

The Counterfeiting of Healthcare Products

The Issue

The counterfeiting of healthcare products represents an unacceptable threat to patients' welfare. It can also damage healthcare companies, not simply through lost sales, but also by involuntarily associating them with sub-standard and dangerous products.

The extent of the counterfeiting problem is impossible to quantify. However reports from various organisations, including NGOs, national regulatory agencies and pharmaceutical companies, indicate that most industrialized countries with effective regulatory systems (e.g. USA, most of EU, Australia, Canada, Japan, New Zealand) have a low proportion, i.e. less than 1% of the market value. However, many countries in Africa and parts of Asia and Latin America have areas where more than 30% of the medicines on sale can be counterfeit; while in many of the countries of the former Soviet Union the proportion of counterfeit medicines is above 20% of market value. In over 50% of cases medicines purchased over the internet from illegal sites that conceal their physical address are counterfeit.

Healthcare products are in high demand and easily transportable, and are therefore particularly attractive to counterfeiters. It is therefore an issue of key importance to the industry and GSK.

GSK's Position

- GSK is a research-based company dedicated to fighting disease by bringing innovative medicines to patients throughout the world and to the healthcare providers who serve them. GSK is committed to the best possible standards of product quality.
- There is no such thing as a "good" counterfeit. Any counterfeiting of a healthcare product is unacceptable since the products have been manufactured and /or packaged outside the properly controlled channels.
- Fake medicines can kill people. They either poison them, or they do not help to cure or immunise them so they die of the disease they have or contract.
- GSK recognises that the pharmaceutical industry has a role to play in helping to minimise the counterfeiting of our products and is committed to a comprehensive programme of action against counterfeiting.
- However, GSK cannot tackle this issue alone. The prevention and detection of counterfeits is primarily a matter for national governments worldwide which must be encouraged to recognise the dangers associated with the practice and ensure its effective regulation by the relevant authorities.
- The dangers of counterfeiting are increasing in these days of globalised trade. The WHO has identified trade "involving several intermediaries and free trade zones" as a key driver of counterfeiting activity.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

- GSK recognises that technology has a role to play in helping to stem the flow of counterfeit medicines. We keep a range of current and developing options under review for their potential and applicability in different market scenarios.
- Technology however is not a “magic bullet” that will stop the counterfeiting problem on its own. It needs to be combined with other measures including tough legislation and regulations against counterfeiting, rigorous enforcement, stiffer penalties and diligent surveillance on the part of the authorities.

BACKGROUND

1. Definition

The WHO definition of a counterfeit product is *“one that is deliberately and fraudulently mislabelled with respect to identity and / or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, the wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging.”*

GSK accepts that this definition excludes violations or disputes concerning patents. In other words, even illegal, patent-infringing generics should not be viewed as “counterfeits”. Likewise, we recognise that medicines not authorised for marketing in a given country, but authorised elsewhere, should not be considered counterfeits.

2. The extent of the problem for Healthcare Products

Healthcare products are an attractive target for counterfeiting because they are a high value item in relation to their bulk, and a fake can be made relatively cheaply. For pharmaceutical products, counterfeits represent a peculiar danger because of the way in which they reach the consumer: the doctor who prescribes the product and is well informed about its efficacy rarely sees it, and the patient normally has little or no knowledge about the product or even his own medical condition to allow him to be a discerning consumer.

- Figures for the level of counterfeits are hard to establish. Because the activity is criminal and hidden from view, it is very difficult to measure. However, some estimates have been made:
- A WHO/IFPMA workshop on counterfeits in 1992 declared: “The Counterfeit Intelligence Bureau (a division of the International Chamber of Commerce) estimates that 5% of all world trade in 1991 was counterfeit. This is likely to be greater for pharmaceuticals which are in high demand and easily transportable. Estimates from a wide spectrum of countries range from 0% to over 60% in sectors of the market that are inadequately controlled”.
- A WHO/IFPMA CEO roundtable on 3 November 1999 reported that the WHO Counterfeit Working Group has found that between 10-20% of drug samples in developing countries fail quality tests (and there is a wide variation between countries).

3. Adverse health effects of Counterfeits

- **Counterfeits can kill.** Fake medicines kill people. They either poison them, or they do not help to cure or immunise them so they die of the disease they have or contract. In these cases, counterfeit drugs can be more dangerous than narcotic drugs.

GLOBAL PUBLIC POLICY ISSUES

GlaxoSmithKline's Position

- **Counterfeits are never safe to use.** Counterfeit medicines are rarely as efficacious as genuine ones, and are not manufactured under the same strict conditions of quality control, safety and hygiene. Patients taking them are therefore exposed to unknown risks.
- **Counterfeits deceive patients.** Patients buying or being given counterfeit medicines are unlikely to know that what they have is not genuine and could be harmful. There is no question of a consumer making an informed decision to buy a fake medicine.
- **Counterfeits destroy confidence in healthcare systems.** Public confidence in pharmacists, doctors and nurses who unwittingly distribute counterfeit medicines, can be damaged by counterfeit medicines. Such a loss of confidence harms patients and the public as much as the health system.

4. Key drivers of counterfeiting

- **Monetary Gain.** The overriding reason for counterfeiting is the huge sums of money that can be made. Low manufacturing costs and high profits for fake medicines attract criminals who see their manufacture and distribution as an easy way to make money.
- **Lack of legislation and proper enforcement.** Where there is poor legislation controlling the manufacture, import and distribution of healthcare products, or a lack of enforcement measures, counterfeiters can easily escape detection and prosecution.
- **Weak national drug regulatory enforcement.** In countries where the enforcement of pharmaceutical legislation is weak, counterfeiters can remain unpunished.
- **Feeble penal sanctions.** The lack of, or lenient, custodial sentences for criminals who are convicted of counterfeiting – in contrast to harsher sentences for narcotic drug pushers – can allow counterfeiting to grow. Financial penalties are simply factored into overheads by counterfeiters.
- **Transactions involving many intermediaries.** Where medicines pass through many intermediaries, or there are several paper transactions, the opportunities for counterfeiters to insert their products into the system increases.
- **Free trade and deregulation.** Facilitating trade within and between countries (via, amongst other means, increased use of the internet) gives counterfeiters greater scope to introduce their fake products into official distribution channels. Consumers become used to seeing a variety of packs and so are less wary of what may in fact be a counterfeit.
- **Lack of cooperation between stakeholders.** If the drug regulation authority, customs authority, the police, the government, the health system and industry do not cooperate properly, then it is easier for counterfeiters to escape detection, arrest and penal sanctions.
- **Lack of political will.** Governments in some countries regard counterfeiters as legitimate employers of local labour and their exports as economic benefit.
- **Consumer ignorance.** Most consumers do not know that their medicine may be fake. Recognising a counterfeit product is usually very hard.

5. GSK's Response

GSK aims to protect patients worldwide from counterfeits of its products and in each case takes all appropriate steps to safeguard public health, including working with those government ministries and authorities that have responsibility for public welfare in the affected market. GSK rigorously investigates and where appropriate takes legal action against the manufacturers, distributors, retailers and other parties involved in counterfeiting our products. Furthermore, in countries where counterfeiting of our products is prevalent, the product and packaging incorporate features that discourage the manufacture of counterfeits and help detection. It is a condition of GSK business that wholesalers must report any offers to supply suspected counterfeit GSK products and to report, isolate and withhold from sale any such stock that is received. Procedures are in place to apply controls to the sale and disposal of GSK products, manufacturing equipment, packaging and other materials used in the production of GSK products. GSK also works in close co-operation with pharmacists, wholesalers and other pharmaceutical companies to ensure that suspected counterfeiters and their intermediaries are thoroughly investigated and, where appropriated, prosecuted.

6. External Partnerships

In June 1997, GSK joined the Pharmaceutical Security Institute (PSI), an industry-wide programme dedicated to countering the rapidly increasing trade in illegal and counterfeit medicines. Funded by the majority of research-based multinationals and operating under the auspices of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), the PSI's functions include the supervision of worldwide enquiries into counterfeiting, and liaison with law enforcement agencies in bringing the perpetrators to justice.

The effectiveness of these measures, however, will be limited if external agencies do not adopt adequate measures of their own. It is unacceptable for authorities to tolerate counterfeits simply because the products are close copies of the original without appearing to pose a hazard to health. GSK is therefore committed to working with the IFPMA, the WHO including active participation in the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), national and international governments and other appropriate bodies to encourage co-ordinated action to create an environment hostile to counterfeiting.

GSK welcomes Article 61 of TRIPs which imposes obligations on WTO members to "provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale". Unfortunately, implementation of the article has not been universal, especially in developing countries, where counterfeiting is most prevalent. Stronger and more specific legislation is needed to allow for action against counterfeiting of products to be taken. Political will is needed to mobilise resources for implementation of effective countermeasures.

Effective regulation and political will, combined with industry's own commitment, will forge a successful partnership for the elimination of counterfeiting.

7. Anti-Counterfeiting Technology

GSK recognises that technology has a role to play in helping to stem the flow of counterfeit medicines.

Different technological approaches, ranging from the simple to the more complex, are available or in development, and are either routinely used - or else are under review - by the pharmaceutical industry. Examples include overt verification tools such as holograms or colour-shift inks (they are cheap but relatively easily copied) and more sophisticated covert tools, such as invisible printing and digital watermarks (while more effective, are more expensive and require special devices to check).

Forensic technology, essentially chemical or biological tags built into medicines packaging, are even more secure against copying but are more costly and provide no visible reassurance to customers. Serialization using unique numbers encoded in barcodes or radio frequency identification (RFID) ie. the tagging of products with a unique electronic product code, allow products to be verified within the supply chain and/or at the point of dispense. However, they can require an expensive technical infrastructure. Certain risks have also been linked to RFID such as damage to biotechnology products (due to electromagnetic waves) and data privacy issues. Doubts also remain regarding how robust RFID technology currently is. Product verification by consumers using mobile phones and texting technology is also gaining attention.

GSK is not wedded to any one particular technology solution. We keep all options under review and are willing to consider engaging in pilot studies designed to road test new programmes for applicability in different scenarios. Careful consideration particularly needs to be given to the applicability of certain technologies in developing countries, where computer and technological illiteracy, lack of infrastructure and cost may limit the ability of any one particular technology to deliver solutions.

Technology however is not a “magic bullet” that will stop the counterfeiting problem on its own. It needs to be combined with other measures including tough legislation and regulations against counterfeiting, rigorous enforcement, stiffer penalties, and diligent surveillance on the part of the authorities.

Revised June 2010