

GENERIC MEDICINE PRICES AND THEIR DISTRIBUTION IN MALTA

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ABSTRACT

OBJECTIVES To analyse the composition of the private pharmaceutical retail market in Malta on the basis of the originator or generic status of available medicines and to observe the change in prices of generics and originators over time.

METHOD The prices of a sample (n=435) of medicines in Malta were analysed for an eight year period (2002 to 2009). The variation in price in the generic and originator segments was calculated. Thirty-one active ingredients with generics available were identified and the Average Retail Price Per Unit (ARPPU) and the Lowest Retail Price Per Unit (LRPPU) were calculated. The average discount from the originator price was calculated, per compound and also by drug class.

KEY FINDINGS The sample population contained 17.2% generic products. The mean drop in the ARPPU was of 10.87% and for the LRPPU of 21.42% for the LRPU. The average discount was 14.59% in 2002 and 37.19% in 2009.

CONCLUSION The number of generic medicines in Malta has increased in the last eight years, with a consequent decrease in the lowest prices available for the set of medicinal compounds.

KEYWORDS Generic medicines, price discount and originator products

INTRODUCTION

The high cost of medicines for sale at the neighbourhood pharmacy is cause for concern both locally¹ and elsewhere.² Public and private consumers are facing budgetary constraints in dealing with a growing range of medicinal products and an increasing number of patients,³ especially in view of the fact that life expectancy is on the rise and with it the incidence of non-communicable disease.⁴

Generic medicines are seen as the key to ease the financial pressures within healthcare systems worldwide.^{5,6,7} The entry of a generic product onto a market usually has a two-fold downward effect on prices. Firstly, the generic is cheaper, because it costs less to produce, and secondly because it needs to have a competitive edge to impact the end-consumer.⁸

Generics are essential from an economic viewpoint, as they introduce competition to a situation where patent holders have held a manufacturing monopoly for the term of the patent period.^{9,10} This period of monopoly leads to a high price being exacted for a unique product, in this case for innovative drug molecules.

The local market had not been analysed with respect to its relative composition of originator or generic medicines. No specific information was available regarding the prices of generic medicines in relation to their respective originator products. The aims of the study were to analyse the composition of the private pharmaceutical retail market in Malta on the basis of the originator or generic status of available medicines and to observe the change in prices of generics and originators over time.

METHOD

A sample (n=435) of medicines was drawn from the 3100 medicines which had a Marketing Authorisation according to the Malta Medicines Authority in October 2009. The sample was drawn by selecting in descending order on the basis of highest volume of sales in three community pharmacies over an eight year period (2002-2009). Fields included in the data set were the originator or generic status, prescription-only status (POM) or non-prescription (OTC) status and drug class. The latter classification was based on the one used by the British National Formulary (BNF).

Medicine prices were compiled from computerized EPOS data generated by a live system that contained the prices as recommended by the competent authorities. A set of originator drugs which had generic equivalents by the end of 2009 was selected from the sample. This data set consisted of thirty-one active ingredients. The Average Retail Price Per Unit (ARPPU) and the Lowest Retail Price Per Unit (LRPPU) for each active ingredient was calculated for 2002 and 2009. The unit measurements in the ARPPU and LRPPU were calculated by dividing the prices obtained for the medicines by the pack size so as to obtain a comparable variable.

The average percentage discount from the originator price to the generic version was calculated for the thirty-one active ingredients for the years 2002 and 2009, by tabulating the retail prices of originator and generic versions for the two years in question, and including tags for OTC/POM and drug class identifiers.

RESULTS

The sample population contained 17.2% generic products. The mean increase in price for the whole sample was 17.86%. The mean for the originator segment showed an increase of 18.22%, with that for the generic segment rising by 16.2%. When the prices were composited into a retail medicine index the increases were 11.01%, and 11.05% and 10.68% respectively.

Of the 31 active ingredients considered in the second part of the study, 16 had no generic equivalent in 2002, as opposed to the fact that all had at least one in 2009. This is reflected in the mean discount from the originator price for the data set, which rose from 14.59% to 37.19%. The greatest percentage discount observed is that for the Retail Price Per Unit (RPPU) of omeprazole 20mg capsules, and the lowest for paroxetine 20mg tabs, where the price of the originator and generic brands have simply decreased side by side to almost identical levels (Figure 1). The class exhibiting the greatest discount from the originator price was the gastro-intestinal (GIT) segment, with cardiovascular (CVS) medicines in second place. The CVS segment was, however, the most populated, with 13 active ingredients as opposed to the second most popular, the anti-infective drugs (AB & OTH), with 6, out of a total of 31 compounds (Figure 2).

Twenty-seven out of the group of compounds were POM medicines, with the average discount from the originator price to the lowest available rising to 38.41% from 30.88% in this case. No appreciable change was noted for OTC medicines (27.28% to 28.92%).

DISCUSSION

The fact that the prices of medicines exhibited an increase over an eight year period is not anomalous. The prices of both originator and generic drugs showed an upward movement. This statement is somewhat mitigated by the fact that upon further scrutiny it transpires that the prices for the OTC segment (16.22%) increased more than the POM one (7.21%). A greater increase in OTC medicine prices might be explained by the fact that this segment is highly incentivised and results in the cost being passed on to the consumer. The mean drop in the lowest price available for retail for the thirty-one active ingredients studied, 21.42%, is not substantial when considered as a single variable.

Studies in the EU have shown that the price of a generic medicine drops to 80% that of the originator within the first year of launch, leading to savings being passed on to the consumer¹¹. Savings are even greater in the United States where prices drop by 80% after one year.¹² The intense generic competition in the North American market instigates greater investment in the research and development of innovative compounds. Expenditure on R&D exhibited an increase after the publication of the Hatch-Waxman Act, legislation which facilitated the introduction of generic medicines in the United States.¹³

Although the local market has no originator branded manufacturers, all the major companies maintain strong representation, and the presence of generics is vital on two counts. Firstly, to ensure that monopolistic situations are not maintained, thus providing the stimulus to bring newer protected products to the local market and secondly, to provide competition on the basis of price and exert downward pressure.¹³

The great majority of the medicines in the originator/generic pairings are POM medications. Almost half of the pairings surveyed belonged to the cardiovascular group of drugs. The use of this class of drugs increases with age, as the cardiovascular system begins to experience problems of decreasing cardiac output and increased peripheral resistance.¹⁴ It can be deduced that generic drug manufacturers are following the lead of the branded originator companies and launching products targeted at the elderly, so as to take advantage of this increasing demographic shift.

CONCLUSION

The entry of generic products on the market does not have a significant impact on retail prices. Further investigation into the pricing strategy of generic products is required. Measures could be introduced to ensure that generic medicines enter the market at a discount to the originator product. It might be proposed that the granting of a Marketing Authorisation for a generic version of a product that is already present on the market under another brand, would only be undertaken if the Recommended Retail Price would be at a fixed percentage cheaper than the latest mean price for the Defined Daily Dose.

Without an effective education campaign, the further penetration of generic medicines, will be inevitably delayed.^{15, 16} This will prevent immediate savings in spending on pharmaceuticals and thus reduce accessibility to medical care. It is incumbent to enable a balance to be struck between the needs of innovation and branded manufacturers and those of lower-priced, high volume and accessible generic products.

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“THE NUMBER OF GENERIC MEDICINES IN MALTA HAS INCREASED IN THE LAST EIGHT YEARS, WITH A CONSEQUENT DECREASE IN THE LOWEST PRICES AVAILABLE FOR THE SET OF MEDICINAL COMPOUNDS”

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“THE GREAT MAJORITY OF THE MEDICINES IN THE ORIGINATOR/GENERIC PAIRINGS ARE PRESCRIPTION-ONLY MEDICATIONS. ALMOST HALF OF THE PAIRINGS SURVEYED BELONGED TO THE CARDIOVASCULAR GROUP OF DRUGS”

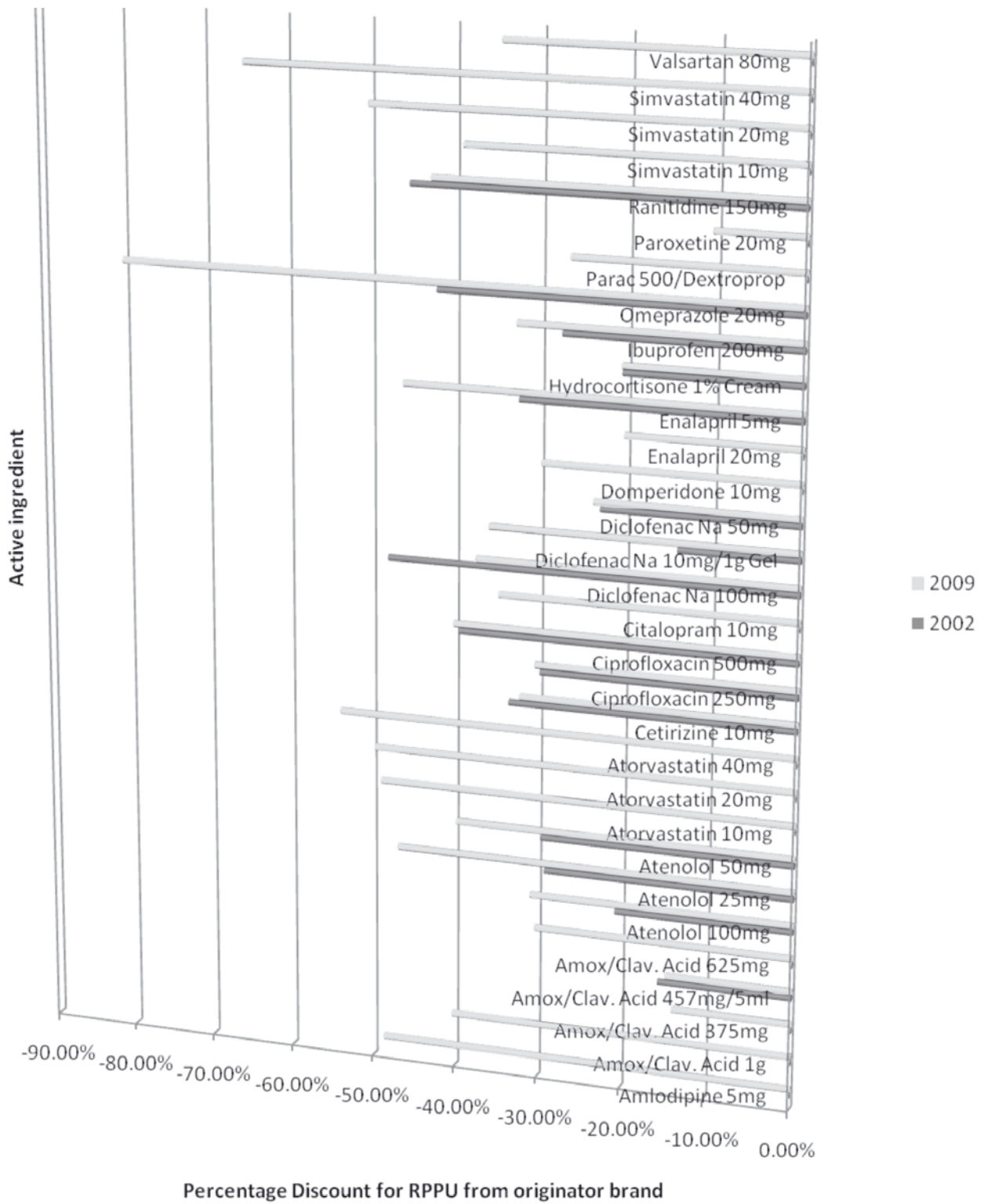


Figure 1 - The percentage discount for the RPPU from the originator product for each active ingredient for 2002 and 2009

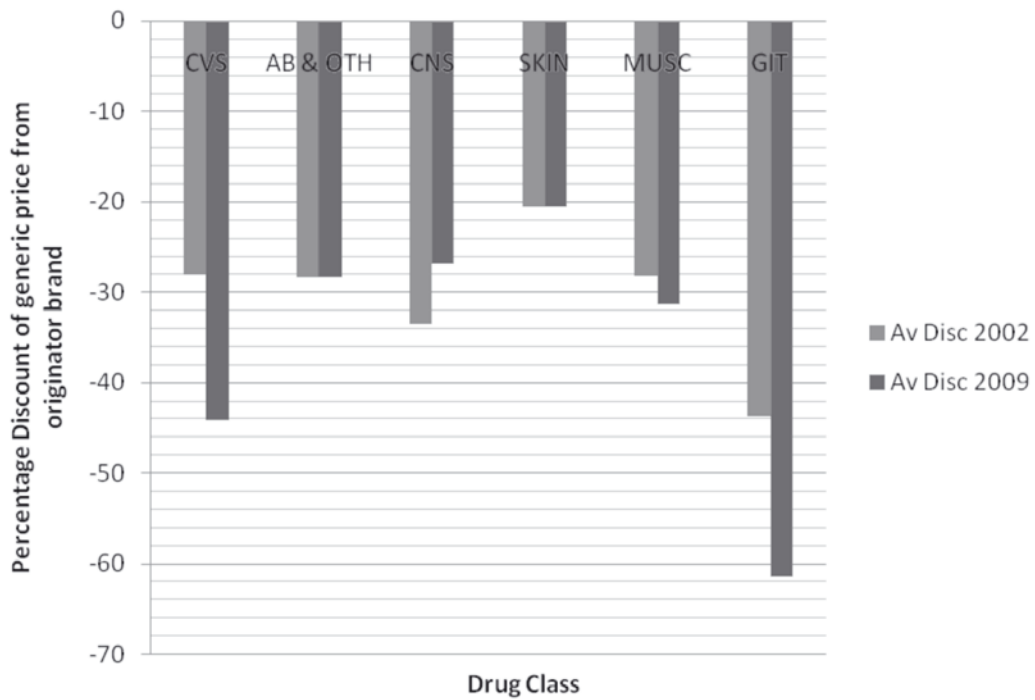


Figure 2 - The percentage discount by drug class in 2002 and 2009



“THE ENTRY OF GENERIC PRODUCTS ON THE MARKET DOES NOT HAVE A SIGNIFICANT IMPACT ON RETAIL PRICES. FURTHER INVESTIGATION INTO THE PRICING STRATEGY OF GENERIC PRODUCTS IS REQUIRED”