

# Towards a transparent pricing system in South Africa: trends in pharmaceutical logistics fees

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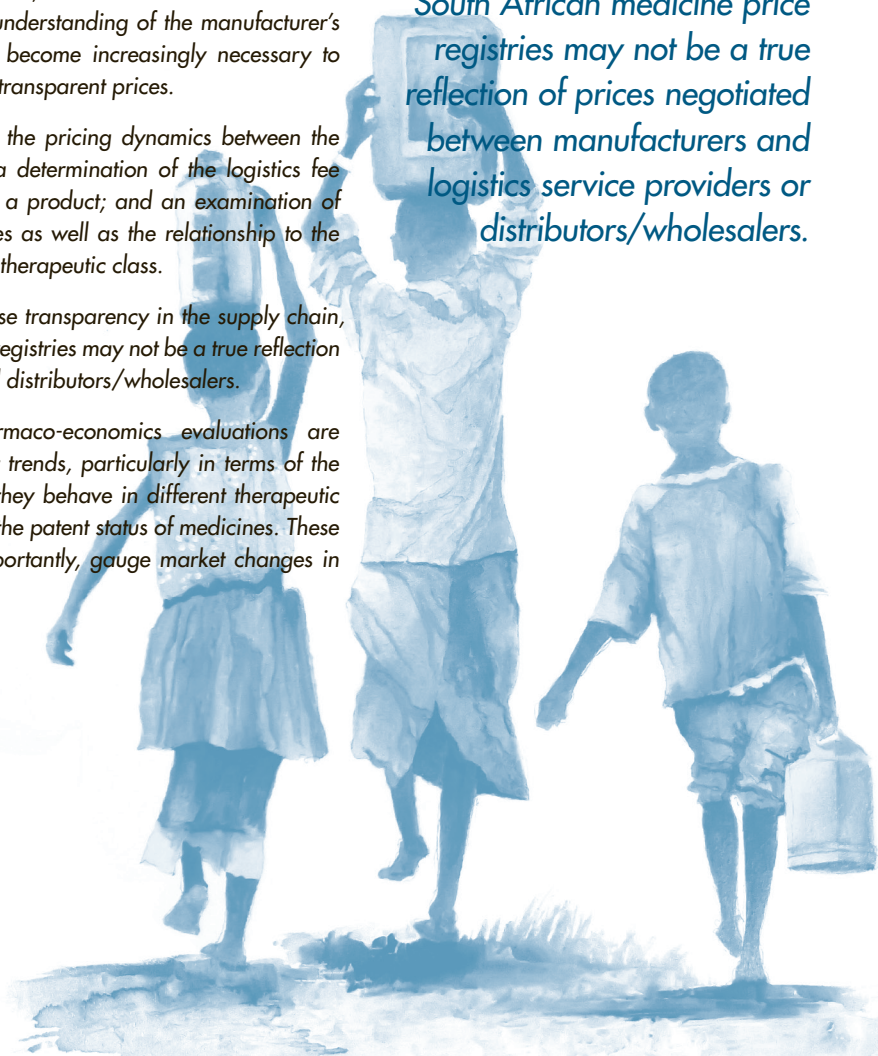
South Africa has instituted various mechanisms to render the pricing of pharmaceuticals more transparent, including the Single Exit Price (SEP) that clarifies the price at which a manufacturer may sell a medicine to logistics service providers or medicine dispensers. The SEP consists of an ex-manufacturer price, a logistics fee and Value Added Tax. However, as more countries look to South Africa for lessons from its pricing policies, an understanding of the manufacturer's price, logistics fees and their relationship has become increasingly necessary to support the principle that the SEP leads to more transparent prices.

This chapter provides a descriptive analysis of the pricing dynamics between the ex-manufacturer's price and the logistics fee; a determination of the logistics fee relationship to the number of manufacturers of a product; and an examination of logistics fees among different therapeutic classes as well as the relationship to the essential medicine status of a product within the therapeutic class.

The findings reveal that despite efforts to increase transparency in the supply chain, prices reflected in South African medicine price registries may not be a true reflection of prices negotiated between manufacturers and distributors/wholesalers.

Initiatives to conduct larger, in-depth pharmaco-economics evaluations are required for a deeper understanding of market trends, particularly in terms of the ex-manufacturer's price and logistics fee: how they behave in different therapeutic medicine classes and in response to changes in the patent status of medicines. These findings should guide policy decisions and importantly, gauge market changes in response to the various policies.

Despite efforts to increase transparency in the supply chain, prices reflected in South African medicine price registries may not be a true reflection of prices negotiated between manufacturers and logistics service providers or distributors/wholesalers.



## Introduction

The current landscape of the South African healthcare system has to a large extent stemmed from the country's previous political dispensation. This history has resulted in gross inequality in access to and affordability of health care in an already severely under-resourced system grappling with a high disease burden.<sup>1</sup> Post-apartheid efforts to resolve this tenuous situation revolved around the restructuring of the South African healthcare sector, which resulted in the publication of the National Drug Policy in 1996.<sup>2</sup> Among the economic objectives of this policy has been the need to reduce the cost of medicines in both the private and public sectors.<sup>2</sup> To meet these objectives, the policy document importantly included the establishment of a 'Pricing Committee' tasked to monitor and regulate medicine prices. The policy also highlighted the need for "total transparency in the pricing structure of pharmaceutical manufacturers, wholesalers, providers of services, such as dispensers of drugs, as well as private clinics and hospitals".<sup>2</sup> Importantly, these policies were intended to apply only to the private sector, as medicines procurement in the public sector continued to be based on a national competitive tender process, limited to locally registered products.<sup>3</sup>

Previously in the private sector, medicine price inflation, medicine price transparency, and medicine price uniformity represented significant problems in an unregulated medicines market.<sup>4</sup> The loss of benefits to consumers resulting from the high levels of discounting and payment of incentives within the pharmaceuticals supply chain had raised serious concerns in the National Department of Health (NDoH) and made it difficult to determine the true price of a medicine.<sup>5</sup> The introduction of government medicine pricing interventions aimed at reducing the prices of medicines and controlling the mark-ups instituted by the various stakeholders along the entire supply chain from the manufacturer to the final medicine dispenser, saw the prohibition of said discounts and rebates in the pharmaceutical sector; mandatory offering of generic substitution; the application of a Single Exit Price (SEP) from manufacturers (which included a logistics fee for logistic service providers such as wholesalers or distributors); and a separate dispensing fee for retailers.<sup>3,6,7</sup>

After much challenge and repeated litigation in the South African courts, the SEP was introduced in 2004, and was determined for each medicine on the basis of the net value of sales, including discounts from the previous year.<sup>3,8</sup> Pharmaceutical manufacturers make submissions to the NDoH for SEPs for new medicines. This price is determined by the manufacturer and signifies a fixed price at which manufacturers and importers have to sell medicines, without an opportunity to offer discounts.<sup>9</sup> The ex-manufacturer price, logistics fee and Value Added Tax (VAT) constitute the three components of the SEP. The SEP is adjusted on an annual basis and these maximum annual increases are regulated.<sup>10</sup>

The final logistics fee, as submitted in the manufacturer application for SEP or SEP adjustments, is available on a price list found on the NDoH website. The logistics fee is determined through negotiation between the manufacturer or importer and the logistic service provider.<sup>9</sup> The process and contracts are not made public. Wholesalers and distributors are paid a logistics fee by manufacturers, from the SEP; however, whether all logistic service providers are able to negotiate the same fee or whether this fee is as reflected in the medicines database is not evident.<sup>3</sup>

Fundamentally, the objectives of attaining price transparency are to improve economic efficiency; obtain accurate price information to assist policymakers and researchers; empower buyers to negotiate more strategically; and to hold pharmaceutical firms more accountable for prices.<sup>11</sup> Previous editions of the *South African Health Review* have covered the development and implications of pharmaceutical pricing policies.<sup>12-16</sup> The most recent Health Policy and Legislation chapter in the *Review* (2013/2014) also briefly mentioned the progress of legislation in this area.<sup>17</sup> Previous Medicor Medicines Reviews provide some information on generic medicine use, and the effect of newly launched and expensive medicines in the private sector market, as well as changes in SEP for a basket of medicines.<sup>18,19</sup> However, none of these reviews examined the impact of policy implementation on the prices of medicines, or whether transparency has been achieved. Thus no information exists as to the effect of SEP adjustments on logistics fees, or whether increases in SEP reflect an increase in both the ex-manufacturer price and logistics fee increases, on an annual basis, as a result of increasing costs of doing business for both manufacturers and wholesalers or distributors.

South Africa has undergone a number of policy changes pertaining to supply chain and pharmaceutical pricing.<sup>12-17</sup> Improved understanding and knowledge of the realities of the ex-manufacturer price, and logistics fees and their relationship have become increasingly necessary, especially in the light of published policy, requesting comment for the regulation of the logistics fee component of the SEP.<sup>20</sup> In addition, a Gazette notice has been issued for comment on suggested changes to what is perceived as a bonus or a perverse incentive,<sup>21</sup> which could impact on what is being charged as a logistics fee, and might actually be considered a discount. Should this Gazette be implemented, logistics fees will have to be disclosed and be non-discriminatory.

Another proposed policy to reduce medicine prices is International Benchmarking.<sup>3</sup> The methodology implies that South African medicine prices will be compared with those of a basket of countries. The selection of the countries was based on a number of factors, one being that the prices of the products in those countries were publicly available. Should other countries want to include South Africa in their basket of countries for benchmarking, South Africa would be an attractive option due to the availability of the Medicines Pricing database.

Finally, there is a move to introduce universal health coverage in South Africa through National Health Insurance (NHI).<sup>22</sup> Currently, in the public sector, the government is responsible for providing essential medicines for the South African population. Essential medicines can be defined as those medicines that satisfy the priority healthcare needs of the population, developed with careful consideration of disease prevalence in South Africa, evidence of medicine efficacy and safety, and comparative cost-effectiveness.<sup>23,24</sup> Essential medicines are not charged to patients as a separate fee in the public sector. As mentioned, equity in health care for all South African citizens was of fundamental importance in developing the National Drug Policy, and the implementation of an Essential Medicine List (EML) played a pivotal role in achieving this. Under NHI, the EML may not operate solely in the current public sector but be included under NHI-funded plans, which will incorporate a unified set of

treatment guidelines and clinical pathways. While there is still some way to go before the two sectors operate under a unified NHI system, it would be interesting to understand how a medicine deemed essential in the public sector is priced in terms of the SEP (including the logistics fee) in the private sector under the current system.

As a surrogate to determine transparency, the primary objectives of this study were therefore to examine pricing dynamics between the ex-manufacturer price and the logistics fee; to determine the logistics fee relationship to the number of manufacturers of a product; and to examine logistics fees among different medicine classes, as well as the relationship to the essential medicine status of a product within medicine classes. This investigation is also important for other African countries referring to South Africa's experience and lessons learnt in implementing pricing policies. African countries are seeking to institute pricing interventions in order to improve the availability, affordability and acceptability of medicine access,<sup>25,26</sup> especially in the supply and distribution chain.<sup>27</sup>

## Methodology

A cross-sectional descriptive study was undertaken to examine the SEPs for a basket of medicines over a five-year period. Data used in the study were retrieved from the South African Medicine Price Registry on private sector prices for originator and generic medicines from 10 December 2009 to 20 December 2013.<sup>28</sup>

The research was designed to focus on a set of acute and chronic conditions that have been identified to cause significant morbidity and mortality globally. These include cardiovascular diseases, diabetes, asthma, respiratory tract infections and mental illness. The global core list of medicines generated by the World Health Organization and Health Action International (WHO/HAI) Medicine Pricing Survey,<sup>29</sup> plus medicines (in the same dosage form) in each core medicine class in the South African Medicines Formulary,<sup>30</sup> were selected for detailed analysis to elicit logistics fee comparisons between medicine classes.

The SEP is made up of the ex-manufacturer price, logistics fee and VAT. VAT is charged at a standard 14% across the board and is calculated from the sum of the ex-manufacturer price and the logistics fee and added to the combination of these two prices. The ex-manufacturer price, logistics fee and the SEP for all selected medicines were collected and expressed in South African Rand. These prices were obtained from the locked database and no further price adjustments for that year were possible, i.e. all SEP adjustments had been made for that year. The relationship between the three variables over the five-year period was plotted for all originator medicines and the corresponding lowest-priced generic option, where available in the dataset specific to that strength. To ensure commonality and consistency of results, the lowest-priced generic as at 10 December 2009 was chosen for each of the originator medicines in order to display trends throughout the designated study period. Data for the following originator medicines: indomethacin, amoxicillin, trimipramine, cefotaxime and co-trimoxazole, were not available for the entire study period and were therefore excluded. The pricing data for paracetamol syrup (schedule zero) were not included as schedule zero medications are currently exempt from pricing regulations in South Africa.<sup>31</sup>

The ex-manufacturer price, logistics fee and the SEP inclusive of VAT for each sample medicine were recorded as at 20 December 2013. These results were investigated statistically using correlation analysis to determine the relationship between the number of manufacturers and the logistics fee as well as to make descriptive comparisons in relation to medicine class and the logistics fee. The essential medicine status as listed in the most recently published Standard Treatment Guidelines and Essential Medicines List (EML) for two levels,<sup>24,32,33</sup> was recorded for each surveyed medicine to elaborate on this relationship to the logistics fee.

The annual logistics fee as a percentage of the SEP of the originator and lowest priced generic was compared to the consumer price index (CPI). This was done for the years 2009–2013. The CPIs in percentage, as obtained from Statistics South Africa, were 7.26 (2009); 4.1 (2010); 5.01 (2011); 5.75 (2012) and 5.77 (2013).<sup>34</sup> The CPI "expresses the current prices of a basket of goods and services in terms of the prices during the same period in a previous year, to show effect of inflation on purchasing power".<sup>35</sup> The CPI is a measure of inflation. In Canada, the Canadian Patented Medicines Prices Review Board sets maximum introductory prices for newly patented medications, and regulates the prices of medicines by calculating a consumer price index adjustment factor.<sup>36,37</sup> The CPI is also one of the measures that the Minister of Health should consider when reviewing the SEP on an annual basis.<sup>38</sup>

## Results

The changes in the SEP components for the originator and lowest-priced generic medicines were tracked for 50 medicines (see Table 1 for list of medicines).

Of these, 16 medicines did not have any generic competition. The relationship between the changes in ex-manufacturer price, logistics fee and SEP over the five-year period showed that the majority of medicines surveyed could be grouped into one of two categories, i.e. Trend 1 (Table 2) and Trend 2 (Table 3), which was demonstrated using quinapril as an example. Both tables reveal an anticipated steady increase in the SEP over the study period. However, they differed with regard to changes in the ex-manufacturer price and logistics fee components. Table 2, showing the trend observed for 65.1% of medicines (of which 73.6% were originator medicines), revealed that it was common for the ex-manufacturer price to increase in proportion to the SEP, while the logistics fee remained constant or was slightly increased. Table 3, showing the trend apparent for only 20.1% of medicines (of which 47.1% were originator medicines), revealed that increases in the ex-manufacturer price were met with proportional decreases in the logistics fee. The remaining 14.8% of medicines displayed trends that were different from both Table 2 and Table 3. These trends were not included as they also differed from each other, but they are available on request.

Table 1: Summary of trends for 50 medicines surveyed from 10 December to 20 December 2013

Medicine Class	Medicine	Patent status	Trend 1	Trend 2	Neither Trend 1 or 2	
Short-acting beta <sub>2</sub> agonists	Terbutaline 0.5mg/dose INH	Originator	x			
		Lowest-priced generic	None available			
	Fenoterol 100mcg/dose INH	Originator	x			
		Lowest-priced generic	None available			
	Salbutamol 100mcg/dose INH	Originator	x			
		Lowest-priced generic			x	
Beta <sub>1</sub> selective beta blockers	Nebivolol 5mg tab	Originator	x			
		Lowest-priced generic			x	
	Metoprolol 100mg tab	Originator		x		
		Lowest-priced generic	None available			
	Bisoprolol 5mg tab	Originator		x		
		Lowest-priced generic		x		
	Acebutolol 200mg cap	Originator	x			
		Lowest-priced generic	None available			
	Atenolol 50mg tab	Originator	x			
		Lowest-priced generic		x		
Proton pump inhibitors	Rabeprazole 20mg tab	Originator	x			
		Lowest-priced generic	None available			
	Pantoprazole 40mg tab	Originator	x			
		Lowest-priced generic			x	
	Esomeprazole 20mg tab	Originator	x			
		Lowest-priced generic	None available			
	Lansoprazole 30mg cap	Originator			x	
		Lowest-priced generic	x			
	Omeprazole 20mg cap	Originator	x			
		Lowest-priced generic	x			
	HMG CoA reductase inhibitors	Simvastatin 20mg tab	Originator	x		
			Lowest-priced generic			x
Atorvastatin 10mg tab		Originator	x			
		Lowest-priced generic			x	
Fluvastatin 80mg tab		Originator		x		
		Lowest-priced generic	None available			
Lovastatin 40mg tab		Originator	x			
		Lowest-priced generic	None available			
Pravastatin 40mg tab		Originator	x			
		Lowest-priced generic	x			
Rosuvastatin 5mg tab		Originator	x			
		Lowest-priced generic			x	
Sulphonylureas	Gliclazide 80mg tab	Originator	x			
		Lowest-priced generic		x		
	Glimepiride 4mg tab	Originator	x			
		Lowest-priced generic		x		
	Glipizide 5mg tab	Originator	x			
		Lowest-priced generic	None available			
	Glibenclamide 5mg tab	Originator	x			
		Lowest-priced generic			x	
Fluoroquinolones	Ciprofloxacin 500mg tab	Originator	x			
		Lowest-priced generic	x			
	Moxifloxacin 400mg tab	Originator	x			
		Lowest-priced generic	x			
	Levofloxacin 250mg tab	Originator			x	
		Lowest-priced generic			x	
	Gemifloxacin 320mg tab	Originator	x			
		Lowest-priced generic	None available			
	Norfloxacin 400mg tab	Originator	x			
		Lowest-priced generic	x			
	Ofloxacin 400mg tab	Originator	x			
		Lowest-priced generic	x			

Medicine Class	Medicine	Patent status	Trend 1	Trend 2	Neither Trend 1 or 2	
Acetic acid derivatives	Diclofenac 50mg tab	Originator		x		
		Lowest-priced generic	x			
	Ketorolac 10mg tab	Originator	x			
		Lowest-priced generic	None available			
Angiotensin-converting enzyme inhibitors	Enalapril 5mg tab	Originator	x			
		Lowest-priced generic		x		
	Fosinopril 20mg tab	Originator	x			
		Lowest-priced generic		x		
	Trandolapril 2mg cap	Originator				x
		Lowest-priced generic	None available			
	Perindopril 4mg tab	Originator	x			
		Lowest-priced generic				x
	Ramipril 1.25mg tab	Originator	x			
		Lowest-priced generic	x			
	Quinapril 5mg tab	Originator	x			
		Lowest-priced generic			x	
	Captopril 25mg tab	Originator	x			
		Lowest-priced generic	x			
	Benazepril 10mg tab	Originator			x	
		Lowest-priced generic	None available			
Lisinopril 5mg tab	Originator	x				
	Lowest-priced generic	x				
Long-acting Benzodiazepines	Diazepam 5mg tab	Originator	x			
		Lowest-priced generic	x			
	Flurazepam 30mg cap	Originator	x			
		Lowest-priced generic	None available			
	Chlordiazepoxide 25mg tab	Originator	x			
		Lowest-priced generic	None available			
Tricyclic antidepressants	Amitriptyline 25mg tab	Originator		x		
		Lowest-priced generic		x		
	Clomipramine 25mg tab	Originator			x	
		Lowest-priced generic	x			
	Dosulepin 25mg tab	Originator	x			
		Lowest-priced generic			x	
	Imipramine 25mg tab	Originator	x			
		Lowest-priced generic	x			
	Lofepramine 70mg tab	Originator			x	
		Lowest-priced generic	None available			
	Third-generation Cephalosporins	Ceftazidime 500mg inj	Originator	x		
			Lowest-priced generic			x
Ceftriaxone 1g inj		Originator	x			
		Lowest-priced generic	x			

Note: INH – inhaler, tab – tablet, cap – capsule, inj – injection.

Table 2: Distribution of SEP, ex-manufacturer fee and logistics fee over five years, where the logistics fee is constant (quinapril – originator)

Year	Ex-manufacturer price	Logistics fee	SEP
2009	78.35	5.09	95.12
2010	78.35	5.09	95.12
2011	85.95	5.59	104.36
2012	85.95	5.59	104.36
2013	90.94	5.91	110.41

All prices are in Rand.

Table 3: Distribution of SEP, ex-manufacturer price and logistics fee over five years, where there is an inverse relationship to the logistics fee (quinapril – generic)

Year	Ex-manufacturer price	Logistics fee	SEP
2009	41.02	4.35	51.72
2010	41.02	4.35	51.72
2011	41.02	4.35	51.72
2012	43.72	2.62	52.83
2013	46.25	2.78	55.89

All prices are in Rand.

Table 4: Median SEP components as at 20 December 2013<sup>a</sup>

Disease	Medicine Class	Medicine Name/Strength/ Dosage Form	Median Log/SEP (%)	Median Ex-Man/ SEP (%)	No. of Manufacturers	EML
Asthma	Short-acting beta <sub>2</sub> agonists	Terbutaline 0.5mg/dose INH	2.97	84.76	1	N
		Fenoterol 100 mcg/dose INH	7.76	79.97	1	N
		Salbutamol 100mcg/dose INH	5.37	82.37	3	Y
Cardiovascular disease	Beta, selective beta blockers	Nebivolol 5mg tab	9.61	78.12	2	N
		Metoprolol 100mg tab	6.22	81.5	1	N
		Bisoprolol 5mg tab	8.78	78.95	6	N
		Acebutolol 200mg cap	3.98	83.75	1	N
		Atenolol 50mg tab	10.94	76.79	10	Y
Ulcer	Proton Pump Inhibitors	Rabeprazole 20mg tab	10.22	77.51	1	N
		Pantoprazole 40mg tab	10.07	77.66	7	N
		Esomeprazole 20mg tab	2.97	84.76	1	N
		Lansoprazole 30mg cap	7.90	79.83	9	N
		Omeprazole 20mg cap	10.44	77.29	7	Y
Cardiovascular disease	HMG CoA Reductase Inhibitors	Simvastatin 20mg tab	8.78	78.95	18	Y
		Atorvastatin 10mg tab	9.61	78.12	10	N
		Fluvastatin 80mg tab	6.22	81.5	1	N
		Lovastatin 40mg tab	13.16	74.57	1	N
		Pravastatin 40mg tab	13.16	74.57	4	N
		Rosuvastatin 5mg tab	8.78	78.95	3	N
Diabetes	Sulphonylureas	Gliclazide 80mg tab	8.37	79.35	8	Y
		Glimepiride 4mg tab	8.78	78.95	9	N
		Glipizide 5mg tab	5.36	82.37	1	N
		Glibenclamide 5mg tab	11.19	76.54	4	Y
Infectious disease	Fluoroquinolones	Ciprofloxacin 500mg tab	8.78	78.95	17	Y
		Moxifloxacin 400mg tab	9.09	78.64	6	Y
		Levofloxacin 250mg tab	10.97	76.76	5	N
		Gemifloxacin 320mg tab	13.16	74.57	1	N
		Norfloxacin 400mg tab	7.64	80.09	4	N
Pain/inflammation	Acetic Acid Derivatives	Diclofenac 50mg tab	10.92	76.83	6	Y
		Indomethacin 25mg cap	10.44	77.29	7	Y
		Ketorolac 10mg tab	8.32	79.41	1	N
Infectious disease	Sulphonamide and Trimethoprim Combination	Co-trimoxazole 240mg/5mL susp	9.06	78.64	8	Y
Pain/inflammation	Anilides	Paracetamol 120mg/5mL syr	11.28	76.45	4	Y
Cardiovascular disease	Angiotensin-converting enzyme inhibitors	Enalapril 5mg tab	10.17	77.54	4	Y
		Fosinopril 20mg tab	11.49	76.2	3	N
		Trandolapril 2mg cap	9.69	78.03	1	N
		Perindopril 4mg tab	7.98	79.75	4	N
		Ramipril 1.25mg tab	10.97	76.76	2	N
		Quinapril 5mg tab	5.17	82.56	2	N
		Captopril 25mg tab	12.64	75.09	8	Y
		Benazepril 10mg tab	6.22	81.5	1	N
Central nervous system	Long-acting Benzodiazepines	Diazepam 5mg tab	12.06	75.68	4	Y
		Flurazepam 30mg cap	7.25	80.48	1	N
		Chlordiazepoxide 25mg tab	7.25	80.48	1	N
Depression	Tricyclic Antidepressants	Amitriptyline 25mg tab	10.97	76.76	4	Y
		Clomipramine 25mg tab	7.8	79.93	3	N
		Dosulepin 25mg tab	11.49	76.24	1	N
		Imipramine 25mg tab	10.97	76.76	2	N
		Lofepamine 70mg tab	8.16	79.57	1	N
		Trimipramine 25mg tab	13.16	74.57	1	N
		Dothiepin 75mg tab	13.59	74.14	2	N
Infectious disease	Aminopenicillin	Amoxycillin 500mg cap	8.38	79.35	16	Y
Infectious disease	Third-generation Cephalosporins	Ceftazidime 500mg inj	13.61	74.1	2	Y
		Cefotaxime 500mg inj	12.3	75.42	4	Y
		Ceftriaxone 1g inj	8.77	78.95	13	Y

Table 4 reflects the median logistics fees and median ex-manufacturer price expressed as a percentage of the SEP for each medicine in the selected class, together with the total number of manufacturers and EML status as at 20 December 2013.

The results reveal that there were large variations in the logistics fee components between all classes of medicines, and that the median spread of the logistics fee increased as the number of medicines available in each class increased. Overall, a weak correlation exists between the number of manufacturers and the logistics fee for each medicine in a class (Pearson's correlation coefficient  $r=0.09$ ); however, this does not necessarily indicate that logistics fees are not levied as a means of introducing final price competition. This phenomenon may actually be class-dependent, as it was noted that medicines with the highest logistics fee component were also the medicines that had limited competition (1–2 manufacturers) in certain medicine classes only, i.e. short-acting  $\beta_2$  agonists, fluoroquinolones, tricyclic antidepressants and third-generation cephalosporins.

Medicines on the EML represent those that had the highest number of different manufacturers in every medicine class surveyed. In most instances, they also had median logistics fees higher than the logistics fee of other medicines in their group, with the exception of the following medicine classes: tricyclic antidepressants, fluoroquinolones, HMG CoA reductase inhibitors and short-acting  $\beta_2$  agonists.<sup>a</sup>

Overall, the ex-manufacturer price and logistics fees relative to the SEP varied widely across all medicine classes studied. The results show that 54.4% of the median logistics fee segment were less than 10%. As a medicine class, third-generation cephalosporins had the highest median logistics fee segment at 12.3%.

The findings revealed that for the majority of surveyed medicines (74.4%;  $n=61$ ), the logistics fee/SEP percentage (as indicated in the medicines price database) was generally above the CPI for each year. Of the remaining medicines that were below the CPI (25.6%,  $n = 21$ ), all except four were originator medicines.

Of the 258 medicines surveyed, four medicines, namely fosinopril, bisoprolol, pantoprazole and moxifloxacin, also had clones manufactured by the originator company. Table 5 shows the differences in the SEP components of these medicines as at 20 December 2013.

Apart from bisoprolol, both the ex-manufacturer price and the logistics fee for the originator medicine were higher than those for the respective clone, but the percentage of logistics fee and ex-manufacturer price of the SEP remained the same or quite similar. The ex-manufacturer price and the logistics fee for the highest-priced generics for each of the medicines in Table 5 were lower than those for the originator and the clone.

## Discussion

The price of medicines has long been established as an important measure in ensuring medicine accessibility.<sup>39</sup> However, the pricing of medicines is reliant on policies unique to each country. South Africa's efforts in trying to achieve accessible and affordable medicines in the private sector have been described as anticompetitive by several industry players.<sup>40,41</sup> Despite the benefits of increased transparency, empirical evidence has shown that highly regulated markets with low medicine prices may have unintended consequences.<sup>42–44</sup> Price regulation, specifically price ceilings, may result in perverse

Table 5: Price component comparisons of originator, clones and the highest-priced generic medicines (20 December 2013)

Medicine	Ex-manufacturer's fee	Logistics fee (Ic)	VAT	SEP	Unit SEP	Log/ SEP (%)	Ex-man/SEP (%)
Fosinopril 20mg tab							
Originator	169.34	25.54	27.28	222.16	7.41	11.49	76.22
Originator generic	149.79	23.08	24.2	197.08	6.57	11.71	76
Highest-priced generic	124.38	7.46	18.46	150.31	5.01	4.96	82.75
Bisoprolol 5mg tab							
Originator	74.04	7.58	11.43	93.05	3.1	8.15	79.57
Originator generic	74.04	7.58	11.43	93.05	3.1	8.15	79.57
Highest-priced generic	39.93	5.99	6.43	52.35	1.75	11.44	76.28
Pantoprazole 40 tab							
Originator	306.64	39.75	48.49	394.89	14.1	10.07	77.65
Originator generic	191.25	25.82	30.39	247.45	8.84	10.43	77.29
Highest-priced generic	184.46	23.90	29.17	237.54	8.48	10.06	77.66
Moxifloxacin 400mg tab							
Originator	334.13	30.98	51.12	416.23	41.62	7.44	80.28
Originator generic	241.21	28.95	37.82	307.98	30.79	9.39	78.32
Highest-priced generic	243.14	27.02	37.82	307.98	30.79	8.77	78.95

All prices are in Rand.

<sup>a</sup> INH – inhaler, tab – tablet, cap – capsule, susp – suspension, syr – syrup, inj – injection, Log – logistics fee, Ex-man – Ex-manufacturer, EML – essential medicines list. All manufacturer medicines on the NDoH tender list were considered for the study in the same strength, dosage form and pack size as the originator medicine. VAT averaged 14% of the SEP for all medicines surveyed

economic effects for businesses.<sup>45</sup> Consequently, business may be forced to take other actions to recover their lost profits. This may have been the case in South Africa, post-SEP implementation, when firms possibly altered the logistics fee to recover profits lost from changes in the ex-manufacturer price, or created market incentives by paying higher logistics fees to create an economic incentive to market their products. It was previously cited that originator companies with no other generic competition often paid low or no logistics fees to wholesalers who were desperate to stock their products. This placed generic companies at a disadvantage, as wholesalers would often 'squeeze' them for higher logistics fees to make up for the loss sustained in dealings with originator companies.<sup>46</sup> However, the occurrence of this may be class-dependent, as observed in the current study.

The results of this study indicate that the number of manufacturers was not a determinant of the logistics fee component of the SEP for the majority of the medicine classes surveyed, and that EML status generally resulted in higher logistics fee components. Furthermore, the dynamics between the ex-manufacturer price and the logistics fee do not follow expected market trends, according to which they should ideally increase collectively as they are both exposed to the same inflationary pressures over time. These findings confirm arguments that the ex-manufacturer price and logistics fee reflected in the medicines database are not the actual and accurate representation of the fees negotiated by manufacturers and wholesalers.

The results reflected in Tables 2, 3 and 4 are consistent for a country like South Africa, where although the SEP is transparent, the ex-manufacturer price and the logistics fee component of this price are not; therefore, the mark-ups in the distribution chain are not very clear. Manufacturers could also be using a higher logistics fee to incentivise wholesalers and distributors to stock their products and thus create the push for their products down the chain. The logistics fee has previously been quoted as generally being between 10% and 15% of the final price in an unregulated market.<sup>43</sup> Slightly more than half of the medicines in this study had a reported logistics fee of less than 10%. The results show that despite the similarity in the type of products (dosage form and storage conditions), medicines still do not attract the same logistics fees.

As mentioned, the ex-manufacturer price/cost represents the highest segment of the final selling price, or in South Africa's case, the SEP. According to IMS Health Incorporated, the ex-manufacturer price is associated with manufacturers, particularly originators, needing to recover costs associated with initial research and development, as well as regulatory approval, marketing and production, among other factors (including a profit margin), which further differ between types of medicine, manufacturers and countries.<sup>47</sup> Generic manufacturers, however, generally have relatively low development and manufacturing costs, which was also evident in this study, even between originator medicines and their clones.<sup>47</sup> One would expect that even though the ex-manufacturer price is likely to differ, the logistics fee should be the same, as is observed for bisoprolol tablets. A valid recommendation stemming from this and previous studies is the implementation of uniform distribution fees for similar products, with clear stipulation of distribution costs and activities applied to all stakeholders.<sup>7,48</sup>

One would expect that both the ex-manufacturer price and the logistics fee would increase, as they are both exposed to the same CPI changes, while the ex-manufacturer prices might increase more due to international currency fluctuations. In 2014, the Pricing Committee considered various inflators for different medicines, whether these were generic medicines (fully imported or locally produced) or originator medicines.<sup>38</sup> The premise was that the cost pressure for each of these medicines would be different and that the extent to which each would be affected by inflation and the exchange rate would also differ.<sup>38</sup> This is also evident when looking at the differences in logistics fees between originator medicines and their clones as one would expect these to be identical; however, our findings show that they do differ in certain instances. This could be to ensure that prices are more competitive than those being set by the generic medicines.

Results reveal that as a class, no particular medicine group uniformly displayed high or low logistics fee components. Instead they displayed a spread of logistics fees depending on either the EML status of the medicine or the number of manufacturers. The differences in logistics fees could be attributed to a range of factors, including differences in product type, product categories in operation and labour requirements attached to different medicines. However, this is a further illustration that the logistics fees disclosed on the database are not the actual fees paid.

There is room for greater transparency with regard to logistics fees for medicines in South Africa. Allegations of exploitation of the logistics fee by pharmaceutical companies have led to the proposed cap on the logistics fee as opposed to a fixed fee.<sup>49</sup> This policy will, however, require monitoring on implementation to ascertain whether it is feasible. Transparency in this segment of the supply chain should be strived for, and could possibly be achieved through logistics fee contracts being made public, or through negotiations between the National Department of Health and wholesalers and distributors.<sup>7</sup> Considering all of the evidence on price transparency, the majority of the empirical studies have found that greater price transparency leads to lower and more uniform prices.<sup>42</sup> Furthermore, price competition through discounts in the supply chain is not transparent or fair, as distributors are not rewarded for services rendered, but for their ability to negotiate discounts. Such systems are not sustainable in the long term, as healthcare payers and patients do not capture the envisaged potential savings from a generic medicines market where companies compete on price.<sup>49</sup>

South Africa has already begun the process of implementing several of the recommendations made by the World Health Organization in relation to the regulation of mark-ups in the pharmaceutical supply and distribution chain.<sup>44</sup> However, these processes can be further strengthened by attaining complete transparency in the price components of the SEP. South Africa currently applies an umbrella policy to all medicines, but should also consider applying such policies to select medicine groups only, noting that not all medicines share the same health benefit or status, e.g. essential medicines. The South African EML identifies the minimum medicines that patients should have access to; these are the "most efficacious, safe and cost-effective medicine for priority conditions".<sup>23,24</sup> It is therefore imperative to ensure that these medicines are attainable and affordable at all times, and that they are subjected to tighter pricing and margin regulations.



It is important to note that a potential future role for logistics service providers exists under NHI. These providers could be used to supply medicines to public health facilities as a departure from the current Medicine Depot model. As such, it is necessary for a supply chain to be sustainable in the private sector in order to ensure that these systems exist for NHI.

The actual contractual agreements for logistics fees are not in the public domain and could not be used to compare reported trends with actual trends.

## Recommendations

Research on SEP reveals gaps in the literature regarding how the various players in the supply chain have adjusted their daily practices to survive imposed policies. It is therefore recommended that more qualitative research (documenting the views of the various stakeholders) be undertaken, as well as quantitative research to determine whether the logistics fees reflected on the NDoH website are a true reflection of the prices actually being paid.

The results of this study foreground a dire need for more robust information on medicine pricing in the South African pharmaceutical sector to guide further policy decisions, gauge market changes in response to the various policies, and ensure transparent pricing. These results are important in that they aid policymakers in selecting and implementing policies that will make medicines more inexpensive for patients, whilst ensuring the viability of the supply chain, rather than merely instituting an umbrella policy that will interfere with regular market competition and dynamics. While many studies have looked at benchmarking, very few studies have investigated the implementation and impact of distribution chain fees. This aspect is also not made transparent to all stakeholders. Whilst the SEP is transparent, the components other than VAT remain opaque and this is further highlighted by the NDoH's efforts to regulate the logistics fee, introduce international benchmarking, remove further discounts and bonuses, and conduct pharmaco-economic evaluations.

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