Emerging Market Stakeholder Impact of Pharmaceutical Drug Patent Expiration

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ABSTRACT

This qualitative phenomenological research project focused on the impact of pharmaceutical drug patent expiration on various stakeholders in South Africa, viz., pharmaceutical companies (originator and generic), medical doctors, pharmacists and patients. A key objective was to understand how each stakeholder group was affected by the loss of drug patent and subsequent entry of generic drugs. The entry of generic drugs has a substantial effect on the originator company, driving them to enforce various marketing strategies to mitigate this effect. The research takes a closer look at strategies employed by originator companies during this period. Furthermore, the research explores the relationships amongst stakeholders, and how it influences their decision-making process when it comes to originator and generic drugs. The research also acknowledges the health challenges that exists in South Africa, and the impact that it has on the pharmaceutical and health sector.

Keywords **:** Healthcare; Drug patent expiration; Emerging market; South Africa; Stakeholders; Accessibility

INTRODUCTION

This study investigates the phenomenon of drug patent expiration in an emerging economy, South Africa, and the effect it has on the various stakeholders involved: pharmaceutical companies, pharmacists, medical doctors and patients. These relationships are governed by various patent laws and regulations within the health sector, which may differ in developed and developing countries.

The pharmaceutical industry is undergoing increased pressure from patent expirations, budget constraints and the resultant impact on their customers and business relationships (Paul, Mytelka, Dunwiddie, Persinger, Munos, Lindborg & Schacht, 2010). Patent expirations serve as a huge financial burden and market share loss (Pearce, 2008) to companies, also allowing other pharmaceutical companies to manufacture and sell bioequivalent versions of the original drug (ScottMorton, 2000) and thereby heightening competition and price wars (Wilkie, Johnson, & White, 2012). Companies therefore have to explore various strategies to lessen the impact of generic entry into the market. These strategies may include promotional, product-related, pricing or creative partnerships (Gregson, Sparrowhawk, Mauskopf & Paul, 2005). The entry of generic products and its impact is dependent on a number of factors such as approval to market, pricing and reimbursement, prescription and distribution. It is thus evident that drug patent expiration not only has a profound effect on pharmaceutical companies, but also on doctor prescribing methods, pharmacy margins, pharmacist right of substitution and most importantly the health and financial impact on patients (Garattini & Tediosi, 2000).

Pharmacists play a prominent role in drug distribution once a product has lost its patency. This is greatly impacted by the relationship between pharmacies and pharmaceutical companies, as well as the relationship between the pharmacist and the patient. Pharmacists are governed by certain laws regarding product distribution which may differ from country-to-country (Vaughan, 2001). In certain countries like South Africa (SA), pharmacists are encouraged to use generic medicines instead of the original as stated in the right of substitution policy. They are therefore perceived to be in greater support of the generic market rather than products from the originator companies, due to the substitution laws and pricing models. It is also believed that certain pharmaceutical companies and pharmacies may at times engage in business deals influencing the use of a particular drug (Manchanda, Wittink, Ching, Cleanthous, Ding, Dong, Leeflang, Misra, Mizik, Narayanan, Steenburgh, Wieringa, Wosinska, & Xie, 2005). The dilemma often faced by pharmacists is the decision-making process, whether to dispense products scripted by the doctor, or whether to substitute the generic offering.

Medical doctors play a vital role in the prescription and distribution of either original drugs or generic drugs. A doctor's decision-making process may be as a result of prescription habit and compliance, patient influence, openness to shared decision-making, quality and safety profile of the medication, financial incentive from a third party, or marketing from pharmaceutical companies (Deegan & Drake, 2006). The decision made by the doctor has a direct influence on the patient in terms of health, the pharmacist in terms of dispensing, as well as the pharmaceutical companies in terms of market share and revenue drive (Coscelli, 2000). These decision-makers therefore have a direct influence on the various strategies adopted by pharmaceutical companies to increase their

market share and overcome the challenges generics may present with.

At the centre of this drug life cycle phenomenon is the patient. Drug patent expiration and the entry of generics often results in the adoption of various pricing strategies. Generic companies usually introduce their drugs at a lower price, which is beneficial especially to those patients who are price sensitive. Thomas (2006) also makes mention that the introduction of the generic market may benefit consumer welfare in various ways, e.g., price competition resulting in reduction of the average price of generics. Patient perceptions of generic drugs are, however, that their quality and safety profile is compromised even though it is considered to be 'bioequivalent' to the original branded drug?(Garattini & Tediosi, 2000).

It seems then that pharmaceutical companies, pharmacists, and doctors, all exert influence on the medication provided to the patient, impacting not only their decision-making process, but also the health outcome of the patient. The challenge comes in understanding the dynamics and complexities of these stakeholders when a drug loses its patent, and the impact thereof.

METHODOLOGY

The primary problem highlighted in the literature is the extent to which each stakeholder is affected by the expiration of a drug, and the varying strategies implemented to manage this change process. The overarching question this research sought to address was: 'What is the impact of pharmaceutical drug patent expiration on the various stakeholders i.e., pharmaceutical companies, pharmacists, medical doctors and patients?' This main research question gave rise to a secondary question: 'How this phenomenon influences their decision-making processes?' The main and secondary research questions sought to address the following problems: How significant is product patent expiration on the various stakeholders? What strategies are implemented by stakeholders to mitigate the effect of drug patent expiration? What are the common themes amongst these stakeholders? What is the future impact on these stakeholders? To address all of these, we chose an explorative research methodology, based on a hermeneutic phenomenological approach which adopted more of an interpretivist philosophical framework, with the objective of exploring and understanding a particular social phenomenon (drug patent expiration) within a particular emerging market context (South Africa) (Welman & Kruger, 1999). We used a qualitative approach, to gain an in-depth perspective of the various views and opinions of a number of stakeholders, viz., pharmaceutical companies, pharmacists, doctors and patients. It was therefore important to note that matters regarding corporate pharmaceutical marketing strategy, and patient records, were all highly sensitive information (Kappe, 2013) – non-disclosure agreements of confidentiality were therefore agreed upon to ensure that all company and patient information were protected and concealed. Any pharmaceutical company names or products mentioned in the interviews and discussion were assigned a specific code to ensure confidentiality and anonymity (Dearnley, 2005). As part of primary data collection, face-to-face, semi- structured interviews were engaged in, allowing some form of structure but also leaving room for the participant to expand on his/her thoughts and ideas. Secondary data was also collected, and these were from pharmaceutical industry reports and relevant government papers (Greener, 2008). The purpose of including secondary data was to facilitate data interpretation and a means of addressing particular research issues. Due to the nature of the research, the researchers selected 43 participants using a non-probability approach through purposive sampling. The sample included the four main stakeholders affected by drug patent expiration: **Pharmaceutical Companies (16)** – directors, managers and sales representatives from both originator and generic companies; **Pharmacists (5)** with experience in either the private or government sector or both; **Medical doctors (8)** with experience in either the government or private sector or both. The sample included general practitioners as well as specialists; and, **Patients (14)** of varying ages (young adults-geriatrics) and who were either medical aid- or non-medical aid users. Furthermore, a representative from the health government sector was interviewed, who provided insight into South African patent policies. For those participants who were based abroad or out of town, the researchers conducted the interviews either telephonically or via Skype. A set of 10-14 questions were drawn up, relevant to the objectives of the topic and the stakeholder being interviewed. The average interview time was 1 hour. Each interview was audio recorded and transcribed once the interview was complete. Audio recordings allowed the researchers to capture a real and authentic account of the interview without any bias or subjectivity. Field notes were also taken to ensure concise data gathering and the capturing of relevant information. Throughout the data collection period, the researchers documented reflective notes of their own personal experience. This process, also referred to as memoing, was important as it allowed the researchers to be mindful of external factors and events which they may have overlooked (Groenewald, 2004). To facilitate the process of coding the interview transcripts, and revealing common themes pertinent to the phenomenon, a computer-aided qualitative data analysis software tool (CAQDAS) known as Atlas ti was used. Additionally, this software technique allowed for data to be represented graphically facilitating ease of interpretation by the researchers. The data analysis process focused on three types of coding, viz., open-, axial- and selective coding.

FINDINGS & DISCUSSION

The initial open coding process resulted in 225 codes. After further analysis, the codes with the least applicability were excluded and those that were repeated were merged with the relevant codes. The final sum of codes was 195, embodying the various elements pertinent to the impact of drug patent expiration, and the perceptions from the 43 participants based on their own experience in the health and pharmaceutical industry. Once the open coding process was completed, the researchers proceeded to utilise the axial coding process in order to allocate the codes into their suitable family codes. By comparing and contrasting the various codes, the researchers were able to establish key themes appropriate to the research topic. The family codes were:

- Value of patents and patent expiration
- Policies that govern the system
- Pharmaceutical industry response to patent expiration
- Caring and curing
- Collaboration amongst the various stakeholders
- Perspectives: originator vs. generic drug industry
- South African healthcare challenge
- Future of the pharmaceutical industry

Figure 7 provides a representation of the frequency of each of the family codes that arose through interviews with the 43 participants. The family codes with the highest frequency were, perspectives: originator vs. generic drug industry (21%), collaboration amongst the various stakeholders (20%), and caring and curing (19%).

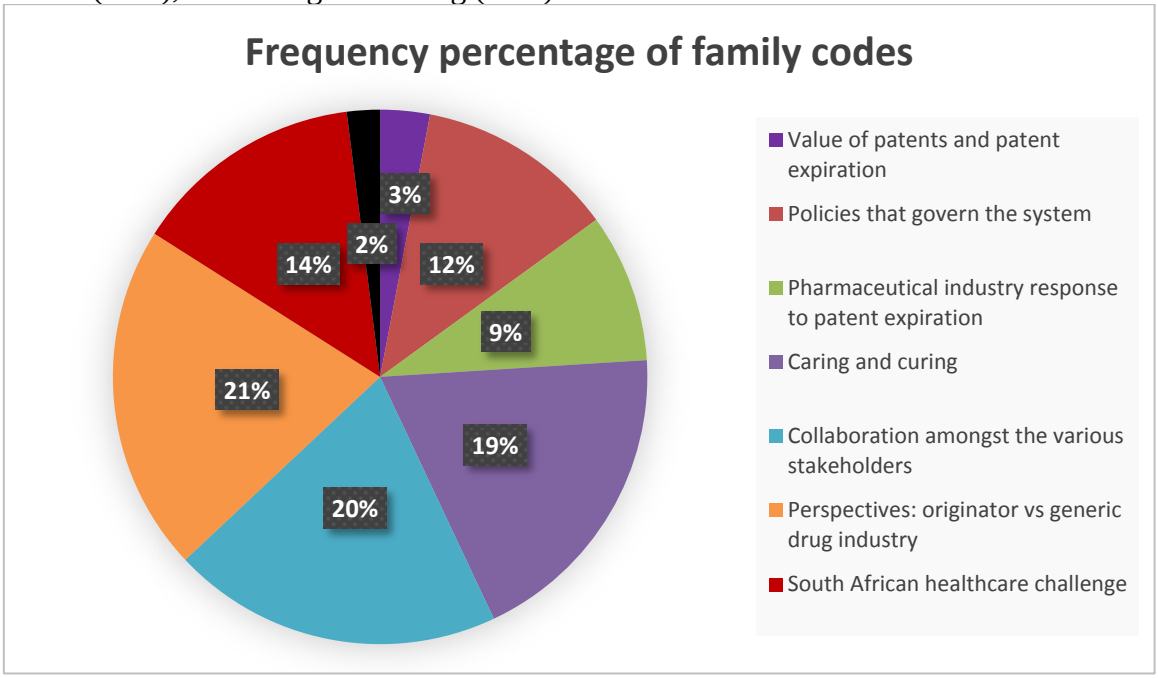

Figure 1. Breakdown of family codes

Table 9 represents the top 20 codes with the highest frequency, as well as their associated code family.

Table 1. Top 20 open codes

Code Name	Frequency	Code Family
Generic drugs	96	Perspectives: originator vs. generic drug industry
Medical aids	38	Policies that govern the system
Pharmacists	38	Collaboration amongst the various stakeholders
Affordability	30	Perspectives: originator vs. generic drug industry South African healthcare challenge Value of patents and patent expiration
Clones/biosimilar	30	Pharmaceutical industry response to patent expiration
Pricing	29	Pharmaceutical industry response to patent expiration

Code Name	Frequency	Code Family
Sales representatives	28	Collaboration amongst the various stakeholders Pharmaceutical industry response to patent expiration
Marketing strategies	27	Pharmaceutical industry response to patent expiration
Relationships	26	Collaboration amongst the various stakeholders
Generic companies	23	Perspectives: originator vs. generic drug industry
Patent expiration	22	Value of patents and patent expiration
South African context	21	South African healthcare challenge
Originator companies	21	Perspectives: originator vs. generic drug industry
Incentivization	20	Collaboration amongst the various stakeholder
Education- disease	20	Caring and curing Collaboration amongst the various stakeholders
Original drugs	18	Perspectives: originator drugs vs. generic drugs
Quality of products	18	Caring and curing Perspectives: originator vs. generic drugs
Research and development	16	Perspectives: originator vs. generic drug industry
Access to medications	16	South African healthcare challenge Value of patents and patent expiration Future of the pharmaceutical industry
Efficacy of products	15	Perspectives: originator vs. generic drug industry

As part of the thematic analysis process, the researchers continued with the final stage of the data analysis known as selective coding. This process allowed the researchers to review all the codes and families, and establish core concepts to discuss in the final paper. A thorough review and streamlining of data allowed for a more comprehensive discussion on the significant factors contributing to the topic. The researchers used a conditional relationship guide to contextualise the principal phenomena, providing further structure and insight. The relationship guide served to aid the researchers' process of reflection by asking the questions: what, when, where, why, how and with what result or consequence. Answering these questions assisted in developing core concepts pertinent to the topic being researched (Scott, 2004) .

The interrelationship diagram (Figure 12) represents the various themes/family codes that are either classified as the *Influencer* on other themes, *Outcomes* as a result of the influencer or *Links* between the influencer and outcomes. These discovered patterns are also summarised in Table 13. The connectivity matrix (Table 14) displays the various family codes and the interlinking relationship between them. The matrix should be interpreted by analysing the themes in the rows and their influence on the subsequent theme in the column, e.g., the theme 'value of patents and patent expiration'is considered an influencer for the theme 'caring and curing', as demonstrated in the matrix.

Interrelationship Diagram of Family Codes

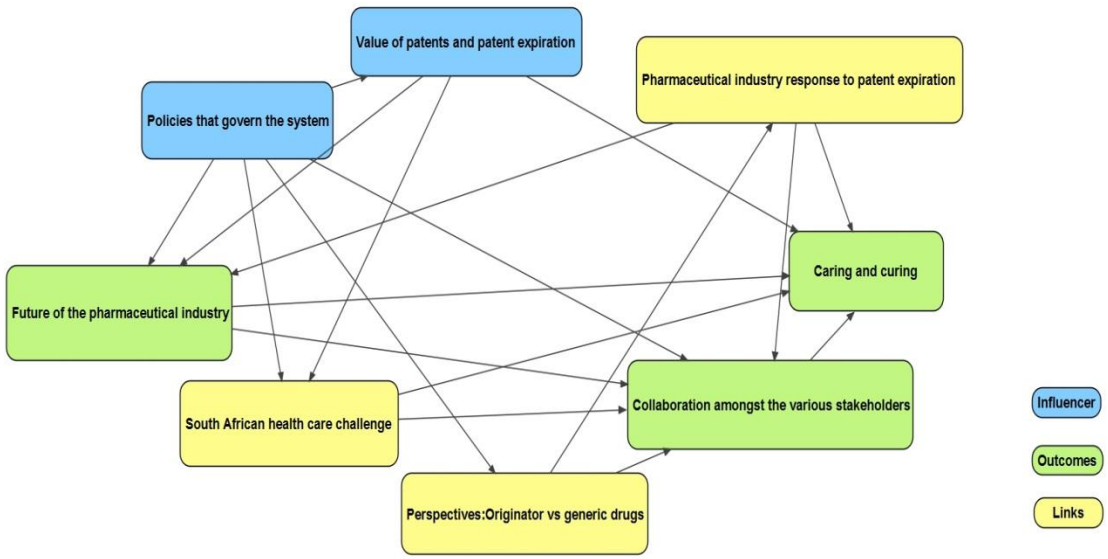

Figure 2. Interrelationship diagram of the family codes

Table 2. Family codes- Influencer, Links and Outcomes

Influencer	Links	Outcomes
Policies that govern the system	Pharmaceutical industry response to patent expiration	Collaboration amongst the various stakeholders
Value of patents and patent expiration	Perspectives: Originator drugs vs. generic drugs	Caring and curing
	South African healthcare challenge	Future of the pharmaceutical industry

Table 3. Connectivity matrix for family codes

	Value of patents and patent expiration	Policies that govern the system	Pharamceutical industry response to patent expiration	Caring and curing	Collaboration amongst the various stakeholders	Perspectives: Orignator vs generic drugs	South African healthcare challenge	Future of the pharmaceutical industry	SUM
Value of patents and patent expiration	0			1			1	1	3
Policies that govern the system	1	0			1	1	1	1	5
Pharamceutical industry response to patent expiration			0	1	1			1	3
Caring and curing				0					0
Collaboration amongst the various stakehol0ders				1	0				1
Perspectives: Orignator vs generic drugs			1		1	0			2
South African healthcare challenge				1	1		0		2
Future of the pharmaceutical industry				1	1			0	2

Value of Patents and Patent Expiration

The family code, *Value of drug patents and drug patent expiration* (85 quotations) emerged as a compelling influencer on the subsequent family codes. This family code had two main sub-codes: the *Purpose and value of drug patents*, and the impact of *Patent expiration.* It is essential to have a good understanding of the value of both drug patents and expiration, so as to comprehend the complexities of the pharmaceutical industry. When evaluating the value of drug patents, it was evident that participants from both the originator and generic sectors fully understood the value of a drug patent and incorporated it into their business plans. There was a consensus amongst these participants that the drug patent policy served to protect originator brand medicines and allow them the benefit of monopoly of sales. Once this patent expires, generic companies are allowed to apply for the launch of a generic drug. This understanding of drug patents is supported by Smit and Bredenkamp (2013) and Vaughan (2001), who discussed drug patent as safeguarding the originator company for a certain period of time, which is ussually 17-20 years. Healthcare practitioners also offered similar viewpoints on the understanding of drug patent policy. With regards to the patient sector, most of the participants interviewed were not too familiar with drug patents and the processes associated with it. They were, however, more familiar with the drug patent expiration period and its link to the entry of generic drugs and cost saving. All the stakeholders interviewed (corporates, pharmacists, doctors and patients) had a similar understanding of the value of drug patent expiration and the implication on the health sector. Participants, particularly patients, doctors, pharmacists and generic companies, associated drug patent expiration with the entry of generic drugs, and access to affordable essential medication. Jansen (2002)

reiterates the fact that drug patent expiration often signals the entry of lower-priced generic drugs in comparison to originator drugs. It was further highlighted that, due to the significant lower cost of generic drugs, originator companies risk losing market share on their branded products (Kappe, 2013). This sentiment was echoed by a few particpants working in the orignator pharmaceutical inustry. Many of the particpants from the various sectors viewed drug patent expiration as a necessary and valuable process, especially considering the socio-economic status of many patients living in South Africa. This family theme, as can be seen in the interrelationship diagram, had a direct impact on the themes South African healthcare challenge, Caring and Curing, and Future of the pharmaceutical industry.

Policies That Govern the System

Pivotal to the health and pharmaceutical industry are the numerous laws and regulations that govern it. It emerged through interviews with key stakeholders, that the government played a crucial role in the policies set out to manage the healthcare system. This resulted in the second family code being *Policies that govern the system* (109 quotations). The subsequent sub-codes to this theme were *Government and its policies*, *Drug patent registration processes*, and the *Power of medical aid schemes*. CORP_MCC member_7, who is a member of the medicines control council and who serves as an advisor to the Department of Health, offered a great amount of insight into the policies that govern South Africa. The policies relevent to the South African sector are:

- TRIPS (trade-related aspects of intellectual property rights) Agreement – Oversees the management of patent protection and ensures the access to cost-effective medication (Croix & Liu, 2008).
- Medicines Control Council (MCC) – Oversees the process of drug registration, ensuring stringent regulatory controls with regards to efficacy and safety of the drug (Smit & Bredenkamp, 2013).
- SAPRA (South African Health Products Regulatory Authority) – CORP_MCC member_7 explained the newly implemented SAPRA model aimed at managing quick and efficient access to medication (Gouws, 2015).
- South African National Drug Policy – This policy makes the necessary provision for generic drugs and motivates the government and healthcare practitioners to support the generic industry (Gouws, 2015).
- Medicines and Related Substance Control Act – CORP_MCC member_7, as well as Smit and Bredenkamp (2013), point out that this Act stipulates that pharmacists are obliged to offer generic drugs, which is often more cost effective, to the patient.

The biggest *Challenge for drug registration* expressed by pharmacuetical company participants (both originator and generics) was that of the time duration to register a drug. Due to the time delay in drug registration, the drug patent life is significantly reduced which impacts on the amount of time the originator company has to recoup investments made in the drug. The patent process entails rigorous clinical trials, as well as scrutiny from the regulatory board of the MCC, resulting in a prolonged period before the drug is launched (Sereno, 2010; Smit & Bredenkamp, 2013). The sub-code of *Medical aid schemes* was a prominent topic and was discussed by every participant, whether they were members or not. Medical schemes play a key role in the selection of generic or originator drugs. Many patients who are members of medical schemes explained that more often than not they have to pay in a co-payment for their medication. Patients and medical doctors conveyed their frustration with medical schemes, noting that it is very rarely that an originator drug is on their formularly and whether they are fully reimbursed. This is also dependent on the type of medical scheme and the level of membership. Garattini and Tediosi (2000) assert that one of the factors determining drug entry into the market is medical aids. Sedjo and Cox (2008) go on to state that cheaper generic drugs are more favourable to medical schemes due to significant cost saving for the both the patient and medical scheme. This theme of *Policies that govern the system* was considered an influencer on many of the other themes, hence indicating its significant impact on the overall pharmaceutical and health industry.

Pharmaceutical Industry Response to Patent Expiration

As discussed by many of the corporate participants, drug patent expiration is an inevitable process that needs to be carefully considered in terms of business plan and strategy. Sub-codes which emerged from the family code *Pharmaceutical industry response to patent expiration* (138 quotations) included: *Product pipeline*, *Strategies to mitigate drug patent expiration* and *Employee morale*. This section was particularly pertinent to orignator companies who are greatly affected by the loss of drug patent. Directors of originator companies all reinforced how vital a healthy product pipeline is, especially during the period of drug patent expiration. Conitnous research and development is of utmost importance to ensure sustainability of the company, and the production of innovative drugs. McKellar et al. (2012) supported this idea that a thriving product pipeline is necessary for continued profits and development of new drugs. The two most common strategies employed by originator companies to mitigate the impact of drug patent loss, based on the interviews, was the *introduction of*

a pricing stratgy or *the launch of a clone/biosimilar*. There were mixed reviews by partcipants from the pharmacuetical sector regarding the pricing strategy. Some were in favour, stating that reducing the price of the originator was the only reasonable option to maintain some share of market. Other participants noted that it would result in a 'price war' and also hinder the credibility of the originator company. Agrawal and Thakkar (1997) contended that a company could either maintain their current price and risk losing sale volumes, or lower their prices. Smit and Bredenkamp (2013), who looked specifically at the effect of pricing and market share, conclude that even when originator brand drugs decrease their prices, generic drug prices are being decreased to an even greater extent. The implication of this is that originator drugs will be considered relatively more expensive even when their absolute price was higher. The pricing startegy is therefore a complex one and would require considerable thought by the originator company. Wilkie et al. (2012) therefore suggests that originator companies should rather refocus their strategy on the brand loyal customer rather than the price sensitive customer. The lastest trend amongst originator companies is the launch of a clone which is viewed as an effective strategy to increase drug patent life, maintain share of market, and subsequently maintaining financial gains. Although many of the corporate participants viewed this as an effective strategy, a great percentage of patients as well as health care practioners interviewed were not too familiar with the clone drug. This indicated a lack of clone/biosimilar knowledge amonsgt some of the stakeholders. Those who were familiar with clones, were in favour due to it being the exact same product from the trusted originator company, and also at a slightly lower price. Launching clones, also refered to as 'own generics' has fast become a popular strategy to mitigate the impact of drug patent expiration (Ghislandi, 2012; Smit & Bredenkamp, 2013; Wilkie et al., 2012). Another factor important for consideration during drug patent expiration is the impact it has on the employee morale, especially the sales representatives who are responsible for the direct marketing of the drug to healthcare practioners. Six participants, who are currently sales representatives and have experience with originator brands, all referred to the significant impact drug patent expiration has on them. Feelings of anxiety, ambiguity, and fear were common amongst those who had experience with losing patent on a drug they marketed. The biggest fear was loss of their job, due to their respective company's decision to cut costs, pre-empting drastic financial losses. As discussed by Smit and Bredenkamp (2013), sales representatives are imperative for the building of brand awareness of a particular drug. One of the managers from an originator company reiterated that when a company loses patent, promoting brand awareness may no longer be necessary, resulting in the retrenchment of sales representatives.

Caring and Curing

The outcome theme *Caring and curing* (167 quotations) was further divided into the sub codes: the *Right to health*, the *Impact of the various stakeholders on the patient*, as well as *The decision-makers.* This family theme was very much centred around the patient and the experiences of the patient within the health sector. Patients who frequented the public sector expressed their concerns with the lack of health personnel, medication stock issues, as well as long waiting periods to be treated. Another point that was raised by these particpants was the fact that the only medication they received in the public sector was generic drugs. To some particpants this was an issue and others remained indifferent. The majority of the patients who frequented the private sector were medical aid members. Their biggest gripe was the fact that certain medication (mainly orignator drugs) were not fully reimbursed by medical aids, which resulted in them having to pay co-payments. Grabowski et al. (2011) explains that medical aids favoured generics, due to the lower cost and would most likely add them on the formulary. This would necessitate a co-payment by a patient if he/she chooses to use the originator drug. This feeling of frustration extended to the pharmaceutical industry and, in particular, towards the originator company. Many patient participants had a negative perception towards pharmaceutical companies, implying that their main objective was to make money with unreasonable drug prices and not catering to the needs of society (Margolis, 1991). With regards to the decision-makers in the health sector, it seems that with the entry of generic drugs, the power of the script has shifted from the medical doctor to the pharamcist. Pharmacists and medical schemes have a greater influence over the selection of either a generic or originator drug. According to CORP_MCC member_7 and Smit and Bredenkamp (2013), pharmacists are obliged to offer the generic drug to the patient and medical schemes generally have generic drugs on their formularies.

Collaboration amongst The Various Stakeholders

The family code, Collaboration amongst the various stakeholders (172 quotations), gave rise to four sub codes: The relationship between pharmaceutical companies and healthcare practitioners, The relationship between healthcare practitioners and patients, The relationship between pharmaceutical companies and medical funders, and the Question of ethics. The relationship betweeen pharmaceutical companies and healthcare practitoners is a significant one, as it is the primary method of ensuring adeqaute product- and disease information to the patient. Pharmaceutical companies are not allowed to market directly to patients, hence the doctor and pharmacist serves as the middle-man. Sales

representatives from both orignator- and generic companies are often the face of the company, and play a prominent role in relationship-building. Campbell (2007) reinforces the fact that, although relationships may differ, 94% of all medical doctors have a relationship with the pharamceutical industry mainly via sales representatives. Some doctors interviewed noted that even though they valued sales representatives, there was the question of bias, and the fact that a sales representative would drive a particlar product as instructed by the company. This veiwpoint was particularly evident amongst the specialists. Fugh-Berman and Ahari (2007) acknowledge this controversial relationship between doctors and sales representatives and apparent market strategy. Most of the doctors and pharmacists did, however, regard sales representatives as their main source of receiving information regarding a new product development or related disease information. Sales representatives are therefore viewed as an intergral part of a company's strategy to build good brand awareness and rapport with doctors and pharmacists (Kappe, 2013). Pharmacists interviewed highlighted that originator companies invested more time and effort in doctors in comparison with pharmacists. This viewpoint was reiterated by many of the managers and directors from various companies, who further added that it is strongly linked to the power of the script. Once a drug loses patent, pharmacists tend to demonstrate a more persuasive role when discussing generic substitution, hence generic companies would have a greater presence amongst pharmacists (Ghaibi et al., 2015). Some of the originator company particpants acknowledged that orignator companies need to invest more time in buidling relationships with pharmacists, so as to build a strong brand awareness and loyalty. This is particularly important when an originator company decides to launch their own generic, and require a shift of focus to the pharmacist. Ghislandi (2012) supports the idea that brand loyalty is developed through long-standing business relationships. With reference to the relationship between pharmaceutical companies and medical funders, there seemed to be a great gap between originator companies and medical funders. This sentiment was echoed by partcipants from both the originator and generic company participants. According to Thomas (2006) and Sejo and Cox (2008), medical funders consider generic drugs more favourable due to cost saving benefits for both the patient and medical funder. Some participants from originator companies once again acknowleged that it is necessary to improve business relationships with medical funders to facilitate market access of medication. This relationship would become quite pivotal if the orignator company should launch a clone at some point, which would be priced slightly lower than the original drug. Through engaging with participants from the various stakeholder groups, a common theme that emerged was the question of ethics and how it impacts the health sector. The pharmacuetical industry has developed somewhat of a reputation for incentivising healthcare practitoners to script their products (Margolis, 1991). Coscelli (2000) and Garattini and Tediosi (2000) point out that pharamceutical companies may enforce various incentive strategies targeted at healthcare practitioners. One such incentive may be promotional items or sponsorships. Most of the doctors indicated that, although the indsutry was considered to engage in perverse incentivisation, this has changed quite drastically over time due to more rigid policies in place. Many of the patients interviewed still have a negative perception towards pharmaceutical companies in terms of their business ethics with healthcare practioners. With regards to the relationship between generic companies and pharmacies, many doctors and originator company participants believed that pharmacists may be incentivised to script generic drugs. This viewpoint is supported by Grabowski, Long and Mortimer (2011). PHARM_member_3, who works as a key account manager, reinforced that their main objective when engaging in negotiations with stakeholders is that dealings are always patient-centric.

Perspectives: Originator vs. Generic Drug Industry

Interviewing participants from the different stakeholder groups provided great insight into the different persepctives relating to the originator industry and the generic industry. The main family code was *Perspectives*: *Originator vs. generic drug industry* (250 quotations). The two main sub-codes that emerged from this theme was *Originator companies*: *The innovators* and *Generic companies*: *The heroes*. Healthcare practitoners viewed originator drugs as being effective, safe and also being quite costly. Many of them did however attribute the increased price with the neccessity to recoup research and development costs. McKellar et al. (2012) and Vaughan (2001) both refer to the value research and development offers for new drugs, that are essential for the health sector and society in general. Although many of the healthcare practitioners noted that they would prefer the original drug, circumstances did not always allow for this. Key challenges with initiating originator drugs was the cost factor, medical aid formularies and switching of drugs at pharmacy level. Paul et al. (2010) is in agreement with the fact that healthcare budgets are becoming strained, hence influencing the switch from orignator drugs to generic drugs. Pharamcists offered a similar viewpoint to originator drugs, noting that although they acknowledged the innovative aspect of it, the cost factor was an issue. Most patients perceived orignator drugs to be of a greater quality but at the cost of having a higher price tag. They were not too informed on the research and development invested in originator drugs. The discussion regarding generic drugs triggered varying responses from the stakeholder groups.

Participants who viewed generic companies as heroes, did so on the premise that generic drugs signalled the entry of affordable medication. Patients demonstrated the most favourable stance, in comparison to the other stakeholders, towards generic drugs due to access to essential medication at a cost effective price. Garattini and Tediosi (2000) explain that generic drugs not only demonstrate equal bioequivalence to orignator drugs, but are also a more cost effective alternative to the originator drug. Patients who were members of medical schemes also noted that with generic drugs they did not have to pay a co-payment. Particpants, mainly doctors, questioned the efficacy and safety of some generic drugs. Particpants also based their selection of a generic or originator drug on their diagnosis, and whether it was acute or chronic. Garattini and Tediosi (2000) further add that some may perceive generic drugs to be inferior to originator drugs with regards to safety and efficacy. Some patients and doctors noted that they would opt for the originator drug if they were suffering from a serious condition, such as cancer or diabetes. For a regular cold or flu, they would be okay with the generic drug. Manchanda et al. (2005) indicates that one of the determinents for scripting either generic or originator drugs is whether the patient is suffereing from an acute or chronic condition, and whether it is life-threatening or not. Although questions have been raised regarding the efficacy and safety of generic drugs, the Medicines Control Council attests to having the necessary regulatory bodies in place to ensure efficacy and safety of registered drugs (Department of Health, 2015).

South African Healthcare Challenge

The theme of South African healthcare challenge (117 quotations) gave rise to the sub-codes: Healthcare in the emerging market, The impact of the emerging market challenges and The burden of disease. The economic and political situation of South Africa has a direct impact on both the public and private healthcare sector. As a developing country and emerging market, South Africa is plagued with financial strain as well as the increased burden of disease. Lack of resources and access to cost-effective medication prevailed as the leading frustration amongst many patients and doctors, especially those from, and working in, lower socio-economic areas. Inflated prices of essential medication in South Africa presents with serious public health issues, especially considering the alarming increase in the HIV/AIDS pandemic (Croix & Liu, 2008; Miziara & Coutinho, 2015). Participants from originator companies shared their concerns of the viability of their businesses in an emerging market, and the lack of necessary support systems for research and development. According to these particpants, the South African government was more in favour of the generic industry, which has signifcant implications on the sustainability of origiantor companies and the development of innovative drugs. This prevailing concern on the sustainability of healthcare in South Africa, led to the theme of The future of the pharmaceutical industry.

Future of the Pharmaceutical Industry

The future of the pharamceutical industry (37 quotations) was identified as an outcome theme, and had one sub-code: *Generic industry growth vs. originator industry decline.* Particpants from both the orignator and generic companies agreed that the outlook for generic drugs in South Africa seemed more favourable than that of originator drugs. The South African government supports and encourages generic substitutes, as well as parallel importation. The justification for this stance is that the lives of society are of greater importance than commercial interests of the pharmaceutical industry (Vaughan, 2001). Pharmaceutical inustry reports also indicate a significant shift from originator drugs to generic drugs. According to the five forces analysis (Marketline, 2014), the key driver of competition in the South African pharmaceutical industry was ‘substitutes’. These substitutes refer to cheaper generic drugs that are considered to be safe and of equal quality to the originator drug. South Africa is experiencing an increase in the ageing population and burden of disease, therefore the government will be more inclined to support the generic market for cost-effective alternatives (Deutsche Bank, 2015).

CONCLUSION

The purpose of this research was to investigate the phenomenon that is drug patent expiration and the impact it has on the various stakeholders. The primary stakeholders identified for this research included participants from the pharmaceutical sector (originator and generic companies), doctors, pharmacists and patients. Drug patent expiration is identified as one of the challenges experienced by originator drug companies. On the contrary, it is also viewed as a positive outcome for generic companies who can then develop cheaper medication for distribution to those patients who require it. There are many factors at play during this period of drug patent expiration, having a profound influence on both the pharmaceutical and healthcare sector (Agrawal & Thakkar, 1997; Pearce, 2008). The researchers proceeded with an in-depth literature review, exploring the several concepts pertinent to drug patent expiration. Forty-three interviews were conducted with willing participants from various regions in South Africa, as well as one participant from Texas U.S.A. These interviews were audio recorded, transcribed and analysed using a computer-aided qualitative data analysis tool, Atlas ti.

Through in-depth investigation and analysis, the primary and secondary questions of the research were answered. The main question being: '*What is the impact of pharmaceutical drug patent expiration on the various stakeholders?'* and the secondary question being: '*How does this phenomenon influence their decision-making process?*' The main themes that emerged from the analysis were: value of patents and patent expiration, policies that govern the system, pharmaceutical industry response to patent expiration, caring and curing, collaboration amongst the various stakeholders, perspectives: originator vs. generic industry, South African healthcare challenge, and future of the pharmaceutical industry. The main research findings were:

- Drug patent expiration is an inevitable process which has significant impact on originator companies. This impact can be mitigated by ensuring a thriving product pipeline, efficient marketing strategies, as well as maintaining sound business relationships with key stakeholders. This sentiment on the importance of product pipeline was echoed by McKellar (2012) as well as Gupta et al. (2013).
- The research also highlighted the fact that originator companies should not only invest in relationship-building with medical doctors, but also pharmacists who play a key role in providing product- and disease education to the patient. The value of good ethical relationships go beyond drug patency, and promotes strong brand awareness and loyalty to the company and drug (Wilkie et al., 2012).
- Drug patent expiration is necessary for the development and launch of generic drugs, especially in a country that is beset with financial difficulties and disease burden. Generic companies allow for access to affordable medication, especially in the public sector (Garattini & Tediosi, 2000; "Generics boost," 2013; McKellar et al., 2012). Recent government policies have ruled in favour of pharmacists offering the cheaper generic drug to patients and educating them on the drug itself. The pharmacists, however, are not allowed to switch the product from an originator to a generic if the patient decides against it, or if the doctor specifically indicates 'no switching' (Department of Health, 2015; Garattini & Tediosi, 2000; Gouws, 2015).
- There is a great need for education on generic drugs and clones. This research identified that patients and some healthcare practitioners are still unfamiliar with these drug classes, especially regarding safety and efficacy in comparison to the originator drug. Improved education and transparency will decrease the level of ambiguity, facilitating a more informed decision-making process. A greater sense of understanding of the pharmaceutical industry, and their processes, will also put to bed many negative perceptions held against them.
- Medical funders play a pivotal role in the health sector and also contribute to marketshare loss for originator companies. Medical aids and insurers offer more favourable stances towards generic drugs due to the cost-saving factors (Grabowski et al., 2011; Sedjo & Cox, 2008; Thomas, 2006). The biggest issue with medical aids, raised by patient participants, is that of co-payments. Medical aid schemes will reimburse only a certain amount for a particular drug, leaving the patient to settle the shortfall between the amount on formulary and the actual price of the drug. The relationship between originator companies and medical funders seemed to be strained due to the competition between originator and generic drugs to be on formulary. It is essential for both originator and generic companies to familiarise themselves with medical funder procedures. These collaborative liaisons with medical funders will facilitate the process of ensuring access to essential medication to patients.
- The government is a key stakeholder in overseeing health policies of the country and ensuring that they are well regulated. One of the challenges experienced by pharmaceutical companies is the prolonged time period to register a drug. This time delay results in pharmaceutical companies increasing their prices in order to recoup investments during a now shortened patent period. In order for the government to drive down the cost of medication, the Medicines Control Council needs to improve on their speed and efficiency for registering a drug. According to the Pharmaceuticals in South Africa Industry Report, the South African Health Products Regulatory Agency (SAHPRA) will be facilitating the process of improving operational delays in the MCC (Marketline, 2014). The government should also ensure that the necessary quality control systems for generic drugs are in place, and that policies safeguard against any unethical business transactions. Efficient regulation and control of medicines in South Africa is not a choice, but rather a necessary aspect of national health (Gouws, 2015).

It is evident that the interplay between the pharmaceutical industry and the health sector is a complex and dynamic one. The views and opinions of originator and generic drugs may differ, but it is clear that both these divisions offer value to society. The dilemma then lies in how to regulate the generic and originator companies, while promoting both innovation and access to cost-effective medication. DOC_member_4 summed this point quite well: *"In a perfect world, research and*

development would be driven through government [channels] rather than private [ones]. The right to manufacture and distribute a medication would then be sold to a company. Obviously that is a little bit utopian" (P22 22:14 (19:19)).

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