Dave Elder
GlaxoSmithKline and JPAG

The cost of drug counterfeiting

The World Health Organisation (WHO) in 2010 described counterfeit medicines as those which are "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 or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."[1] The WHO also now uses the term 'spurious/falsely labelled/falsified/counterfeit (SFFC) medicines'. In addition, there is the related phenomenon of sub-standard medicines, classified by the WHO as: "Genuine medicines produced by manufacturers authorised by the National Medicines Regulatory Authority (NMRA), which do not meet quality specifications set for them by national medicines." Most of these counterfeit/imitation medicines are manufactured in Asia (predominantly India and China) and Latin America, where patents carry little weight, enforcement agencies are lax and there is a cheap, abundant workforce.

The cost of counterfeiting to the global economy was estimated to be about $75 billion in 2010, and this figure exceeds the illicit drug trade by around 50% ($50 billion). The supply and distribution of counterfeit medicines is also growing exponentially (90% increase versus 2005), which is to be expected when one considers that the counterfeiting business is far more lucrative and less risky than illicit drug activities[2], with those involved in it far less likely to be prosecuted than those engaged in illicit drug trafficking[3].

Counterfeiting activities targets both the broad based cheaper generic medicines and the high end innovator products. The developing world is particularly vulnerable to these activities as there is inadequate monitoring and control systems in place compared to the developed world[4]. Worryingly, the drugs targeted in the developing world are typically life-saving medicines designed to treat malaria, tuberculosis (TB) and HIV/AIDS[5], whereas in the developed world the targets are lifestyle drugs such as those for erectile dysfunction, hair loss and weight loss[6].

The situation is especially severe for Internet-purchased drugs. The European Agency for Access to Safe Medicines (EAASAM) has indicated that about 50% of all medicinal products purchased from unrecognised/unidentified websites are counterfeit, and that 10% of the total market in developing countries and about 1% in developed countries are also counterfeit[6]. Those established websites that sell counterfeit medicines are mainly based in North America (in particular, Canada), whereas temporary websites, with Internet links that change daily, tend to originate in Eastern Europe and China[2].

Counterfeit drugs are manufactured without any thoughts to quality, efficacy or even safety of the intended patient. Manufacturing is often performed in totally inadequate premises, typically by unskilled workforces and worryingly, there is also evidence that licensed plants are used to divert or subvert legal supply chains[7]. About one third of all counterfeit medicines contain no active ingredients and those containing active components are typically of the wrong dose (usually sub-potent) or contain the wrong active ingredient. They might also contain elevated levels of contaminants or adulterants. This often leads to non-treatment, injury or death of the patient. Counterfeit medicines consequently have a huge impact on global health outcomes, particularly for diseases such as HIV/AIDS, malaria and TB. Indeed, it has been estimated that over 700,000 deaths/annum from malaria and TB can be attributed to sub-standard medicines[8].

So what is being done to halt the counterfeit trade? Global technical initiatives to address counterfeiting have met with limited success. Strategies include unique physical/chemical identifiers, serialisation of individual products, enhanced supply chain security, improved labelling/packaging and mobile phone product authentication, for example, mPedigree. Global cooperation is increasing, with the US Food and Drug Administration and the European Medicines Agency increasing their oversight. Certain countries have their own specialised anti-counterfeiting agencies, for example, the UK and Nigeria[2]. IMPACT, which brings together some 193 countries and trans-national organisations such as INTERPOL, was set up in 2006 and has been a successful model for cross-country collaborative efforts. The Medicrime Convention within the EU[9] criminalises the sale of medicinal products that have been deliberately manipulated with respect to identity, history or source. Cross country operations are also increasing, for instance, Operation Pangea III resulted in the seizure and subsequent destruction of counterfeit medicines to the value of $2.6 billion.

However, it is clear that much more needs to be done, urgently, including enhancing trans-national cooperation and improving global surveillance of the medicinal products' supply chains, allied with enhanced global legislation/litigation[2].

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