GSK Public policy positions

Falsified and substandard healthcare products

The Issue

In May 2017, the World Health Organisation (WHO) approved replacing the term 'substandard/spurious/ falsely labelled/ falsified/ counterfeit' (abbreviated to SSFFC but frequently referred to as "counterfeit") with 'falsified and substandard.' This move was prompted by a concern that intellectual property issues, particularly patent infringement, were being conflated with issues around public health.

This paper sets out GSK's position on the dangers presented by both falsified and substandard healthcare products. It covers the measures we take to minimise the risk of our products being falsified, including through use of technology. It also touches on how we ensure the quality of our products through Good Manufacturing Practice (cGMP) regulations, as well as through our supply chain standards.

GSK's Position

- GSK is a research-based company dedicated to fighting disease by bringing innovative healthcare products to patients throughout the world and to the healthcare providers who serve them.

- Falsified and substandard healthcare products represent a danger to public health. They can poison the people who use them; fail to cure or immunise them; and in extreme cases, kill.

- Falsified healthcare products are a public health threat which can involve both patented and generic medicines. Patent infringement disputes which may arise in the ordinary course of business should not be confused with disputes related to the production of falsified healthcare products, where there is a deliberate intent to mislead consumers as to the origin and quality of the product.

- GSK recognises that we have an important role to play in helping to minimise the falsifying of our products, including exercising our trade mark rights. We are committed to a comprehensive programme of action to combat this, which includes packaging features designed to help detection, participating in training sessions to raise awareness of the dangers of such products, working with customs, law enforcement and government authorities; and ensuring the safe disposal of GSK packaging equipment.

- However, GSK cannot tackle this issue alone. The prevention and detection of falsified products is primarily a matter for national governments worldwide, who must be encouraged to recognise the dangers associated with this issue and ensure its effective regulation by the relevant authorities.

- GSK recognises that technology has a role to play in helping to stem the flow of falsified healthcare products. Technology however is not a "magic bullet" that will stop the falsifying problem on its own. It needs to be combined with other measures including tough legislation and regulations, rigorous enforcement, stiffer penalties and diligent surveillance on the part of the authorities.

- We manufacture our healthcare products to the highest standards through stringent quality control and quality assurance processes, according to Good Manufacturing Practice (cGMP) regulations. Contract manufacturers making our products are expected to comply with GSK standards, and are audited to provide assurance that standards are met.

- We have procedures to ensure a rapid response to incidents involving product quality, safety or efficacy. We can recall any of our commercial products in the market, if needed, directly from patients, from suppliers such as pharmacies or hospitals, or from distributors or wholesalers.

- We recognise that substandard healthcare products can inadvertently exist in the supply chain, even though they may be made by registered manufacturers. Products can be of good quality when they leave a manufacturing site but can subsequently degrade because of inappropriate conditions during transport and storage. GSK therefore works to ensure distributors and customers are aware of appropriate handling and storage requirements, in order to maintain product quality. These are printed on every pack of our healthcare products.

Background

Definitions

In May 2017, the WHO agreed that the term 'substandard/ spurious/ falsely labelled/ falsified/ counterfeit' should be replaced with the term 'falsified and substandard', defining each element in the following way:

Falsified: Medical products that deliberately misrepresent their identity, composition or source.

Substandard: Authorised medical products that fail to meet either their quality standards or their specifications, or both.

GSK welcomes the change in definitions which bring increased clarity for stakeholders.

Adverse Health Effects

Falsified healthcare products are not manufactured under the same strict conditions of quality control, safety and hygiene as genuine products, and therefore are rarely as efficacious. Patients taking them are exposed to unknown risks, and are unlikely to know that what they have is not genuine and could be harmful.

Falsified pharmaceuticals represent a particular danger because of the way in which they usually reach the end-user; the doctor who prescribes the product rarely sees it; and the patient normally has little or no knowledge about the product to enable them to identify it as falsified. By harming patients, falsified healthcare products destroy confidence in healthcare systems. Public confidence in pharmacists, doctors and nurses who unwittingly distribute these products can be damaged.

The Size and Nature of the Problem

Accurate figures relating to the level of falsified healthcare products are hard to establish due to the clandestine nature of this criminal activity. In addition, as technology improves, it is easier for criminals to accurately reproduce packaging, making it increasingly difficult for consumers to distinguish between authentic and falsified products. Healthcare products are however known to be an attractive target for falsifying because they are a high value item in relation to their bulk, and falsified versions can be made relatively cheaply.

An additional and evolving aspect of falsified and substandard medicines is how they are adding to the rising prevalence of antimicrobial resistance. When pathogens encounter medicines containing too low a dose of active ingredient, this enables drug-resistant mutations to multiply and spread. Pathogens with short life-cycles and high rates of reproduction are most likely to become drug-resistant - including those which cause malaria, HIV and other infections. This resistance not only puts patients at risk, but can also place an increasing burden on already strained health systems.

Key Drivers of Falsified Healthcare Products

- **Monetary Gain**. Low manufacturing costs and high profits for falsified healthcare products attract criminals who see their manufacture and distribution as an easy way to make money.
- **Lack of legislation** and proper enforcement controlling the manufacture, import and distribution of healthcare products results in falsified products escaping detection.
- **Weak penal sanctions**. The lack of, or lenient, custodial sentences for criminals who are convicted of falsifying – in contrast to harsher sentences for narcotic drug pushers – can be viewed as an enabler. Financial penalties are simply factored into overheads by those who falsify healthcare products.
- **Transactions involving many intermediaries.** Where healthcare products pass through many intermediaries, or there are several paper transactions, the opportunity for falsified products to be placed into the system increases.

- **Poorly regulated distribution channels.** Facilitating trade within and between countries (via, amongst other means, increased use of the internet[1]) offers greater scope for falsified healthcare products to be introduced 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 falsified product.
- **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 those who falsify healthcare products to escape detection, arrest and penal sanctions.
- **Lack of political will.** Governments in some countries regard those who produce falsified products as legitimate employers of local labour and their exports as economic benefit.
- **Consumer awareness**. Technological advances have meant it is easier for criminals to accurately reproduce packaging making it increasingly difficult for consumers to distinguish between authentic and falsified products.
- **Unregulated websites.** Many internet sites offering healthcare products operate outside the regulatory framework, concealing their physical addresses and preying on consumer ignorance. The best way to guarantee a product is genuine is to purchase it from the approved supply chain, recognising that this too can be infiltrated with falsified products.

Trade mark infringement of GSK products

Notwithstanding the WHO's decision of May 2017 to adopt new terminology reflecting the public health threat posed by falsified healthcare products, the World Trade Organisation (WTO) TRIPs Agreement (Article 61) continues to define products which infringe a trademark as 'counterfeit', and 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*".

A trade mark is anything which distinguishes a good or service from its competitors. Trade marks play a pivotal role in engendering trust and confidence in a company's products, and are of particular importance in the healthcare industry where quality and safety issues are fundamental. Whether or not a falsified healthcare product infringes a trade mark and/or constitutes a legally defined counterfeit is a factual determination and decided on a case by case basis by a competent court in the relevant jurisdiction. Trade marks can therefore, in specific circumstances, be an important tool in the fight against counterfeit products.

As a private company, we have a responsibility to patients and shareholders to exercise our trade mark rights against counterfeit products. Enforcement of our trade mark rights contributes to the removal of potentially harmful products from the marketplace, as well as protecting GSK assets. We take all appropriate steps to safeguard the public from the risk of counterfeit healthcare products including working with customs, law enforcement and 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 training sessions to raise awareness of the dangers of such products. Recognising the need to raise public awareness about the risk associated with buying healthcare products from non-traditional outlets, GSK also supports awareness campaigns such as 'Fight the Fakes' www.fightthefakes.com run by the IFPMA (International Federation of Pharmaceutical Manufacturers and Associations).

GSK has well established internal procedures for dealing with suspected counterfeit products and provides training for staff. We rigorously investigate and, where appropriate, take legal action against the manufacturers, distributors, retailers and other parties involved in counterfeiting our products. Furthermore, the product and packaging incorporate features that 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 those suspected of counterfeiting, and their intermediaries, are thoroughly investigated and, where appropriate, prosecuted.

[1] The WHO has stated that it believes approximately 50% of medicines sold online from unauthorized sources are falsified.

A holistic approach to tackling falsified healthcare products

There is increasing interest in using technology to tackle the problem of falsified healthcare products and different technological approaches, ranging from the simple to the more complex, are routinely used by the pharmaceutical industry. In addition, research and development into new technology solutions is ongoing. Examples include overt verification tools such as holograms or colour-shift inks and more sophisticated covert tools, such as invisible printing and digital watermarks (which, whilst more effective, are more expensive and require special devices to check).

Forensic technology, essentially chemical or biological tags built into the packaging of healthcare products, are even more secure against copying but are costlier 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. The European Union's Falsified Medicines Directive 2011 is one example of where product verification at the point of dispense by pharmacists is being systematically introduced. 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.

GSK's Pharmaceutical Quality System

GSK it committed to manufacturing our products to the highest possible standards. To that end, we have developed and implemented a single Pharmaceutical Quality System (PQS) that defines the quality standards and systems for our businesses associated with Pharmaceuticals, Vaccines and Consumer Healthcare products and clinical trial materials. The PQS is regularly updated to seek to ensure it keeps pace with external regulatory changes, and reflects both operational improvements and new scientific understanding to support the delivery of consistent and reliable products. Our PQS includes adherence to Good Manufacturing Practice (cGMP) regulations, to which we manufacture our healthcare products and with which we expect our contract manufacturers to comply.

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