

Economic and Social Effects of Parallel Importation of Pharmaceutical Products on Organisational Performance in Pharmaceutical Firms in Kenya

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Abstract

The purpose of this paper is to analyse the effect of parallel importation of pharmaceutical products on the organisational performance of pharmaceutical firms in Kenya. The paper is guided by research objectives that are focused on: the economic effects of parallel importation of pharmaceutical products on organisational performance and the social effects of parallel importation of pharmaceutical products on organisational performance. This paper concludes that the issue of economic and social effects of parallel importation and how they affect the organizational performance of pharmaceutical companies in Kenya is rich for exploration and recommends that a study be conducted focusing on parallel importation and organizational performance of pharmaceutical companies; especially now that a clear legal framework on parallel importation has been put in place.

Key Terms: Economic Effects, Social Effects, Organisational Performance, Pharmaceutical Products.

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Introduction

Parallel importation of pharmaceutical products refers to the process through which goods are genuinely produced and protected through a trademark, patent, or copyright in one market and then imported to another market without the authorisation of the local owner of the intellectual property right (Taleizadeh, Hadadpour, Cárdenas-Barrón, & Shaikh, 2017). In Europe, parallel importation has been existence since the 1970s and was rampant in countries such as the Netherlands, the United Kingdom, and Germany (Morabito, 2015). As such, many pharmaceutical companies around the world today are multinationals based in developed countries. For instance, Pfizer, GlaxoSmithKline, Johnson & Johnson are found in the United States; Novartis and Roche are located in Switzerland; while Sanofi and Bayer are found in France and Germany, respectively.

Parallel importation creates grey markets as the manufacturer's products are purchased at lower prices and resold in other markets at higher rates. The aspect of parallel importation has been at the nucleus of scholarly debates on international trade, development and public health as some scholars argue that parallel importation inhibits access to pharmaceutical products such as medicines while others are of the contrary opinion. International business literature primarily focusing on Europe points out that parallel importation can either be active or passive (McKeith, 2014). Passive parallel importation involves importers buying goods from a foreign country so as to sell them in domestic markets. On the other hand, active parallel importation involves an international distributor or licensee of an IPR entering a local market so as to compete with the rights holders or official domestic licensee.

In 2001, a conference in Doha on public health led to the Doha declarations which led to the amendments on the Trade-Related Agreement on Intellectual Property Rights (TRIPS) agreement that gave the World Trade Organisation

members freedom to choose their own system of exhaustion rights without challenge. The TRIPS allows countries to determine the exhaustion type they want to adopt. According to Calboli and Lee (2016), the principle of patent exhaustion focuses on the patentee's ability to control a product's first sale where the product is patented. In other words, the patent holder is remunerated through the first sale of a product and thereafter, the right holder is said to have exhausted their rights. The exhaustion can be national, regional and international.

Parallel imports have been allowed on a regional and international scale for many developed and developing countries. After TRIPS agreement, legal protection of Intellectual Property Rights provided a territorial basis in which countries have their own policies on parallel importation. In their study, Dobrin and Chochia, (2016) posit that parallel trade is a common practice in the European Union. Also, the United States of America has continued to recommend drug re-importation.

Regional exhaustions have led to price and quantity pressures which are also dependent on the market size. Dubois and Sæthre (2018) postulate that within the European Economic Area, price differences on pharmaceutical products have created arbitrage opportunities for pharmacy retailers to use during pharmaceutical imports. This affects the sharing of profits among pharmaceutical companies, retailers, and parallel traders; thereby inducing price competition. In Shanghai, under the Free Trade Zone, policies for parallel import are established to ensure that benefits to all that are involved in parallel trade such as in pharmaceutical and automobile sectors (Wu, & Yan, 2018). Parallel importation, depending on its implementation, leads to economic and social development. This, of course, depends on the legal implications of the trade.

Essentially, parallel importation is a measure that prevents divisions in the importation market and discriminations in pricing on national or international scales. Morabito (2015)

notes that pharmaceutical companies set prices for same products in different levels in different countries and the customer's access to the product does not affect the patent holder's right to receive remuneration in countries where the product is first sold. This protracts divisions on developed and developing countries. Rapid globalisation trends have continued to increase the size of grey markets. Developing countries find themselves at a disadvantaged point, especially when it comes to competition on a global scale due to challenges that come with parallel importation such as price discrimination and regulatory challenges.

In developing countries, parallel importation is useful, especially in times when medicines are limited, and charges for available drugs are exorbitant. However, there are difficulties that are experienced while attempting to use parallel importation in a bid to promote public health and access to medicines (Morabito, 2015). Fundamentally, over the years, there have been debates on pharmaceutical patents which have raised pertinent questions on whether IP protection affects the public's ability to access pharmaceutical products such as essential medicines. For developing countries, Wu and Yan (2018) append that the evolution of parallel imports of pharmaceutical products, especially in countries such as India is the pivot of learning for other countries. There is an insistence that developing countries should learn the rules of international intellectual property. The countries should not just follow the rules and regulation; the following should be from the point of knowledge. This helps to achieve goals and avoid legal risks. Multinational pharmaceutical companies should ensure that they consider the situations in developing countries and thus improve the capacity of independent research and development. In Sub Saharan Africa, there is an indication that there are non-patent factors that deal with the issue of access to pharmaceutical products (Calboli, & Lee, 2016).

In South Africa, approximately 26% of the population lives on less than 2 dollars a day which is below the international poverty line of 1.25 dollars a day. Therefore, it becomes

difficult for this population to access pharmaceutical products such as ARV drugs (McKeith, 2014). The division on parallel importation is not only found from the perspective of the availability of drugs, but it is also found from the perspective of the pharmaceutical companies. The companies have a monopolistic focus in which they would like to have a long term grip on being the only providers of pharmaceutical products (Dubois, & Sæthre, 2018). Therefore, the companies seek to ensure that they are the only producers of products such as medications.

In the East African Community, Warwire (2015) states that national exhaustion excludes parallel importation; regional importation allows parallel imports only from country parties in regional trade agreement; while international exhaustion allows parallel importation from any country. For instance, in Tanzania and Uganda, there are patents that are granted to pharmaceuticals while in Burundi and Rwanda, there are flexibilities that are made in their laws but they are yet to provide pharmaceutical patents.

In many stances, international exhaustion is encouraged to ensure that third parties are able to import pharmaceutical products at cheaper rates from markets that are cheaper than the home markets. Additionally, under compulsory licenses, parallel importation in some countries allows the importation of generic medicines produced in third world countries (Warwire, 2015). This favours the interests of consumers and access to medicines which are sold legitimately for the lowest possible price. Intellectual Property Rights (IPRs) serve a societal purpose in that they are public policy tools that lead to innovation and creativity, which leads to economic and social developments (McKeith, 2014).

Further, Warwire (2015) notes that Kenya has the most developed pharmaceutical industry in Sub Saharan Africa, after South Africa, with a number of local manufacturing companies, large multinationals, and subsidiaries among others. The local manufacturing companies are limited in terms of research and development as well as the capacity

for production. This means that limited pharmaceutical companies are engaged with non-sterile and over the counter products, which confines the capability of pharmaceutical companies to meet the current and future pharmaceutical needs of the country. There is an extent up to which parallel importation is allowed, which is dependent on the legal framework.

Limitations and stern competition have led to the rise of alternative pharmaceutical products. The biggest challenge in alternative pharmaceutical products has been the production of counterfeit products. The Kenyan Industrial Property Act was enacted in 2001 under Section 58(2) and authorises parallel importation, while the Trademarks Act is silent on parallel importation (Inimah, 2016). The Industrial Property Act enables the use of the international exhaustion principle, which provides flexibilities for the country. The rights holders cannot bar parallel imports from entering local markets as their rights in that market are exhausted. Incorporating the principle of international exhaustion of rights into the national laws through the Constitution, allows Kenya to have access to parallel imports on an international scale. Ambiguity in legal aspects of parallel importation leads to the emergence of parallel imports of pharmaceutical products as an independent sector (Kranni, 2014). A nexus is hard to come by between the pharmaceutical companies that take part in parallel imports and those that are in manufacturing. This is because those in parallel imports are part of the supply chain.

In 2008, Kenya passed an Anti-counterfeit Act, which prevented the damage caused by products such as fake medicines (Quet, 2017). However, there have been controversies in the country in which a thin line exists between counterfeit drugs and parallel importation which brings challenges in the business environment of the pharmaceutical industry. In this business environment, there has also been stiff competition between local and international pharmaceutical companies.

From the viewpoint of the pharmaceutical industry, there is the view that allowing parallel importation of pharmaceuticals slows down the development of new pharmaceuticals. This hinders the pace of innovation in the industry, which, in turn, hinders not only the performance of the pharmaceutical industry but also the performance of individual pharmaceutical companies (Quet, 2017). In lieu of this, the companies, therefore, seek to ensure that strong patents for pharmaceutical products are implemented on a global scale so as to ban parallel trade.

In Kenya, parallel importation is quite controversial in the pharmaceutical industry. Stakeholders in the industry have been divided into different aspects of parallel importation, thus sprouting contentious issues that further drive parallel importation as complex in nature. The vague nature of legislations and regulations on parallel importation of pharmaceutical products also has an impact on the performance of pharmaceutical organisations. In this aspect, a review by Chorev (2015) reveals that the primary research conducted is quite unreliable due to poor design and execution of the studies. The review also shows that while parallel importation has increased access to medicine, it has also opened doors for increased access to counterfeit medicines due to unclear regulations. This affects the performance of multinationals, especially those involved in original manufacturing and distribution.

Studies show that ambiguous legislation has led to an influx of parallel importers in Kenya who have changed the functioning equilibrium of multinational pharmaceutical companies in the country. The operations of multinational pharmaceutical companies such as Pharmaceutical firms in Kenya have changed due to the competition brought about by parallel importers. However, the studies do not present how parallel importation changes the operation of the multinational pharmaceutical companies. Also, there is a limited pool of studies on how parallel importation affects pharmaceutical companies in Kenya. This creates a knowledge gap on parallel importation of pharmaceutical products in Kenya.

Economic Effects of Parallel Importation of Pharmaceutical Products on Organisational Performance Price Discrimination

Generally, the pharmaceutical sector is characterised by factors that are highly related to parallel imports lead to economic effects which include price structures and pharmaceutical spending. According to Altug and Sahin (2017), the pharmaceutical industry is quite complex, and the emergence of parallel imports presents even more diverse and adverse implications for the industry. Parallel importation exploits price differentials between products that are identical but are present in different markets. Price differentials are determined by regulatory requirements as well as certain technological specifications.

Consequently, theoretical and empirical studies showcase diversity in the pharmaceutical industry. Brekke, Holmås, and Straume (2015) studied the effects of price regulation and parallel import of patent-protected pharmaceuticals. The study, theoretically, directed that when it comes to bargaining power, the distributors have higher bargaining power as compared to producers of parallel imports. When price regulations, are strict, parallel trade becomes less profitable, which increases the producers' bargaining power. Empirically, the study found out that stricter pricing regulation does away with parallel imports, but this has no negative impact on the producer's organisation performance as indicated in the profits attained. In the long run, considerations of price caps determine the efficiency of the pharmaceutical companies, and therefore, their performance.

Economic effects of parallel imports vary across different countries, and this means that the effects can be viewed from a different angle. In their opinion, Granlund and Köksal-Ayhan (2016) revealed in their study that the price differences between the exporting and importing countries are the driving force for any parallel trade to take place. This depends on the cost of the trade market and the pharmaceuticals' availability. The prices for manufacturers

vary between countries, and this is dependent on macro and micro factors. These factors include regulation of prices, supply monopoly and exchange rate variations. As an arbitrage business, parallel importation takes advantage of price imbalances in different markets. In Germany, the early 2000s saw parallel imports leading to very small cost reduction in health insurances. However, original producers, there were faced with high losses in market share and profits. This means that when pharmaceuticals for parallel trade are available, then, price competition in the destination country also increases (Calboli, & Lee, 2016).

In China, the analysis by Wu and Yan (2018) on parallel importation in the automobile and pharmaceutical industries suggests that price differences of the same product locally and abroad can have a negative effect on economic development. For instance, in the automobile industry, Wu and Yan insist that the price system of imported cars is surrounded by monopoly in which parallel importation adjusts the price systems of import automobiles. However, when it comes to parallel importation of pharmaceuticals, there is no precedent for parallel importation for medicine; as such, there is minimal focus on pricing systems. The focus is on achieving goals and avoiding legal risks. Parallel importation is not as sophisticated as in countries such as India because the health care system in China is not well developed.

Price wars characterise the competitive pharmaceutical industry in Kenya with lucrative returns that are in excess of 20% of the investment (Oyoolo, & Bett, 2017). The entrance of parallel importers in the market makes the pharmaceutical industry even more complex. MPCs import original brands from their parent company headquarters to Kenya and then undertake price promotion activities. Sales are done through local partners or directly. This impacts price discrimination as behaviour-based and determines the decisions by two competing companies in terms of price and quality.

Market Segmentation

It is evident, then, that in the pharmaceutical industry, parallel trade is justified by the free movement of pharmaceutical goods, promotion of common markets and benefits to the consumers. A free market creates an environment in which competitive movement of goods is fully acceptable, which would lead to equalised price differences. However, Kranni (2014) posits that not all countries or regions have a free market such as the EU; therefore, prices cannot be equalised. The prices for pharmaceutical manufacturers vary from country to country due to a number of reasons which include different price regulations from the viewpoint of national regulatory environments, supply-side monopolistic power, price discrimination, and price-setting response due to changes in the exchange rates.

Manufacturers have to compete with the prices of parallel imported products, and as such, they have to reduce the market price. A review by Lehnhausen (2016) indicates that the reduction of the market price reduces expenses for healthcare providers. For drug manufacturers who intensively focus on research and development, revenues decrease while profits also fall. The incentive to innovate is also reduced as imported pharmaceutical products enter the market. When there is low investment in research and development, there is a negative effect on innovation generation. There are also reduced cost-effective drugs and delays in the launch of products, especially in low-price countries. To stay afloat in the global competitive markets, manufacturers have to impose mark-ups that are very high, and at times, the mark-ups are doubled so as to keep away new entrants into the market. The manufacturer gains price advantages.

For multinationals, trade barriers or changes in the trade have effects on how markets are segmented in their areas of operation (Calboli, & Lee, 2016). The manufacturing companies can either be involved in the research and development of new drugs or actual production of the drugs. This is an indication that the companies rarely get

involved in the process of parallel importation. However, they are a vital part of the trade process as they are involved in the distribution and sales of pharmaceutical products. The manufacturing companies also produce the products in lieu of who the consumers are; that is, depending on the demand of consumers. To produce required products, the manufacturers have to keep in mind the different types of markets that are available for the consumers. For instance, markets in developed countries differ from markets in developing countries, and so do the consumers of pharmaceutical products.

In the East African region, Kenyan prices for pharmaceutical products are viewed as the highest since it is the headquarters of the East African market. It is, therefore, from Kenya that pharmaceutical products such as drugs are registered before transported to neighbouring Tanzania and Uganda (Warwire, 2015). Since the specifications and regulations for each government differ, it is no surprise that these differences lead to differences in price. The market segmentation, therefore, has economic effects on the pharmaceutical industry.

Demand and Supply Conditions

In many instances, the distribution channel is infiltrated by the establishment of alternative supply networks in the form of parallel importation, which is likely to affect the demand and supply conditions in the industry. A study by Méndez (2018) sought to investigate the impact of parallel trade in markets for pharmaceuticals in Denmark. The study found out that demand and supply conditions affect parallel importation economically. This increases price competition due to the differentiation of prices. Market segmentation was also found to be useful in understanding the effects of parallel importation. Economic effects of parallel importation were found to lead to profit variations for original producers.

Intellectual property rights protection provides manufacturers with market power which can help to prevent competition and also understand the demands of

the consumers and market. Empirical review by Lehnhausen (2016) shows that this market power is held until generic competition arises. Manufacturers do not have the ability to influence the distribution of their goods directly. Through the exhaustion of IPR, the rights of manufacturers to decide on where they will sell their products are withdrawn. This affects the supply of pharmaceutical products. From this point of view, it is notable that there is a conflict of interest of parallel imports from the intellectual property right holder's angle as well as the consumer's angle. Wu and Yan (2018) showed that parallel import brings, to a certain extent, damages to the interests of intellectual property right holders in the importing country. The market share for the right holders shrinks as parallel import products get a part of the market share. This has adverse effects on the intellectual property right holders whose returns start to dwindle.

In the Eastern and Southern region, Kenya is the largest producer of pharmaceutical products and about 50% of the pharmaceutical products in the region are from Kenya. The setting up of many MPCs in the country is an indication of the demand and supply conditions whereby there are high demand and limited supply (Oyoolo, & Bett, 2017). The level of demand dictates the behaviour of a company and also that of the market since demands in the market are dependent on the price.

High demand is an incentive for manufacturers to seek ways in which to increase profit and in the same way, demand fuels parallel importation. The product that is in demand will be imported more so in countries such as Kenya, in which importers are keen on profits (Harrington, 2017). Demand is what determines which drugs, pharmaceutical equipment and consumables are imported into the country.

Social Effects of Parallel Importation of Pharmaceutical Products on Organisational Performance

Consumer Welfare

Pharmaceutical manufacturers carry out production and research and development activities at a global level which makes them active in the international market. Duso, Herr, and Suppliet (2014) indicate that the theoretical aspect of the welfare effects of parallel trade is ambiguous and dependent on the preferences of the patients and the national price regulations. This brings about two aspects of welfare; the economic and consumer welfare. This section, however, is concerned mainly with consumer welfare. Consumer welfare is an important aspect of pharmaceutical companies. Original producers of pharmaceutical products, manufacturers, as well as parallel importers should bear in mind the consumers as they are whom the products are intended for. Having this in mind, brand names and consumer loyalty are then driving forces for research and innovation.

Social effects of parallel importation point out to the consumers whose concern is the price and quality of goods. A parallel import good should be at a pocket-friendly price and should be genuine so as not to harm the welfare of the consumers. A review by Wu and Yan (2018) indicates that parallel importation has advantages and disadvantages for the consumer. Consumers are able to have access to the increased alternative products whose competition leads to lowered prices. Price competition helps to meet consumer demands. This can, however, has a downside in which the consumers have access to goods that have quality defects or differences. By the same token, Brekke et al. (2015) suggest that the aggregate welfare effects of parallel trade are positive. This is due to the price competition that leads to price convergence; which results in welfare improvements for the payers.

Granlund and Köksal-Ayhan (2016) aver that consumer perceptions of parallel imports are continually changing. Their study sought to find out whether the EU enlargement

led to parallel import competition. The results indicated that while the enlargement of the EU had no effect on parallel import trade, consumer perceptions seemed to propel price and product competitions. Cross-nationally, consumer preferences differ, and so do the range of available pharmaceutical products. McKeith (2014) notes that choices of informed consumers in competitive markets are not dictated by drug consumption; but by medical norms, incentives and insurance constraints.

In developing countries, however, consumer perceptions are also led by a lack of political will and leadership which identifies the domestic healthcare needs of the people(Quet, 2017). In Sub Saharan Africa, for instance, the health care system is marred with a lot of corruption, and this creates perceptions from the consumers that they cannot be properly assisted. This creates leeway for counterfeit drugs affecting the performance of the legally set up pharmaceutical companies.

Apart from poor leadership, people from Sub-Saharan Africa are continually grappled with poverty which means that they can not to afford even the minimum healthcare needs. This limits their access to pharmaceutical products. It is important to note the pharmaceutical companies, more so the multinationals, cannot compare the profits gained from developed and developing countries. This is the reason that most companies focus on developed countries, which is an economically sound decision.

Parallel importation influences welfare negatively. Lehnhausen (2016) indicates that in countries with no difference in the need for drugs, welfare decreases. In cases where the territorial arrangements entered in to by manufacturers and producers with authorised distributors

in a given geographical region fails for one reason or another, then this undermines the ability of pharmaceutical companies to safely and effectively distribute their products to the market. This can potentially cause harm to consumers.

Conclusion

Parallel importation in the country has been marred with controversies especially due to the penetration of substandard medicinal substances which enter the country through some unscrupulous parallel importation traders. Additionally, the principles and policies on parallel importation in the country have been conflicting due to the lack of clear guidelines. In September 2019 Section 44 of the Kenyan Pharmacy and Poisons Act was gazetted and includes rules on parallel importation of medicinal substances. These rules are aimed at ensuring that medication is made affordable and accessible to all through a legal framework for parallel importation. In a broader context, the legal framework focuses on ensuring that parallel imports are valuable to patients. Scholarly literature on parallel importation in developing countries and more so in Kenya is scanty making it difficult to establish the effect of parallel importation on pharmaceutical companies. To fill in this gap, this paper has discussed the economic and social effects of parallel importation and how they affect the organizational performance of pharmaceutical companies in Kenya. This paper recommends that a study be conducted focusing on parallel importation and organizational performance of pharmaceutical companies; especially now that a clear legal framework on parallel importation has been put in place.

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