

Counterfeit prescription drugs¹

The World Health Organization (WHO) defines a counterfeit drug as:

“A medicine, which 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 or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging” [WHO, 2009]

However, there is no standard, international definition for ‘counterfeit drugs’ and legal definitions can vary from country to country.

The phenomenon of drug counterfeiting is relatively recent, having first been identified as an emerging problem by the WHO in 1985. Since then the scale of the problem has substantially increased to the point that, today, it is estimated that counterfeits make up 10-15% of the worldwide drug market and substantially more in some developing countries [Morris and Stevens, 2006]. The market for counterfeit drugs is also growing fast, with the US-based Centre for Medicines in the Public Interest predicting that, without significant action taken to curb the trade, counterfeit drug sales will reach US\$75 billion globally in 2010, an increase of more than 90% from 2005 [WHO, 2006]. With so much money to be made, drug counterfeiting has become increasingly attractive for organised crime and improved access to modern technology has allowed counterfeiters to develop more sophisticated methods for imitating products and packaging.

The consequences of counterfeit drugs can be drastic for individual health, global health and for the global pharmaceutical industry:

- At the level of the individual patient, the drugs may fail to treat or prevent the targeted disease or, even worse, poison, disable or kill the person.
- At the larger scale of community, national or international public health, counterfeit drugs can have devastating effects by contributing to the development of antimicrobial resistance. Incorrect dosing (in particular, lower levels) of medication can help foster resistance, which is a great concern for widespread infectious diseases such as tuberculosis and malaria. A 2006 study published in the *American Journal of Tropical Medicine and Hygiene* found that 68% of artemisinin-derived anti-malaria drugs tested in Laos, Myanmar, Vietnam and Cambodia did not contain the correct amount of active ingredient [Alter Hall et al., 2006]. Resistance is now emerging to artemisinin-based therapies, which is of great concern given that these are the most potent and fast-acting of the current anti-malarial drugs.

Counterfeit vaccines are also prevalent and can have the important effect of preventing the acquisition of herd immunity (not to mention causing many deaths). In 1995 during the meningitis outbreak in Niger, the government received a donation of vaccines from Nigeria which turned out to be counterfeits, with no active ingredients. At least 50,000 fake vaccinations are estimated to have been given, resulting in 2,500 deaths [WHO, 2006].

- Finally, counterfeit drugs also have a significant impact on the pharmaceutical industry’s business. This is due not only to the violation of patents and the subsequent loss of income but also to loss of reputation, since counterfeiting can destroy public trust in the safety and efficacy of pharmaceutical products.

For all of the above reasons, the growth of the counterfeit drug market should be considered an important emerging risk.

¹ This paper aims to illustrate some of the contributing factors to the emergence of risks described in the IRGC report “The Emergence of Risks: Contributing Factors”. This report is part of phase 1 of IRGC’s project on Emerging Risks. More information can be found online at <http://irgc.org/Project-Overview.219.html>

There are a number of factors that act to amplify the risks related to the trade in counterfeit drugs.

First of all, there are many key **unknowns** because accurate information and knowledge about the size (how big is the market?) and nature (what kinds of counterfeits?) of the problem is difficult to gather. Not only is it often difficult to detect suspicious products and to quantify their effects on patients (it is unknown how many deaths in the developing world are due to counterfeit drugs, but an estimate of 192,000 in China alone in 2001 signals the scale of human suffering involved [Cockburn et al., 2005]), but there is also a lack of warnings and of public awareness about the problem. Ignorance of the risks and attributes of counterfeit medicines on the part of patients and health professionals not only increases vulnerability but also lowers detection and reporting rates for counterfeits [IMPACT, 2008].

Reluctance on the part of pharmaceutical companies to make their own data available compounds these knowledge-related difficulties. Commercial motivation, fears of reputation loss and competition mean most companies keep information about counterfeiting of their drugs strictly confidential [Cockburn et al. 2005]. These **information asymmetries** that exist between the pharmaceutical companies and law enforcement act to amplify risks, as do (arguably even more so) the information asymmetries between the counterfeiters themselves (who have perfect knowledge of the counterfeit market and the composition of the drugs) and all other stakeholders, including the public.

Changing **social dynamics** propelled by globalisation – e.g., rapid growth of international trade, greater access to products and information, increased use of e-commerce – also facilitate the growth of the counterfeiting phenomenon. For example, large volumes of international trade in pharmaceutical products and longer, highly fragmented supply chains (site of manufacture, freight forwarder, distribution centre, warehouse, pharmacy, hospital, etc. can all be widely dispersed and even in different countries) make it easier for counterfeit products to find their way onto the market. Parallel trade² in the European Union (EU) makes distribution of pharmaceuticals easier and the tracking of counterfeit products more difficult [Sanofi Aventis, 2008]. Increased use of the Internet creates another route to market under circumstances of no, little, or ineffective regulation and e-commerce has proved an effective distribution tool for drugs that are otherwise highly regulated or not authorised on some markets for safety reasons. It is estimated that more than 50% of drugs purchased on the internet from sites that conceal their physical address are counterfeit [IMPACT, 2006].

Populations exhibit **varying susceptibilities** to the risks of counterfeit drugs, as their degree of development and poverty tends to influence whether the risk is amplified or attenuated. In many low-income countries, pharmaceuticals are “often the largest household health expenditure of all” and, as a consequence, illness is a major cause of household poverty [Cohen, 2006: 77]. Poor populations thus have a more powerful incentive to buy lower-priced drugs, and counterfeits are often sold for less than branded products. Less developed countries are also more likely to suffer from a lack of the necessary skills and resources to protect and enforce intellectual property rights and civil liability laws (which can protect consumers against mis-sold or defective goods) may be weak or absent. A weak rule of law and/or corruption within drug regulatory agencies and judicial systems all amplify the risks that counterfeit drugs can infiltrate the market, since counterfeiters can operate with little fear of being caught or punished [Morris and Stevens, 2006; Aldhouse, 2005].

Conflicts of interests, too, play a central role in risk amplification. Individuals are interested in improving or maintaining their personal health via access to pharmaceuticals, but at affordable prices. Demand for cheaper products thus creates incentives for counterfeiters,

² Parallel trade (also called parallel imports or grey imports) occurs when products marketed by the patent owner (or with the owner's permission) in one country are imported into another country, without approval of the patent owner. Parallel trade exists for two main reasons: because different versions of the same product are produced for different national markets, or because of price differences between national markets. There is a significant volume of parallel trade in pharmaceuticals within the European Union.

whose interest is in profit, rather than improving the health of customers (the development of generics should have addressed some of the cost and affordability issue, but most counterfeiting is not of generic medicines)³. Even the pharmaceutical industry, whose material interests are *both* profit and improving the health of customers, is faced with a serious conflict of interests when dealing with the problem of counterfeiting – on the one hand, industry wants to help stamp out the counterfeiters, but on the other hand it does not want to make public any information that may affect its commercial interests, including any knowledge it has of its drugs being counterfeited [Cockburn et al., 2005]. Even governments can be reluctant to report their discoveries of counterfeit drugs (as evidenced by the very few incidence reports by member countries to WHO), possibly because countries don't want known the extent of their problem or lack of success in dealing with it [Gibson, 2004].

There are a number of international, national and private sector initiatives to combat drug counterfeiting. Examples include: the WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT) initiative; operations by Interpol (such as Operation Storm, in conjunction with IMPACT, which uncovered 16 million does of counterfeit drugs in Southeast Asia in 2008); the US Food and Drug Administration's dedicated anti-counterfeiting task force; and initiatives by pharmaceutical companies such as the implementation of technological developments to make packaging more sophisticated or to enable tracking of products so as to guarantee the security of the supply chain.

In addition, there are many broader anti-counterfeiting initiatives, which may encompass counterfeit drugs but do not address the problem from a public health perspective. Some examples are the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS); the Anti-Counterfeiting Trade Agreement (under negotiation); and the World Intellectual Property Organization's Advisory Committee on Enforcement (ACE). There are many more, including national and EU initiatives.

Because, from a public health perspective, the main risks of counterfeit drugs pertain to their quality, safety and efficacy, when the term 'counterfeit' is used it is generally referring to drugs that are falsely labelled (with regard to content, place or date of manufacture or expiry date), spurious (containing no, incorrect or insufficient active ingredient) and substandard (low quality due to poor manufacturing processes, transportation or storage). However, in the context of many of the anti-counterfeiting initiatives above (whether drug-specific or broad) the term 'counterfeit' refers expressly to the violation of intellectual property (IP) rights such as patents, trademarks or copyright.

These definitional issues, because of their legal implications, make governance of risks related to counterfeit drugs particularly challenging and complicated. Essentially, this is because governance efforts are trying to address two overlapping but distinct issues: 1) protection of public health from low quality, unsafe or ineffective drugs and 2) protection of IP rights (and, by extension, of incentives for innovation). Trying to attack both issues at once may not be the most efficient and effective course of action and many people fear that addressing the public health issues from within the rubric of IP rights could have the side-effect of undermining access to essential drugs, especially for populations in developing countries. Therefore, such an approach can act as a risk amplifier.

Such fears stem from the fact that populations in many developing countries cannot afford patented, branded drugs and must rely on supplies of generic drugs, which are identical in terms of quality, safety and efficacy, but much cheaper because the costs of research and development of the drug are not factored into the price. When generic drugs to treat HIV became available, the price of a basic three-drug cocktail dropped from US\$10,000 per year to less than US\$150 [Boseley, 2006]. If anti-drug counterfeiting initiatives define counterfeit drugs in such a way as to include health concerns *and* IP issues, it is possible that a generic drug may be seized and labelled as counterfeit because, for example, its name, shape or

³ Generic drugs are manufactured without a license from the innovator company and are marketed once the patent or other exclusive rights have expired. However generic drugs contain the same active ingredients and are as effective, but much cheaper than, brand-name drugs.

colour bears close similarity to a trademark [Shashikant, 2009]. Even the WHO definition of counterfeit drugs has been criticised for being ambiguous as to whether or not it incorporates IP issues. The words ‘identity’ and ‘source’ (see definition on page 1) could potentially be interpreted as referring to the trademark/trade name and the patent holder, respectively [Shashikant, 2009].

Although the World Trade Organization (WTO) TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) and the related Doha Declaration on TRIPS and Public Health have been purposely conceived so as to ensure that developing countries can retain access to generic drugs – either by producing generics themselves or, if they do not have the production capacity, then by importing them under compulsory licensing⁴ – there have been accusations that developed countries have tried to undermine the spirit of this agreement. For example, an Oxfam report in 2006 accused the US of bullying developing countries into not using the measures provided for in TRIPS, pressuring them to implement higher levels of IP protection, and trying to prevent countries like India and Thailand (large manufacturers and exporters of generic drugs) from producing generics [Oxfam, 2006].

A recent example of action by developed countries that would seem to run counter to the objectives and spirit of the TRIPS agreement is the seizure by the EU of generic medicines in transit on route from India to destinations such as Brazil, Columbia and Peru. Shipments of generics were seized on the grounds that they infringed patents in EU member states (enforcement of EC regulation no. 1383/2003 [EC, 2003]) and were therefore counterfeit. Some of these were medicines used in the second-line treatment of HIV/AIDS and were part of a UNITAID-funded shipment that had even been approved by the WHO [Shukla and Sangal, 2009]. However, the drugs in question did not enjoy IP protection in India, the country of origin, nor in the countries of destination. Article 52 of TRIPS mentions seizure as a means of IP enforcement only when IP rights are violated “under the laws of the country of importation” [TRIPS, 1994]. Despite assurances from the EU that it does not want to see a repeat of such an incident and that it is changing one of its internal regulations to avoid future confusion by customs officials, India (perhaps with Brazil) is still planning to take the EU to court at the WTO for violating the TRIPS agreement [Lynn, 2009; Sen, 2010]. In this case, a focus on IP protection by the EU may have amplified public health risks in the importing countries.

The central issues in the risk governance of counterfeit drugs thus revolve around agenda-setting and conflict resolution. Determining priorities in this situation is not straightforward owing to the concentrated interests involved (pharmaceutical companies) and the important equity considerations (basic right of access to affordable medicines; needs of developing countries). Analysis and deliberation of potential trade-offs will have to be performed and the influence of powerful interest groups such as the pharmaceutical industry will have to be carefully managed. This will be complicated further by the fact that it is not just national governments who have the authority or responsibility to deal with these issues alone – they must also deal with them within intergovernmental contexts and make sure that a multi-disciplinary, coordinated effort is made through organisations such as the WTO, WHO and World Intellectual Property Organization (WIPO).

The question should not be whether to give priority to protection of the interests and rights of the IP holder *or* to those of the patient; but rather how to reconcile a) the need to encourage medical research and pharmaceutical innovation through IP protection with b) the need to provide affordable medicine to poor populations. This is a formidable challenge for governance, but one that must be addressed in order to safeguard public health and private innovation from the risks posed by drug counterfeiting.

⁴ Compulsory licensing allows for the production of a patented product without the consent of the patent owner. Under TRIPS, this is allowed in case of “national emergencies”, “public non-commercial use” or “government use” (see Article 31b). Usually, production should be for domestic consumption only, but in the Doha Declaration on TRIPS and Public Health, WTO members agreed that countries unable to produce the drugs domestically can import drugs made under compulsory licensing abroad [TRIPS, 1994; Doha Declaration, 2001]. 4

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