# GSK Public policy positions

## 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 potentially dangerous products.

The size of the counterfeiting problem is impossible to quantify. GSK experience is that the emerging markets have proved to be more vulnerable to counterfeit medicines permeating the market place. Counterfeiting of healthcare products is however a global public health issue. It is one that affects patients as well as the manufacturers of both branded and "generic" medicines. Even low cost generic anti-malarials are widely counterfeited.

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. We are 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.

– Counterfeit 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 an important 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.

– 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

### Definition

The international community no longer talks just in terms of 'counterfeit' medicines. Rather the WHO references 'Spurious, Falsely-labelled, Falsified, Counterfeit' (SFFC) products which themselves are defined differently in different countries, demonstrating how the nature of the problem of SFFC medicines varies from country to country.

Historically, however, dating back to 1992 and the first international meeting on SFFC medicines, the WHO definition of a counterfeit product has been *"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 agrees 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.

## The Size of the Problem

Accurate figures relating to the level of counterfeiting of healthcare products are hard to establish due to the clandestine nature of this criminal activity and because, as technology improves, counterfeit packaging becomes increasingly sophisticated and more difficult to detect. However, healthcare products are undoubtedly an attractive target for counterfeiting because they are a high value item in relation to their bulk, and a counterfeit can be made relatively cheaply. And for pharmaceutical products, counterfeits represent a particular danger because of the way in which they usually reach the end-user; 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.

## Adverse Health Effects of Counterfeits

– Counterfeit 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.
– 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 counterfeit 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.

## 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 counterfeit 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 opportunity 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[1]) gives counterfeiters greater scope to introduce their counterfeit 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.

[1] The WHO has stated that it believes approximately 50% of medicines sold online from unauthorized sources are 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 counterfeit. Technological advances have meant it is easier for criminals to accurately reproduce packaging making it increasingly difficult for consumers to distinguish between authentic and counterfeit products.
– Unregulated websites. Many internet sites offering medicines and healthcare products operate outside the regulatory framework, concealing their physical addresses and preying on consumer ignorance. The only way to guarantee a product is genuine is to purchase it from the approved supply chain.

## GSK's Response

GSK aims to protect patients worldwide from counterfeits of our products and in each case takes all appropriate steps to safeguard public health, including working with customs, law enforcement and those government ministries and authorities that have responsibility for public welfare in the affected market. We use the World Customs Organisation's IPM database which is intended to enable customs to more readily identify consignments of counterfeit GSK products. We also participate in authority training sessions to raise awareness of the dangers of counterfeit healthcare products and assist in the identification of counterfeit GSK products. Recognising the need to raise public awareness about the risk associated with buying medicines from non-traditional outlets, GSK also supports awareness campaigns such as 'Fight the Fakes' run by the IFPMA (International Federation of Pharmaceutical Manufacturers and Associations) (see www.fightthefakes.com).

GSK has well established internal procedures for dealing with suspected counterfeits and provides training (including an e-learning module) for its staff. We rigorously investigate and, where appropriate, take 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 cooperation with pharmacists, wholesalers and other pharmaceutical companies to ensure that suspected counterfeiters and their intermediaries are thoroughly investigated and, where appropriate, prosecuted.

## 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. Serialisation using unique numbers encoded in barcodes or radio frequency identification (RFID) i.e. 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. 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**.**

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