

Potential conflicts in the fight against counterfeit drugs

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Abstract

This analysis looks at the best way to deal with the proliferation of fake drugs, and considers the conflict that arises when government agencies aim to reduce the harmful effects of the fake medicine trade while the pharmaceutical firms seek profit maximization. It is demonstrated that the pharmaceutical industry might wish to encourage better law enforcement rather than improved information policies, even when the latter would lead to a greater reduction in the fake drug trade.

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1. Introduction

The spread of fake and substandard drugs is a major problem in both developed and developing countries. Evidence suggests that they can lead to therapeutic failure or drug resistance; in some cases, they led to death. The WHO (2006), for example, reports that during a meningitis epidemic in Niger in 1995, more than 50,000 people were inoculated with fake vaccines resulting in 2500 deaths. In one of the few reports that present quantitative data collected in a controlled and methodical manner, Shakoor, Taylor and Behrens (1997) indicate that 36.5% of the samples of chloroquine and selected antibacterials from Nigeria and Thailand were substandard with respect to pharmacopoeial limits. Dondrom et al. (2004) attempt to assess the prevalence of counterfeit antimalarial drugs in Southeast Asia, and they observe that 53% of the tablet packs purchased in their study were labelled as manufactured by an authorized firm but did not contain any active ingredient. Kelesidis et al. (2007) review the existing literature on counterfeit antimicrobial drugs and conclude that the problem has titanic proportions and similarly devastating effects. In fact, fake drugs are almost certainly detrimental to public health, they undermine public confidence in medicines and, in addition, counterfeiting damages the pharmaceutical supply system and the benefits that this might generate in terms of research and new products. Morris and Stevens (2006) highlight a number of factors that potentially encourage the fake-drug-trade, the foremost of these being the fact that counterfeiting is a lucrative criminal business. Hence, the Declaration of Rome (WHO, 2006a), art. 2, states that, "Because of its direct impact on health, counterfeiting medicines should be combated and punished accordingly."

In order to combat counterfeit drugs, the World Health Organization launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) in February 2006. The main objective of IMPACT is to stop the production and trading of fake medicines. IMPACT is a partnership of international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturing associations and drug and regulatory authorities. The inclusion of all concerned parties is consistent with the recommendations of the WHO (WHO, 1999). Given that counterfeiting damages both public health and the profits of the pharmaceutical industry, the collaboration of manufacturers and public authorities seems logical. However, profit maximization may not necessarily go hand in hand with a reduction in the counterfeit drugs trade.

This paper develops a simple model of vertical product differentiation and price competition between an authorized pharmaceutical firm and a counterfeit producer, and considers the possibility of Government intervention through either improved law enforcement or an "information policy", which consists of providing potential patients with the means for distinguish between fake and genuine drugs. The lack of information on substandard drugs is a major source of concern and this has been considered by other authors. For instance, Cockburn et al. (2005) analyse this phenomenon and suggest that pharmaceutical companies do not publicize the problem due to the belief that it would harm sales and brand-name products. This paper takes a different approach, and it is shown that the pharmaceutical industry and public agencies aimed at fighting counterfeit trade might have different preferences with respect to the best policy option. In fact, though all agents agree on the main objective, which is the reduction of counterfeiting, strengthening the legal disincentive to produce and distribute counterfeit drugs might simply benefit profit maximization rather than simply leading to a reduction in counterfeit products.

2. Competition between pharmaceutical firms and counterfeit drug producers

Two pharmaceutical firms compete in the market for a specific drug. Firm 1 is assumed to be the producer of a fake drug, whereas Firm 2 has been authorized to produce the same drug with a certified quality standard. The product of Firm 1 is substandard with respect to pharmaceutical quality and testing limits and thus, the trade of the counterfeit drug is socially undesirable. This is clearly a strong assumption, provided that many persons have no access to genuine drugs and it could be beneficial for them to face the risk of prejudicial side-effects instead of passively observe the course of their diseases. However, the aim of this paper is to show the existence of a conflict of interests in the fight against fake drugs, even when it is assumed that all counterfeit drugs are substandard and detrimental to public health. Hence, products are differentiated by their “perceived quality”, which is related to the capacity of individuals to distinguish between counterfeit and brand drugs. Explicitly, the main difference between fake and genuine drugs is their intrinsic quality in terms of principal active ingredients, but the potential recipients of these drugs are not always in a position to judge since they may be illiterate. For example, fake drugs are sold and packaged as if they were the genuine article. Let $s_1 \leq s_2$ be the perceived quality of product 1 and 2, respectively. Firms compete in prices and hence, Firm 1 must sell its product at a lower price with respect to Firm 2 in order to obtain a positive demand, $p_1 < p_2$. Provided that the counterfeiter faces neither research costs nor quality controls, it is assumed that production costs are higher for Firm 2. For the sake of simplicity, we thus assume that the marginal cost faced by Firm 1 is lower than the marginal cost of Firm 2, $c_1 < c_2$.

Each potential patient can buy just one unit of a given drug or, alternatively, nothing; hence, individual utility is equal to

$$U = \begin{cases} \mathcal{G}s_i - p_i, & \text{if the individual buys the drug,} \\ 0, & \text{otherwise} \end{cases} \quad (1)$$

where $i = 1, 2$ and \mathcal{G} can be interpreted as the preference for quality, which might depend on the level of income or the risk-propensity, for example. The value of \mathcal{G} is bounded from both below and above, $\underline{\mathcal{G}} < \mathcal{G} < \bar{\mathcal{G}}$, where heterogeneity in individuals’ preferences is constrained by $\bar{\mathcal{G}} < 2\underline{\mathcal{G}}$. The previous assumption is justified by a common inclination for high quality and effective drugs. In particular, consumers’ preferences are uniformly distributed in the interval $(\underline{\mathcal{G}}, \bar{\mathcal{G}})$, and the total population is normalized to one. Each patient is indifferent between buying the counterfeit drug or the brand drug if

$$\mathcal{G} = \frac{p_2 - p_1}{\Delta s}, \quad (2)$$

where $\Delta s = s_2 - s_1$. Hence, demand functions faced by Firm 1 and Firm 2 are equal to

$$D_1 = \frac{p_2 - p_1}{\Delta s} - \underline{\mathcal{G}}, \quad (3)$$

$$D_2 = \bar{\mathcal{G}} - \frac{p_2 - p_1}{\Delta s}. \quad (4)$$

Firms choose the price p_i in order to maximize profits

$$\Pi_i = (p_i - c_i)D_i. \quad (5)$$

This simple optimisation problem is solved by each firm and implies the equilibrium prices

$$p_1 = \frac{1}{3}[2c_1 + c_2 + \Delta s(\bar{g} - 2\underline{g})] \quad (6)$$

$$p_2 = \frac{1}{3}[2c_2 + c_1 + \Delta s(2\bar{g} - \underline{g})] \quad (7)$$

Substituting (6) and (7) into (3) and (4) we obtain

$$D_1 = \frac{\Delta c - \Delta s(2\underline{g} - \bar{g})}{3\Delta s}, \quad (8)$$

$$D_2 = \frac{\Delta s(2\bar{g} - \underline{g}) - \Delta c}{3\Delta s}, \quad (9)$$

where $\Delta c = c_2 - c_1$ and hence,

$$\Pi_1 = \frac{[\Delta c - \Delta s(2\underline{g} - \bar{g})]^2}{9\Delta s}, \quad (10)$$

$$\Pi_2 = \frac{[\Delta s(2\bar{g} - \underline{g}) - \Delta c]^2}{9\Delta s}. \quad (11)$$

As can be observed, increased differential of perceived quality lowers the demand and profits of the unauthorized Firm 1, whereas the increased costs differential Δc results in lower profits for the authorized Firm 2. In addition, consumer demand might be at a corner for either fake drugs or real drugs depending on the relationship between quality and cost differentials. In particular, when the perceived quality differential, weighted with quality preference, is higher than the cost differential,

$$\Delta s(2\underline{g} - \bar{g}) \geq \Delta c \Rightarrow D_1 = 0. \quad (12)$$

Conversely, sufficiently high cost differential implies that consumer demand for genuine drugs is equal to zero,

$$\Delta s(2\bar{g} - \underline{g}) \leq \Delta c \Rightarrow D_2 = 0. \quad (13)$$

Hence, an interior solution exists if and when $\Delta s(2\underline{g} - \bar{g}) < \Delta c < \Delta s(2\bar{g} - \underline{g})$.

3. Effects of Government intervention

It is now assumed that a Government agency intervenes in the market in order to curtail counterfeit trade. Two different policies are considered here, namely the enforcement of property rights laws and the consequent prosecution of Firm 1, and an ‘‘information policy’’.

While the prosecution of Firm 1 results in increased costs of production, provided that Firm 1 can internalise the expected cost of sanctions, the “information policy” is aimed at providing individuals with the means for distinguishing between fake and authentic drugs. In other words,

$$c_1 = c(LE), \quad c'_{LE} > 0, \quad (14)$$

$$s_1 = s(I), \quad s'_I < 0, \quad (15)$$

where LE stands for improved Low Enforcement policy and I for Information policy. Government agency intervention affects both counterfeit pharmaceutical trade and firms' profits. In particular, considering law enforcement it can be observed that

$$\frac{dD_1}{dLE} = \frac{\partial D_1}{\partial c_1} \cdot \frac{dc_1}{dLE} = -\frac{1}{3\Delta s} c'_{1,LE}. \quad (16)$$

Reduction of counterfeit pharmaceutical trade is proportional to the efficiency with which the enforcement of law affects production costs, and it depends inversely on the perceived quality differential. Regarding profits of Firm 2,

$$\frac{d\Pi_2}{dLE} = \frac{\partial \Pi_2}{\partial c_1} \cdot \frac{dc_1}{dLE} = \frac{2[\Delta s(2\bar{\vartheta} - \vartheta) - \Delta c]}{9\Delta s^2} c'_{1,LE}. \quad (17)$$

In other words, the profits of the authorized firm increase with improved law enforcement.

Another possibility for the Government agency consists of altering the perceived quality of counterfeit drugs by providing citizens with adequate information. The effects of this policy on both the demand of fake drugs and profits of Firm 2 are

$$\frac{dD_1}{dI} = \frac{\partial D_1}{\partial s_1} \cdot \frac{ds_1}{dI} = \frac{\Delta c}{3\Delta s^2} s'_{1,I}, \quad (18)$$

$$\frac{d\Pi_2}{dI} = \frac{\partial \Pi_2}{\partial s_1} \cdot \frac{ds_1}{dI} = \frac{\Delta c^2 - \Delta s^2(\vartheta - 2\bar{\vartheta})^2}{9\Delta s^2} s'_{1,I}. \quad (19)$$

As in the previous situation, Government intervention both reduces fake drug trade and results in increased profits for Firm 2.

The choice of the Government agency between these two alternative policies crucially depends on the level of the production cost differential, the perceived quality differential and the efficacy in affecting the cost structure or the consumers' perception of quality. Obviously, Firm 2 is also interested in combating fake drugs, due to the possibility of monetary benefits as shown in (17) and (19), but while the Government agency aims to reduce the diffusion of harmful medicines, Firm 2 is moved by profit maximization. In order to highlight the potential conflict of interests between Firm 2 and the Government agency, it is initially assumed that the agency is indifferent to intervention through law enforcement or by providing individuals with adequate information.

Assumption 1 (Government agency indifference).

$$\frac{1}{3\Delta s} c'_{1,LE} = -\frac{\Delta c}{3\Delta s^2} s'_{1,I}. \quad (\text{A1})$$

Assumption 1 ensures that one additional dollar spent on either law enforcement or diffusion of information has the same marginal utility in terms of reduction of counterfeit drug trade. Under A1, it is interesting to analyse what the preferred policy for Firm 2 will be. Substituting A1 into (19) and comparing with (17) it is possible to obtain

$$\Delta s(2\bar{\vartheta} - \vartheta) < 3\Delta c \Rightarrow \frac{d\Pi_2}{dLE} > \frac{d\Pi_2}{dI}. \quad (\text{20})$$

Proposition 1. Under A1, Firm 2 prefers improved law enforcement in order to maximize profits when $\Delta s(2\bar{\vartheta} - \vartheta) < 3\Delta c$; the firm is indifferent between the two policies when $\Delta s(2\bar{\vartheta} - \vartheta) = 3\Delta c$, and prefers information diffusion otherwise.

Proof. The proof follows from the effects of Government agency intervention under A1, see (17) and (19).

Proposition 1 states that when $\Delta s(2\bar{\vartheta} - \vartheta) < 3\Delta c$, Firm 2 faces an incentive to encourage improved law enforcement. The interest of this conclusion relies on the reality of the assumption regarding the relationship between quality and cost differentials. For example, counterfeit firms are succeeding in fooling consumers by using official-looking packaging, while, of course, the production costs are much higher for authorized firms. It should be noted that Firm 2 prefers improved law enforcement even when (13) holds, that is, when the demand for real drugs is equal to zero.

Assumption 1 can be relaxed in order to show the existence of a “region of conflict” when the Government agency has a preference for the information policy.

Assumption 2 (Government agency preference for information policy).

$$\frac{1}{3\Delta s} c'_{1,LE} + \xi = -\frac{\Delta c}{3\Delta s^2} s'_{1,I}. \quad (\text{A2})$$

where $\xi > 0$.

A2 states that the marginal utility of the information policy in terms of reduction of fake drug trade is equal to the marginal utility of law enforcement plus a positive parameter ξ and hence, the Government agency prefers to invest in providing information about drugs quality.

Under A2, the preferences of Firm 2 are now analysed. Substituting A2 into (19) and comparing with (17), it follows that

$$\xi < \frac{2\Delta c + \Delta s(2\bar{\vartheta} - \vartheta)}{3\Delta s[\Delta c + \Delta s(2\bar{\vartheta} - \vartheta)]} c'_{1,LE} \equiv \xi^* \Rightarrow \frac{d\Pi_2}{dLE} > \frac{d\Pi_2}{dI}. \quad (\text{21})$$

Proposition 2. Under A2 and for $\xi < \xi^*$, the Government agency prefers to fight against counterfeit drug trade via the information policy, whereas Firm 2 prefers improved law enforcement in order to affect the cost structure of Firm 1.

Proof. The proof follows from a simple comparison between equations (17) and (19) under A2 and (21).

A corollary of Proposition 2 is that when the information policy is much more effective in reducing counterfeit trade with respect to improved law enforcement ($\xi \geq \xi^*$), both the Government agency and Firm 2 agree on the policy to be adopted..

Corollary. When $\xi \geq \xi^*$ both the Government agency and Firm 2 prefer the information policy in order to combat fake drugs.

It should be noted that the above conclusion follows from the different objectives of the two agents being considered. In particular, the Government agency aims to reduce the quantity of fake drugs in the market, while Firm 1 seeks profit maximization. A limitation of this approach is that Assumption 1 and 2 mean that it is possible to draw conclusions without explicitly considering policy costs. In other words, it is important to bear in mind that the different levels of efficiency of the two policies is affected by costs, though this is not explicitly stated in A1 and A2. In order to assess the effects of real strategies to combat counterfeit drugs, however, differential efficiency should be assessed and hence, it would be possible to evaluate the existence of potential conflicts of interest.

4. Conclusions

Fake medicines might be detrimental to public health and therefore, it is necessary to develop strategies to combat counterfeit trade. All of the parties concerned, from Government agencies to pharmaceutical manufacturers and consumers, are usually encouraged to take part in the development of plans for reducing this phenomenon. However, this paper shows that a conflict between agencies aimed at reducing counterfeit trade and firms motivated by profit maximization might arise. In particular, when the differential of perceived quality between fake and genuine drugs is low and counterfeit producers face very low costs of production, pharmaceutical firms might encourage improved law enforcement rather than information policies, even when the latter option would result in a greater reduction in fake drug trade. Therefore, caution should be exercised when including the pharmaceutical industry in task forces that combat counterfeit drugs.

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