta makes the learning experience even better with its student-friendly atmosphere surrounded by the serenity of the island.

Charyl Fava

The Doctorate in Pharmacy programme is a course with a difference since it delivered using a mixed learning approach. It involves distance-learning via online-teaching and lectures through video-conferencing by specialised foreign pharmacists who share their expertise with the students. This course also consists of practice-based learning, such as clinical rotations in a rehabilitation hospital, where a patient-centred approach together with evidence-based decision-making are highlighted within the multidisciplinary team. I highly recommend this course to other pharmacists as it enhances skills in different pharmaceutical areas resulting in holistic patient-centred care.

Jessica Spiteri

I graduated as a pharmacist in 2013 and have practiced my profession both in community and administrative settings. I strongly believe that professionals should continuously enhance their knowledge to be better equipped to exercise their profession. The Pharm.D. programme gives the opportunity to study various aspects of pharmacy with the main focus being the clinical scenario. The lectures have been very useful in guiding students on how to approach and work though clinical cases in real-life settings. The clinical module has been the most challenging and motivating part of the course. I strongly recommend this programme to pharmacists interested in taking their profession to the next level, be it clinical pharmacy or policy-making.

I would recommend this course to all pharmacists who are passionate about serving patients in a hospital setting

DOCUMENTATION AND ANALYSIS OF AFTER-HOURS DRUG INFORMATION REQUESTS IN A GENERAL HOSPITAL

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Abstract

OBJECTIVES To document, analyse and evaluate drug information (DI) requests received by shift pharmacists during after-hours in the inpatient pharmacy at Mater Dei Hospital.

METHOD A documentation tool entitled 'After-Hours DI Documentation Form' was developed for the purpose of recording DI requests received after-hours. A pilot study was conducted using the developed tool, which was validated by an expert panel. Subsequently, DI requests received over a 6-month period were recorded. Data was analysed qualitatively.

KEY FINDINGS Results obtained from a total of 65 shifts from a possible 82 were included in the study. A total of 224 DI requests were recorded using the documentation form. From these, 50.4% were received during night shifts and 49.6% during day shifts. Seventy-two percent of all requests were placed by nursing staff. Pharmacists provided information verbally over the telephone in 91.5% of cases. The requester was provided with information within 30 minutes in 99.1% of situations. The majority of requests (88.4%), concerned one type of medication. A total of 240 reference sources were consulted by pharmacists. Textbooks were the most commonly used in 37.5% of cases. Most requests (76.8%) fell within the category of drug administration, drug identification and availability. The 224 requests involved 254 different medications, 53.6% of which were injectable formulations.

CONCLUSION The documentation form developed and used during this study can be used to record DI requests received. Measures need to be implemented to increase the use of online sources by pharmacists during the provision of DI.

KEYWORDS After-hours, Documentation, Drug Information, Shift Pharmacist

Introduction

Mater Dei Hospital (MDH) is an acute, general and teaching hospital which provides pharmaceutical services, including management of drug information (DI) requests, on a 24-hour basis. Pharmacists have been traditionally viewed as the healthcare professionals best-suited to provide DI.[1] During normal working hours, DI services are provided by the Pharmacy Department through a specialised Medicines Information division. During after-hours, DI services, along with other pharmaceutical services, fall under the responsibility of shift pharmacists, who operate on continuous and uninterrupted 12-hour shift schedules from the MDH inpatient pharmacy. The aim of this study was to document, analyse and evaluate DI requests received after-hours as regards their content and management.

Methods

Permission for this study was obtained from the Head of Pharmacy Services at MDH. A documentation tool entitled 'After-Hours DI Documentation Form' was developed to record DI requests received after-hours. The tool was based on guidelines published by the American Society of Health-System Pharmacists and the Royal Pharmaceutical Society.[2-4]

The tool was subjected to a pilot study, which consisted of the first 10 DI requests received, and was validated by an expert panel composed of two shift pharmacists, two non-shift pharmacists, two staff nurses and two non-healthcare professionals with a background in education. Information related to the request and information provided to the requester was recorded in this tool. Information included (a) date and time of receipt of the request, (b) personal information of the requester, (c) details of the medication(s), (d) description of request, (e) information provided by pharmacist, (f) source consulted by pharmacist to provide information, (g) classification of request, (h) method used by pharmacist to deliver the information, (i) time taken to respond to request and (j) any other relevant information such as impact on patient care. DI requests received by one group of shift pharmacists were recorded using the tool developed. Documentation took place over a 6-month period.

DI requests received fell within a vast number of categories, with drug administration being the most frequent and responsible for 113 from a possible 253 categories

Results

A total of 65 shifts were observed. No DI requests were received during 5 of these shifts. A total of 224 DI requests were received and documented using the developed tool during the 60 studied shifts.

A total of 50.4% of requests were received during night shifts and 49.6% were incurred during day shifts. Nurses placed the most requests (72.3%), followed by medical doctors (23.2%). In the majority of cases (91.5%), DI was provided over the telephone. This information was relayed to requesters within 30 minutes in 99.1% of occurrences. Information on one type of medication was asked in 88.4% of requests.

Pharmacists used a total of 240 references to answer requests. Textbooks were the most commonly used source (37.5%), with the third edition of the 'Injectable Medicines Administration Guide' published by the Pharmacy Department of the University College London Hospitals being used in 82.2% of these instances (Figure 1).

DI requests received fell within a vast number of categories, with drug administration being the most frequent and responsible for 113 from a possible 253 categories (44.7%) (Figure 2). The requests documented concerned a total of 254 different medications, with drugs of the same active ingredient but different formulation considered to be separate entities. Most requests received were for injectable medications (53.6%) and solid oral dosage forms (30.7%) (Figure 3). Parenteral phytomenadione (vitamin K1) was the medication most commonly associated with DI requests (5.1%). Anti-infective agents, including antibacterial, antifungal and antiprotozoal medication represented 16.5% of all medications for which DI was requested.

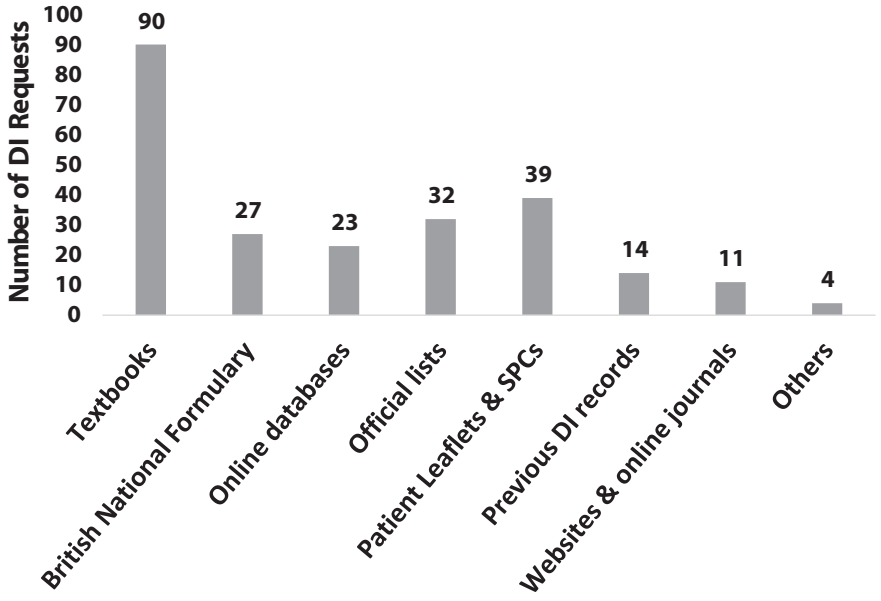

Figure 1: Reference sources used to respond to DI requests

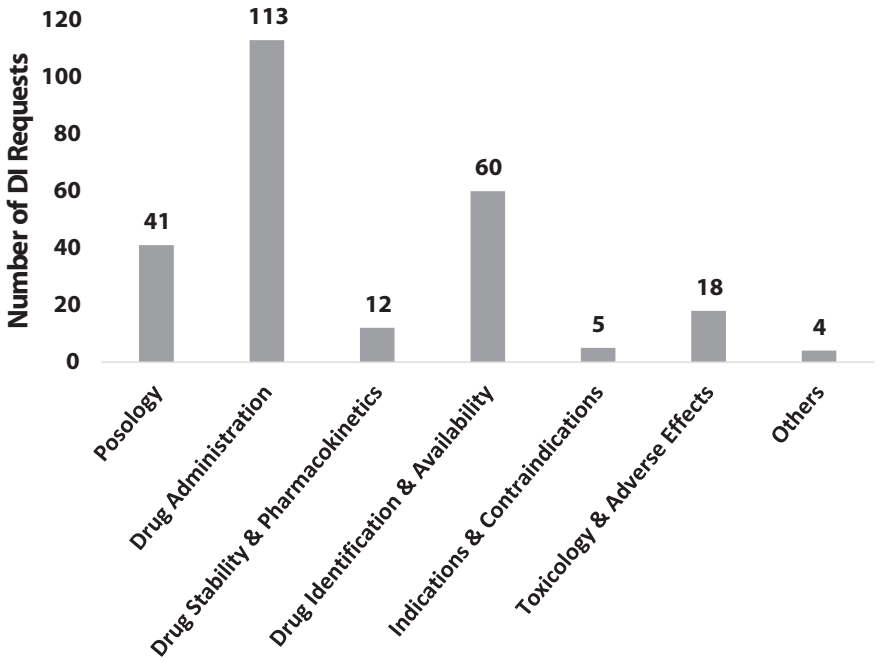

Figure 2: Categories of DI requests

Discussion

The developed documentation tool can be used by shift pharmacists to record DI requests received after-hours. This is important since in the vast majority of situations, DI was provided to requesters over the telephone and not in writing and the form would provide documentation of the request. Documentation provides accountability, can be analysed by auditors to identify possible improvements to the system and can serve an important role in the judgement of medico-legal disputes should these arise in the aftermath of supplying DI.[3] It will provide statistical proof of high workloads which is evident in the case of day shifts where results showed an almost equal number of DI requests as night shifts, despite consisting of less after-hours.[5] It is recommended that the documentation tool is converted to an online format which will improve retrieval of information and allow real time recording of requests.

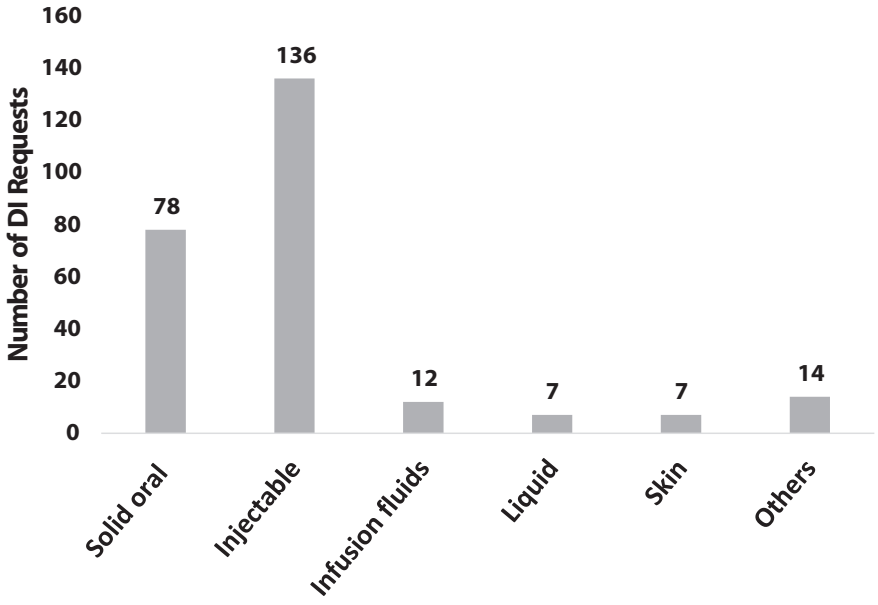

Figure 3: Dosage formulations of drugs in DI requests

The developed documentation tool can be used by shift pharmacists to record DI requests received after-hours

Nurses made the most use of DI services after-hours, possibly accounting for the high amount of requests that fell within the category of drug administration, drug identification and availability since at MDH such responsibilities fall under the role of nursing personnel. The most commonly used reference textbook by pharmacists was related to the subject of drug administration. The majority of medications on which DI was requested were of a parenteral nature, which require more expertise to administer when compared to other dosage formulations. At the time the study was carried out, a drug administration guidebook was being developed by the Pharmacy Department at MDH. This study has shown the importance of such a reference guide since it would address the needs of nursing staff. Implementation of a knowledge database or an intranet DI website could reduce the amount of DI requests to shift pharmacists which could be addressed through this document being made available to nurses. Pharmacists may thus have more time to dedicate to clinically-centred requests.[6-7]

Use of textbooks by shift pharmacists to provide DI could give rise to problems. Textbooks carry the burden of not having automatic updates and there needs to be constant monitoring to ensure that latest editions are available.[2] Drug dosage regimens and clinical indications change frequently and by the time that printed textbooks are made available, the information may have already become outdated.[8] Textbooks limit the system to the site of the pharmacy since pharmacists would need to return to the pharmacy to consult the printed material before providing DI. Although online resources were in some instances used by shift pharmacists, it is still recommended that measures are taken to increase their use by, improving the computer system and increasing the number of user-friendly online DI databases. The main limitation of this study was that DI requests were recorded from one shift group. The requests were recorded from all days of the week including Sundays and Public Holidays since the shift system was uninterrupted. This ensured a wider pool of data and therefore increased the validity of results obtained.

Conclusion

After-hours DI requests can be documented using the research tool developed. The majority of DI requests were related to drug administration. Increasing availability of online reference sources is recommended to ensure access to up-to-date information and flexibility of provision of service from pharmacists who are not restricted to operate from the pharmacy department in the hospital.

References

1. Blacow NW. Role and value of drug information centres. Proc R Soc Med. 1977;70:250-2.
2. American Society of Health-System Pharmacists (ASHP). ASHP guidelines: Minimum standard for pharmacies in hospital. Am J Health-Syst Pharm. 2013;70:1619-30.
3. Ghaibi S, Ipema H, Gabay M. ASHP guidelines on the pharmacist's role in providing drug information. Am J Health-Syst Pharm. 2015;72:573–7.
4. Royal Pharmaceutical Society (RPS). Professional standards for hospital pharmacy services: Optimising patient outcomes from medicines [Online]. London (UK): RPS; July 2014:1-33 [cited 2016 Feb 5]. Available from: URL: www.rpharms.com/support-pdfs/rps---professional-standards-for-hospital-pharmacy.pdf
5. Ho SS, Kwan FK, Lui AC. Pharmacy-based drug information services in Hong Kong hospitals. Am J Health-Syst Pharm. 1998;55:1164-6.
6. Costerison EC, Graham AS. Developing and promoting an intranet site for a drug information service. Am J Health-Syst Pharm. 2008;65:639-43.
7. Bastholm-Rahmner P, Eiermann B, Korkmaz S, Gustafsson LL, Gruven M, Maxwell S, et al. Physicians' reported needs of drug information at point of care in Sweden. Br J Clin Pharmacol. 2011;73(1):115-25.
8. Paparella S. Drug information resources: Essential but may be error prone. J Emerg Nurs. 2010;36(3):250-2.

PHARMACIST INTERVENTION IN PATIENT MONITORING IN A PSYCHIATRIC SETTING

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Abstract

OBJECTIVES To develop a 'Patient Monitoring Tool' (PMT) to evaluate the quality of pharmaceutical care provided to patients in a psychiatric setting and to determine benefits of ward-based pharmacist services in this setting.

METHOD A PMT consisting of 'Patient Monitoring Guidelines' (PMG) and a 'Pharmaceutical Care Issues Documentation Sheet' (PCIDS) was developed. The tool was tested for validity, applicability, practicality and reliability and used to monitor 30 patients in an acute psychiatric ward. The PMT was implemented and evaluation was carried out after 4 weeks using a self-administered evaluation questionnaire.

KEY FINDINGS The developed PMT was found to be valid, applicable, practical and reliable for use in the psychiatric setting. A total of 75 pharmaceutical care issues (PCIs) were identified; 55 involved psychotropic medications. A positive evaluation of the tool was obtained.

CONCLUSION This study demonstrated that the proposed tool can be implemented in an acute psychiatric setting and patient monitoring may lead to optimisation of patient care. Pharmacist incorporation into the multi-disciplinary healthcare team and direct patient involvement may further enhance the value of such services.

KEYWORDS Patient Monitoring, Pharmaceutical Care Issues, Pharmacist Intervention, Psychiatry

The tool developed allows standardisation of patient monitoring and documentation of pharmaceutical care issues

Introduction

Psychiatric patients are a high-risk patient population posing several challenges for the provision of safe and effective pharmaceutical care.[1] Many psychotropic medications have a narrow therapeutic index and polypharmacy is common. Moreover, patients with psychiatric conditions are becoming an aging population, mirroring the demographics of the general population with an increased potential for medical co-morbidities requiring treatment with additional non-psychotropic medications leading to potential drug-drug and drug-disease interactions.[2]

Over the past few decades the pharmacist's role has evolved from being predominantly product-focused to patient-oriented, targeted at improving the quality of drug therapy and enhancing patient safety through clinical pharmacy services.[3] Patient monitoring and provision of recommendations regarding dosing and administration of medications, contemporary evidence-based treatment guidelines, adverse drug reactions, drug-drug interactions and therapeutic drug monitoring are pharmacist interventions which may contribute to prevention and resolution of pharmaceutical care issues (PCIs), leading to cost reductions, shorter hospital stays and improved patient care.[4] Documentation of PCIs instils pharmacist accountability, enhances continuity of care and demonstrates the importance of PIs in the provision of high-quality pharmaceutical care and optimisation of patient outcomes.[5,6]

The aim of this study was to develop a 'Patient Monitoring Tool' (PMT) to evaluate the quality of pharmaceutical care provided to patients in a psychiatric setting and to determine benefits of ward-based pharmacist services in this setting.

Method

This study was carried out at Mount Carmel Hospital (MCH), a 400-bed hospital offering mental health and geriatric services. Approval was granted by the Clinical Chairperson and Head of Pharmacy Services at the hospital.

A draft 'Patient Monitoring Tool' (PMT) consisting of 'Patient Monitoring Guidelines' (PMG), a comprehensive six-step method guiding the pharmacist during patient monitoring,

and a 'Pharmaceutical Care Issues Documentation Sheet' (PCIDS), allowing standardised documentation of PCIs identified, were developed. A panel of 8 healthcare professionals from within and outside the hospital was asked to validate the draft PMG and PCIDS. Each validation panel member was given a consent form, a draft version of the tool and a validation questionnaire to assess presentation, comprehensiveness and validity and allowing inclusion of further comments. The validation questionnaires were scored out of a total score of 11 for the PMG and out of 10 for the PCIDS. The PMT was amended following validation and a second draft was developed.

A pilot study was undertaken to assess the applicability and practicality of the PMT to determine its feasibility and adequacy for use in the practical scenario. The principal investigator (MM) followed the PMG during the monitoring of 10 patients and documented identified PCIs in the PCIDS. Inter-observer reliability testing was determined by asking another investigator to monitor the same 10 patients. Both investigators were pharmacists. Data was inputted into IBM SPSS® version 21 to analyse the correlation between scores obtained by the two investigators using the Kappa statistic. Subsequently, a meeting between the two investigators was held to discuss PCIs identified, including any discrepancies and their relevance to clinical practice.

No changes to the PMT were made following the pilot study so the 10 patients were included in the actual study. A total of 30 patients were monitored in the actual study to evaluate the quality and safety of pharmaceutical care provided. Patients were chosen by convenience sampling from those admitted at the Mixed Admissions Ward (MAW), an acute ward for both male and female patients between the age of 12 to 90 years experiencing a first or an acute psychiatric episode. On completion of this study and following appropriate training of two other pharmacists, the PMT was implemented for use in practice during weekly patient monitoring sessions in which medication review of newly admitted patients is carried out. Evaluation of the tool was undertaken one month after implementation using a self-administered questionnaire.

Results

Validation of the PMG resulted in a mean validation score of 10.7 (range 10.5 to 11.0) and the mean validation score for the PCIDS was 9.6 (range 9.5 to 10.0). The applicability and practicality study demonstrated that the PMT is applicable and practical to use in the psychiatric setting and no further amendments were deemed necessary. Monitoring of patient's treatment was fairly time consuming, however time taken generally depended on the complexity of the patient's situation. During inter-observer reliability testing, 20 out of a total of 25 identified PCIs were common to both pharmacists. This resulted in a Kappa value of 0.574 implying moderate agreement between PCIs identified by the two pharmacists. During the post-study meeting it was agreed that although some inconsistencies between PCIs identified did exist, these minimal differences which could be attributed to difference in professional experience and judgement had no detrimental effect on the patients' medical condition.

Demographics of the 30 patients monitored are shown in Table 1. Seventeen patients (8 male and 9 female) were identified as high-risk patients, namely ≥ 65 years old or suffering from co-morbidities including cardiovascular disorders, diabetes, hepatic and/or renal impairment. A total of 164 medications were prescribed in the 30 patients monitored, with the majority (n=100) being psychotropic medications. An average of 6 medications was prescribed for each patient, ranging from 1 to 12 medications per patient. The most commonly identified PCIs included long-term use of benzodiazepines, clinically significant interactions and improper drug selection. A quantitative analysis of PCIs identified is compiled in Table 2 and categorisation of PCIs is shown in Table 3. Experience from implementation of the PMT was positive and evaluation demonstrated that the tool is fit for purpose, user friendly and ensures standardisation of the service.

Patient Demographics	
Gender	
Male	17
Female	13
Mean age (range) of patients in years	**54.4 (23-88)**
Males	52.9 (23-88)
Females	56.4 (30-75)
Total number of medications	**164**
Regular medications	136
Psychotropic	85
Non-psychotropic	51
PRN (as needed) medications	28
Psychotropic	15
Non-psychotropic	13
Mean number (range) of medications per patient	**5.56 (1-12)**
Males	4.94 (1-10)
Females	6.38 (5-12)

Table 1: Patient demographics according to gender (N=30)

	Number of PCIs
Total number of patients in whom PCIs were identified	27
Total number of PCIs identified	75
Mean number (range) of PCIs identified per patient	2.5 (0-7)
Males	3.08 (0-6)
Females	2.06 (0-7)

PCIs: Pharmaceutical care issues

Table 2: Quantitative analysis of pharmaceutical care issues identified (N=30)

Discussion

At MCH, similar to other local settings, a large proportion of pharmacist time is being spent on administrative services which could be delegated to pharmacy technicians and other trained staff.[7] This study confirms the applicability of the developed tool as a means to introduce a structured clinical pharmacy service in a psychiatric hospital. Promoting safe medication use in a psychiatric hospital necessitates adopting lessons learnt from other health care settings, whilst concomitantly focusing on strategies directed at the unique challenges of psychiatry.[8]

A significant proportion of PCIs identified involved psychotropic medications. This result differs to studies by Alderman[2] and O'Hare[9] et al. in which the majority of

Pharmaceutical Care Issue	Frequency	
Too many drugs for indication	7	**Drug selection (n=40)**
Improper drug selection	13	
Identified clinically significant interactions	15	
Need for additional drug	5	
Unclear/Unconfirmed indication	0	
Inappropriate dosage form	0	**Dosage form**
Dose too low	4	**Dose Selection (n=16)**
Dose too high	6	
Dosage regimen not frequent enough	4	
Dosage regimen too frequent	1	
Drugs given PRN despite practice not recommended	1	
Drugs with slow titration	0	
Untreated indication	0	**Drug effect**
Prescribing error (wrong or missing information)	1	**Logistics (n=1)**
Others *(including long-term use of benzodiazepines, medications to be used with caution in patients with comorbidities, wrong timing of doses)*	18	**Others (n=18)**

Table 3: Categorisation of pharmaceutical care issues identified (n=75)

pharmacist interventions were related to non-psychotropic drugs. A plausible explanation may be that the majority of medications (73%) prescribed in patients included in this study are psychiatric medications.

The evolution of the pharmacist's role from a product-centred profession to one which makes the patient the fulcrum of its activities has been ongoing in various Maltese healthcare settings such as geriatric and rehabilitative care[10-12] and rheumatology.[13-15] However, in the psychiatric setting, evolution of the pharmacist's role is happening at a much slower pace.[16] This may be due to lack of human resources and the stigma associated with mental health. Nevertheless, the pharmacy department at MCH aims to extend the services offered to include clinical services in this setting, together with allocation of more manpower. This may be done through adaptation of clinical pharmacy standards established in other settings[11,12] to enhance patient monitoring and enable identification of PCIs to ensure safe and effective medication use and improve patient outcomes. Standardisation of documentation of PCIs may be considered as the first steps towards enhancing the quality of patient care.[11,12]

Various limitations of the study were identified. Patient monitoring was carried out on a small sample of inpatients, in an acute ward, under the care of six consultant psychiatrists which may limit extrapolation of results to the entire patient population at MCH. Identification of PCIs relied heavily upon experience and professional judgement of the pharmacist and patient monitoring was carried out solely through review of medication records which sometimes consisted of poorly recorded and/or incomplete documentation. Moreover, PCIs identified and recommendations made did not take into consideration patient input, hence important PCIs including adverse drug reactions and adherence to treatment could not be determined.

Conclusion

This study demonstrated that pharmaceutical care being provided to inpatients at MCH may be optimised. The tool developed allows standardisation of patient monitoring and documentation of PCIs. The provision of clinical pharmacy services such as monitoring of patients in an acute psychiatric ward can contribute to amelioration of patient care and safer use of medications. The value of the provision of such services may be further enhanced through direct patient interaction and the integration of the pharmacist into the multidisciplinary healthcare team especially during ward rounds.

References

1. Rothschild JM, Mann K, Keohane CA, Williams DH, Foskett C, Rosen SL et al. Medication safety in a psychiatric hospital. Gen Hosp Psychiatry. 2007; 29:156-62.
2. Alderman CP. A prospective analysis of clinical pharmacy interventions on an acute psychiatric inpatient unit. J Clin Pharm Ther. 1997;22:27-31.
3. Elenbaas RM, Worthen DB. Clinical pharmacy in the United States: Transformation of a profession. USA: American College of Clinical Pharmacy (ACCP): 2009.
4. Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL. Clinical pharmacists and inpatient medical care: A systematic review. Arch Intern Med. 2006;166:955-94.
5. Spinewine A, Dhillon L, Mallet L, Tulkens PM, Wilmotte L, Swine C. Implementation of ward-based clinical pharmacy services in Belgium: Description of the impact on a geriatric unit. Ann Pharmacother. 2006;40:720-8.
6. Viktil KK, Blix HS, Moger TA, Reikvam A. Interview of patients by pharmacists contributes significantly to the identification of drug-related problems. Pharmacoepidemiol and Drug Saf. 2006:15:667-74.
7. Wirth F, Azzopardi L, Gauci M, Zarb Adami M, Serracino Inglott A. Time and motion study for pharmacists' activities in a geriatric hospital. IJPP. 2009;17:373-76.
8. Canaday BR, Yarborough PC, Malone RM, Ives TJ. Documentation of pharmacotherapy interventions. In Schwinghammer TL, Koehler JM, editors. Pharmacotherapy casebook: A Patient-Focused Approach. New York: McGraw-Hill; 2009:29-35.
9. O'Hare JD, McKee HA, D'Arcy PF. Analysis of drug information queries received by the pharmacy in a large psychiatric hospital. J Clin Hosp Pharm. 1984;9:139-42.
10. Vella E, Azzopardi LM. Evaluation of pharmacist clinical recommendations in a geriatric hospital. JEMP. 2011;1:2-5.
11. Mamo M, Wirth F, Azzopardi LM, Serracino-Inglott A. Standarsing pharmacist patient profiling activities in a rehabilitation hospital in Malta. Eur J Hosp Pharm. 2013;1-5.
12. Wirth F, Azzopardi LM, Serracino Inglott A. Quality management system for clinical pharmacy services: Quality assurance for pharmacist professional services. Germany: Scholar's Press;2013.
13. Conti L, Wirth F, Azzopardi L, Mallia C, Camilleri Vassallo F, Coleiro B et al. Pharmaceutical care aspects in systemic lupus erythematosus. Hospital Pharmacy Europe. 2009;43:48-51.
14. Griscti S, Serracino-Inglott A, Zarb-Adami M, Azzopardi LM, Mallia C, Azzopardi L et al. Management of rheumatoid arthritis. Hospital Pharmacy Europe. 2010;49:20-1.
15. Grech L, Coleiro B, Borg A, Serracino-Inglott A, Azzopardi LM. Evaluation of the impact of a pharmaceutical care service offered to rheumatoid arthritis patients within an ambulatory setting. American Journal of Pharmacy and Health Research. 2013;1(7): 2321–3647.
16. Bugeja A, Attard Pizzuto M, Serracino-Inglott A, Azzopardi LM. Pharmacist intervention in a psychiatric setting. Eur J Hosp Pharm. 2015:1–5.

IMPACT OF PHARMACIST ADVICE ON METABOLIC SYNDROME

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Abstract

OBJECTIVES The aim of this study was to determine the effect of pharmacist intervention on lifestyle modifications and pharmacological treatment in overweight and obese patients suffering from metabolic syndrome.

METHOD Patients were recruited from the community setting according to the International Diabetes Federation definition inclusion criteria for metabolic syndrome. Anthropometric and biochemical tests were performed at baseline (t=0). Patients were assessed for medication compliance, occurrence of side-effects, lifestyle and risk factors using a questionnaire. Patients were re-assessed three months after pharmacist intervention (t=1).

KEY FINDINGS A total of 35 patients participated in the study. Following pharmacist intervention there was a statistically significant improvement in compliance to medications (p=0.005) and statistically significant reduction in occurrence of side-effects (p=0.009), weight (p=0.005), waist circumference (p=0.000), body mass index (p=0.005), fasting blood glucose (p=0.015), total cholesterol (p=0.001) and triglyceride (p=0.000) levels.

CONCLUSION Pharmacist intervention improved patient motivation to change their lifestyle. Pharmacists can play an important role in the management of metabolic syndrome.

KEYWORDS Lifestyle Modifications, Medication Compliance, Metabolic Syndrome, Pharmacist Intervention, Side-Effects

Introduction

Metabolic syndrome is a major health threat and public health challenge causing a financial burden globally. It is associated with a five-fold increase in type 2 diabetes mellitus (T2DM) and a two-fold increase in cardiovascular complications.[1] The primary cause of metabolic syndrome is obesity. Obesity causes insulin resistance or hyperinsulinaemia, which in turn results in activation of the sympathetic nervous system and an increase in appetite and over-eating. It also exerts negative actions on the cardiovascular and renal systems, resulting in hypertension. Hyperinsulinaemia enhances predisposition to T2DM and hypercholesterolaemia.[2]

Various institutions have defined metabolic syndrome, however the one most commonly used is the International Diabetes Federation (IDF) definition which states that obesity is a criterion to classify patients as suffering from metabolic syndrome. Obesity is measured using waist circumference (WC), however if body mass index is > 30 kg/m^2 central obesity can be assumed and WC measurement is not required. This definition also states that patients also need to be suffering from two of the following conditions namely raised triglycerides, reduced high-density lipoprotein cholesterol (HDL-C), raised blood pressure (BP) and/or raised fasting plasma glucose (FBG) and are receiving treatment for these conditions.[3]

The aim of this study was to determine the effect of pharmacist intervention on lifestyle modifications and pharmacological treatment in overweight and obese patients suffering from metabolic syndrome.[1]

Method

Approval from the University of Malta Research Ethics Committee was granted. Thirty-five patients were recruited by means of posters displayed in prominent places at a community pharmacy clinic and using flyers which were personally distributed to obese patients. Informed consent was obtained from each patient prior to pharmacist intervention. The inclusion criteria were: WC ≥ 94cm in males and ≥ 80cm in females and suffering from two or all of the following conditions, namely T2DM, hypertension and hypercholesterolaemia, according to the IDF definition.

Pharmacist intervention improved patient motivation to change their lifestyle... Pharmacists can play an important role in the management of metabolic syndrome

During the pre-intervention (t=0), a questionnaire was administered to patients to collect information about medical check-ups and medication-taking patterns, occurrence of side-effects, self-monitoring of blood pressure (BP), blood glucose and cholesterol, family and social history as well as dietary and exercise patterns. Patients' anthropometric and biochemical parameters were measured. WC and height measurements were taken using a measuring tape, with WC measured mid-way between the lower margin of the last palpable rib and the top of the iliac crest. Weight was recorded using the Beurer® BF Limited Edition 2013 electronic scale. The point-of-care (POC) Beurer® BM 55 BP monitor was used to obtain systolic and diastolic BP and pulse readings. The POC AccuTrend® Plus device was used to quantitatively measure blood triglycerides (TGs), blood total cholesterol (TC) and fasting blood glucose (FBG). Subsequently pharmacist intervention was undertaken by the investigator (SLM) where patients were advice on diet and exercise was provided and information booklets on metabolic syndrome, cardiovascular diseases, cholesterol, diabetes, diet, exercise and obesity were given to patients.

After three months, the patients were contacted by telephone and a post-intervention appointment was set (t=1). A questionnaire to assess change in treatment and lifestyle since the first intervention was administered. Measurement of anthropometric and biochemical parameters was repeated using the same equipment. Statistical analysis was performed with IBM SPSS® version 20. The chi-square (X^2) test was used to assess the association between two categorical variables, the paired-sample t-test was used to compare the pre- and post-intervention results, the independent sample t-test was used to compare mean parameter scores between the two groups clustered by age or gender, and the Pearson correlation test was used to measure the strength of the relationship between any two anthropometric and/or biochemical parameters. A p value less than 0.05 was considered statistically significant.

Results

Out of the total 35 patients recruited, 31 were female and 4 were male. The mean age was 70 years, ranging from 41 to 86 years. The most common combination of metabolic syndrome components was hypertension and dyslipidaemia (n=18), followed by hypertension, diabetes and dyslipidaemia (n=9), hypertension and diabetes (n=6) and diabetes and dyslipidaemia (n=2). The most common medication prescribed for hypertension, dyslipidaemia and T2DM was perindopril (n=19), simvastatin (n=21) and metformin (n=16) respectively.

Prior to pharmacist intervention 14 out of the 35 patients experienced side-effects, where 9, 7 and 10 patients reported side-effects from their hypertension, T2DM and dyslipidaemia treatment respectively. Side-effects reported in patients suffering from hypertension included dizziness (n=4), increased frequency of urination (n=4) and swollen ankles (n=5). Patients on treatment for hyperglycaemia reported diarrhoea (n=5) and patients on treatment for dyslipidaemia reported musculoskeletal-related side-effects, including muscle weakness (n=4), muscle cramps (n=3) and muscle pain (n=3). After pharmacist intervention, 10 patients claimed to have stopped experiencing side-effects. The X^2 test showed a p-value of 0.009, implying that pharmacist intervention decreased incidence of side-effects (Table 1).

Number of patients experiencing side-effects at t=0		**Number of patients experiencing side-effects at t=1**	
Yes	No	Yes	No
14	21	4	31
$X^2(1)=6.774$, p=0.009			

Table 1: Comparison of side-effect occurrence before (t=0) and after (t=1) pharmacist intervention (N=35)

Number of patients compliant to medication at t=0		Number of patients compliant to medication at t=1	
Yes	No	Yes	No
20	15	30	5
$X^2(1)=7.778$, p=0.005			

Table 2: Comparison of medication compliance before (t=0) and after (t=1) pharmacist intervention (N=35)

Parameters	t=0 (mean ± SD)	t=1 (mean ± SD)	p-value
Weight (kg)	78.65 ± 18.81	77.43 ± 18.26	0.005*
BMI (kg/m^2)	31.37 ± 6.78	30.84 ± 6.30	0.005*
WC (cm)	104.34 ± 11.49	98.11 ± 11.33	0.000*
SBP (mmHg)	151.61 ± 23.10	147.30 ± 18.43	0.075
DBP (mmHg)	89.86 ± 11.30	88.13 ± 12.52	0.224
FBG (mmol/L)	5.45 ± 1.61	4.89 ± 1.61	0.015*
TC (mmol/L)	5.39 ± 0.9	5.05 ± 0.90	0.001*
TGs (mmol/L)	1.73 ± 1.13	1.45 ± 1.09	0.000*

*p-value < 0.05 is considered statistically significant; SD: Standard Deviation

Table 3: Comparison of anthropometric and biochemical parameters before (t=0) and after (t=1) pharmacist intervention (N=35)

Mean weight, BMI, WC, FBG, TC and TGs decreased significantly in all patients after pharmacist intervention

As regards medication compliance, before pharmacist intervention 15 patients stated that they rarely or occasionally miss a dose of their medication. The most common reasons for missing a dose were forgetfulness (n=11) and feeling well with or without medication (n=2). Patient compliance to medication increased post-pharmacist intervention since the number of patients who stated that they miss a dose decreased to 5 (p=0.005) (Table 2). The anthropometric and biochemical findings are compared in Table 3. Mean weight, BMI, WC, FBG, TC and TGs decreased significantly in all patients after pharmacist intervention. The mean readings for systolic and diastolic BP decreased after pharmacist intervention, however improvement was not statistically significant (p>0.05).

Discussion

A study conducted by Tavares et al., stated that compliance to medications tends to be lower in patients with a higher number of comorbidities, especially elderly patients.[4] Most patients who claimed to miss medication doses in this study claimed to do so due to forgetfulness (n=11). Given the age of the participants, cognitive impairment is expected. Tavares et al., stated that older people were found to be less compliant to their treatment due to forgetfulness and complicated dosage regimens.[4]

Occurrence of side-effects decreased significantly after pharmacist intervention, indicating that pharmacists could have an important role in advising patients on how to reduce and manage their side-effects. With their knowledge and expertise in pharmacology, pharmacists are in a position to effectively manage patients to reduce side-effects and increase medication compliance, improving quality of care. Furthermore, the findings indicate that pharmacists have an important role in promoting lifestyle changes through patient education and advice.

This study is limited by the small sample size and challenges in patient recruitment since testing was invasive. Questionnaire responses may not be accurate since they depend on truthfulness of patients.

Conclusion

The findings indicate that pharmacists are in a position to play an important role in the management of patients suffering from metabolic syndrome through provision of advice and education about their disease states, beneficial effects of pharmacological treatment, side-effects which can be expected and their prevention and effective management, as well as on lifestyle modifications. Pharmacists have the potential to reduce morbidity and mortality in patients suffering from metabolic syndrome.

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References

1. Zimmet P, Alberti KG, Serrano Ríos M. A new international diabetes federation worldwide definition of the metabolic syndrome: the rationale and the results. Rev Esp Cardiol. 2005;58(12):1371-6.
2. Landsberg L. Obesity and the insulin resistance syndrome. Hypertension Research. 1996;19 Suppl 1:S51-5.
3. International Diabetes Federation. The IDF consensus worldwide definition of the Metabolic Syndrome. Brussels: International Diabetes Federation; 2006.
4. Tavares N, Bertoldi A, Thume E, Facchini L, Franca G, Mengue S. Factors associated with low adherence to medication in older adults. Rev Saude Publica. 2013;47(6):1092-1101.

USE OF INTERNET PHARMACIES BY THE PUBLIC

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Abstract

OBJECTIVES The objectives of the study were to observe the number of Maltese patients who purchase medicines over the internet, to evaluate how well-informed the public, doctors and pharmacists are when selecting a legal internet pharmacy and to appraise the awareness of doctors and pharmacists on the possibility of their patients using the internet to purchase medicines that may cause adverse effects or drug interactions with the medications they themselves may dispense or prescribe.

METHOD A self-administered questionnaire was devised following an adaptation of another questionnaire entitled 'The Use of Online Pharmacies by British Colombia Residents' carried out by the British Columbia Centre for Social Responsibility in 2009.[1] This questionnaire was distributed to members of the general public. Two other questionnaires were designed and distributed to pharmacists working in community pharmacies and physicians. Data obtained from these studies was analysed using SPSS® version 22.

KEY FINDINGS Nine hundred and seventeen participants took part in this study. Ninety seven per cent (n=888) revealed that they purchased products over the internet and 5.1% (n=47) purchased medicines online. From the 915 participants who answered a question regarding the safety of internet pharmacies, 79.9% (n=731) felt that internet pharmacies were not as safe as local community pharmacies. Nineteen of the 47 participants who ordered medicines online were willing to self-diagnose their medical condition and 3 of the 43 participants mentioned that they had suffered from side-effects following the use of medicines purchased over the internet. Fifty-three per cent of both pharmacists and doctors agreed that patients should be given the opportunity to purchase medicines over the internet if the source was reliable.

CONCLUSION Maltese patients need to be educated on how to choose a legal internet pharmacy. Purchasing from sites that promote self-diagnosis or provide prescription-only medicines (POMs) without a prescription should be discouraged. The importance of educational campaigns to increase awareness among healthcare professionals was also identified.

KEYWORDS Authenticity, Internet Pharmacies, Online Pharmacies, Risks.

Introduction

An increasing number of people are using the internet for online medical services, one of which is for the purchase of pharmaceuticals.[2] Legitimate online pharmacies can be recommended to patients as these are regulated. However, illegitimate online pharmacies that sell POMs without a prescription and possibly counterfeit pharmaceuticals or medicines of dubious quality, are a problem.[3] Among the various types of internet pharmacies that exist, there are a substantial amount that operate illegally.[4] Patients should expect the same high standard of pharmaceutical care from internet pharmacies as that from a physical one. The public may find it difficult to distinguish between a legal or rogue internet pharmacy.[5]

Presently there are no internet pharmacies established in Malta. The Maltese public may however purchase medicinals for their personal use from online pharmacies that are based overseas. Article 85c of Directive 2011/62/EU which amends Directive 2001/83/EC concerns the sale of medicinal products over the internet. This sets the rules regarding the standards and regulations that must be maintained by internet pharmacies. As a consequence of this Directive, the European Commission (EC) introduced the European Union (EU) authenticity logo which must appear on all legally operating websites in the EU by June 2015.

The aim of the study was to assess the popularity of internet pharmacies with the Maltese public and if there is a serious risk to public health as a consequence.

Method

Three self-administered questionnaires were used for data collection. A draft copy of the questionnaire aimed at the general public was developed in English, validated and subsequently translated to Maltese. A pilot study was performed on the draft questionnaire in English. No ethics approval was necessary for this study. The final draft of this questionnaire was converted to an online survey using Google Docs®. People 18 years and over were eligible to participate in the study. The questionnaire was disseminated by means of an invitation to members of the public in the form of a covering letter including a link to the questionnaire. It was circulated through a social media group with approximately 18,000 members and

also by posting it on the researcher's Facebook® webpage. E-mails were sent to different contacts and to members of an organisation for senior citizens. University students were also invited to participate in the study. Hard copies of the questionnaire were distributed as well.

Another two questionnaires for doctors and pharmacists working in retail pharmacies were developed. The final version of these questionnaires was distributed online. An e-mail was sent to all registered pharmacists via the Pharmacy Council. The questionnaire was also circulated through the social media group 'Maltese Pharmacists and Pharmacy Students' and hard copies were distributed to pharmacists attending lectures organised by the Malta College of Pharmacy Practice at the University of Malta. The questionnaire for doctors was circulated by the editor of the Synapse® which is a local journal. Hard copies were sent to doctors. Data from these three questionnaires was collected over an 8-week period from October 2014 to end of November 2014 and analysed using SPSS® version 22.0.

Results

A total of 917 responses were received from the questionnaire for the general public. Eight hundred and eighty-eight participants (96.8%) declared that they have purchased products online. Five per cent (n=47) of the participants used the internet to purchase medicines.

From a total of 915 participants who answered the question regarding the safety of internet pharmacies, 179 (19.6%) felt that buying medicines over the internet was as safe as buying medicines from a local pharmacy. Seven hundred and thirty one participants (79.9%) felt that this practice was not as safe as using a local pharmacy. Thirty of the 47 participants who ordered medicines online claimed that they ordered medicines from internet pharmacies in the EU, while 6 participants used online pharmacies outside the EU. Ten participants did not know the country of origin of the online pharmacy. Eighteen of the participants carried out checks to verify if the internet pharmacy was authentic. Two reasons why the public purchased medicines online were lower cost (20 out of 27) and lack of availability of medicines locally (29 out of 40). Three out of 42 participants suffered from side-effects following the use of medication purchased online. A total of 80 pharmacists participated in the study devised for pharmacists working in retail pharmacies. Forty-two pharmacists were in favour of patients using internet pharmacies if the source was reliable. The reasons given may be seen in Figure 1.

The reasons why pharmacists do not recommend the use of internet pharmacies to family members, friends or patients are presented in Figure 2. The main concerns were that pharmacists did not trust the sites or the quality of the medicines originating from online pharmacies. From the results in Table 1, it may be inferred that pharmacists perceived the risk that POMs are sold without a prescription as the highest risk to patients using internet pharmacies. Three other risks followed with equal scores. These were that the product has not passed through the required checks to ensure its quality, safety and efficacy, underage people can order controlled substances and medicines purchased are expired, unsafe or counterfeit. Pharmacists rated the risk that the patient or healthcare system may suffer a financial burden due to the need of remedial care following treatment with medicines purchased over the internet as the least important concern.

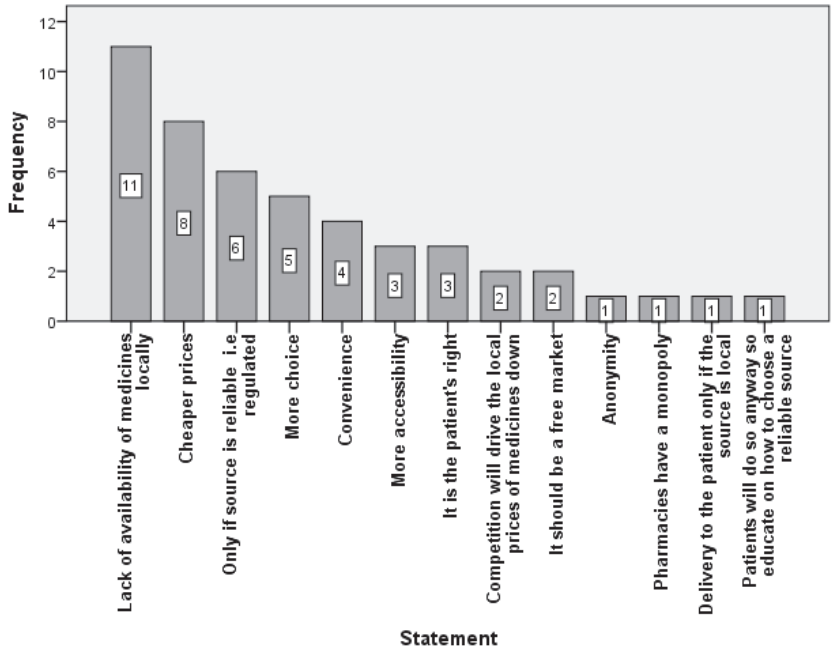

Figure 1: Reasons given by pharmacists as to why patients should be given an opportunity to procure medicines online if the source is reliable

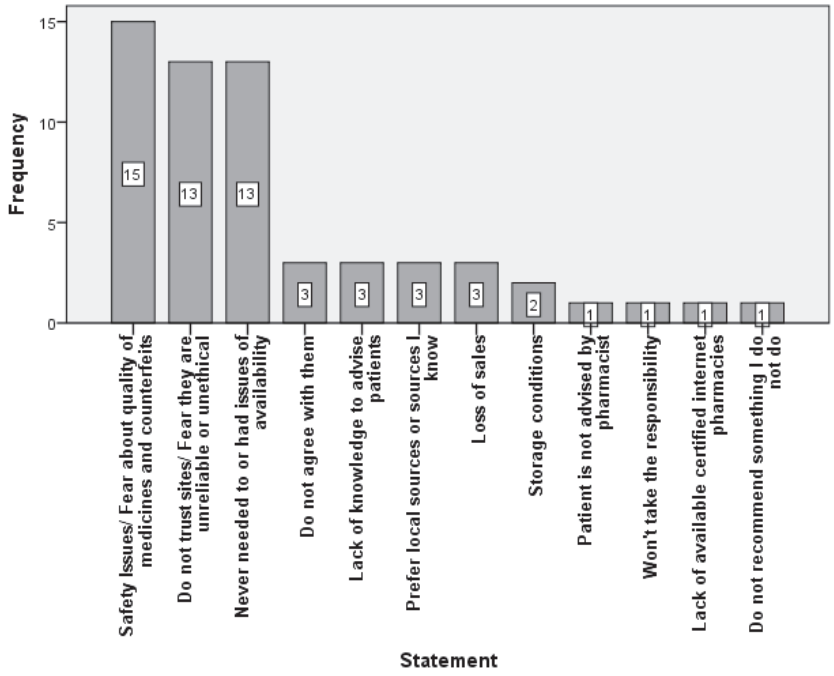

Figure 2: Reasons as to why pharmacists do not recommend the use of online pharmacies to family members, friends or patients at the pharmacy

	Mean	Standard Deviation
POMs are sold without a valid prescription	3.76	0.557
The product has not passed through the required checks to ensure its safety, quality and efficacy	3.75	0.703
Minors and children can order controlled substances	3.75	0.606
The medicines purchased are expired, unsafe or counterfeit	3.75	0.606
Problems with resistance e.g. in the case of antibiotics	3.47	0.826
In the case of temperature sensitive pharmaceuticals, the medicines may be spoiled if precautions are not taken during delivery	3.68	0.612
Financial burden to the patient or healthcare system, due to the need of remedial care following treatment with medicines purchased over the internet	2.86	1.003
Improper packaging of the medicines e.g. absence of a patient information leaflet, the language is not in English, unconventional packaging or damaged packaging	3.26	0.807
Ease to obtain prescription drugs by drug addicts or abusers	3.50	0.886
Misdiagnosis due to the absence of face to face consultations between patients and qualified medical staff	3.74	0.568
Cyber-doctors offering a medical opinion are not qualified medics but a computer database deciding appropriate therapy and thus deceiving the public	3.64	0.733
The lack of interaction with the pharmacist for advice	3.58	0.689
Patients self-diagnose and treat themselves via the internet and internet pharmacies	3.59	0.610

X^2 (12) =169.053, p<0.001

Table 1: The importance of risks when patients purchase medicines from internet pharmacies according to pharmacists

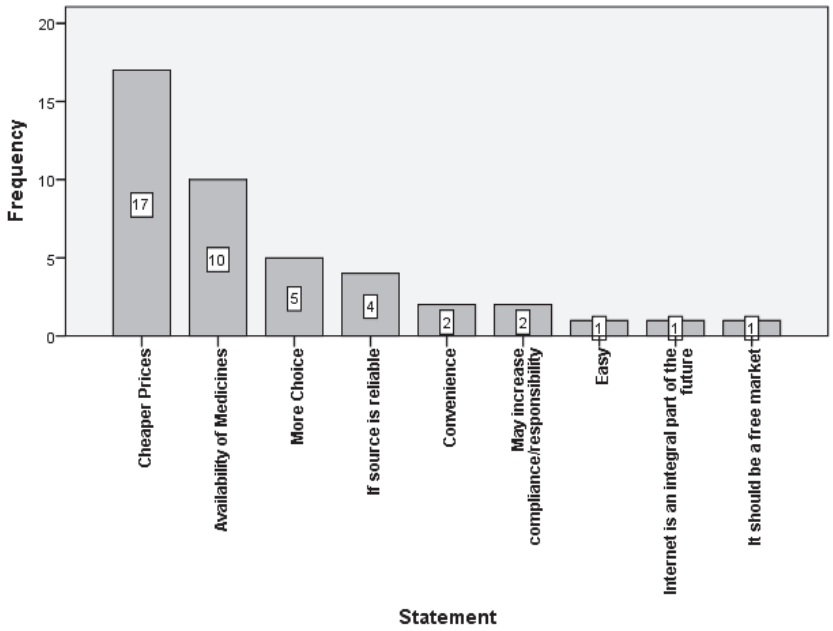

Figure 3: Reasons given by doctors as to why patients should be given an opportunity to buy medicines over the internet if the source is a reliable one

Fifty-nine responses from registered physicians practising in Malta were received. Thirty-one of these participants were in favour of using internet pharmacies if the source was reliable. The advantage of cheaper medicines purchased from internet pharmacies, availability issues of medicines locally and providing a wider choice of medicines to the patient were highlighted. A reason why doctors were not in agreement with the use of internet pharmacies even if the source was reliable was due to fear that advice from doctors and pharmacists would be bypassed by patients. Doctors believed that there was a lack of safety or control over internet pharmacies and that it was difficult to decide if the source was reliable. Doctors rated the risk that the product did not pass through the required checks to ensure safety, quality and efficacy as the most important risk for patients. Financial burden suffered by the patient or the healthcare system due to requiring remedial care following treatment with medicines purchased over the internet was rated as the risk of least importance. Five doctors were asked for advice by their patients following side-effects experienced due to medicines purchased from online pharmacies. Thirty-one doctors claimed that they never asked their patients whether they were using medications purchased online when prescribing. Six doctors identified patients who were abusing from illegal drugs purchased online.

Discussion

From this study it was determined that 5.2% (n=47) of the population use internet pharmacies and from these, three experienced side-effects following the use of medicines purchased online. Not many use internet pharmacies and the numbers who experienced side-effects following their use is low. It was determined that 79.9% (n=731) of the general public felt that internet pharmacies were not as safe as brick and mortar pharmacies. Although the majority of the participating doctors and pharmacists (52.5%) were in favour of the use of internet pharmacies if the source was reliable, many expressed their lack of trust for these sites and fears regarding the safety of the medicines originating from their use.

Conclusion

Internet pharmacies may be beneficial to our healthcare system. There must be a balance on how to regulate online pharmacies to avoid patient harm and at the same time ensure that over-regulation will not result in the loss of significant benefits to the patient.[6]

References

1. McCormick AV, Cale JL, Cohen IM, Corrado R. The Use of Online Pharmacies by British Colombia Residents [Internet] Canada: University of the Fraser Valley Centre for Safe Schools and Communities; 2009 [cited 2016 Jan 12]. Available from: URL: https://www.library.yorku.ca/find/Record/3209857.
2. George C. Internet Pharmacies: Global Threat Requires a Global Approach to Regulation. Hertfordshire Law J. 2006;4(1):12-25.
3. Oliver AJ. Internet Pharmacies. Regulation of a Growing Industry. J Law Med Ethics. 2000;28(1):98-101.
4. Mariz S. Medicines and the Internet. Journal of the Malta College of Pharmacy Practice. 2010;(16):8-9.
5. World Health Organisation. Regulatory Information: Internet Purchase of Pharmaceuticals: a review of a regulatory experience. WHO Drug Information 2001;15(3&4).
6. Schafer A. Canadian Internet Pharmacies: Some Ethical and Economic Issues. Can Pharm J. 2008;141(3):191-7.

AVAILABILITY OF MEDICINAL PRODUCTS ON THE MALTESE MARKET AS AFFECTED BY REGULATION

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Abstract

OBJECTIVES To evaluate availability issues of medicinal products in Malta and to identify therapeutic groups for which no products are authorised or available.

METHOD An extensive review of the Malta Medicines List (March 2015) was carried out and key factors affecting availability were identified.

KEY FINDINGS An estimated average of 62% of authorised medicinal products are actually placed on the Maltese market and the lowest availability rates recorded were for authorisations made via Article 126(a) of Directive 2001/83/EC.

CONCLUSION Smaller European member states such as Malta share availability issues as regards medicinal products and initiatives should be implemented to prevent such situations from impacting public health.

KEYWORDS ATC Codes, Availability, Malta Medicines List, Medicinal Products

Introduction

The market of medicinal products in the European Union is a highly regulated area. Medicinal products are regulated differently compared to other products and placement of these products on the market is not solely the responsibility of the manufacturer. Market authorisations are granted by the regulatory authorities of member states or the European Commission (EC) after being assessed by relevant expertise. Such authorisations can however only be granted after the manufacturer has applied for them, which may lead to situations where medicinal products are not equally available in all member states.[1]

Unavailability of some medicinal products is a threat to public health and welfare since it may create problems for patients, healthcare professionals and also governments. Consequences for patients will depend on the severity of their disease or condition and the availability of therapeutic alternatives. Availability of human medicinal products on small markets such as Malta is a public health concern which requires adequate attention. The aim of the study was to evaluate availability issues of medicinal products in Malta and to identify therapeutic groups for which no products are authorised or available.

Method

This study was divided into three phases. In phase 1 review of the Malta Medicines List (March 2015) issued by the Medicines Authority (MA) outlining all medicinal products authorised in Malta was carried out. The products in this list were re-grouped according to the Anatomical Therapeutic Chemical (ATC) classification system, a system of alphanumeric codes developed by the World Health Organization for classification of drugs and other medicinal products. After grouping them according to their ATC codes, the products were further sub-divided according to their route of authorisation, namely national marketing authorisations, authorisations made via Article 126(a) of Directive 2001/83/EC2 and parallel import licenses. In phase 2 Maltese wholesale dealers were consulted to develop a database of medicinal products licensed with the MA that are subsequently placed on the local market, and phase 3 involved identification of discontinuities in the availability of medicinal products. Reasons why these

On average 62% of the products authorised in the Malta Medicines List are subsequently placed on the market and made available to patients

products were not marketed were identified and tabulated and statistical analysis of the outcomes was performed. The length and duration of each phase varied according to the response rate from marketing authorisation holders and wholesale dealers. Each phase of the study was carried out with the assistance and advice of the staff at the Licensing Directorate at the MA.

Results

On average 62% of the products authorised in the Malta Medicines List are subsequently placed on the market and made available to patients. The average availability rate for all products pertaining to ATC Code A 'Alimentary Tract and Metabolism' was 49%. Several groups in this category were found to have significantly low availability rates. In the category of products for 'bile and liver therapy' (Group A05), five products were licensed and only two of these have been placed on the market. Similarly, for 'anti-obesity preparations' (Group A08) only one product is licensed and marketed locally. For 'digestives, including enzymes' (Group A09), only two authorised products were identified, out of which only one is marketed. For 'tonics' (Group A13), three out of four products are available in Malta, and no products have been authorised for systemic use with respect to 'anabolic agents' (Group A14), For Group A15, 'appetite stimulants', one product is authorised and subsequently marketed and for 'other alimentary tract and metabolism products' (Group A16) two products have been authorised, however none have been placed on the local market.

The average availability rate for products pertaining to ATC code B 'Blood and Blood-Forming Organs' was 44%, representing the lowest average availability rate for licensed medicines recorded for all ATC codes. Only one group within this therapeutic category was considered at risk of availability problems namely 'other haematological agents' (Group B06) where three products are licensed but only two have been placed on the market. The average availability rate for products in ATC code C 'Cardiovascular System' was calculated to be 57% which is higher compared to the first two therapeutic categories. Only Group C04 for 'peripheral vasodilators' was considered to pose a potential availability problem as only two products are licensed in this category and both are marketed locally. However, at the time the study was carried out one of these products was experiencing a temporary availability problem and therefore only one medicinal product was considered available in Malta for this therapeutic group.

For ATC Code D, 'Dermatological Products', average availability rate was 69%. For both 'preparations for treatment of wounds and ulcers' (Group D03) and 'medicated dressings' (Group D09) only one product is licensed and marketed. In ATC Code G, 'Gynaecological Anti-Infectives and Antiseptics', the average availability rate was calculated to be 70% and none of the subgroups within this category were considered to run the risk of availability problems due to having significantly higher rates of marketed medicines with respect to other therapeutic codes. The average availability rate calculated for ATC Code H, 'Systemic Hormonal Preparations, excluding sex hormones and insulins', was also 70% and two subgroups were considered at risk of availability problems, namely 'pancreatic hormones' (Group H04) and 'products for calcium homeostasis' (Group H05), where for both groups only two products are licensed and marketed in Malta.

For ATC Code J, 'Anti-Infectives for Systemic Use', the average availability rate was calculated to be 57% and none of the products in this category were considered to be at risk of availability problems due to having significantly higher rates of marketed medicines with respect to other therapeutic codes. In ATC Code L, 'Antineoplastic and Immunomodulating Agents', the average availability rate of licensed medicines was 61% and no therapeutic groups in this category were considered to be at risk of availability problems. In ATC Code M, 'Musculoskeletal System', an average availability rate of 65% was noted for licensed medicines and only Group M09 'other drugs for the disorders of the musculoskeletal system' was considered to have an availability risk since only one product is placed on the local market.

An average availability rate of 66% was recorded for ATC Code N, 'Nervous System' whereas the highest recorded availability rate (78%) for licensed medicines was that for ATC Code P, 'Antiparasitic Products, Insecticides and Repellents'. Group P02, 'antihelminthics' was considered to be subject to an availability threat as only two products are licensed and marketed. For ATC code R, 'Respiratory System', an average availability rate of 61% was recorded for licensed

The general trend observed for all ATC codes was that the lowest rates of availability were recorded for authorisations made via Article 126(a) of Directive 2001/83/EC

medicines and no therapeutic groups in this category were considered to be at risk of availability problems. The availability rate for ATC code S, 'Sensory Organs', was higher at 67% and Group S03, 'ophthalmological and ontological preparations', was identified as being subject to availability risk as only one product is licensed and marketed.

For ATC Code V 'Various', the average availability rate of licensed medicines was 48%. A number of subgroups within this therapeutic group were considered to be at risk of availability issues, namely Group V01 'allergens', Group V04 'diagnostic agents' and Group V07 'all other non-therapeutic products', where no products in these groups are available locally despite some products being authorised. No products are licensed for Group V20, 'surgical dressings' and only one product is available on the market for Group V06, 'general nutrients'.

The general trend observed for all ATC codes was that the lowest rates of availability were recorded for authorisations made via Article 126(a) of Directive 2001/83/EC.[2] This could be attributed to the fact that several authorisations made via this route are submitted with the intention of placing the product in question on the national government formulary list. This is done through submission of an application in the Government tender process and if the marketing authorisation holder is not awarded the tender, the applicant may decide that it is not feasible to place the product on the Maltese market.

Discussion

Smaller EU member states share some common and general availability problems. These countries generally do not have a local research and development based pharmaceutical industry and this, together with the fact that they are considered economically unattractive countries, may deter their inclusion as reference or concerned member states in mutual recognition or decentralised procedures. Moreover, although smaller member states are selected in these procedures, the launch of the product on the local market may not occur post-authorisation for a number of reasons, such as labelling in the national language.[1,3]

The size of the market and its national language are closely related. Article 63 of Directive 2001/83/EC specifies the requirement of having the labelling and package leaflet translated into a country's national language. While this is not considered to be a problem for larger markets, it may be thought to unfeasible for smaller markets. Moreover, pharmaceutical companies may not be willing to accept the extra costs involved, such as setting up of a pharmacovigilance network for markets that cannot sustain profitability.

Repackaging facilities are easily available in all member states and the packaging site in charge of the repackaging operation should be registered in the marketing authorisation application and should perform the activities in accordance to GMP requirements. However, some marketing authorisation holders may refuse to use them either since these may incur a comparatively higher additional cost or potentially due to a company's policy that prohibits the handling of the pharmaceutical product by third parties. Overlabelling or affixing stickers with a different language on packaging may decrease such costs, however this is only applicable for products authorised via parallel distribution or for an emergency situation, such as a product supply shortage.

The introduction of country-specific information in labelling or product information, such as blue-box requirements, may decrease the motivation of a pharmaceutical company to make its product available on a small market. In an effort to counteract this, Malta has not introduced any such blue-box requirements to eliminate this burden on marketing authorisation holders.

Unavailability of medicinal products has been identified as a problem and a priority issue, particularly for member states with small markets such as Malta

Conclusion

Unavailability of medicinal products has been identified as a problem and a priority issue, particularly for member states with small markets such as Malta. The potential detrimental effect that this may have on public health can sometimes be overlooked and health needs and requirements of all citizens from all member states within the EU need to be considered and protected. This is not always compatible with the needs and requirements of the pharmaceutical industry when applicants are to choose suitable markets for their products. Initiatives have been launched to improve the availability situation however, this has not always proved effective as these initiatives are not accompanied by an obligation to market. The choice of whether products are placed on a particular market should not depend solely on business feasibility and appropriate solutions to this problem can only be achieved through discussion and collaboration at high level between the EC, member states and stakeholders.

References

1. Heads of Medicines Agencies (HMA). Availability of Human Medicinal Products: Report of Task Force of HMA MG. Madeira (Portugal): HMA;2007.
2. European Commission (EC). Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [Online]. Official Journal of the European Union 2004;136:34-57 [cited 2016 Feb 3]. Available from: URL: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2004_27/dir_2004_27_en.pdf
3. Traulsen JM, Almarsdottir AB. The argument for pharmaceutical policy. Pharm World Sci. 2005;27:7-12

APPLYING QUALITY SYSTEMS TO COMPUTERISED STOCK MANAGEMENT SYSTEMS

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Abstract

OBJECTIVES To investigate the impact of applying quality systems to an established computerised stock management system of a local pharmaceutical wholesale dealer.

METHOD An established computerised stock management system was analysed to determine the compliance of recorded data with actual stock. A risk assessment of all the steps for each parameter was carried out and a risk management plan was established as necessary following risk evaluation. After a one-year period, the same parameters were re-evaluated using the same methodology and compared with baseline.

KEY FINDINGS All parameters showed an improvement from baseline at the end of the study.

CONCLUSION The application of quality systems to computerised stock management systems should be a mandatory requirement to ensure data reliability in line with Good Distribution Practice (GDP)[1] ensuring batch traceability and reconciliation throughout the storage, distribution and recall procedures and other GDP-related activities.

KEYWORDS computerised stock management, expiry dates, quality systems, standard operating procedures, stock balance

The application of quality systems to computerised stock management systems may be considered as a mandatory requirement to ensure compliance with Good Distribution Practice and safeguard public health

Introduction

Pharmaceutical companies have established computerised stock management systems on which critical activities related to GDP rely. These include invoicing, purchasing, batch recalls, crediting of returned stock, stock-taking and control of expired medicines. IT systems (hardware and software) may be adequate to satisfy the new GDP requirements.[1] Inappropriate data inputting procedures may result in unreliable data being present in the system. This leads to repercussions including sale of medicines which are expired, frequent out-of-stock situations, loss of batch traceability, over-stocking, lack of regulatory compliance of invoices and stock abuse by employees. Apart from placing the company in a precarious regulatory position, this may lead to patients' health being placed at risk especially when products with serious safety issues have been distributed by the company and cannot be traced.

The introduction of quality systems to computerised stock management systems aims at identifying the risks associated with data inputting, data processing and reports retrieval to ensure that all GDP-related activities which rely on the IT system can be carried out in a reliable manner. The aim of this study was to investigate the impact of applying quality systems to an established computerised stock management system of a local pharmaceutical wholesale dealer.

Method

Using the database of a well-established wholesale dealer's stock management system, a number of parameters related to stock management were chosen as 'Targets' for which quality systems were applied. Parameters targeted included stock database (check for duplicate cards or inaccurate descriptions), batch accuracy, expiry date accuracy, stock quantity accuracy and client database accuracy. A comparative target analysis was carried out to determine whether the quality systems put in place after baseline were successful by the pre-set deadline. After a one-year period, the same parameters were re-evaluated using the same methodology and compared with baseline.

Results

All chosen parameters indicated a statistically significant improvement from baseline values to the second data point (1 year after baseline) at the end of the study period, ranging between 1 and 17% improvement after quality systems were introduced (Figure 1).

Discussion

This study revealed that notwithstanding that the computerised system under study was established and used for several years before the study was undertaken, the lack of established quality systems to direct its implementation resulted in several serious failures. The weaknesses which were identified at baseline and which were improved after the 1 year period included the aspects that procedures took a very long time to be carried out and procedures not carried out in line with GDP (e.g. batch numbers were not adjusted after stock taking as their traceability would be lost within a few weeks due to poor data inputting practices). The presence of unreliable historical data, the lack of reporting features that were important for monitoring stock activities and data inputting procedures were identified and to this effect, the software had to be upgraded by the program developers to ensure that the required reports could be generated by the system. Several existing features of the IT stock management system were not being exploited by the employees leading to less efficient operations and duplication of work. The IT manager and employees who had access to the system were not applying safe data inputting practices and the system contained a number of bugs which had not been previously identified by other employees since such bugs were only activated when certain data processes were carried out.

Further studies could look at the financial implications and determine the financial viability of applying quality systems to IT stock management systems. The lack of reliable historical IT data and other factors such as changes in stores employees, national economy and methodology to determine the cost of man-hours of various employees involved in stock management would make it difficult to establish financial viability in a reliable manner.

Conclusion

This study revealed that well-established computerised stock management systems contain unreliable data resulting from human error. These lead to shortcomings that could have an impact on public health and financial repercussions on the company. The application of quality systems to the running and use of computerised stock management systems results in reduction of stock abuse and better stock management leading to efficient employment of financial, human and logistic resources.

The application of quality systems to computerised stock management systems may be considered as a mandatory requirement to ensure compliance with Good Distribution Practice and safeguard public health. It is in the company's financial interest to ensure that a reliable stock management system is in place so as to safeguard its assets and improve reconciliation of stock and stock accountability.

Reference

1. European Commission. Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use [Online]. Official Journal of the European Union 2013;343/1 [cited 2016 Feb 02] Available from: URL: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF

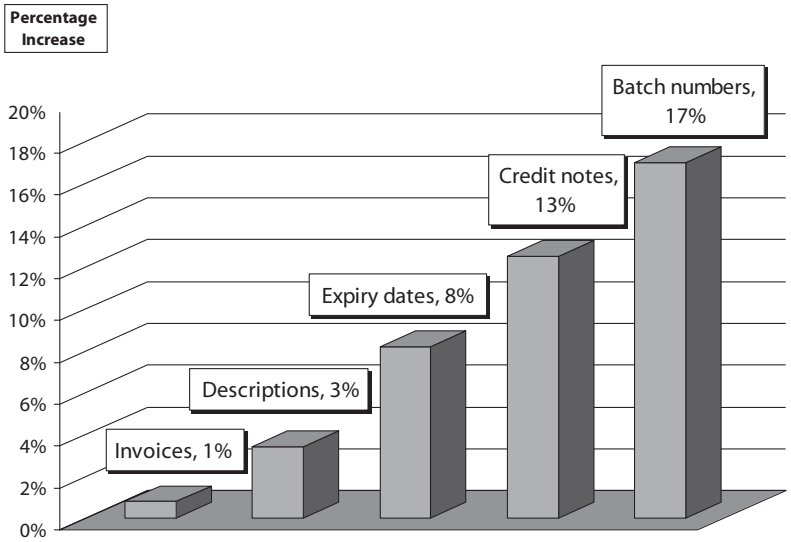

Figure 1: Summary of results for each parameter

PROPOSING GUIDELINES FOR RESPONSIBLE PERSON ELIGIBILITY IN MALTA

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ABSTRACT

OBJECTIVES To assess the current training and further education available to prospective Responsible Persons (RPs), to gather feedback from current RPs and industry stakeholders' experiences and to recommend guidelines on what training and experience prospective RPs should undergo to become eligible for the role.

METHOD A focus group was organised with key stakeholders from the industry including representatives from the Medicines Authority, University of Malta and the Central Procurement and Supplies Unit (CPSU). Feedback on individual experiences was gathered.

KEY FINDINGS The most common recommendation from the focus group was the emphasis on the importance of having practical experience relative to the size and complexity of the operation.

CONCLUSION Guidelines to be proposed for a framework on accepting RPs should consider experience supported by knowledge on obligations and duties to be fulfilled by the RP.

KEY WORDS Good Distribution Practice, Regulatory Affairs, Responsible Person Eligibility

Introduction

Article 79(b) of EU Directive 2001/83/EC states that the holder of a wholesale dealer's license in Europe is to have "a Qualified Person designated as responsible, meeting the conditions provided for by the legislation of the Member State concerned."[1] To comply with this directive the Maltese Law specifies that the Responsible Person (RP) has to be registered with the Pharmacy Council as a pharmacist and recognised as suitable by the Malta Medicines Authority (MA).[2] The MA does not interview prospective candidates to assess their competence and knowledge prior to recognising their role as RP. It currently recognises any registered pharmacist that is listed on the wholesale dealers license application form. Principles of Good Distribution Practice (GDP) require that RPs have experience and knowledge in areas related to distribution of medicines such as risk management, change and deviation control.[3]

Method

Legislation regarding eligibility for RPs in Europe was identified. The search yielded minimal results. Guidelines and recommendations from concerned organisations were assessed and relevant findings recorded. Non-European frameworks for countries where a mutual recognition agreement exists with the EU such as Canada and third countries were explored to gain an outside perspective on the subject. A focus group was carried out with stakeholders from the pharmaceutical industry. The group consisted of 6 participants representing pharmaceutical regulatory authorities, academia and the pharmaceutical industry. The questions asked aimed to gather current perception of the different stakeholders on the role of the RP, procedure for becoming a RP and the need for a RP. Challenges that RPs face and recommended training for RPs were also discussed.

There was agreement that experience was the most important asset required by a RP... This experience had to be relevant to the complexity of the activity involved

Results

There was agreement between the focus group participants that the RP is mandated to release medicines for distribution by ensuring that they have been stored and distributed in accordance with GDP guidelines. It was agreed that this can be done through establishment of an effective quality system that is relevant to the complexity of the distribution activity. RPs must be practical, knowledgeable and able to adapt to the exigencies of the company whilst being aware of their corporate social responsibility without compromising on product quality or integrity.

In the first question, the participants were asked to state what they understood by the term 'Responsible Person'. The current RPs described their current function as: ***"Releasing medicine for use, carrying out the registration process and monitoring, taking care of legal aspects involved and documentation keeping".*** Participants with less technical backgrounds focused on quality of medicines: ***"The person who is the gateway for medicinal products to be released on the markets following purchase from a manufacturer and wholesale dealer supplier ensuring that GDP guidelines are adhered to, safeguarding the integrity of the medicines".*** The representatives from the Medicines Authority made reference to the national and EU legal framework: ***"The Responsible Person is the person mandated by law to ascertain what the activities of a wholesaler are in line with the legal requirements and EU GDP guidelines. On a practical level the RP is the person to see that the products passing from the suppliers to the clients are safe and their quality has been maintained".***

There is a general consensus that the industry understands that the function of a RP is to release medicines for distribution and safeguarding quality of medicines throughout the supply chain through compliance with GDP guidelines. The group highlighted the legal responsibility of the RP and the authority this brings about in decisions regarding acceptance or rejection of goods.

The second question of the focus group asked the participants to describe the role of the RP. The answers were similar for all participants since they were aware of the role of the RP and where jurisdiction started and ended. It was understood that the RP is the key player in the supply chain and that the role takes over from the Qualified Person in the chain of responsibility. The role of an RP is to ensure compliance with GDP guidelines through use of an effective quality system. The third question of the focus group aimed to disclose challenges faced by RPs from aspects of the industry. Different feedback was given from each stakeholder. The established RP felt that the constant struggle between the lack of appreciation of the role of the RP and financial costs involved with compliance was the biggest challenge. A participant who was a newly appointed RP felt that the major challenge faced was the lack of resources available to provide support in improving knowledge. The stakeholder from the industry stated that the biggest challenge was the struggle faced trying to obtain and deliver the medicine quickly to the patient despite delays due to regulatory procedures. Another challenge faced was the costs with respect to GDP compliance. The regulator's perspective was more balanced as both sides of the story were laid out. There were compliance and financial pressures involving the RP and license holder.

The final question aimed to identify the expectations of the industry regarding the experience and background of the RP and their opinion in reaching the desired level of knowledge and experience. There was agreement that experience was the most important asset required by a RP. This experience had to be relevant to the complexity of the activity involved. Knowledge on basic and advanced concepts was deemed important but secondary to experience.

Discussion

Maltese Legislation dictates that the RP must be a pharmacist and must be deemed suitable by the Medicines Authority.[2] The RP who is nominated by the License Holder, must ensure that wholesale dealing activities are carried out in line with EU Guidelines of GDP. A company may have more than one RP who is nominated for the same license, in such cases all RPs would be equally responsible for the activities carried out by the company. The rationale behind the law choosing pharmacists as the sole eligible candidates for the role of RPs was that the pharmacy course adequately prepared pharmacists for the role. As regulations increased in complexity, there is a need for course updating. To tackle this problem, new credits and modules may be considered within the course and as refresher courses. Moreover from this study it transpired that the focus needs to be on experience.

Conclusion

Although having improperly trained or inexperienced RPs is a local problem, the consequences of an error committed by these individuals may have ramifications all over the European Community. The European Union relies heavily on its member states' controls to ensure that a single European market can be maintained in a safe and absolute manner. As the saying goes, "Experience is the best teacher" (Anon) and having experienced RPs is one way of mitigating the problems stated above. RPs are part of a team of individuals and are responsible for compliance. They have obligations to their employers and patients. This study has highlighted the importance of including experience within guidelines for criteria necessary to become an RP. More awareness is needed about the importance of the RP's role as prospective RPs need to be fully aware of the responsibility they are taking on, as well as the consequences of their actions. The industry needs to appreciate and support the RP in their work as without support the RP cannot function.

References

1. European Commission. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [Online]. Official Journal of the European Union 2001; L311/67 [cited 2016 Feb 02] Available from: URL: http://ec.europa.eu/health/files/eudralex/vol-1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf
2. Subsidiary legislation 458.37 Wholesale distribution and brokering of medicinal products and active substances regulations [Online]; 2012 [cited 2016 Feb 02]. Available from: URL: www.justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=11275&l=1
3. European Commission. Information From European Union Institutions, Bodies, Offices And Agencies, European Commission Guidelines Of 5 November 2013 On Good Distribution Practice Of Medicinal Products For Human Use [Online]. Official Journal of the European Union 2013;C343/1 [cited 2016 Feb 02] Available from: URL: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2013:343:0001:0014:EN:PDF

PHARMACEUTICAL RESEARCH AT THE DEPARTMENT OF PHARMACY

Three members of the Department of Pharmacy have recently successfully completed their PhD studies. They were working on research projects in the field of clinical pharmacy with a focus on rheumatology, point-of-care pharmacogenetic testing and clinical analysis. Results from the projects have led to innovative tools, application of innovative point-of-care testing, methods of analysis and pharmacokinetic correlations.

AN EVALUATION OF A PHARMACEUTICAL CARE MODEL IN PATIENTS WITH RHEUMATOLOGICAL DISORDERS

Louise Grech

One of the exciting challenges of undertaking a PhD research in any field lies with the potential of the research's contribution towards innovation and subsequently dissemination of the innovative outcomes through the best possible networking platforms. This study, which is an example of translational pharmacy practice, aimed at developing and implementing valid instruments essential for a pharmacist-led pharmacotherapy assessment service in the field of rheumatology. The idea of this research was first discussed within a group of multicultural and dynamic clinical-research pharmacists from the University of Malta and the University of Strathclyde, where the late Professor Steve Hudson, with whom I had conducted my Masters of Philosophy research, was based. The outcome of the research was development and clinical implementation of an innovative medication assessment tool specific to rheumatoid arthritis, denoted as the RhMAT. In clinical practice, the RhMAT provides a quality system to assess pharmacotherapy adherence to evidence-based medicine within the philosophy of pharmaceutical care models and highlighted the impact of the role of the pharmacist in further improving quality of care and service provided to rheumatology patients. Results obtained through the innovative RhMAT were disseminated through various local and international pharmacy conferences. The work was successfully disseminated at international fora within top-expert authorities leading the field of rheumatology namely the British Society for Rheumatology, the European League Against Rheumatism and the American College of Rheumatology.

PHARMACOGENETIC IMPLICATIONS IN CLOPIDOGREL THERAPY: A PHARMACIST-LED MANAGEMENT APPROACH

Francesca Wirth

The aim of this research in the contemporary field of personalised medicine was to genotype patients undergoing percutaneous coronary intervention (PCI) for the CYP2C19 loss-of-function (LoF) *2 allele, enabling pharmacogenetics-guided individualisation of antiplatelet therapy. Presence of the CYP2C19 LoF *2 variant allele is associated with reduced CYP2C19-mediated activity which impairs clopidogrel bioactivation and increases the risk of stent thrombosis and other adverse outcomes after PCI. The research was undertaken in collaboration with the Department of Cardiology and Molecular Diagnostics Unit at Mater Dei Hospital, where different genotyping assays including a novel rapid point-of-care method were used and compared. Around a fourth of the patients (26%) were genotyped as carriers of at least one *2 allele, implying that they have reduced production of the active metabolite of clopidogrel, hence predisposing them to complications post-PCI. These patients were candidates for alternative antiplatelet therapy to clopidogrel. Moreover, a correlation between presence of the *2 allele and development of coronary in-stent restenosis was obtained, making this study one of very few studies reporting such an association. The findings have important implications for Malta since they demonstrated that implementation of pharmacist-led antiplatelet therapy individualisation in clinical practice, guided by pharmacogenetic testing, has the potential to limit patient morbidity and mortality post-PCI, as well as reduce healthcare costs.

DISTRIBUTION OF CIPROFLOXACIN IN THE PERIPHERIES

Janis Vella

Peripheral arterial disease (PAD) is a chronic and debilitating condition, with smoking and diabetes mellitus (DM) being the greatest risk factors. Patients suffering from PAD and DM are more likely to develop foot infections which are difficult to treat. Poor control of these foot infections often necessitates lower limb debridement and amputation. The study was carried out in collaboration with the Department of Surgery of the University of Malta. Blood and tissue samples were collected from 50 patients (33 male and 17 female) who were admitted for debridement or amputation procedures at Mater Dei Hospital. These patients were suffering from varying degrees of PAD. These samples were analysed using innovative High Performance Liquid Chromatographic methods. The concentration of ciprofloxacin, a commonly used antibiotic to treat these foot infections, was found in the samples. This was done to determine whether the administered antibiotic was reaching the site of infection at concentrations which were high enough to eradicate the causative organism. Concentrations of ciprofloxacin found in the tissue were compared to patient history and characteristics to determine which factors influence the amount of antibiotic reaching the tissue. It was found that the concentration of ciprofloxacin reaching the tissue was dependent on the degree of PAD, the number of medications that the patient was taking and the concentration of ciprofloxacin in plasma. This study helps in more adequate dosing of ciprofloxacin in PAD patients. This can cause less undesirable effects and better treatment outcomes, avoiding unwanted complications and achieving higher levels of therapeutic success in the process.

Information about activities and research projects within
the Department of Pharmacy is available at www.um.edu.mt/ms/pharmacy.

The site also includes links to published research papers and poster presentations
presented at international conferences.

Malta Pharmaceutical Students Association: Pharmacy Students in Action

Tricia Micallef, Academics and Publications Officer

MPSA members participating in World Pharmacist Day activities

In 2015, MPSA executive members strove to highlight importance of being active healthcare professionals in the context of public education and various health campaigns were held. Activities to educate patients on the use of generic medicines were carried out in collaboration with the Department of Pharmacy of the University of Malta as part of 'World Pharmacist Day'. Blood pressure (BP) measurement and blood glucose (BG) monitoring was undertaken during these activities. MPSA members also participated in 'Science in the City' in collaboration with The Chamber of Pharmacists, where students discussed women's health and put on a short performance depicting a typical scenario encountered within the community pharmacy setting emphasising the importance of presenting a prescription to pharmacists. Other members targeted a younger age group by attending the third edition of the 'JChallenge Youth Village', where BP, BG and body mass index measurement were also performed.

On campus, MPSA continued to raise awareness on various topics such as the importance of healthy eating on 'World Diabetes Day' and breast cancer awareness throughout the month of October, where a bake sale was held in collaboration with the Malta Health Students' Association and pink was worn every Wednesday. Moreover, the association formed part of the 'Solidaritree' campaign affiliated with the Malta Community Chest Fund, contributing in fundraising events such as 'Christmas on campus' with other student organisations.

The MPSA Executive members 2015 - 2016

AUTHOR GUIDELINES

Manuscript Preparation

All contributing authors should include their full name, affiliation at time of running the study, postal address, telephone and fax numbers and email address on the title page of the manuscript. One author should be identified as the corresponding author.

Manuscripts should include title page, abstract, text, references, tables and figures. The pages of the manuscript must be numbered.

Manuscripts should not exceed 2000 words (including abstract and references, excluding title page, tables and figures).

Abstract

The format for the abstract is structured and should include objectives, method, key findings and conclusion.

Keywords

Three to five keywords should be provided.

Introduction

The introduction should provide a background to the study and should clearly state the aims of the study. Provide a definition for any abbreviations and symbols that are used.

Methods

This section should describe the subjects, setting and methods in sufficient detail to allow possibility of replication of the study. Include details of ethical approval, if applicable, in this section.

Results

This section should present the salient results of the study. Epidemiological description of sample population, where relevant, and details of response rates should be provided. Data should not be repeated in figures and tables. Describe statistical analysis undertaken.

Discussion

In the discussion a summary of the main findings of the study is to be presented and these are to be discussed in the context of international published literature and contributions to the field. Limitations and strengths of the study should be highlighted.

Conclusion

A brief conclusion section should summarize the prominent findings of the study. It is advisable to emphasize the contribution to the field of study by the current findings.

Acknowledgements and funding

Any funding received for the study should be declared in this section.

References

References should be listed in numerical order as they appear in the text. All citations in the text must have an entry in the reference list and vice versa. All the reference numbers in the text should be in superscript.

The references should be listed at the end of the manuscript according to the International Committee of Medical Journal Editors Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Please see http://www.nlm.nih.gov/bsd/uniform_requirements.html

Tables and Figures

Maximum of a total of 4 tables and/or figures.

Tables and Figures should be numbered consecutively and each must start on a separate page at the end of the manuscript. Graphs, pie charts, figures and tables are to be supplied separately on Excel and as pdfs.

Each table and figure must have a title. Define any abbreviations used. If values are cited in a table or figure, the unit of measurement must be stated.

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For further information please refer to the full summary of product characteristics or to our website www.actavis.com.mt

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