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REFERENCE PRICING FOR PHARMACEUTICALS

USE OF NSAIDS AND PATIENT SAFETY

STANDARD OPERATING PROCEDURES IN PHARMACEUTICAL QUALITY SYSTEMS

Picture taken by Jakov Cordina (B.Pharm) from the traditional pharmacy bench at the Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta.

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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.

Traditional pharmacy bench

A traditional pharmacy bench of the type that would have been the centrepiece of most pharmacies until recently was presented to Professor Juanito Camilleri, the Rector of the University of Malta at the Department of Pharmacy on Thursday the 6th of October 2011.

Dating from 1919, the pharmacy bench had been located at Portelli's Pharmacy in Paola until recently. Its acquisition was co-ordinated by the Malta Pharmaceutical Association on the initiative of pharmacist Reginald Fava. The bench was sponsored by Associated Drug, Beta Pharma, Chemimart, Novartis, Starpharma, the Malta Pharmaceutical Association and the Faculty of Medicine and Surgery.

The event was held at the Department's upper foyer, where the traditional pharmacy bench is located, an area dedicated as a study area for pharmacy students. Rector Professor Camilleri, ex-Chancellor Professor John Rizzo Naudi, Professor Godfrey Laferla, Dean, Faculty of Medicine and Surgery, Professor Lilian Azzopardi, Head of Department, Ms Janis Vella from the Malta Pharmaceutical Association and Mr Noel Pace, President of the Malta Pharmaceutical Students' Association addressed the students, staff and department's collaborators on this occasion. Rebecca Tonna, a third year pharmacy student carrying out her pharmacy practice project on the historical aspects of pharmacy delivered a presentation about the history of pharmacy in Malta with particular reference to the dispensing equipment and dispensing benches used in pharmacies in earlier times.

The bench is a very valuable addition to the collection of medicine containers and equipment used in the preparation and dispensing of medicine compiled by Seychell in 2010. Seychell's study forms part of a research programme in the Department on the historical aspects of the pharmacy profession in Malta which included studies carried out by Zerafa (1991), Borg (1998), Grech (2002) and Abela (2010) as part of their undergraduate and postgraduate studies.

CONTENTS

EDITORIAL

Two years have now elapsed since the Minister for Health Dr Joe Cassar during the Annual Pharmacy Symposium mentioned the need for pharmacy practice in Malta to evolve by considering formalising pharmacist prescribing while ensuring a safe, timely and efficient service to Maltese society.

A number of other countries including the United Kingdom have taken the subject of Pharmacist Prescribing very seriously and the concept is now established on a firm basis resulting in an evidence-based improvement in the rational use of medicines. The Department of Pharmacy at the University of Malta has along the years evolved its curriculum. This upgrading of the curriculum has taken into consideration that this present generation of students will be in a position to take up the organised function of prescribing of medicines effectively rendering a safe and rational service.

The Malta Pharmaceutical Association (MPhA), a pharmaceutical society which looks into professional matters without the shackles of a trade union, may devote attention to this subject with greater vigour. The Association having supported since its conception the successful implementation of the MPharm degree, having also supported the addition of Mathematics at Intermediate level as a special entry requirement to the course of pharmacy, should now focus on the introduction of pharmacist prescribing. The course of pharmacy at the University of Malta is at all times kept at the required top notch standards and new graduates can take up present day and future roles both in community pharmacy, hospital services and the pharmaceutical industry with confidence.

The articles dealing with pharmacoeconomic aspects of pharmacy published in this journal indicate clearly that pharmacy needs to evolve and pharmacists prescribing rights, if applied intelligently, may in many cases improve the quality of prescriptions especially in the scenario of the Pharmacy Of Your Choice (POYC) scheme. Pharmacist prescribing undertaken in collaboration with physicians may enhance a more rational pharmacoeconomic drug regimen such as by swapping to a less expensive generic product in certain cases and may lead to the rationalisation of medicines through a medicines review exercise particularly for those patients who are managed by a number of separate specialist clinics. Such scenarios may be a good start to pilot a project in pharmacist prescribing.

Tanya Formosa, Gillian Soler and Yvette Azzopardi working under the supervision of Dr Maurice Zarb Adami looked at pharmacoeconomic aspects which relate to costs of medicines involved in establishing their price, the POYC and the perception of generic medicine use. Doris Baldacchino has shown how the pharmacist could contribute to safer use of NSAIDs. She worked under the direction of Professor Lilian Azzopardi and her work was published as a book by Lambert Academic Publishing, a leading German publishing house of academic research. The book is entitled The Use of NSAIDs and Patient Safety.

While the profession of pharmacy makes these strides forward especially in the areas of pharmaceutical care and clinical pharmacy the contribution of pharmacists to the pharmaceutical industry is also providing significant stimulus to the development of the pharmaceutical industry in Malta. Pharmacists play a key role in all areas of the pharmaceutical industry and are recognised to show excellence in regulatory affairs aspects. The two articles in Standard Operating Procedures (SOPs) by Simon Serge and Enas Mansor are evidence of the depth and breadth covered by pharmacists in this area. Simon Serge and Enas Mansor carried out their research under my supervision.

The impact of pharmacy education on young students is the key to the future evolvement of pharmacy. The Malta Pharmaceutical Students' Association (MPSA) empowers the students in encouraging them to improve their communication skills – a tool indispensable in evolving from good dispensers to excellent prescribers. The MPSA helps to implement formal education for future pharmacists. A casual look at the students' contribution shows the versatility of pharmacy education. Areas of voluntary active participation by pharmacy students include Mental Health, HIV/AIDS and Dementia. Pharmacy students organised blood donation sessions, Ask your Pharmacist and Know Your Medicines campaigns. The MPSA provided skills training courses with emphasis on communication. The pharmacy students and the staff of the department of pharmacy as well as the pharmacists working in various areas are to be congratulated for the team work which is continuously going on to the benefit of the pharmacy profession.

The Editorial Board would like to recognise the support provided by Actavis sponsors of this journal without whose contribution, it would not have been possible to achieve such a fruitful and rewarding publication.

Professor Anthony Serracino-Inglott

Reference Pricing for Pharmaceuticals: A Policy Perspective

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Abstract

Objective To analyse the introduction of reference pricing systems for pharmaceuticals in Malta, their effectiveness and adequacy to-date, and to propose possible improvements.

Method A study on 18 interviewees associated with pharmaceutical and economical pricing policies was performed. A literature review analysis of the local published media regarding the subject was also undertaken to confirm personal interpretations given and to bridge information gaps.

Key Findings There are two separate reference pricing systems in place; one for the private and another for the public health sector, operating via different economic mechanisms. Reasons for resorting to such systems centred around the lack of access and affordability of medicines. This situation had emanated from an inefficient business environment, lack of proper government regulation and management and an imbalance of power between medicines' suppliers, consumers and patients. A total of 18 respondents participated in the study. Two out of the 18 respondents considered the system successful, 6 deemed it unsuccessful and 7 thought the system had limited success. Results show that reference pricing may be regarded as a fair and simple means of monitoring and comparing local medicine prices with those of other countries. Reference pricing systems do not cater for many of the problems associated with such pricing.

Conclusions Reference pricing cannot be taken out of context in an integrated pharmaceutical system. The situation must be tackled holistically to address the real issues hindering the establishment of fair prices of medicines for Maltese consumers. Policy systems should be constructed in accordance with Malta's particular political, economic and cultural requirements in line with local and European Union (EU) legislation.

Keywords pharmacoeconomics, reference pricing, pharmaceutical pricing policy.

Introduction

Health policy systems represent a challenge for every government due to existing competing interests. Governments must safeguard public health, secure patient access to safe and effective medicines and contain the health expenditure within the required limits. Industrial policy obligations must also be considered.

Economic sustainability measures can be directed towards one or more of the four stakeholders in the health system, the four 'P's, namely the pharmaceutical industry, physicians, pharmacists and patients. Reference pricing is one such measure aimed at the pharmaceutical industry where a maximum level of financing is established for a drug in comparison with a group of drugs that are considered therapeutically equivalent.[1]

The aims of this study were to explore circumstances that led to the introduction of reference pricing for pharmaceuticals in Malta, to observe systems used locally and to observe how these compare with mechanisms in other EU countries. The level of effectiveness and adequacy of these systems since their implementation and possible ways of how they may be improved were also noted.

Method

Although pricing of medicines in Malta is a much discussed topic locally, documented information in the context of the local scenario is very scarce. To this effect, a qualitative study was carried out to obtain a detailed description of the subject matter. Data was then complemented with thematic frameworks, charting and mapping data to make it as illustratable as possible.

A study on 18 interviewees associated with pharmaceutical and economical policies was performed. The population considered consisted of relevant local and European politicians, high public service officials in their respective government departments, local pharmaceutical industry representatives, academics and experts in pharmacy and economics and relevant opinionists.

A literature review of 66 articles from the local online published media on the subject matter was additionally carried out to confirm personal interpretations given by such interviewees and fill any information gaps.

The research aims were translated into 7 interview questions, piloted and asked to each respondent. Similar opinions and arguments in different interviews were grouped together and quantified. Newspaper articles were printed, classified and important events were listed in chronological order. These were then discussed in relation to the relevant interview questions. Data from both studies was then analysed.

The number of countries used for referencing ranged from 4 to 27 Member States. Malta uses 12 reference countries from the EU and the European Economic Area (EEA) for the private sector medicines and in the public sector system eleven EU countries are used.
Choice of reference countries was based either on geopolitical factors, including similar size, population and geographical positions and historical, political and trade links or on economical factors such as similar Gross Domestic Product (GDP) values or baskets of reference countries from low-priced, medium-priced and high-priced countries. Malta uses 2 different economical systems. A group of countries within 20% points of Malta's GDP per capita in Purchasing Power Standards is used for the public reference pricing system whilst a basket of reference pricing mechanism of high, medium and low-priced countries is used for the private sector system with the selected countries being those where most medicines are imported from and the relevant price databases were available.
The price set varied between ex-factory, wholesale and retail prices. In Malta the two systems use different pricing policies. The private sector system reference price is the average retail price excluding VAT calculated by first taking the average retail price of each category then taking an average of these averages. The public sector reference price is taken as the lowest price from the average wholesale price of the basket of eleven countries, the UK NHS price, Government Health Procurement Services price, where applicable, and the Marketing Authorisation Holder price.

Table 1: Differences in calculating reference price between local system and other EU countries[2,3]

Results

The eventuality of an increase in the price of medicines had been discussed prior to Malta's accession to the EU but no mechanism was in place to prevent excessive increases in prices or to curtail increases once they occurred, resulting in reports of medicines' prices to be considerably higher than other EU Member States' a few years down the line.[4]

The situation could not be contained owing to several factors emanating from the three stakeholders in the economic system namely inefficient business environment and lack of proper regulation and management on the part of government; market failure due to uncompetitive practices by medicine importers and lack of a well informed and empowered consumer society. Reference pricing was introduced as a solution to this problem.

There are essentially 2 systems of reference pricing in Malta; one for the private market, on a voluntary basis, introduced in February 2008 and another for the public sector medicines that is obligatory, established in January 2010. The private sector mechanism applies to all medicines on the private market whilst the public service system is applicable only to new medicines introduced on the government formulary.

Both systems use external reference pricing where prices of the drug manufactured by the same company are compared across a number of countries, also called 'cross-country referencing'. There is however also some degree of internal reference pricing within the government health system where new medicines introduced on the government formulary are compared to others within the same therapeutic group already on the formulary.

Comparing these systems together and to those in different EU countries showed that the mechanism of calculating the reference price differed in three main aspects (Table 1).

Out of the 18 respondents interviewed 2 thought the system was a success, 6 thought it was not successful and 7 stated that it had limited success (Figure 1).

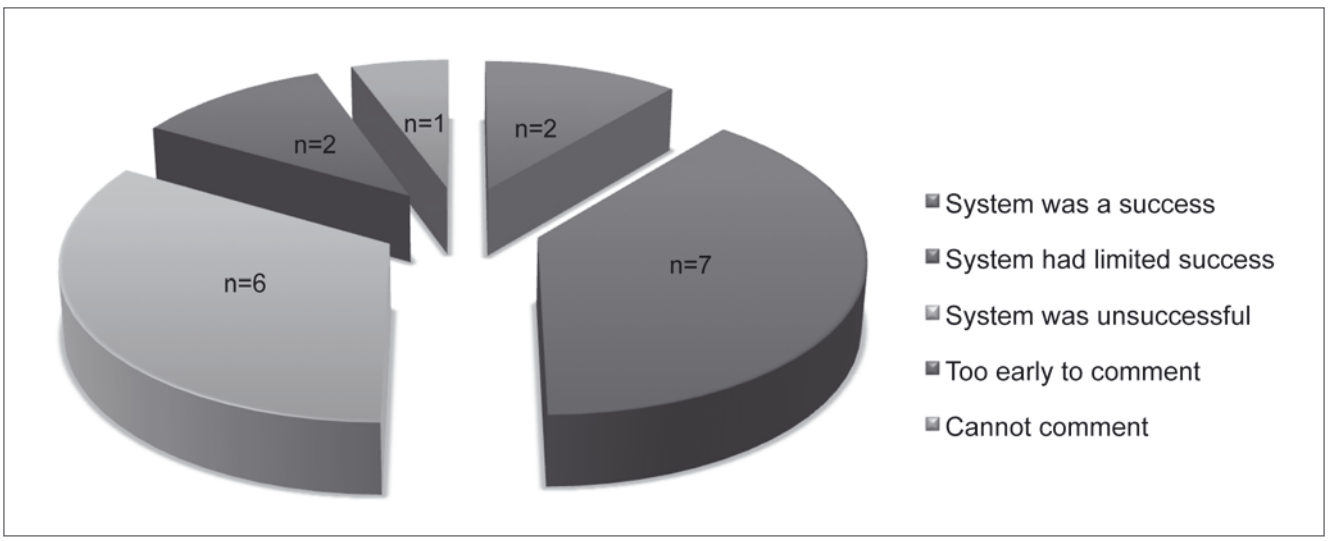

Figure 1: Success of local reference pricing system (N=18)

Discussion

The advantages of reference pricing are that it constitutes a comparative mechanism where prices of medicines in Malta could be compared to those in other EU countries, it does not require an intensive or elaborate infrastructure to operate, it is a good compromise between government and other stakeholders, it is in line with EU legislation, it has been in use for up to 20 years nearly all over Europe and in other non-European countries with some measure of success, it can reduce inflation and government expenditure and it is considered as being better that cost-plus pricing as well as bulk buying practices used in the past.

Reference pricing however also has its limitations such as it may be an arbitrary and artificial concept and cannot be considered a fair price. Many problems associated with pricing of medicines in Malta are not being catered for by this mechanism such as differential pricing policies set by mother companies abroad, doctors' prescribing habits and pro-British tendencies towards branded products, lack of reimbursement systems that are usually considered part and parcel with reference pricing, restricted medicinal entitlement and limited government formulary, inefficient and ineffective government purchasing systems, insufficient competition leading to manipulation in the private market, small volumes and low salaries compared to counterparts in other EU states, high government induced costs such as transport, utility, licensing fees and lack of legal back up, adequate regulation and enforcement, insufficient investment in innovation, limited local industry and high level of importation, inadequately informed and socially and politically disadvantaged consumers.

Regarding the future of reference pricing in Malta the way forward could be divided into short, medium and long-term measures. Short-term measures include acknowledgement of problems affecting the pharmaceutical field and addressing them in a responsible manner to benefit all parties concerned. Through consultation processes and tools available such as government departments and authorities, fora are created for objective information dissemination about important matters such as medicines that are expensive yet essential to the most vulnerable groups of society. Reengineering of procurement procedures to become efficient and effective, curtailing of abuses in the system such as medicinal entitlement, pilfering and expired goods, serious investment in EU standard warehousing and IT systems, better management of the government formulary and more rational use of medicines ensured.

Government-induced costs are to be analysed and revised. Through competent authorities, barriers to trade such as cartels and price fixing and issues constituting such barriers should be tackled allowing true market forces to act in the longer term. Possible measures include liberalisation of pharmacies, sale of over-the-counter medications from other outlets, competition within retail pharmacies on non-medicinals, introduction of full-line wholesalers and therapeutic class referencing and tendering. Measures to actively promote free competition such as incentives to local industry, parallel importation and prescription and dispensing of generics could be also addressed.

Medium-term measures address future possible courses to follow and include fine-tuning the current system, introducing more comprehensive changes to address any unmet needs, adding more pricing policies or completely replacing the current system by a better one. Options should be studied by government and stakeholders and actions for implementation taken accordingly.

Long-term measures aim at considering equity, accessibility and sustainability of government health services. The current restricted system of entitlement to free medicines would have to be reviewed considering options such as introducing new chronic conditions in stages or opting for more drastic yet more sustainable measures such as reimbursement schemes considering also the most socially disadvantaged. Other wider perspective options include the application of cost-benefit analysis or the concept of pay-back mechanisms based on outcome success.

Conclusion

Reference pricing systems cannot be considered in a vacuum out of context of a holistic and integrated pharmaceutical system. Lessons must be learnt from the past where systems such as medicines registration and the Pharmacy of Your Choice Scheme could have benefited more from better planning prior to their implementation. Economic and social impact assessments should be resorted to and results used to set up the necessary legislation, clear strategies and relevant policies, guidelines and protocols in line with set priorities to benefit all those parties involved. The system should be in line with EU regulations and in the spirit of such EU directives, cater for the specific economical, social, and political factors of this country.

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THE FINANCIAL IMPACT OF THE PHARMACY OF YOUR CHOICE SCHEME ON COMMUNITY PHARMACIES

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Abstract

Objective To give an insight into the financial impact of the Pharmacy Of Your Choice (POYC) scheme on community pharmacies.

Method A time and motion study was carried out in three community pharmacies that are enrolled in the POYC scheme to provide information on the time allocated to the various activities pertaining to the scheme. Two different methods were used to calculate the costs incurred to implement the system in the three pharmacies.

Key findings The direct costs that are related to the implementation of the POYC scheme are reasonably close to the government's remuneration.

Conclusion Expenses incurred due to the POYC scheme run into thousands of Euro every year. Consequently, the POYC scheme does not seem to be very profitable for the community pharmacies where it has been implemented. It is highly recommended that the remuneration by the government ought to be revised.

Keywords Pharmacy of Your Choice Scheme, pharmacist remuneration, financial impact.

Introduction

The Pharmacy of Your Choice (POYC) scheme was introduced in 2008. The main aim of the POYC scheme was to reduce the long queues at the Health Centre Government Dispensaries. Moreover, monitoring of patients by the community pharmacists can be improved since they ensure that the medicines prescribed are being administered correctly and more patient advice is given on a one-to-one basis when compared to the previous system.[1] As a result of this POYC scheme, there is also a decrease in wastage because patients are not given medications if they are not required, even though they are entitled to them.[2]

The main problem associated with the POYC scheme is the large number of medicines that are out of stock.[2] This is causing unnecessary stress on the pharmacists and patients. The POYC scheme has also affected the daily running of the community pharmacies where it has been introduced. Due to the increased work load, some pharmacy owners had to employ additional staff. The community pharmacists who are involved in the implementation of the POYC scheme now have an increased work load and therefore do not provide their patients with the same service as before the initiation of the POYC scheme.[3]

This study aimed to identify and quantify the activities pertaining to the POYC scheme that are normally undertaken by the three chosen community pharmacies, together with any expenses incurred. The reimbursement by the government is consequently questioned to assess whether it is adequate.

Method

Three pharmacies were identified for the purpose of this study. They were named Pharmacy A, Pharmacy B and Pharmacy C for the sake of anonymity. When the study was carried out, the pharmacies had approximately 200, 500 and 1,500 registered patients respectively.

A time and motion study was selected for the purpose of this research since it was found that this qualitative approach would provide the best information about the research question.[4] The participants in the study were pharmacists who are directly involved in the POYC scheme.

Two templates, which included all the activities related to the POYC scheme, were designed. One template dealt with the back office work that is involved in the POYC scheme, whereas the other listed all the activities that revolve around the patient. Both templates were validated and reliability tests were performed. These tests confirmed the accuracy and precision of the templates, consequently making them valid for future studies.

The time spent on POYC activities in the three pharmacies was quantified for a period of six working days in each pharmacy. The duration of the study was one week to take into consideration both busy and quiet days, to minimise unnecessary bias.

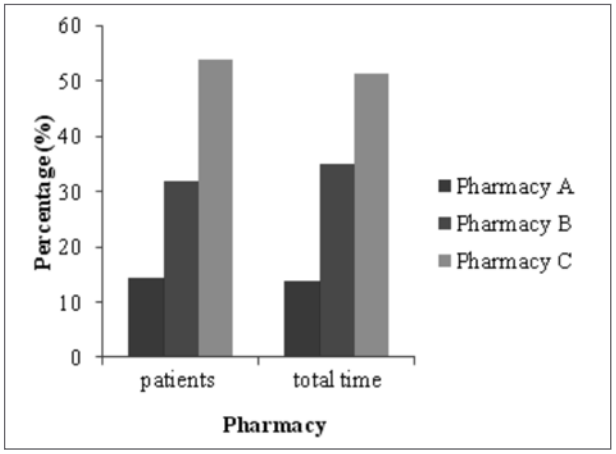

Figure 1: Percentages of patients and the total time spent in the three pharmacies

All the various costs and benefits incurred by the three pharmacies in relation to the POYC scheme were identified and quantified. The time spent on POYC-related activities was converted into monetary terms and the total costs incurred to implement this scheme were identified. These values were subsequently compared to the income from the government to determine whether the latter outweighs the costs.

Two different methods were used to calculate the direct costs incurred to implement the system in the three chosen pharmacies. Method 1 was based on the total time taken on all the activities pertaining to the POYC scheme. This was applied to the three individual pharmacies. The second method was based on the average time taken per patient per pharmacy and the time taken to do back office work was separated from the time taken to deal with the patients.

Results

A total of 598 patients were involved in the study; 86 patients were from Pharmacy A, 190 patients were from Pharmacy B and 322 patients were from Pharmacy C. The total time that was attributed to all POYC-related activities in the three pharmacies was 2900 minutes. About 14% of the total time was spent in Pharmacy A, 35% in Pharmacy B and about 51% in Pharmacy C (Figure 1).

The weighted average time of each activity relating to the POYC scheme was calculated. The results show that some tasks take longer to complete than others. The frequency of most of the tasks occurring in the individual pharmacies varied considerably since the pharmacies had a different number of patients registered with the POYC scheme.

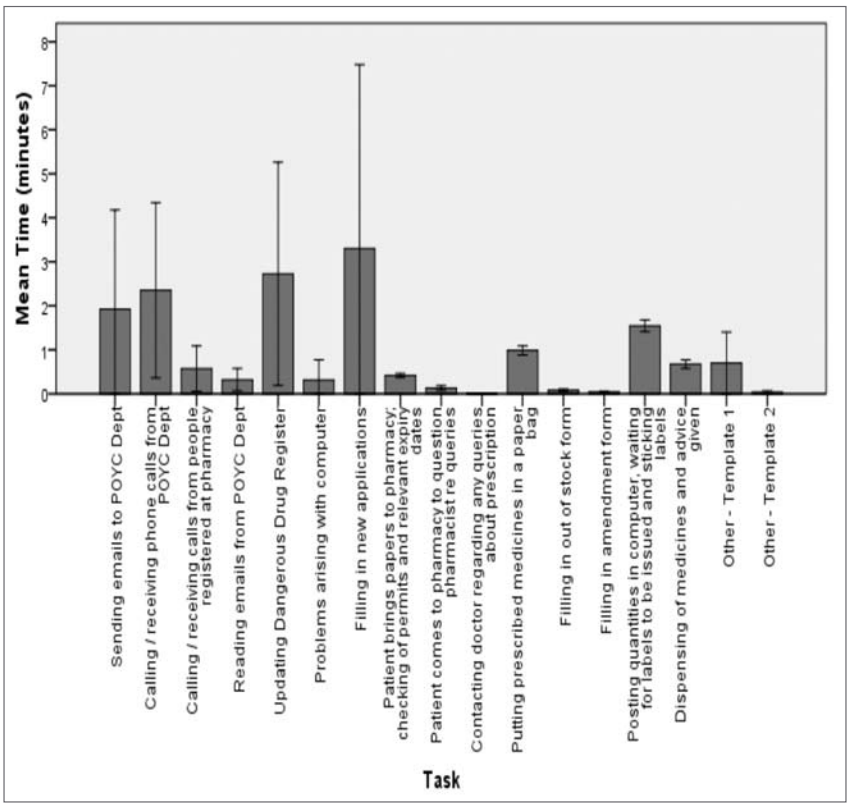

Figure 2: Mean time (minutes) of each task

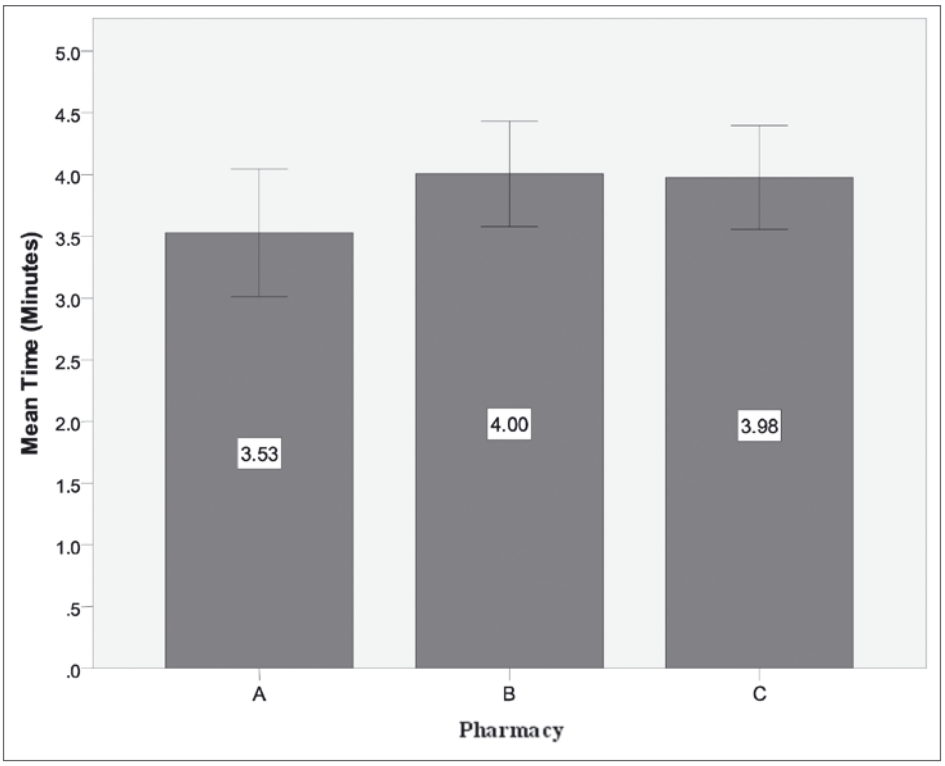

Figure 3: Mean time per patient in three pharmacies

The resulting p value of 0.000 indicates that the mean durations to perform the different tasks vary significantly. If confidence intervals are disjoint, i.e. they do not overlap, this indicates that the mean durations differ significantly. The fact that the confidence intervals do not overlap, explains why the One - Way ANOVA test yields a significant result ($p<0.05$) (Figure 2).

The average time per patient was 3.53 minutes for Pharmacy A, 4 minutes for Pharmacy B and 3.98 minutes for Pharmacy C. The p value, 0.509, exceeds the 0.05 level of significance and indicates that the mean duration per patient do not differ significantly between the three pharmacies. The fact that the three confidence intervals overlap explains why the One - Way ANOVA Test yields a result which is not significant ($p>0.05$) (Figure 3).

The cost models for both methods are shown in Table 1. Overheads are not included.

Discussion

From this study, it is evident that the POYC scheme involves several activities that are related to back office work. These take up a relatively large proportion of the total time that is attributable to the POYC scheme. Nevertheless, such activities are necessary and their importance cannot be underestimated. Back office work and other activities that do not directly involve the patient, such as inputting the dispensed quantities of medication in the computer can be carried out by staff, other than the pharmacist. In this way, more time is dedicated to the patient and to pharmaceutical care.

The overheads for each pharmacy have increased since the start of the POYC scheme. This is particularly so for Pharmacy B and C which have a large number of registered patients. Such overheads include telephone calls, electricity consumption, floor space and an increased

PHARMACY	METHOD 1 (€)	METHOD 2 (€)	REMUNERATION BY THE GOVERNMENT (€)
A	4,991.48	2,203	4,660
B	12,772.76	6,115	11,650
C	18,691.92	11,261	34,950

Table 1: Cost models for the pharmacies and comparison with the remuneration by the Government

number of employed staff, incurring extra expenses on wages. Additional costs which include intangible costs, maintenance costs and opportunity costs must also be considered.

In Method 2, it was assumed that each patient goes to the pharmacy to collect the medicines pertaining to the POYC scheme six times a year. This excludes the prescriptions for warfarin and controlled drugs, changes in treatment and out of stock forms. This is why Method 2 gave different results from those of Method 1.

The remuneration from the government may need to be questioned from different aspects. The remuneration for the patients who receive several medications is the same as for those who only take one type of medication. Furthermore, a patient should theoretically go to the community pharmacy six times a year to collect the medicines that are required from the POYC scheme since a two-month supply is dispensed every time. However, due to the prescriptions for warfarin and controlled drugs, out of stock forms and changes in medication, a large number of patients present at the pharmacy several times a year, at times on a weekly basis, thus adversely impinging on the time-factor. The results obtained from Method 2 indicate that the POYC scheme would be more profitable for the pharmacies if such prescriptions were not included. Since this is not possible and it is not in the patients' interests, the government may consider revisiting the remuneration to the pharmacies, thus making the POYC scheme more worthwhile and reinforcing the incentive for pharmacists.

The main limitation of this study is that the research was conducted in a very short time due to the limited amount of time that was available. Consequently, a small sample size was used. In fact, only three community pharmacies were visited. Generalisations to other community pharmacies that have implemented the POYC scheme are difficult to make. A wider spectrum covering a larger sample spread over a longer period of time, would give a clearer indication of the actual situation.

Most of the overheads, such as the intangible costs and benefits, were only mentioned and were not quantified. Future research should attempt to identify and quantify these costs and benefits. Such studies ought to assess in detail the impact of the POYC scheme on the quality of life of the pharmacist who is involved in its daily implementation.

Conclusion

Despite the fact that the study was carried out over a short period of time, the use of a case study report allows the investigator to throw some light on the issues being explored. While there is no attempt to generalise the results to all pharmacies and pharmacists in the POYC scheme, it is hoped that this study will raise questions about the POYC scheme and open up a forum of discussion.

Expenses incurred due to the system run into thousands of Euros every year. Consequently, not much money is to be made through implementing the POYC scheme. This, however, should not be the case. The service given by the community pharmacies should be adequately compensated for, thus making the implementation of the POYC scheme a worthwhile investment that is rewarding for all stakeholders.

This study was carried out when the remuneration by the government was €23.30 per patient per year. In the future, such payment will increase to €25.63 per patient per year, and later even to €27.96 per patient per year. This however does not necessarily result in larger profits as the incurred costs due to the POYC scheme may also increase. Furthermore, such costs may increase to the extent that the community pharmacies will be worse off than the current scenario. It is therefore recommended that such studies are done and analysed on a regular basis.

Discussions on a broader level regarding the proper implementation of the POYC scheme can be organised. In conducting these workshops, the inclusion of stakeholders, particularly pharmacists who are operating the system in the pharmacies is recommended so that an interactive dialogue will act as an ongoing process to the continued development of the POYC scheme.

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PUBLIC PERCEPTION OF GENERIC PHARMACEUTICALS IN MALTA

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Abstract

Objective To evaluate the perception of the Maltese general public on generic medicinal products.

Method A self-administered questionnaire was compiled and distributed to a sample of the general public. Data collected from the questionnaires was analysed using SPSS® version 19.

Key findings Five hundred and forty four questionnaires were completed. Fifty one percent of the respondents did not know the meaning of the term 'generic medicinal product' and 47% of the respondents became familiar with the term through the questionnaire.

Conclusion Improved communication amongst patients and healthcare professionals on the correct meaning of generic medicinal products and their medical and financial implications is required.

Keywords public perception, generic medicinal product, originator medicinal product.

Introduction

A generic medicinal product is defined as that product which does not have patent protection or which is a chemically identical copy of an originator product whose patent has expired and can now be manufactured by any company interested in doing so. A generic medicinal product must also be bioequivalent to the originator product and must be produced within strict Good Manufacturing Practice limits. Article 10 paragraph 2 (b) of Directive 2001/83/EC defines a 'generic medicinal product' as "a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies."[1]

Use of generic products contributes to the sustainability of a cost-effective healthcare system where the generic medicinal product is not only cheaper and more affordable than the originator product; it also has the same indications and effects and is interchangeable with the originator product. The availability of generic medicines is playing a key role in healthcare and their importance in the developed world is steadily increasing.

Prescribers in Malta are not required by law to prescribe drugs by the International Non-Proprietary Name (INN). On the 14th September 2006, The Times of Malta published an article entitled 'Proposal to ban prescription of brand medicines turned down' which described the suggestion of an amendment to the Medicines Act, whereby doctors would be obliged by law to prescribe by the INN.[2] This would allow greater exposure to generic medicines, which offer a cheaper alternative to their branded counterpart, as well as a greater acceptance thereof by the public since no substitution by the pharmacist needs to be undertaken. The patient would consequently, be getting exactly what is prescribed requiring no explanation with respect to product substitution. This suggestion was, however, turned down by the government, leaving doctors with the capacity to choose whether to prescribe by trade name. Still, pharmacists can legally offer generic alternatives to medicines prescribed according to Article 80 of the Medicines Act 2003 unless the doctor specifically indicates on the prescription that no substitution is allowed.[3,4]

The struggle between originator and generic medicinal products is ongoing, with both sides constantly presenting their advantages and disadvantages. In this dispute however, one must not lose sight of who the ultimate winner or loser is: The patient. The aim of the study was to evaluate the perception of the Maltese public on generic medicinal products.

Method

A self-administered questionnaire for the general public was developed for data collection. The questionnaire was validated in terms of layout, structure and content and tested for reliability through a pilot study. A group of 19

individuals, including an English language teacher, lawyer, financial advisor, two general practitioners, podiatrist, 3 community pharmacists and 10 members of the general public were asked to complete the questionnaire twice within a two-week interval during the pilot study. Amendments to the questionnaire were made and a final version of the questionnaire was developed.

The questionnaire consisted of multiple choice close-ended questions and an open-ended question and was available in both English and Maltese language. The questionnaire was divided into two sections: Patient demographic data (age, occupation and level of education) and perception of generic medications. Complete anonymity was ensured. The questionnaire was distributed via electronic mail with a covering letter to all available contacts of the researcher. The recipients were asked to fill in the questionnaire and forward it to all their own contacts. Data collection was undertaken over a two-month period.

The data collected was inputted into a specifically designed spreadsheet, filtered and then analysed using SPSS® version 19. Descriptive statistics were undertaken and p-values less than 0.05 were considered to be statistically significant. The association between the categorical variables in the study (knowledge of generics and swapping to a generic in an out of stock scenario; knowledge of generics and keeping the generic alternative as opposed to going back to the originator product) was assessed by the chi-square test for qualitative variables. Since this type of analysis is inferring from a part (the sample) to a whole (the population), the margin of error was also calculated (for this sample size the margin of error is 4.2%), so that the safety of generalisation from said part to whole, could be quantified. The reliability of such a generalisation is also dependent on how well the sample is mirroring the whole population.[5]

Results

Five hundred and seventy seven questionnaires were collected. However, 33 questionnaires were deemed to be invalid and were excluded from the study. The total sample size for the study was 544 participants.

Fifty one percent of the participants did not know the meaning of the term generic medicinal product. For those participants who responded 'No' to the question 'Do you know what the term generic medicines means?', a brief description was given together with an example of ibuprofen, with Nurofen® as the originator medicine and Irfen® as the generic medicine. When asked 'Where did you first get to know about generic medicines?' most of the participants (47%) responded that they became familiar with the term through the questionnaire (Figure 1).

Although 51% of the respondents were not initially familiar with the term 'generic medicines', once a description and an example were provided, 58% of these respondents acknowledged using generic medicines in the past.

When asked what they would do if a particular medication was out of stock, most of the consumers (59%) would immediately switch to the generic equivalent however 37% of the respondents would go round various community pharmacies to check whether any left-over stock is available. Three percent of the respondents would prefer to remain with no medication until the originator is back in stock rather than switch to a generic. One percent of the respondents did not respond to this question.

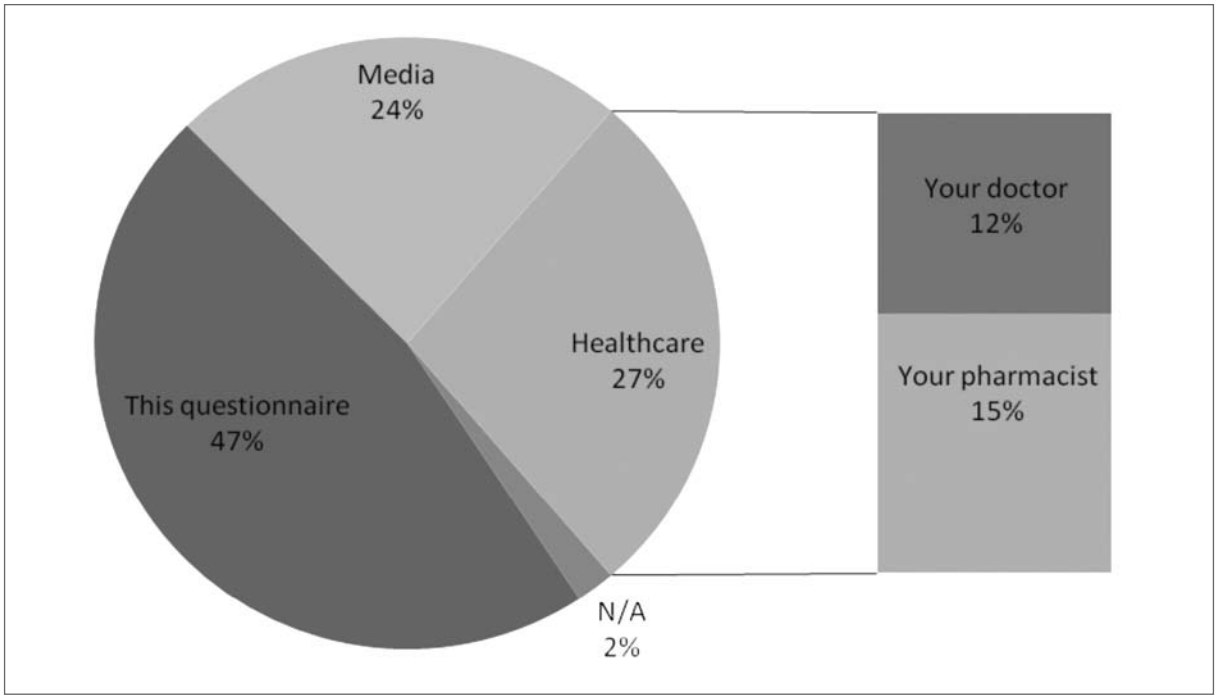

Figure 1: Information obtained about generic medicines (N=544)

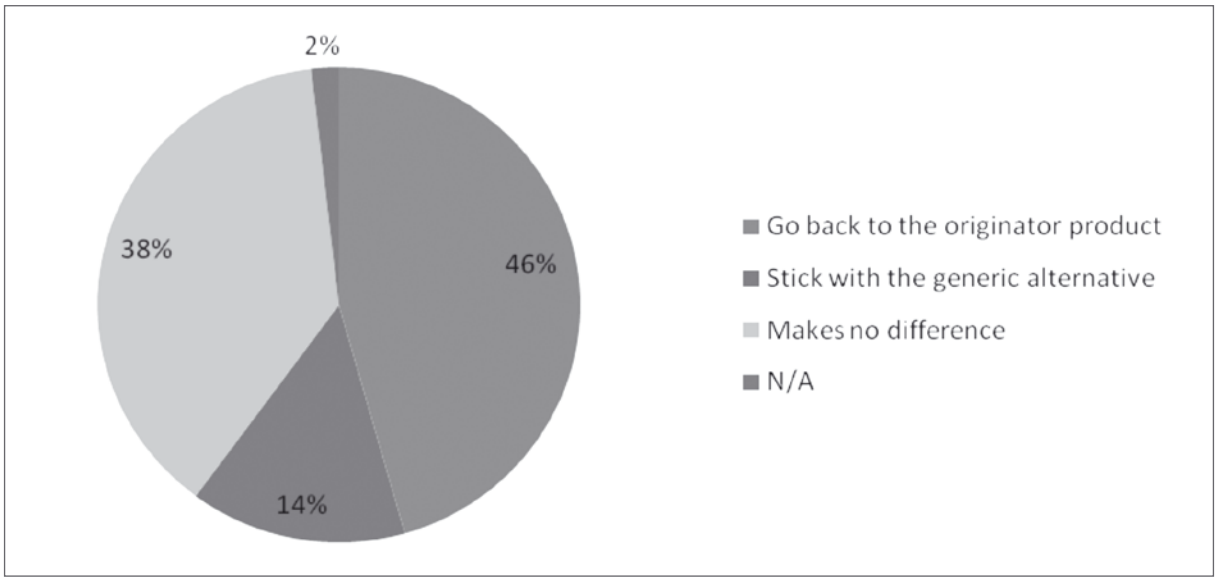

Figure 2: Practice when originator product is re-available (N=544)

When analysed statistically, a higher proportion of respondents who were familiar with the term 'generic medicines' would switch to a generic product immediately if the originator medicine is out of stock and conversely a higher proportion of those who were not familiar with the term would prefer to remain without any medication or go around several pharmacies to check for any left-over stock rather than switch to a generic medicine (p=0.000). Most of the respondents (46%) would switch back to the originator product once it is back in stock (Figure 2).

When analysed statistically, there is an association between the knowledge of the term 'generic medicines' and whether the consumer would go back to the originator or keep taking the generic alternative. Results show that from the percentage of respondents who were familiar with the term 'generic medicines' a higher proportion of respondents will keep taking the generic alternative even when the originator product is back in stock compared to the respondents who were not familiar with the term (p=0.002).

Discussion

The knowledge of generic medicines amongst the Maltese population compares favourably with a study carried out in Jamaica in 2006 where 64% of the respondents had either never heard of the term or were familiar with it but not sure what it meant.[6] Similarly, in studies carried out in Germany in 2005 and in Japan in 2007 and 2008, 63% and 68% of consumers respectively were familiar with the term 'generic medicines'.[7,8]

The healthcare professional has historically been unofficially entrusted with the role of educator when it comes to medicine and health. Taking this into account, the public was asked a question with respect to their source of knowledge concerning generic medicines. The majority of respondents in this study learnt about generic medicines from the explanation provided in the questionnaire and whilst more respondents acquired knowledge of the term from healthcare professionals compared to the media, the difference is marginal. When asked what they would do if a particular medication was out of stock, most of the consumers in this study would immediately switch to the generic equivalent or would go round various community pharmacies to check whether any left-over stock is available. What is worrying is that a percentage of respondents, albeit a small one (3%) would rather stay without their medication until the originator is back in stock. How safe this is, is understandably debatable, and both latter figures may reflect the effects of a lack of knowledge of what generic medicines truly are. This can be further highlighted in the responses to the next question where most of the respondents in this study would revert back to the originator product when it is back in stock and not stick to the generic alternative.

Conclusion

In Malta, the generics market is still in its infancy and as can be seen from the results obtained in the present study, the Maltese population needs more awareness with respect to generic medicines. This can take the form of educational campaigns which seem to be lacking in this field. Such campaigns may be targeted towards the public as well as healthcare professionals, who may then be better equipped and confident to educate their patients. The public awareness campaign may also include specific information to provide correct understanding by consumers of generic substitution. The perception of substandard medicines and generic medicines being interchangeable terms comes from a time before the 1996 World Trade Organisation agreement which provided the 20-year patent protection for pharmaceuticals. Some argue that "the only consistent practical difference between generic and patented drugs is their price".[9]

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USE OF NSAIDs AND PATIENT SAFETY

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Abstract

Objective To assess the pattern of use of non-steroidal anti-inflammatory drugs (NSAIDs) and propose methods whereby pharmacists can help to improve patient safety when these drugs are used.

Method A psychometrically-evaluated questionnaire was administered to 261 patients aged 18 and over who visited 13 different community pharmacies, 1 from each electoral district in Malta and Gozo, chosen by stratified random sampling. Information about the socio-demographic status, symptoms and disease states and the drugs taken in the past 6 months was collected. Analysis of data was carried out using Microsoft Office Excel 2007 and the Biomedical Data Package (BMDP) Software.

Key findings Results show a high prevalence of analgesic (>80% per district) and NSAID use (about 50% per district). The first drug of choice to relieve analgesia was paracetamol (67.1%) followed by diclofenac (37.2%). Ibuprofen was the fourth drug of choice (7.3%). About 65% of patients who took diclofenac stated that they self-prescribe the medication. Statistical analysis of data showed an association between the use of NSAIDs, musculoskeletal pain and menstrual pain (both p=0.010). A number of patients at risk of gastro-intestinal bleeds, cardiovascular events and those suffering from asthma reported taking NSAIDs occasionally. The presence of risks of drug interactions was identified with various drugs.

Conclusion NSAIDs are overused in Malta and are often administered indiscriminately. Pharmacist intervention could ensure the rational and safe use of NSAIDs. This could be achieved by having a shared protocol between pharmacists and prescribers for appropriate prescribing and dispensing and by identifying scenarios where pharmacist prescribing can be carried out to ensure that the analgesic used is appropriate for the individual patient.

Keywords NSAID use, patient safety, community pharmacists, physicians.

Introduction

Non-steroidal anti-inflammatory drugs (NSAIDs) are mostly used to relieve pain of musculoskeletal origin since they exhibit both analgesic and anti-inflammatory effect.[1] These drugs must be used with caution since they can cause serious adverse drug reactions that range from gastro-intestinal (GI) upsets and bleeding to cardiovascular events, damage to the kidneys and stroke.[2,3,4,5] NSAIDs may interact with various other drugs including anticoagulants[6], corticosteroids[7] and selective serotonin reuptake inhibitors[8] where in all these cases the risk of GI bleeding increases. They also reduce the effect of antihypertensive drugs since they can cause fluid retention.[9] Patients on angiotensin-converting enzyme inhibitors will be at a greater risk of kidney damage[10] if they take NSAIDs concurrently.

Various NSAIDs are available in Malta; however no national statistics exist on the actual quantities of different NSAIDs imported locally. No protocols on the use of NSAIDs in specific patients are established in primary care.

The aims of this study were to assess the pattern of NSAID use in the community pharmacy setting, to identify gaps leading to improper use of these drugs and to propose measures to help improve patient safety in relation to NSAIDs administration.

Method

The study was approved by the University Research Ethics Committee. An extensive literature review on the use and safety of NSAIDs was undertaken. A questionnaire was formulated, adapted from similar work done in Italy in 2004.[11] The developed questionnaire was divided into 3 parts; socio-demographic information, symptoms suffered from over the past 6 months and drugs taken over the past 6 months, including corresponding information on these drugs, for example the route of administration, reasons for which the drugs in question were taken, interval and frequency of drug intake and the source of prescription. The questionnaire was validated and tested for reliability by statistical 'Kappa Testing'. The questionnaire was delivered in the form of an interview. An 'Inter-Rater Kappa Test' was performed to ensure that no bias was introduced by the interviewer during the interview.

The setting involved 13 pharmacies, 1 from each electoral district in Malta and Gozo chosen by stratified random, sampling. One afternoon was spent in each pharmacy to carry out the interviews. Subjects were recruited on a voluntary basis and with their informed consent. The collection of data was confidential and anonymous. Analysis of data was carried out using Microsoft Office Excel 2007 and the Biomedical Data Package (BMDP). Safe use of NSAIDs were identified from the reviewed literature.[1,2,12,13]

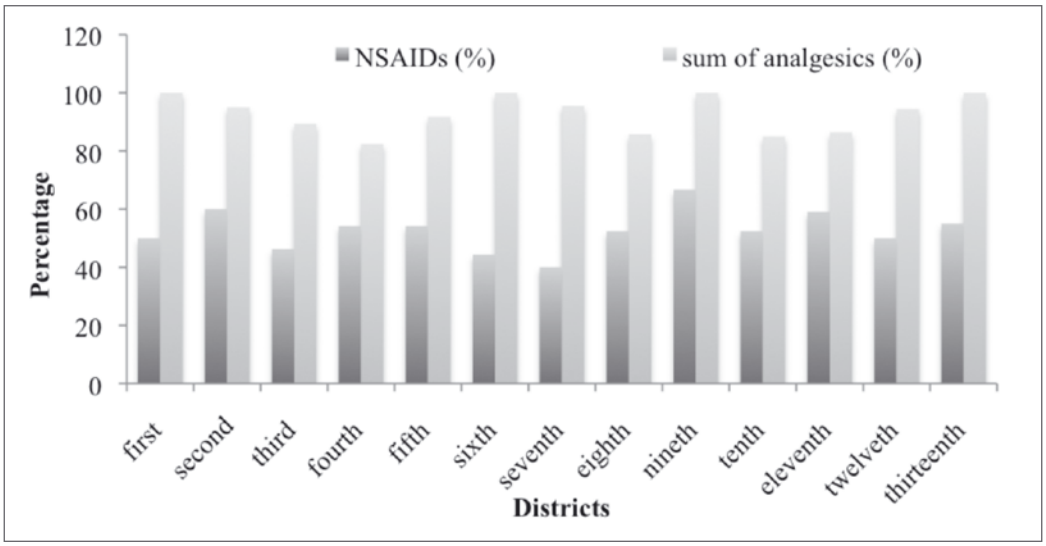

Figure 1: Frequency of different analgesics used by patients by district over the past six months (n=261)

Results

A total of 261 questionnaires were collected. Seventy one percent (n=186) of the respondents were female. The average age was 48 years and the range was 18-79 years. Both Kappa tests performed gave values of over 0.75 indicating reliability of the questionnaire.

Results show that during the study period, more than 80% (n=241) of patients per district had used analgesics for the past 6 months and about 50% (n=131) of these patients had been using NSAIDs (Figure 1).

About 78% of the NSAID users reported taking the drugs for over 6 months, 55% of these stated that they take the drugs every now and then and 65% stated that when they do take NSAIDs they take them only for a day or two.

Looking at the prevalence of NSAID use it was found that 9% more females than males make use of NSAIDs. It was established that 11% more of the younger generation administer NSAIDs when compared to the elderly. Both these facts were also reported in the Italian survey.[11]

When ranking analgesic use (Figure 2) it was found that the first drug of choice as an analgesic was paracetamol with a frequency of 67% (n=175), followed by diclofenac with 37% (n=97).

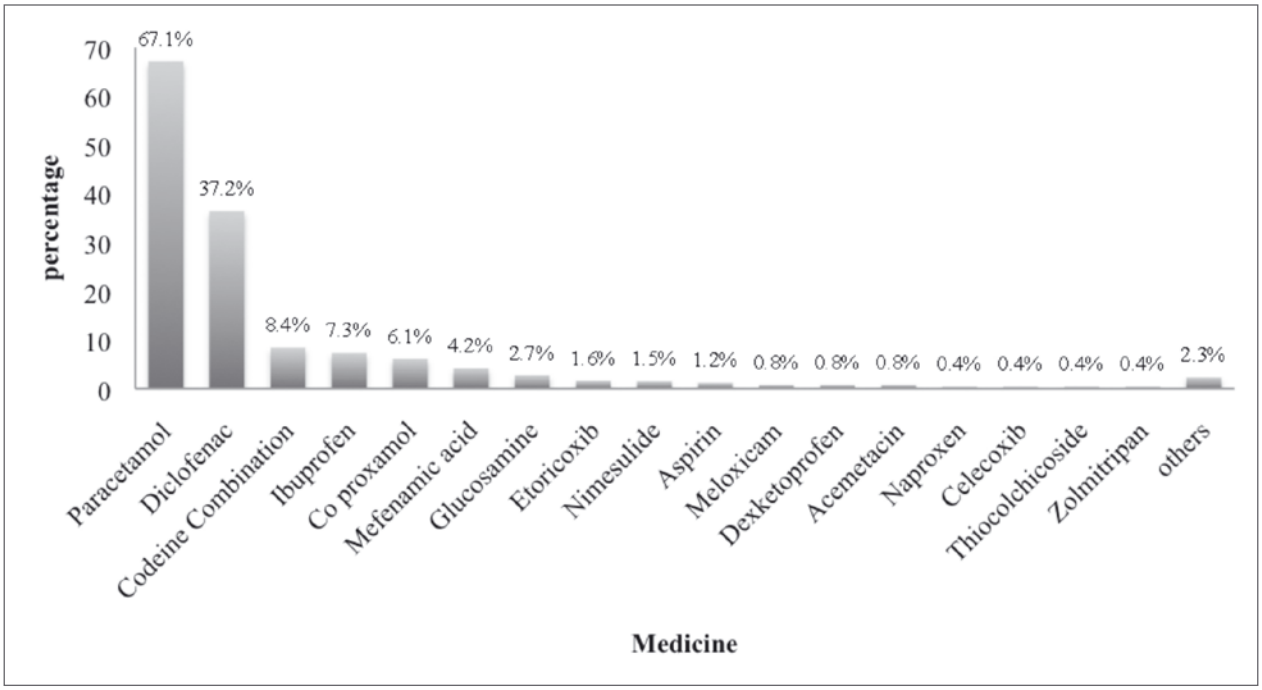

Figure 2: Ranking list of analgesics used in the study (n=261)

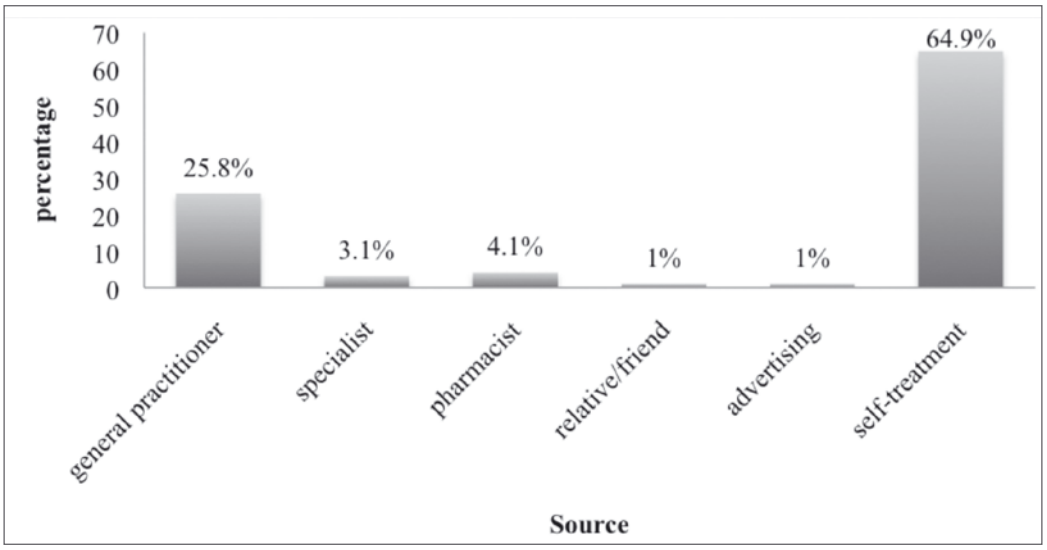

Figure 3: Source of diclofenac prescription and advice (n=97)

Ibuprofen was the fourth commonly used drug with 7% (n=19), aspirin was the tenth commonly used drug with 1% (n=3) and naproxen ranked in the fourteenth place with 0.4% (n=1). About 65% (n=63) of patients taking diclofenac admitted to self-prescribe the drug (Figure 3).

A statistical significant association was found between the use of NSAIDs and musculo-skeletal pain and the use of NSAIDs and menstrual pain (both p=0.010). Patients reported using NSAIDs mainly to treat back pain, sciatica, joint pain and menstrual pain.

Results show that 52% (n=34) of the patients suffering from GI symptoms, 47% (n=50) of the patients suffering from cardiovascular disorders, 35% (n=8) of the patients exhibiting respiratory disturbances and 43% (9) of those with diabetes reported taking NSAIDs. Risk of drug interactions was encountered in patients taking: anti-thrombotics (50%, n=12), the anti-hypertensive drugs including beta blockers, calcium channel blockers and alpha-adrenergic blockers (45%, n=17), diuretics (44%, n=14), angiotensin converting enzyme inhibitors (38%, n=19) and neuroleptics (50%, n=10).

Discussion

This study shows that the overall use of NSAIDs in Malta (50.2%) is nearly double the usage reported in the Italian study (23.1%). Chronic NSAID use, that is daily use of NSAIDs for 4 weeks or more, is similar in Italy (4.2%) and in Malta (5%). Locally, NSAIDs are being used frequently but for short periods of time.

In other studies ibuprofen and aspirin are the most commonly used NSAIDs.[11,14,15] The difference could be attributed to the lack of protocols for NSAID use in Malta. Naproxen, which according to the British National Formulary (BNF)[1] is "one of the first choices as an NSAID because it combines good efficacy with a low incidence of side-effects" has shown very low frequency of use. Most patients self-prescribe the drugs and this indicates the need for framework where pharmacists can undertake prescribing activity so as to guide patients to more rationale options of therapy.

The study indicates that the female population administer more NSAIDs compared to males. Reasons for this could be since females are more prone to conditions for which NSAIDs are indicated such as osteoarthritis, rheumatoid arthritis, dysmenorrhea and menorrhagia.

NSAID use among the younger generation was higher compared to the elderly. One reason for this could be that young people resort immediately to medication that relieves pain fast. Moreover, they may have a lower tolerance to pain. The responsibility of a pharmacist in such circumstances is to recommend non-pharmacological treatment to control pain before resorting to any medications and to remind them that whenever they do self-administer a medicine they should first read the patient information leaflet.

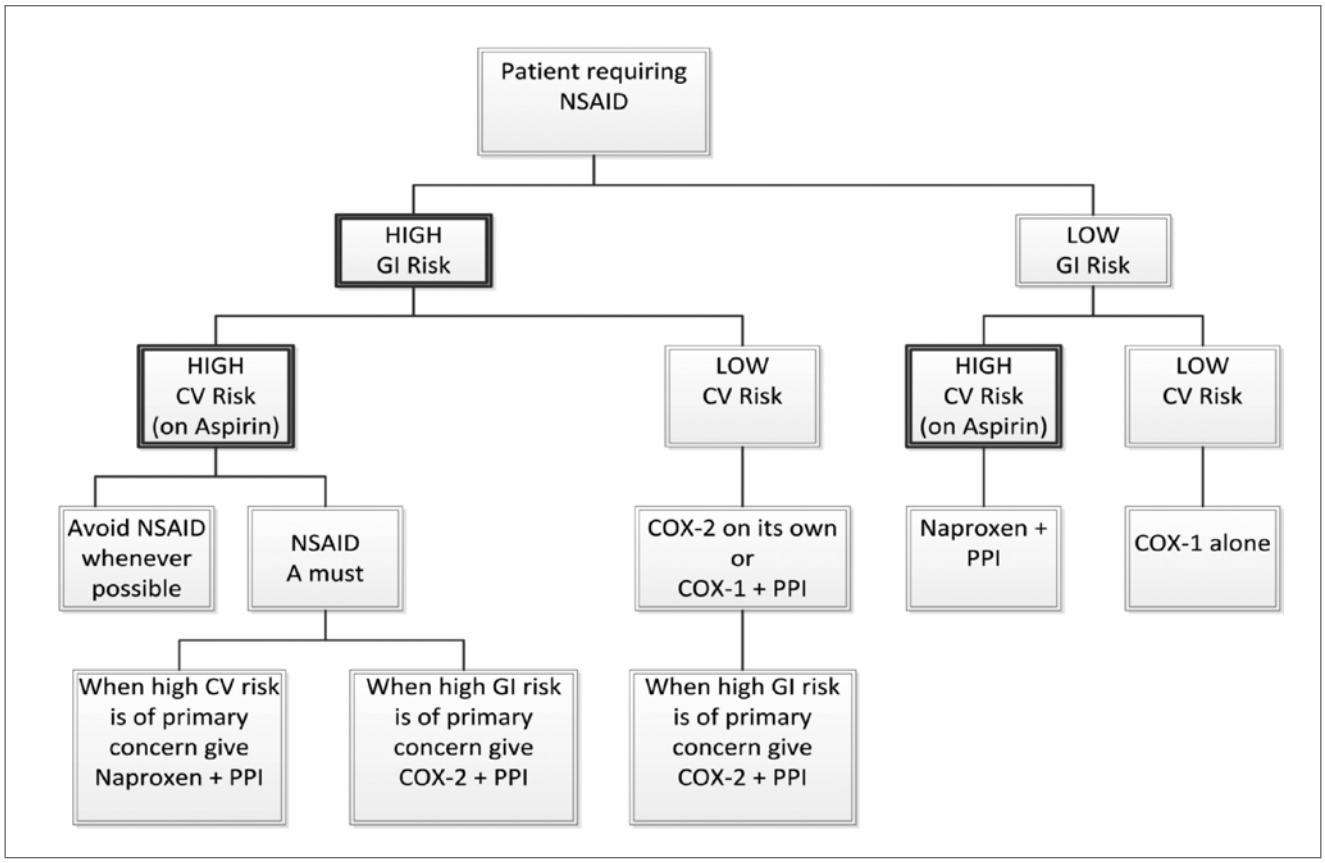

Figure 4: Protocol for NSAID use (Adapted from the Canadian Association of Gastroenterology: Rostom et al, 2009)

This study has shown that the Maltese public are using NSAIDs for their appropriate indications. Yet, there is a high prevalence of NSAID use by patients whose co-morbidities entail caution in the administration of this drug class. Various possibilities of drug interactions were identified indicating that patients need to be better advised about the use of their medication by physicians and pharmacists.

To enhance patient safety with regards to NSAID administration, this study proposes the use of a protocol based on a protocol developed by the Canadian Association of Gastroenterology.[9] This protocol includes recommendations about the use of different NSAIDs depending on the presence or absence of GI and cardiovascular risk factors (Figure 4).

The introduction of a pharmacist prescribing scheme, which could be initiated within a supplementary prescriber model, is suggested wherein doctors and pharmacists work in voluntary partnership to ensure that medicines are being administered properly and safely to all patients.[16]

Conclusion

This study has shown that although NSAIDs are used for a short timeframe, they are still being overused by the Maltese general population. More advice is required regarding rationale use, cautions and interactions. To rectify such a situation this study is proposing the introduction of a protocol for the dispensing and prescribing of this class of drugs and the possibility of introducing a pharmacist prescribing scheme where physicians and pharmacists work in collaboration to ensure optimisation of the risk/benefit ratio of these drugs in each individual patient.

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STANDARD OPERATING PROCEDURES IN PHARMACEUTICAL QUALITY SYSTEMS

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Abstract

Objective To develop explanatory texts for a pharmacy curriculum and reference textbook and to develop model standard operating procedures (SOPs) on key quality and operational pharmaceutical activities.

Method Explanatory texts were written and model SOPs were developed. Emphasis on clarity, conciseness and user-friendliness was made when selecting the writing style and format of the documents.

Key Findings Three explanatory texts entitled 'Master Standard Operating Procedure', 'Preparing a Standard Operating Procedure' and 'Good Manufacturing Practice' were compiled and sixteen model SOPs were developed.

Conclusion Effective SOPs are required to achieve compliance with regulatory requirements and good practice guidelines. Explanatory texts and model SOPs are provided to assist in the development of a pharmaceutical quality management system. The texts developed are an effective training tool on the development of good quality SOPs and the model SOPs are an example of the good quality procedures being recommended.

Keywords Quality Management System, Standard Operating Procedure, Explanatory texts.

Introduction

In the pharmaceutical industry, the quality of medicinal products must be assured throughout the production process of each batch. Quality standards in both design and operation are required to ensure that the production of medicinal products is consistent and controlled to ascertain that the medicinal products are appropriate for their intended use. Good Manufacturing Practice (GMP) is the area of quality assurance which ensures that this requirement is met.[1]

One of the requirements of GMP is for a manufacturer or an importer of medicinal products to have a quality management system (QMS) implemented.[2] Standard Operating Procedures (SOPs) forming part of this QMS transpose the principles and guidelines of GMP into the operations of the organisation and assign responsibilities. Distribution of medicinal products must maintain the standard of quality attained in manufacture and/or importation. This is achieved by following Good Distribution Practice (GDP) guidelines. A distributor of medicinal products should also have a QMS implemented.[3] SOPs forming part of this QMS transpose the requirements of GDP into the actual operations of the wholesale distributing organisation and assign responsibilities.

The design of the QMS will depend on the organisational environment, needs, objectives, products it provides, processes employed and the size and complexity of the organisation itself.[4] The SOPs need to be effective in reaching their objective and need to be relevant for the organisation. For GMP/GDP purposes, SOPs should be available for all activities that can have an impact on product quality. One must establish the steps to be included in a written procedure as it would directly affect the product quality and what may be dealt with otherwise.[5] A simple but effective process of SOP development should be followed and the SOPs must be written, reviewed and approved by the appropriate authorised personnel.

Method

Explanatory texts about the Master SOP, the procedure followed when developing SOPs and the GMP process were compiled. The recommendations in these texts were followed to develop model SOPs covering core quality activities and key operational procedures. The SOPs were developed following a review of the requirements of GMP and also through personal experience of the researcher. The first step in the process was to identify the scope and objective of the SOP. A flowchart was designed where appropriate to simplify the procedure. The procedural steps were written followed by an assignment of responsibilities and appendices. Self-explanatory forms were developed where necessary and included as appendices. The first draft of the model procedures were validated through discussion with peers and amended accordingly producing the final draft. The model SOPs were formatted in a way so as to ensure user-friendliness. An electronic template for these SOPs was made available for adaptation to any particular pharmaceutical organisation.

Results

Three explanatory texts entitled 'Master Standard Operating Procedure', 'Preparing a Standard Operating Procedure' and 'Good Manufacturing Practice' were compiled. The explanatory text of the 'Master SOP' describes the process of SOP management. It defines the procedure for assigning an author, one or more reviewers and an approver and describes the procedure to follow for the effective distribution and updating of the SOPs. The procedure to follow when an SOP is superseded is also described.

The text entitled 'Preparing a Standard Operating Procedure' deals with the process involved in developing the SOP and proposes a practical and effective style for writing the procedure. It discusses the need to plan ahead when developing a pharmaceutical quality system, the procedure of planning, writing, checking and approving the SOP. This text also discusses the need for SOPs within a pharmaceutical organisation.

The third text on 'Good Manufacturing Practice' describes how to apply the principles and guidelines of GMP to a manufacturing organisation through its SOPs. It lists common activities for which SOPs should be implemented and describes them concisely.

Sixteen model SOPs were developed (Table 1).

Discussion

SOPs are a tool for efficiency and regulatory compliance within the pharmaceutical sector when used correctly. They are not written just for the sake of doing so or to satisfy customers and regulators.

The SOP development process starts off by identifying the SOPs to be written, their authors, reviewers and approver. Processes which impact on product quality should all be described by written procedures. Authors should be experienced in the procedure. The person responsible for the execution of procedure should check the SOP. The manager responsible for the QMS should approve it after verifying its conformance with good practice and regulatory requirements and its convergence with the rest of the QMS.

The author begins the SOP development process by planning the SOP, preferably using a tool such as a process flow chart. Visual aids such as flow charts, diagrams, photographs and tables are incorporated to facilitate comprehension of the procedure. SOPs are written for users to follow and should therefore be clear, concise and avoid complex linguistics which users may find difficult to understand. Ambiguity should also be avoided. A logical stepwise procedure is easier to follow correctly and easy-to-follow SOPs are more likely to be correctly interpreted and are less prone to deviations due to human error.

SOP Management	Training
Change Control	Good Documentation Practice
Deviation Management	Self-Inspection
Supplier Approval	Recalls
Equipment Identification	Entry and Gowning
Visitors	Batch Manufacturing Record
Packaging Record	Cleaning of Production Area
Cleaning of Production Equipment	Receipt of Goods

Table 1: Model SOPs developed

Responsibilities should be clearly defined in SOPs. Procedures have a starting point and an endpoint and should never overlap. Trivial instructions should not be included. SOPs should ideally be validated prior to implementation. They must be regularly reviewed and any changes made to the procedure should be controlled and tracked. They should be directed at the user and preferably written in the present or affirmative tense. Changes in the procedure should be effected after the relevant SOP is changed and training has been given to the personnel responsible for its execution.

The first SOP to include in a QMS is the Master SOP. This defines the structure of the QMS and the format of the written procedures. SOP distribution and training to be imparted are defined. The documents to be used in the QMS are defined and formalised. A system for documenting, investigating, correcting, preventing and trending deviations should be defined. The quantity of deviations, their severity and the number of open investigations are key performance indicators for the organisation and should be actively tracked.

SOPs are an effective training tool. They can ensure that a process is performed in the same way irrespective of who is performing the steps and of when the tasks are performed providing harmonisation within the organisation.

SOP writing is a complex task. It is one that requires skill to fulfil its goals. Training may be needed in writing effective SOPs. The reviewers must fulfil their task carefully. This time-consuming activity is an investment that will save on resources at a later stage when senior staff would otherwise be engaged in investigating and managing deviations.

The texts developed are an effective training tool on the development of good quality SOPs and the model SOPs are an example of the good quality procedures being recommended.

Good quality SOPs are the key to an effective QMS and to compliance in operations. They clearly define responsibilities, harmonise activities, facilitate training and enable effective and efficient quality assurance.

Conclusion

It is envisaged that the texts will be of interest to students who intend to take up a career in pharmaceutical manufacture and distribution, as well as to anyone entrusted with developing or maintaining a pharmaceutical QMS. The model SOPs can be used as a template for the key procedures considered. They can also be used to develop further SOPs for the organisation as may be required in the future. The guidance provided in the explanatory texts will be useful in providing direction, for SOPs should be effective in attaining the objectives of the QMS. The benefits to be gained from the effort and manpower used in writing SOPs will be maximised if the guidance and model SOPs are followed.

Good quality SOPs translate into better compliance, less deviations and therefore fewer investigations and corrective actions, no ambiguity regarding responsibilities and less rejection of costly pharmaceutical actives, intermediates and product. These texts and model SOPs serve as a tool to develop better quality procedures.

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STANDARD OPERATING PROCEDURES FOR QUALITY CONTROL IN THE PHARMACEUTICAL INDUSTRY

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Abstract

Objectives To develop quality control standard operating procedures (SOPs) and to highlight the importance of implementation and use of these SOPs in the pharmaceutical industry.

Method A pharmaceutical company, Aurobindo (Swift services), was regularly visited three times per week over a five-month period. The visits consisted of familiarisation visits followed by visits for induction and specific training. A set of SOPs were selected, developed and implemented.

Key findings Nine SOPs were developed and implemented. Seven SOPs were developed using a simple format and two SOPs were developed in the form of flow chart. The average time taken to carry out a procedure was recorded and included in eight SOPs.

Conclusion SOPs are tools which when followed correctly ensure the consistency of a process. This is important in the pharmaceutical industry to achieve high standards of quality. Inclusion of the time taken to carry out a procedure gives an indication to the user whether the task was carried out as expected.

Keywords Standard Operating Procedures, pharmaceutical industry, quality control.

Introduction

Standard Operating Procedures (SOP) are a set of written instructions to help individuals working in a particular setting to carry out specific procedures correctly. The implementation of SOPs in the pharmaceutical industry is important to attain an end result with the expected quality according to good practice guidelines.[1] SOPs should be written by qualified individuals who possess information, knowledge and experience in the particular field.[2] The header of each SOP must include the name of the department, the application field and a descriptive title. All pages of the SOP must be numbered. A Master SOP, which describes the process of SOP management, must be approved by and include the signatures of the company's authorised person and Quality Assurance manager. The procedure of the operation to be followed must be written stepwise.

The use of SOPs can prove to be beneficial in various ways.[3] SOPs inform employees about the health and safety precautions that must be taken into account when performing particular procedures and ensure that tasks are being carried out regularly whilst maintaining the quality and uniformity of batches. By correctly following SOPs, results obtained are more compliant to Good Manufacturing Practice (GMP) requirements.

Method

A pharmaceutical company, Aurobindo (Swift services), was regularly visited three times per week over a five-month period. Various meetings were held with the company manager, head of quality assurance, head of quality control departments and laboratory technicians to discuss the need for implementation of SOPs. The visits consisted of nine familiarisation visits followed by visits for induction and specific training. Following training and an intensive literature review, nine SOPs were chosen for development.

During SOP development, it is important to keep in mind the individual who will be following and performing the particular procedure to determine the amount of information which should be included. The SOPs were written with sufficient detail and information to be followed correctly by an individual with basic knowledge and who does not have much experience with a particular procedure. All information in the SOP was written using simple and concise language and each step in the procedure was written in the imperative form.

There are three types of SOP formats; simple, graphic and flow chart. The selected SOP format depends on the number of decisions to be taken and the number of steps and sub-steps which are needed to organise and structure each SOP.[4] Short procedures with a few decisions are written in simple steps format while long procedures that require a small number of decisions are written in hierarchical steps or graphic format. Procedures that require more decisions to be taken are written in the form of a flow chart. Simple and

Simple steps	Flow chart
Dissolution testing	Purified water testing
Friability testing	High Performance Liquid Chromatography (HPLC)
Operation of analytical balance	
Karl Fisher Titrino	
Infra red identification test	
Disintegration testing	
Identification by Thin Layer Chromatography (TLC)	

Table 1: List of SOPs developed

flow chart formats were chosen to develop the SOPs. Each SOP was tested twice by two laboratory technicians and the average time to perform each procedure was taken.[5-7] The average time taken was included in eight SOPs.

SOP implementation must be effective and best conducted in the work place. The users were trained to follow the SOPs to perform the procedure correctly. The individual responsible for training explained why and how each step in the SOP must be carried out. It was stipulated that each SOP should ideally be reviewed and updated every 6 months.

Results

Nine SOPs were developed and implemented (Table 1). Seven SOPs were written using simple format and two SOPs were written in the form of a flow chart.

The SOPs were developed to attain intended results with respect to compliance with European Pharmacopeia requirements with regards testing of a product's quality. The sections included in each SOP are listed in Table 2.

Discussion

The production of high quality medicinal products is very important for the pharmaceutical industry. The best way to achieve these goals is through SOPs. SOPs are important tools in the pharmaceutical industry and help users to perform the various activities required for the quality control and quality assurance of the product. The success of the pharmaceutical industry relies upon following the SOPs correctly. SOPs have an essential role in the pharmaceutical industry since by following SOPs the requirements of GMP and the European pharmacopeia are met and the expected quality is achieved.

Recording the average time taken to carry out the procedure in the SOP may help the user realise if the procedure was carried out correctly. If the user spends more or less time performing the procedure than is specified in the SOP, this indicates that the user may not be carrying the particular procedure appropriately.

SOP sections
1. Purpose
2. Scope
3. Application field
4. Average time taken
5. Procedure
6. Diagram of instrument
7. European acceptance criteria

Table 2: SOP sections

The main limitation for this study was that not enough time was available to develop the complete library of quality control SOPs for this company. Another limitation was that the time taken to follow the SOP for HPLC testing was difficult to determine since this varied according to the sample being tested.

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Malta Pharmaceutical Students Association Contribution

EMPOWERING STUDENTS TO BE PROACTIVE IN THEIR STUDENT LIFE

Denise Borg, Charlene Galea

With the ever increasing demand of flexible individuals within the workforce, the pharmacy profession is called to fulfil multi-faceted roles. The Malta Pharmaceutical Students' Association (MPSA) strives to complement formal education with various opportunities for future pharmacists to practice and develop their interpersonal skills.

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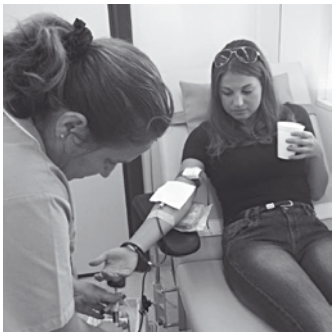
As part of the remembrance activities of the World Mental Health Day and World AIDS Day, two distinct awareness campaigns were organised by MPSA. In partnership with the Malta Dementia Society, an awareness campaign was organised to increase accessibility of the public to information about dementia and to provide information about the support which is available. A stand was set up whereby students provided information on how to best support the patient who is suffering from the condition.

Students manning the informative stand during the 'World Health Day: Focus on Dementia' campaign

For the AIDS awareness campaign, MPSA has collaborated with other campus-based organisations to organise a non-profitable charity party. The 'Play Safe: Red Party' was a successful venture where students gathered with the common aim to raise funds for the organisation called 'Xefaq', a community-based counselling service for persons living with HIV/AIDS. A donation of more than €300 was presented to the organisation which will enable the provision of a free service to persons affected with this condition.

Following an urgent appeal by the local authorities concerning a shortage in blood donations, MPSA decided to help the Blood Bank to increase blood donations by developing a Blood and Organ Donation Campaign on Campus entitled 'Fresh Blood'. This campaign aimed to raise awareness about the need of regular blood donation to ensure that blood is available for all patients when required, by recruiting new blood and organ donors and to encourage existing blood donors to donate regularly.



A student donating blood during the 'Fresh Blood Drive'

The 'Ask your Pharmacist, Know your Medicines' campaign aimed to encourage patients to be aware of the services pharmacists can offer by providing expert advice alongside the supply of medicines. This campaign was held at the Outpatient's Pharmacy, Mater Dei Hospital. A stand was set up whereby pharmacy students and pharmacists could reach out to the patients when collecting their medications from the hospital. Such pharmacist intervention helps patients understand the indications of their prescribed treatment and also simplify drug administration by devising a custom-made medication schedule.

Participating students in the 'Ask Your Pharmacist, Know your Medicines' campaign

This year, MPSA has ventured into a new area, by providing soft skills training courses. A one-day event session was organised to provide pharmacy students with an informal platform which helps promote self-development by interacting with one another. Specifically, students were given training on team building, communication, presentation and networking skills.

Following the positive response, a pharmacy career convention was organised entitled 'Take Your Education to the Next Dose'. An informal discussion was organised whereby pharmacists working within the industrial, clinical, community, regulatory and academic fields were invited to give an account of their work experiences. This enabled students to experience the various opportunities that exist within the pharmacy profession.

Students engaged in a discussion with various professionals during the 'Take your Education to the Next Dose' career convention

The various activities which MPSA organises throughout the year enable students to interact with many different professionals practising in various fields and to develop the necessary skills required within the pharmacy profession. The activities organised by MPSA are fully supported by the Department of Pharmacy at the University of Malta as both entities believe that pharmacy students should experience education beyond academic knowledge.

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).

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

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Three to five keywords should be provided.

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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.

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