Our position on

# Falsified and Substandard Medicines and Vaccines

## What is the issue?

Falsified medicines and vaccines deliberately misrepresent their identity, composition or source. This includes medicines and vaccines where both the product and all packaging components are entirely counterfeit.

Substandard medicines and vaccines are authorised products that fail to meet either their quality standards or specifications or both. Medicines and vaccines may fail to meet those quality standards or specifications due to, for example, diversion from the legitimate supply chain and intended market leading to exposure to inappropriate conditions of storage or transportation.

There are numerous drivers of falsified, and of substandard, medicines and vaccines which have been illegally diverted including criminals looking to make a financial gain; a lack of legislation and adequate 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 patients and healthcare professionals to distinguish between authentic and falsified products.

This paper sets out our view on the dangers of falsified and substandard medicines and vaccines which have been illegally diverted and the measures we take to minimise the risk of harm to our patients from falsified GSK medicines and vaccines. It also touches on how we ensure the quality of our medicines and vaccines through current Good Manufacturing Practice (cGMP) regulations and our supply chain standards.

## What is GSK's view?

- Falsified medicines and vaccines, including those which have been illegally diverted, represent a danger to public health. They can poison the people who use them; fail to treat, cure or immunise them; and in extreme cases, kill. The public health threat from falsified medicines and vaccines can involve both patented and generic medicines.

- 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 and public awareness campaigns (such as those instigated by the 'Fight the Fakes' Alliance) on the dangers of such products; recording trademarks with customs authorities in high risk markets; conducting proactive investigations and collaborating with customs, law enforcement, government authorities and other pharmaceutical companies to identify the source of falsified products; conducting chemical forensic testing of counterfeits and sharing the results with the authorities; conducting a global online monitoring and enforcement programme; filing civil and criminal actions where appropriate; and ensuring the safe disposal of GSK packaging equipment.

- We cannot tackle this issue alone. The prevention and detection of falsified medicines and vaccines is primarily a matter for all national governments, who should recognise the dangers associated with this issue and ensure effective regulation by the relevant authorities. Governments must ensure that regulations and legal frameworks keep pace with technological developments.

- GSK recognises that technology can help to stem the flow of falsified medicines and vaccines. But technology is not a “magic bullet” that will, on its own, solve this issue. It needs to be combined with other measures including clear legislation and regulations, rigorous enforcement, stiffer penalties and diligent surveillance on the part of the authorities.
- We manufacture our medicines and vaccines 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 medicines and vaccines 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 medicines and vaccines due to the clandestine nature of this criminal activity. WHO estimates that at least 1 in 10 medicines in low- and middle-income countries are substandard or falsified, and that countries spend around $30.5 billion per year on substandard and falsified medical 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.

### Adverse health effects

Counterfeit 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; 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.

Illegally diverted medicines and vaccines are often less efficacious due to inappropriate storage conditions including, for example, a failure to keep them in the cold chain. Also, patients may be unable to understand the dosage instructions and other details on patient information leaflets because they are in the wrong language.

By harming patients, falsified medicines and vaccines destroy confidence in healthcare systems and healthcare workers who unwittingly distribute these products. Falsified medicines represent a particular danger because 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 medicines are also often obtained through unauthorised routes, for example, via unlicensed sellers on the internet.

An additional and evolving aspect of falsified medicines and vaccines is how they are adding to antimicrobial resistance (AMR). When pathogens encounter medicines containing too low a dose of active ingredient, this enables drug-resistant mutations to multiply and spread. This resistance not only puts patients at risk but can also place an increasing burden on already strained health systems.

**Our processes for dealing with suspected falsified medicines and vaccines**

We have well-established internal procedures for dealing with suspected falsified products and we provide training for staff. We rigorously investigate and, where appropriate, take legal action against the manufacturers, distributors, retailers and other parties involved in counterfeiting or illegally diverting our products. Products and packaging also incorporate features that help detection.

Wholesalers who work with us must report any offers to supply suspected falsified 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 or illegal diversion, and their intermediaries, are thoroughly investigated and, where appropriate, prosecuted.

**Trademark infringement of GSK products**

A trademark is anything which distinguishes a product from that of its competitors. Trademarks can be protected as a registered intellectual property right and play a pivotal role in strengthening trust and confidence in a company's products. This is particularly important in the healthcare industry where quality and safety are fundamental.

We have a responsibility to patients and shareholders to exercise our trademark rights against counterfeit products. The World Trade Organisation (WTO) TRIPs Agreement (Article 61) 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". Enforcement of our trademark rights contributes to patient safety, through the removal of potentially harmful products from the marketplace.

**The role of technology in tackling falsified medicines and vaccines**

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.

**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 to which we manufacture our medicines, 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 current Good Manufacturing Practice (cGMP) and Good Distribution Practice (GDP) regulations.