

## Can the mobile phone tame Africa's dangerous counterfeit drug trade?

Bright B Simons introduces a novel invention that would allow consumers to validate the quality purchases at the point of sale

If you were to walk down the street in Ikeja, Lagos, visit the first pharmacy you see, and order two packs of your favourite anti-malarial medication, chances are that one of those packs could be a death warrant. The name on that warrant will of course be that of the product's final consumer.

The fake and counterfeit crisis engulfing sub-Saharan Africa and South and East Asia is that crazy, believe it or not.

In fact, some recent tests on antimalarials from Ghana and Nigeria, including a famous set carried out in Lagos by INTERPOL in 2001, have come up with worse results: 80% failure rate for samples representing the most widely prescribed treatment regimens in the two countries. That means: four out of every five antimalarials sampled turned out to be sub-standard, if not outright fakes.

Given the recent political tension about seizures in Europe of Indian pharmaceuticals destined for Africa, it warrants spending a bit of time on the various categories of what in India are known as 'spurious' drugs, and in Nigeria as 'fake drugs', though, as I shall explain, there is a temptation to become obsessive about these typographies.



### Counterfeiting confusion

There is widespread confusion about, on the one hand, counterfeiting that involves the production of medicines under the counterfeiter's own brand but using

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know-how or ingredients patented by a second party, or licensed to a third party in a particular territory; and, on the other hand, the counterfeiting that involves the duplication of a legitimate manufacturer's brand whether or not the duplicator makes use of patented material or not.

As far as public health and safety is concerned, what matters most is that a particular dosage of medicine is wholesome for consumption on the basis of being non-toxic and efficacious (i.e. achieving the advertised physiological result), and, on that basis, having been produced according to good manufacturing practices. For a medication to be deemed efficacious, it should be possible to establish that the active molecule or compound is bioequivalent (equivalent in pharmacological terms) to a benchmark molecule widely and authoritatively associated with the desired and claimed pharmacological effect.

### Role of health authorities

It is the duty of the competent health authorities in each territory to establish whether any product packaged as medicine complies with the standards and principles enumerated above.

In the vast majority of cases, instances of trademark, patent, and license infringements occur in the context of smuggling, illicit trading, regulatory evasion, data fraud, false advertising and outright malice, deceit and licentiousness. But the fundamental issues remain completely clear. In establishing whether a consignment of





medicines is good for human consumption, we are first and foremost interested in establishing whether it has been duly evaluated by the competent health authorities in the territory concerned.

It is up to those authorities to take full recognition of the 'full pedigree' of the consignment concerned, and to judge whether its procurement has violated any laws anywhere, and if on account of those violations there exist probable cause that the contents of the consignment may have been compromised, and are therefore unwholesome for consumption. In the poorest countries, this decision-making process occurs in a setting where the lack of resources may not allow laboratory testing of representative samples of each consignment, or permit the effective inspection of each container at the level of the port to confirm the disclosures on the importer's manifest.

### Market authorisation

In such circumstances, the concern about public health and safety, and its connection to the concern about counterfeiting, both hinge on the concept of 'market authorisation'.

The competent authorities are empowered to issue market authorisation for the lawful sale and distribution of medicines that are made in or imported into the territory based on the most prudent use of the evidence available to them regarding the pedigree of a particular consignment of medication. They may or may not take into account issues of patent and trademark infringement in determining the quality and wholesomeness of a particular consignment. Their decision will be made based on whether in their view national laws require that at

a minimum they consider these issues, but above all it will be influenced by their capacity to rely on primary examination of the product itself to establish quality.

Where, however, there is evidence of criminal conduct in the entry of the product into the territory, such as, for instance, deliberate mislabelling and misreporting, then that in itself may provide sufficient basis to prevent distribution, taking into account social considerations of significant weight, as well as the integrity of the public health system as a whole.

Thus, the prevention of counterfeit and unwholesome medicines entering the legitimate supply chain should not be mired in the pseudo-ideological squabbles we have witnessed in recent times at some of the WHO IMPACT meetings (IMPACT is a special anti-counterfeiting taskforce of the WHO). Misguidedly, some of the protagonists in these skirmishes have focused on the 'definition' of a counterfeit drug, as if much depends on such a definition.

### Importance of compliance

As I have taken pains to show, the range of conditions under which a particular consignment of medicines, or any product, can be declared unwholesome for distribution in any territory is potentially limitless and will always depend entirely on the exact circumstances of the particular case. General 'definitions' agreed on at an international forum rarely settle the matter.

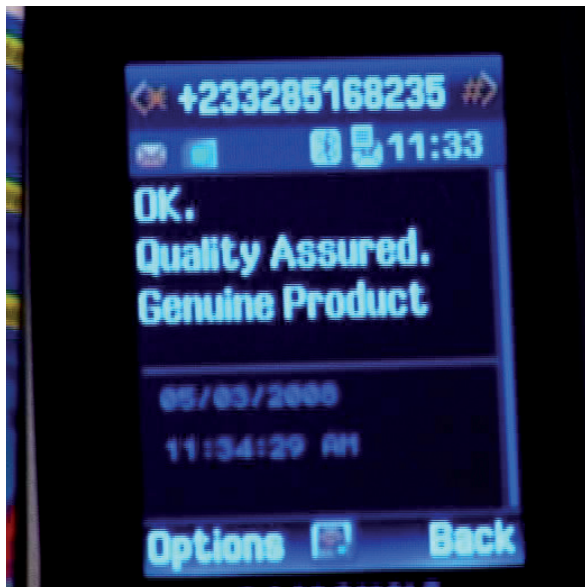
Indeed, in most African countries, and probably in most developing countries as well, the biggest problem is compliance by importers, producers, and distributors, with even the most basic guidelines, and not legal wrangling over exotic issues of definition. What is often

the issue is that under-capacity so afflicts the regulatory authorities that even where blatant disregard for the rules is rampant and glaring, said authorities are constrained from acting. Obvious fakes that do not bear expiry dates and batch numbers, much less registration numbers, are sold under the very noses of regulators with impunity. Persons who are not permitted by law, because of lack of training, to handle any medicines except the most harmless over-the-counter treatments go to the extent of diagnosing ailments and offering medical consultancy services.

The focus on fighting counterfeiting and the illicit trade of unwholesome medicines should therefore fall squarely on policing the integrity of the 'market authorisation' process, which, to recap, is the set of actions by means of which the competent authorities satisfy themselves and the general public that a particular type of medicine, after due consideration of all relevant factors, is allowable for sale. It is by means of this process that the regulator fully becomes a stakeholder and shares the risks of pharmaceutical usage in the community with the manufacturer and the consumer. It is this all-important process that we must safeguard, strengthen, and enrich.

Regulators ought to have the means to ensure that their determinations regarding the wholesomeness of a particular product carry weight in the marketplace. Consumers should, on their part, be able to know what the results of such determinations are, in terms of being able to affirm when they pick up a medication in the market whether or not that product has been certified as wholesome for use and fit for purpose. This does not involve the transfer of responsibility from the regulator to the consumer, but rather it represents a democratisation of power in favour of the consumer, and a reaffirmation of the public legitimacy of the regulator, who hitherto was exotic and distant.

That is the crux of the matter, and here is where the mPedigree platform comes in.



*A life-saving message via the mPedigree platform*

## The mPedigree platform

Time without number, we have had to take pains to explain to interested persons that the mPedigree platform is not aimed at promoting an alternative, or worse novel, regulatory system in the developing world. Its chief and overriding purpose is to create an environment in which the process of market authorisation can flourish. In other words, mPedigree has come to strengthen and enliven existing regulatory measures and frameworks, to the extent that their original utility lies in connecting with the consuming public.

The mPedigree platform operates simply by enabling manufacturers to apply unique, item-level, codes to any retail unit of medicine. It is often best to invoke the familiar example of the mobile phone 'top-up cards' used to 'recharge' airtime for pay-as-you-go phones across the developing world. Now imagine the scratch panel strip part embossed on a pack of medicine, so that when you buy said medicine, you can unveil the code and send it to a widely advertised, and thus memorised 4-digit number, in return for an instant message confirming the key pedigree information of the medicine in question: its originality, brand name, and expiry date.

As one-time codes duplication is impossible. By allowing the regulator to connect with the consumer during each authentication session, it makes it possible, for the first time, that even legitimate manufacturers who nonetheless turn out bad products could easily be sniffed out through mass reporting of adverse reactions to improperly made medicines. Even more fascinatingly, when they are sniffed out, their wares could be recalled with minimum fuss unlike the present situation.

Manufacturers of course have cause to be as pleased as consumers and regulators, if not more so, for the opportunity to recoup marketshare lost to thieving counterfeiters, and, equally importantly, for the possibility, never before possible, to obtain direct, immediate, geographically-sensitive pointers, market intelligence, and consumer feedback right at the point of purchase.

As mPedigree scales up its deployment and refines its functionality, medical doctors will constitute one of the biggest constituencies to woo. Under existing consent frameworks, physicians may soon find an ally in an electronic system that connects their patients' medicinal habits with monitored adherence regimes in order to better serve their needs in the ever-worsening context of high patient-to-doctor ratios and escalating performance pressures.

Generally, any system that widens the scope for information-sharing and democratises access to the information produced can only encourage transformation. Or revolution, to be precise. Only the Deity knows when the limits will be sounded.

For more information please visit:  
<http://www.mPedigree.Net>>[www.mPedigree.Net](http://www.mPedigree.Net)



CPD Challenge

See page 77 to test yourself on this article