Generic medicine prices and their distribution in Malta

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Abstract

The study analysed the composition of the private pharmaceutical retail market in Malta on the basis of the originator or generic status of available medicines. The variation in price of generics over a period of time and discount from originators was also considered.

The prices of a sample (n=435) of medicines taken from those granted Market Authorisations 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 one or more generics available were identified from the sample and the Average Retail Price Per Unit (ARPPU) and the Lowest Retail Price Per Unit (LRPPU) for these compounds were calculated. The average discount from the originator price was also calculated, per compound and also by drug class.

The sample population contained 17.2% generic products, as opposed to the whole population which was split 28.95% to 71.05% (Generic/Originator). The mean drop in the ARPPU was of 10.87% and 21.42% for the LRPPU. The average discount for the set was 14.59% in 2002, and 37.19% in 2009.

Despite volume constraints, the number of generic medicines in Malta has increased in the last eight years, with a consequent gradual, if not dramatic, decrease in the lowest prices available for the set of medicinal compounds tested.

Keywords

Generic medicines, price discount and originator

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Introduction

The oft quoted high cost of medicines for sale at the neighbourhood pharmacy is cause for concern both locally [(1)] and also elsewhere. [(2)] Both 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 ever-increasing financial pressures within healthcare systems worldwide [(5) (6) (7)]. The entry of a generic version of an originator product onto a market usually has a two-fold downward effect on prices. Firstly, the generic is by nature cheaper, because it costs less to produce, with no R&D costs, and also because it needs to have a competitive edge to positively impact on the end-consumer [(8)].

Generics are also 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 and ground-breaking drug molecules or New Chemical Entities.

The local market had not been analysed up to now with respect to its relative composition of originator or generic medicines, and also no specific information was available regarding the behaviour of the prices of generic medicines in relation to their respective originator products. An incisive paper published last year [(11)], broached this subject, with particular emphasis on the Maltese situation and provided an excellent platform for

further research. In this instance, Farrugia and Savvas posit that the active promotion of generic medicines through the various tiers of the healthcare system is necessary to increase and achieve a level of penetration that would generate a sustainable public and private medicines market, whilst at the same time keeping retail prices in check.

Methodology

As of October 2009, 3100 medicines were granted Market Authorisations by the Malta Medicines Authority. [12] 84 medicinal products also were available on the market due to the fact that they were centrally registered with the European Medicines Agency (EMEA). Thus a total of *circa* 3,200 medicines were authorised for distribution in the Maltese Islands. Of these 1500 are utilised solely at Mater Dei General Hospital.

A sample (n=435) of medicines was drawn from those available for sale on the private retail market in Malta. These were selected in descending order on the basis of highest volume of sales in three community pharmacies over the eight year period under study. Medicines that were not available for sale for the whole period were discarded. Fields included in the data set were the originator or generic status, POM or OTC status and drug class. The latter classification was based on the one used by the British National Formulary (BNF). [13]

The selection of the fastest selling items was an intended bias towards excluding the random effect of variation in items which are rarely purchased, and thus do not impact on the average *basket* of medicinal items. Medicine prices were chosen from computerized EPOS data generated by a live system that contained the precise prices as recommended by the competent authorities and also vetted by the Department of Value Added Tax for auditing purposes. (14)

The proportion of generic and originator drugs in the sample and the whole population and the sample were calculated and charted. A set of originator drugs which had one or more 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, using prices at the end of the respective calendar year.

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 sets of medicines for the years 2002 and 2009. This was done 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.

Prices prior to the 1st of January 2008 and the introduction of the Euro (€) were in Maltese Lira (Lm). These were converted to Euro (€) at rate of 0.4293c (Lm) per Euro (€) as established by the Central Bank of Malta.

Results

The sample population contained 17.2% generic products, as opposed to the whole population which was split 28.95% to 71.05% (*Figure I*). 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 thirty-one compounds considered in the second part of the study, sixteen had no generic equivalent in 2002, as opposed to the fact that all had at least one in 2009 (*Figures II and III*). 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 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.

The class exhibiting the greatest discount from the originator price was the GIT segment, with CVS medicines in second place. The CVS segment was, however, the most populated, with 13 active ingredients as opposed to the second most popular, AB & OTH, with six, out of a total of thirty-one compounds (*Figure IV*).

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 by no means anomalous. What is disconcerting is that 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 is the OTC segment (16.22%) that increased substantially 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 this 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. This statement is further qualified when one considers the five medicines studied that are included in the 14-strong WHO core list of essential medicines to be utilised for the purposes of pricing surveys [(6)]. These medicines only decreased by 12.73% over an eight year period.

Comparable 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 immediate savings being passed on to the consumer, whether it be the individual, the state, or a third-party payer. [(15)] Savings are even greater in the United States where prices drop by 80% after one year. [(16)] The intense generic competition in the North American market instigates and stimulates greater investment in the research and development of innovative medicinal compounds. In fact, expenditure on R&D exhibited an exponential increase after the publication of the Hatch-Waxman Act, legislation which facilitated the introduction of generic medicines in the United States [(17)].

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 and patent protected products to the local market and secondly, to provide competition on the basis of price and exert downward pressure [17].

It is interesting to note that the great majority of the medicines in the originator/generic pairings are POM medications. In fact 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 [18]. It can be thus 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 ever increasing demographic shift.

Conclusions

The effect of the entry of generic products on the market does not seem to have had a significant impact on retail prices. Further investigation into the pricing strategy of generic products is required. Even if it might be a contentious and radical step, certain measures could be introduced to ensure that generic medicines enter the market at a significant discount to the originator product. It might be proposed that the granting of a Market Authorisation for a generic version of a product that is already present on the market under another brand,

would only be granted if the Recommended Retail Price would be a fixed percentage cheaper that the latest mean price for the Defined Daily Dose.

Without an effective and widespread education and information campaign, both within the professional healthcare community, and also among the general public the further penetration of generic medicines, both locally and elsewhere, will be inevitably delayed [19] [20]. This will prevent immediate savings in spending on pharmaceuticals and thus directly reduce accessibility to medical care. It is incumbent upon all involved to enable an equitable 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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Figures I to IV

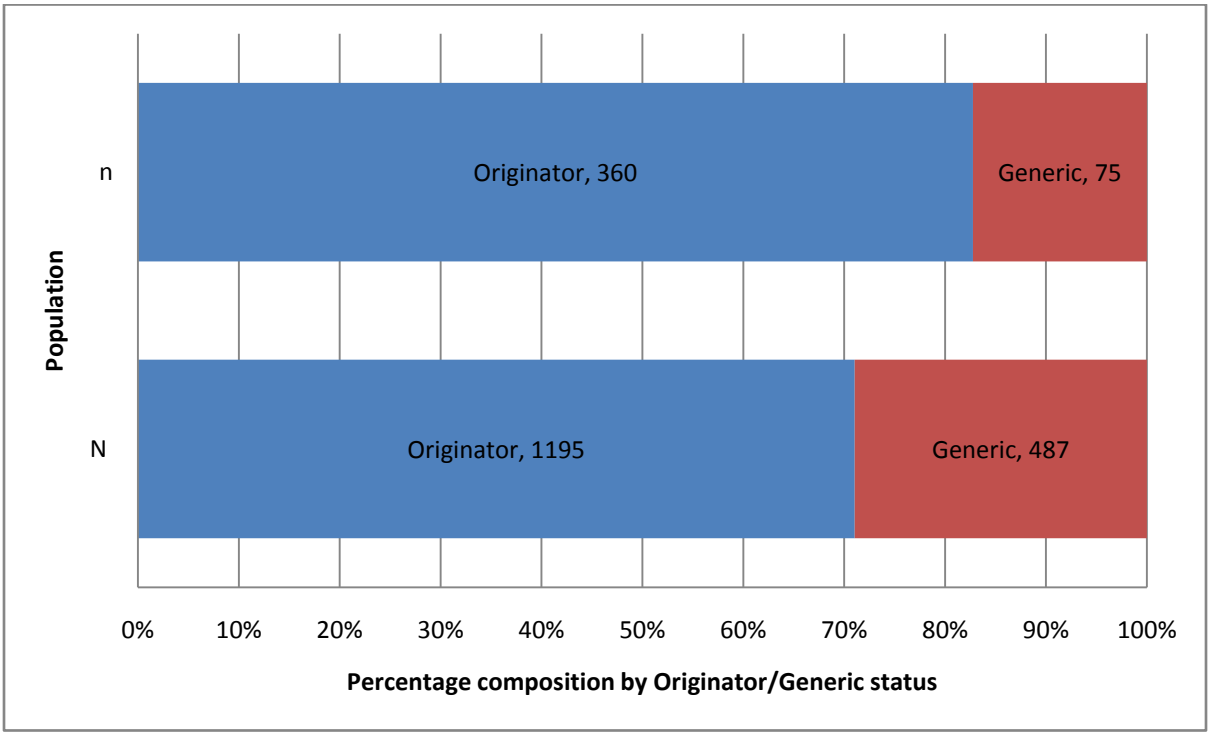

Figure I - The composition of the population, N and subset, n by status

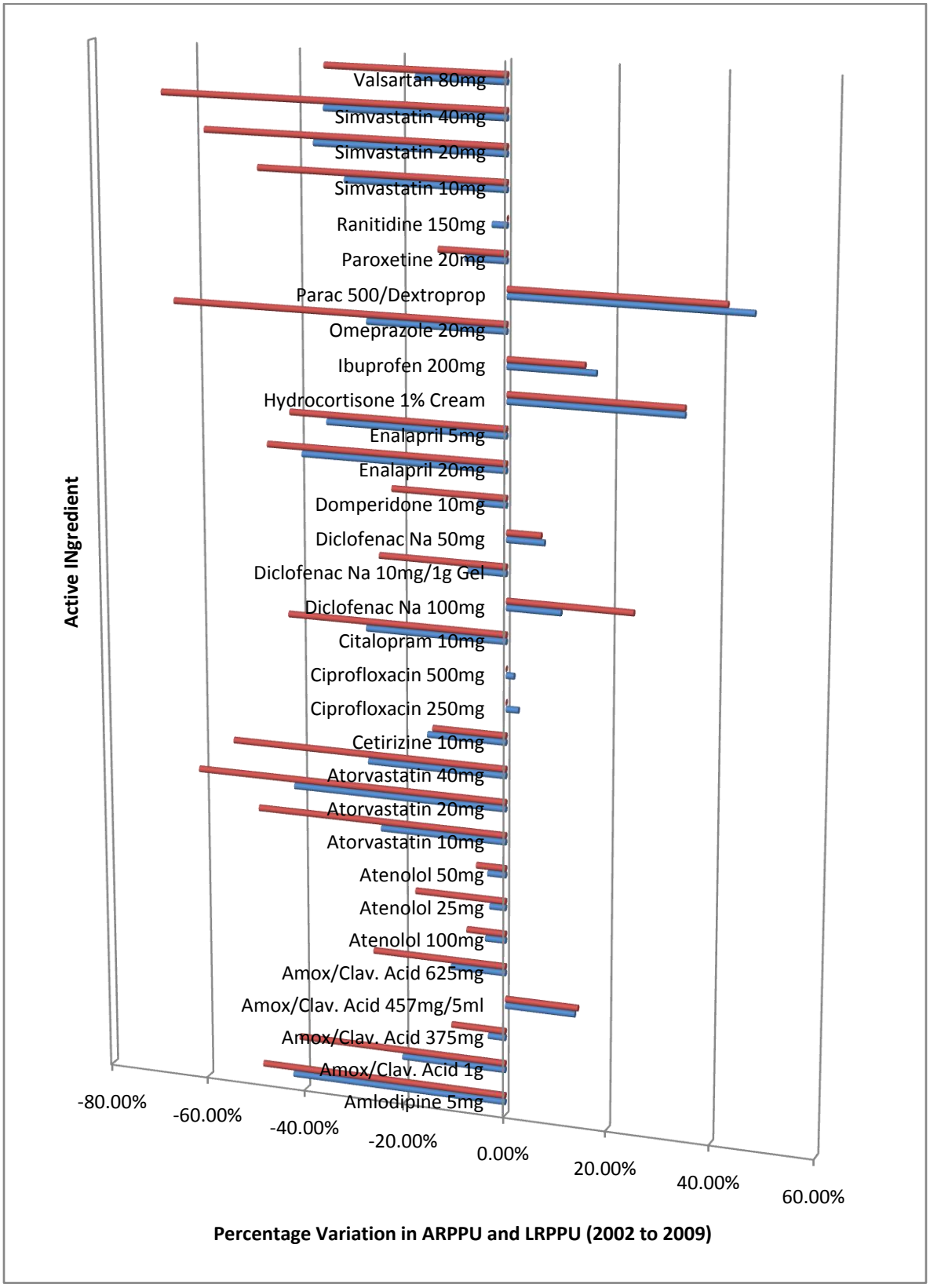

Figure II - The variation in the average and lowest retail prices per unit

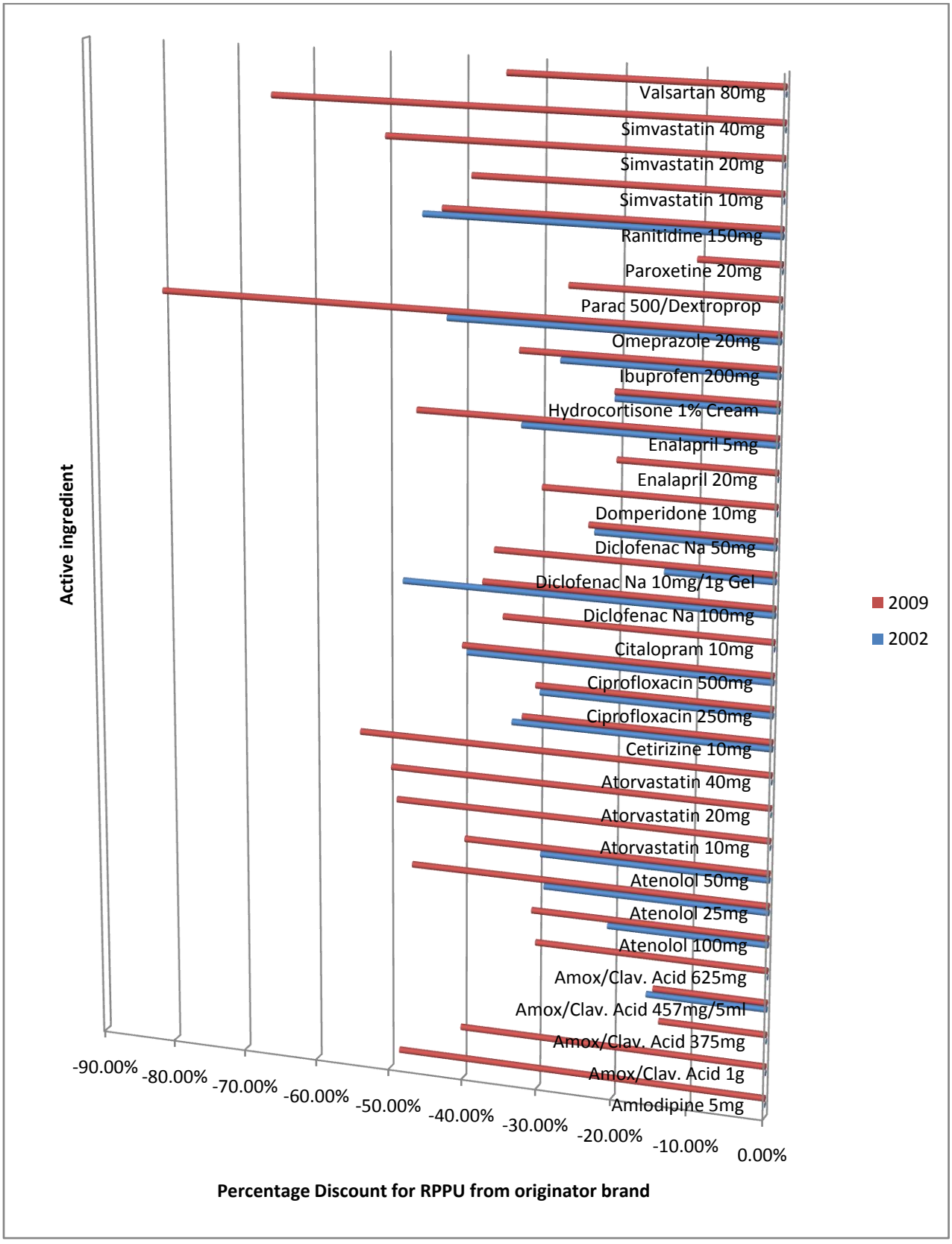

Figure III - The percentage discount by active ingredient for 2002 and 2009

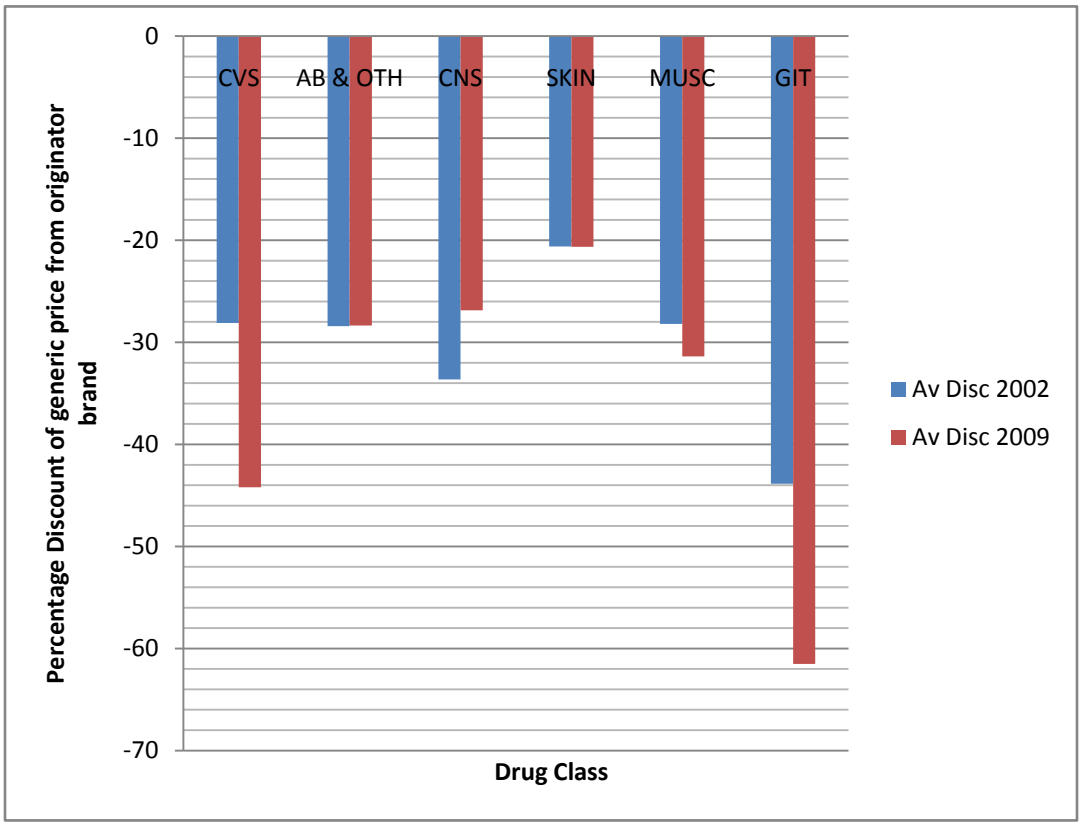

Figure IV - The percentage discount by drug class in 2002 and 2009