



Our position on Falsified and Substandard Healthcare Products

What is the issue?

Falsified medical products deliberately misrepresent their identity, composition or source. Substandard products are authorised medical products that fail to meet either their quality standards or specifications or both.

There are numerous drivers of falsified and substandard healthcare products including criminals looking to make a financial gain; a lack of legislation and proper enforcement; and a lack of cooperation between stakeholders e.g. police and customs authorities. Technological advances are also making it easier for criminals to accurately reproduce packaging, making it increasingly difficult for consumers to distinguish between authentic and falsified products.

This paper sets out our view on the dangers of falsified and substandard healthcare products (e.g. medicines and vaccines). It covers the measures we take to minimise the risk of harm to our patients from falsified GSK products including through use of technology. It also touches on how we ensure the quality of our products through current Good Manufacturing Practice (cGMP) regulations, as well as through our supply chain standards.

What is GSK's view?

- 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.
- The public health threat from falsified healthcare products can involve both patented and generic medicines. Patent infringement disputes which may arise in the ordinary course of business, such as ones between competitor companies, 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 in helping to minimise the falsifying of our products, including exercising our trademark 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.
- But we cannot tackle this issue alone. The prevention and detection of falsified products is primarily a matter for national governments worldwide, who should recognise the dangers associated with this issue and ensure effective regulation by the relevant authorities.
- GSK recognises that technology can help to stem the flow of falsified healthcare products. But technology is not a “magic bullet” that will, on its own, stop the falsifying problem. 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 current 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. So we work to ensure distributors and customers are aware of appropriate handling and storage requirements, to maintain product quality. These are printed on every pack of our healthcare products.

Background

Scale of the challenge

It is hard to establish accurate figures on the level of falsified healthcare products due to the clandestine nature of this criminal activity. As technology improves, criminals can more accurately reproduce packaging, making it increasingly difficult for consumers to distinguish between authentic and falsified products. Healthcare products are 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 cheaply. There is also an incorrect perception that they are meeting an unmet need of patients seeking to self-cure or to find a cheaper cure.

An additional and evolving aspect of falsified and substandard medicines is how they are adding to 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.

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. The active ingredients are usually not present in the right quantity or are completely absent and the products may also contain toxins or contaminants. 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. Falsified pharmaceuticals are also obtained through unauthorised routes, for example, via unlicensed sellers on the internet. 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.



Our processes for dealing with suspected counterfeits

We have well-established internal procedures for dealing with suspected counterfeit products and provide 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. Products and packaging also incorporate features that help detection.

Wholesalers who work with us must report any offers to supply suspected counterfeit GSK products, and isolate and withhold any such stock from sale. Controls are applied 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.

Trademark infringement of GSK products

Although the WHO decided in May 2017 to adopt new language 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'. It 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 trademark is anything which distinguishes a good or service from its competitors. Trademarks play a pivotal role in strengthening trust and confidence in a company's products and are particularly important in the healthcare industry where quality and safety issues are fundamental. Whether or not a falsified healthcare product infringes a trademark 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. Trademarks can therefore, in specific circumstances, be an important tool in the fight against counterfeit products.

We have a responsibility to patients and shareholders to exercise our trademark rights against counterfeit products. Enforcement of those 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.

A holistic approach to tackling falsified healthcare products

Technology is increasingly used to tackle the problem of falsified healthcare products. Different approaches, from the simple to the more complex, are routinely used by the pharmaceutical industry and research into other new technology solutions is ongoing.

Serialisation, using unique numbers encoded in barcodes, QR codes or radio frequency identification (RFID) i.e. the tagging of products with a unique electronic product code, allows 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.

We keep all technology options under review and would consider taking part in pilot studies designed to test new programmes. In particular, it is important to consider whether certain technologies could be used in countries where cost and lack of infrastructure may limit their use.

Recognising the need to raise public awareness about the risks associated with buying healthcare products from non-traditional outlets, GSK supports awareness campaigns such as 'Fight the Fakes' www.fightthefakes.com.

Our Pharmaceutical Quality System

GSK is 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 and vaccines 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) and Good Distribution Practice (GDP) regulations, to which we manufacture our healthcare products and with which we expect our contract manufacturers to comply.