



PUBLIC PERCEPTION OF GENERIC PHARMACEUTICALS IN MALTA

Yvette Azzopardi, Maurice Zarb Adami

Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida.

Corresponding Author: Yvette Azzopardi
Email: yvettegatt@gmail.com

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.

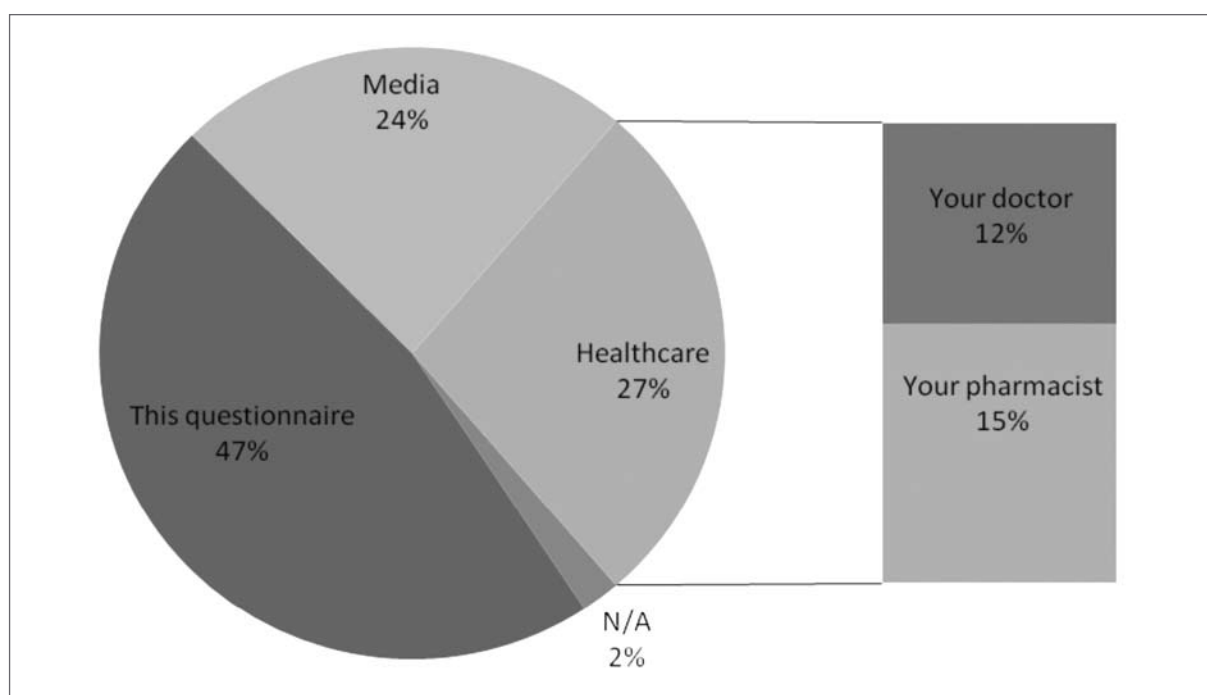


Figure 1: Information obtained about generic medicines (N=544)

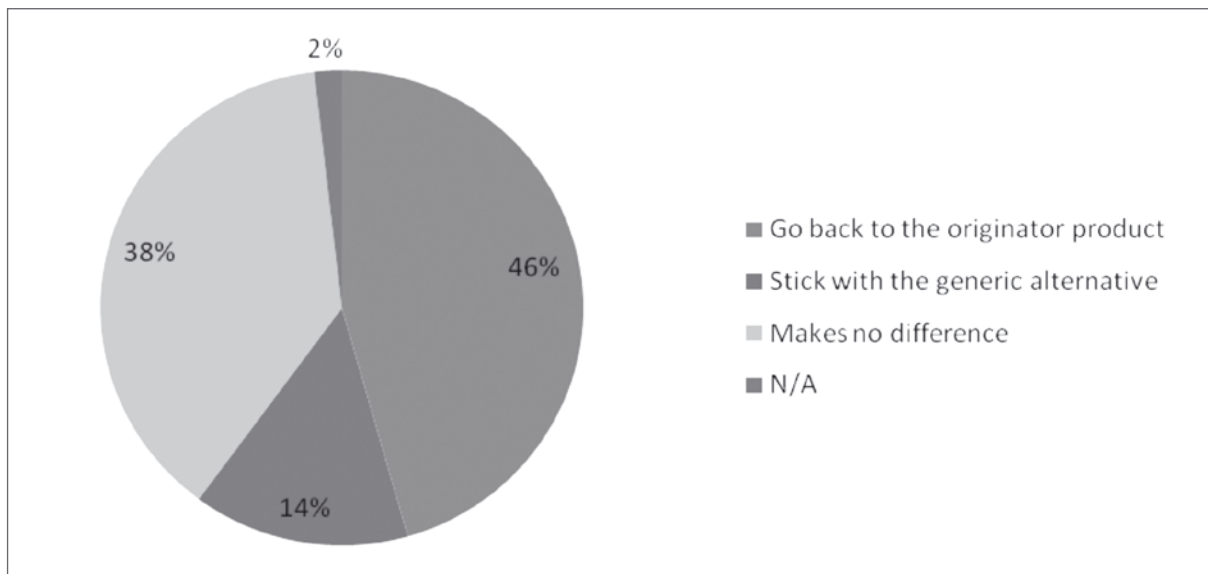


Figure 2: Practice when originator product is re-available (N=544)

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

References

1. The European Parliament and Council of the European Union. Directive 2001/83/EC: Community code relating to medicinal products for human use [Online]. Official Journal of the European Communities 2001;311:67-128 [cited 2012 Feb 3]. Available from: URL: www.mhra.gov.uk/home/groups/es-herbal/documents/websiteresources/con009360.pdf
2. Farrugia M. Proposal to ban prescription of brand medicines turned down [Online]. Times of Malta; 2006 Sept 14 [cited 2012 Feb 3]. Available from: URL: www.timesofmalta.com/articles/view/20060914/local/proposal-to-ban-prescription-of-brand-medicines-turned-down.41494
3. National Medicines Policy and Audit Unit. Generic substitution [Online]. Malta: Health Division [cited 2012 Feb 3]. Available from: URL: www.sahha.gov.mt/pages.aspx?page=878
4. Ministry for Justice and Home Affairs. Medicines Act, 2003 [Online]. Malta: Department of Information; 2003 [cited 2012 Feb 3]. Available from: URL: www.doi.gov.mt/EN/parliamentacts/2003/Act%203.PDF
5. Rowntree D. Statistics without tears: An introduction for non-mathematicians. England: Hamish Hamilton; 2000. p. 17-27.
6. Gossell-Williams M, Harriott K. Generic substitution in Jamaica: Challenges to improving effectiveness. WHO Drug Information 2007; 21(4): 294-299.
7. Himmel W, Simmenroth-Nayda A, Niebling W, Ledig T, Jansen RD, Kochen MM, Gleiter CH et al. What do primary care patients think about generic drugs? Int J Clin Pharm Ther 2005; 43:472-479.
8. Kobayashi E, Karigome H, Sakurada T, Saloh N, Ueda S. Patients' attitudes towards generic drug substitution in Japan. Health Policy 2011; 99:60-65.
9. Ford N, 't Hoen E. Generic medicines are not substandard medicines. The Lancet 2002; 359:1351.