



Falsified Medicines and the Global Public's Health

"Medical products should meet standards of quality, safety and efficacy. The quality of medical products is, however, a major public health concern to the World Health Organization and its Member States... The illegitimate manufacture, distribution, widespread availability and indiscriminate use of substandard/spurious/falsey labelled/falsified/counterfeit medical products have serious consequences on public health."

Report of the regional taskforce on prevention and control of substandard / spurious / falsely labelled / falsified / counterfeit medicines. WHO Regional Office for Africa, May 26th 2011

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Key Findings

- Medicines counterfeiting (or falsification) presents a risk throughout the world that requires effective preventive responses. Falsification involves the knowing misrepresentation of a pharmaceutical product's characteristics and/or provenance, and the deliberate avoidance of legally instituted regulatory processes. Even if they contain the right ingredients, medicines which have been produced in unregulated circumstances are inherently hazardous.
- Both branded and generic medicines can be falsified and sold for profit. Those making them avoid not only research and development costs but also those of good manufacturing practice. Because of technological progress it has also become increasingly easy to make difficult-to-detect fake packaging.
- It is not normally possible for medicines users to know whether or not safe, inadequate or dangerously high levels of active ingredients are present in treatments purchased either directly or via the internet. There is a special need to prevent therapeutic drug falsification in order to safeguard against harm and maintain trust in doctors, pharmacists and other health professionals.
- The overall scale of trading in falsified medicines and the resultant harm done to world health has not been accurately assessed. More investment in its quantification by agencies such as the WHO could in future generate better estimates. The total value of (appropriately defined) counterfeit medicine sales may presently be around one per cent of global medicine sales, although some estimates are significantly higher. In the case of anti-malarial treatments in parts of Asia and Africa there is firm evidence that between 15 and 50 per cent of products purchased are counterfeit.
- Many more people die or are disabled or suffer needlessly prolonged illness because of inadequate access to effective health care than because of drug falsification. However, there is clear qualitative evidence of its potential to harm public health, sufficient to justify robust precautionary responses on the part of stakeholders such as governments, regulatory agencies, pharmaceutical producers and pharmacies that supply medicines.
- In more affluent countries the main risks of medicines falsification are associated with illicit internet supply and related phenomena. However, even in settings like the EU and the US counterfeit medicines on occasions enter the legal pharmaceutical supply chain. More vulnerable communities living in less affluent regions with less well funded regulatory and policing systems and poorer access to affordable care are more at risk from medicines falsification.
- From a public interest perspective it is important not to confuse counterfeiting with other problems, such as infringing intellectual property rights or the accidental production of poor quality medicines in legally regulated environments. The IMPACT initiative (which was launched at a WHO meeting in 2006) was intended to protect the global public's health. It delivered some desirable outputs. But definitional confusions and fears linked to conflicts of interest limited its value and created a need for strengthened inter-governmental arrangements for preventing medicines falsification.
- There is evidence from across the world that increasing numbers of governments are recognising the need for effective action against medicines counterfeiting. The WHO is uniquely placed to add value to their efforts and those of local regulators and other national and international agencies such as the World Customs Organisation through co-ordinating surveillance and evaluative activities, facilitating policy development and contributing to professional and global public awareness and education programmes.
- Agreed WHO activities should be linked to, and help inform, regional working groups that in turn engage directly with national level public and private stakeholders in protecting health and assuring pharmaceutical sector regulation and effective policy implementation. This ought to pave the way for closer, better informed, inter-governmental co-operation.
- If further progress within the structures provided via the WHO proves limited additional initiatives such as the Council of Europe's Medcrime Convention could contribute additional value, particularly if African countries such as Nigeria become signatories. The active engagement of specialised United Nations agencies such as the Office on Drugs and Crime (UNODC) is also likely to strengthen global efforts to protect the integrity of medicines supply and prevent falsification.

Introduction

During the last unique century of human development, medicines and vaccines have – along with advances such as enhanced access to clean water and more adequate food supplies – played an important role in facilitating health improvement. Since 1900 average global life expectancy at birth has risen from under 40 to about 65 years. In the most advanced nations it is now in the order of 80 years for men and women combined, compared with approximately 50 years at the start of the twentieth century.

It is not possible to calculate the exact proportions of such health gains generated by different factors. But assuming that environmental conditions do not degenerate markedly, continuing improvements in life and, in some respects even more importantly, healthy life expectancy are in future likely to be increasingly dependent on the appropriate use of both innovative pharmaceutical treatments and good quality presentations of established medicines.

However, all therapies carry with them risks and problems as well as potential benefits. In addition to issues of cost and affordability, the Thalidomide tragedy highlighted at the start of the 1960s the need for effective drug safety testing, along with good prescribing and the regulation of medicines supply. Key aspects of this last process range from setting and enforcing robust pharmaceutical manufacturing and storage standards to the prevention of medicines falsification.

Problems like medicinal drug counterfeiting are by no means new. In the 17th century, for instance, widespread deliberate adulteration for a period undermined European public confidence in the efficacy of Chinona (China) bark (the natural source of quinine) as a treatment for malaria. The latter was then endemic in many parts of Europe. Some similar problems exist today. In early 2012, for example, avoidable deaths reportedly resulted from the use of sub-standard, probably counterfeit, cardiovascular disease treatments in Lahore, Pakistan (Yaseen, 2012). At around the same time falsified supplies of Avastin, an anti-cancer medicine, entered the US market via Great Britain. It has been suggested that they originated from a Turkish or nearby source (Faucon and Whalen, 2012).

Against this background this brief report examines issues relating to the control and prevention of falsified medicines supply, and the related public health protection and improvement roles of the World Health Organisation and other ‘UN system’ agencies. At one level it is uncontroversial to say that the WHO, in seeking to pursue throughout the world ‘*physical, mental and social well-being*’ rather than just the absence of disease or infirmity, should be concerned with all aspects of medicines and broader pharmaceutical product quality. Yet in recent years tensions surrounding the IMPACT initiative (see page 15) have been associated with concerns that the WHO could become unduly involved in activities that relate to the enforcement of intellectual property rights, as opposed to direct public health protection.

The validity of such suggestions has been strongly challenged by some commentators. But from a public interest perspective establishing a stable and more harmonious approach to defining the role and responsibilities of the WHO in relation to the prevention and coordination of measures to stop medicines falsification and minimise its consequences remains an issue that demands serious attention and timely resolution. The objective of this Matrix Insight/UCL School of Pharmacy joint analysis is to contribute to mutual understanding in this context, and to promote constructive discussion of ways forward.

The first main section discusses issues relating to the definition of terms like counterfeiting, falsification, adulteration, copying and quality in further depth. Linguistic disputes are often indicative of differing underlying values and sometimes unspoken political, commercial or other conflicts of material interest, rather than being central problems in themselves. Nevertheless, it is important in complex areas such as world-wide pharmaceutical care quality management to accurately identify the nature of the various components of any given problem.

This is followed by a brief analysis of the scope and scale of, and likely future trends in, the illegal falsification of the origins and/or content of medicinal and allied products. It is argued that presently the volume of pharmaceutical counterfeiting and the scale of the morbidity and mortality it causes is not possible to estimate quantitatively with any degree of accuracy. Yet there is sufficient qualitative evidence of its occurrence to justify taking a vigorous approach to its control.

Subsequent sections describe selected regional and national level approaches to pharmaceutical sector regulation and the prevention of harm resulting from medicines falsification and the supply of illicit pharmaceuticals via both the legal and illegal medicines supply chain – see Figure 1. Following that, opportunities for establishing more integrated global drug falsification management strategies are explored, along with the part the WHO might in future best play in quantifying the scale of counterfeiting and monitoring the emergence of falsification related challenges likely to have deleterious consequences on health and wellbeing.

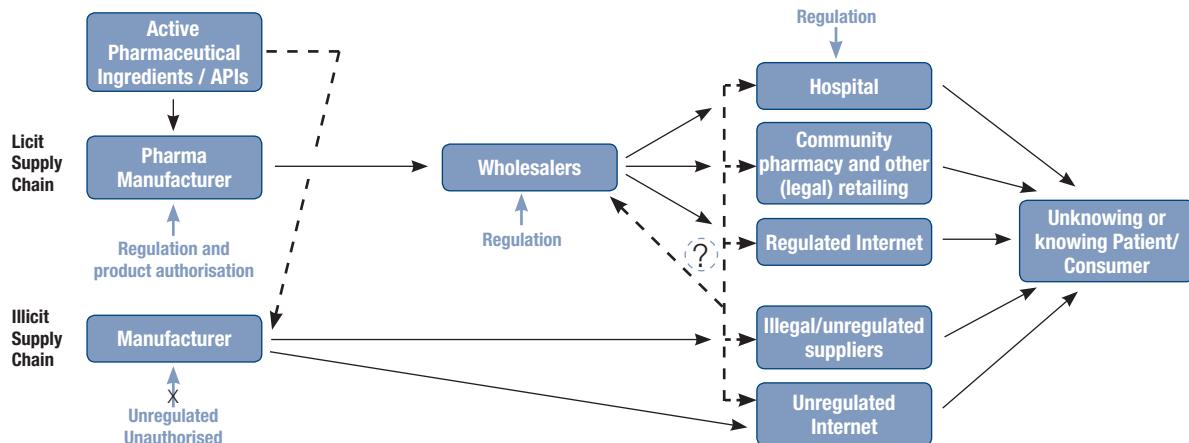
Individuals and communities in the more vulnerable regions of the world, particularly parts of sub-Saharan Africa and south eastern Asia, are in most danger of experiencing the unwanted effects of medicines falsification. They are also at high risk of suffering not only infections such as malaria, TB, leishmaniasis or AIDS, but also (in age standardised terms) events such as strokes and heart attacks (WHO, 2012). Further expanding safe access to high quality and affordable medicines and vaccines and the support needed to use them to good effect is a vital task for the twenty first century, all aspects of which need to be effectively addressed.

The nature of medicines falsification

All pharmacologically active substances are potential poisons. Many other products sold to the public have toxic properties. Yet unlike medicines they are not normally recommended for consumption by children or frail adults, and nor do the great majority claim to have scientifically demonstrable health improving effects. The existence of professions such as pharmacy and medicine and, in the modern era, of drug safety legislation across the world is testimony to the special importance communities attach to maintaining trust in the integrity and purity of pharmaceuticals, and in association with that confidence in medical and other (health) professional guidance.

The threat of medicines falsification therefore has a significance that even in well protected environments demands a high level of attention. Media and related interest in this field is to a degree driven by the perception that drug counterfeiting could at any time affect any individual or family involved in medicines taking. Similar factors help account for the high costs of and rigour required in trials designed to permit new pharmaceutical products to be marketed, and the controversy that can – despite such precautions – surround the unwanted side effects of highly beneficial drug-based treatments. Permitted surgical interventions on occasions carry levels of hazard orders of magnitude greater than those normally judged acceptable for prescription or over-the-counter medicines.

Figure 1. An illustrative model of the licit and illicit medicines supply chains



Source: the authors

Medicines are also in many respects economically unique high technology products. Their research and development requires considerable levels of investment which, once made, cannot be recovered in the same way as, say, outlays on buildings or machinery. The latter can if necessary be resold, whereas money spent on activities such as drug trials is, whatever the result, ‘sunk’. At the same time pharmaceutical research projects are more likely than not to fail. This reality increases the returns needed to justify genuinely innovative research investments. In recent decades research based

pharmaceutical companies have reportedly spent some 15-20 per cent of their gross turnovers on R&D. This is well in excess of the proportion recorded in any other industrial sector, including defence or aerospace.

Yet when approved medicines are normally much easier to copy than other high technology products like, for example, jet engines. Superficially realistic falsified copies are normally almost costless to make, while even legitimate pharmaceuticals typically have comparatively low marginal costs of production as compared with the investments made in their discovery and testing. The juxtaposition of high fixed development outlays against relatively low variable manufacturing expenses, although difficult to explain in public debate, helps to account for the differences in price between original new medicines and subsequently marketed (entirely genuine) generic products that to non-expert audiences may seem unjustifiable.

As in any other area of trade, doubts about the fairness of treatment prices may cause some people to look for less expensive alternatives. However, even low cost generic medicines can be subject to counterfeiting. The fact that members of the public (or indeed health professionals) cannot easily distinguish between, say, inert or potentially toxic falsified products and genuine medicines produced in appropriately regulated circumstances is the fundamental factor underlying such crime.

A lack of formal health care access or (justifiable or not) medical unwillingness to prescribe a medicine can also generate ‘demand side’ incentives for consumers to use supply routes like, for instance, the internet in richer

communities and unlicensed traders in economically less advantaged settings. In some instances legitimate low cost presentations will be provided.¹ But in others counterfeits are offered.

¹ Kamagra is an example of an Indian brand of the drug sildenafil, best known as Viagra in western markets. When the latter was under patent in, for instance, Europe but not in India, it was legal to produce and sell Kamagra in India but not to supply it from European outlets. In no instance would it have been appropriate to describe Kamagra as a counterfeit product. However, because of the relative success of this sildenafil presentation Chinese or other producers have reportedly produced counterfeit Kamagra for supply via internet and other sources.

The need to balance perceived consumer need for ease of access to drugs such as, say, antibiotics, with the imperatives of well-informed supply (and on occasions the reduction rather than the encouragement of medicines consumption in order to maximise welfare) is another ‘special’ characteristic of pharmaceutical markets. Figure 1 underlines the fact that the legal pharmaceutical supply chain is subject to rigorous product authorisation and manufacturing and supply process regulation, designed to safeguard public health. The illegal supply chain by definition omits these two steps.

This logically means that any illegally produced medicine is inherently undesirable, regardless of its actual content, because quality protection procedures have been bypassed. The latter will inevitably make interventions like product recalls in the event of a discovered problem impossible, even in circumstances where the producers of falsified medicines are seeking not to harm those to whom they supply misrepresented treatments.

There are several points at which illegally produced pharmaceuticals can infiltrate legal supply chains. One is at the point of API (Active Pharmaceutical Ingredient) purchase. It can be possible for a legitimate producer to be given a falsified basic active ingredient without their knowledge, albeit that checks should be in place. A second is at the initial distribution level where there is traffic in medicines from manufacturers to pharmaceutical wholesalers, and between short and full line wholesalers.

Falsified products may also be inserted into the legitimate supply chain during the pharmacy supply process and when medicines are purchased directly by consumers. Examples of the latter include various forms of internet and (legal) non-pharmacy pharmaceutical retailing to individual purchasers acting in good faith, as well as sales made to people who should be aware of the risks they are taking when purchasing from unregulated sources.

No responsible stakeholder in public health improvement (see Figure 2) is likely to oppose the introduction of

enhanced measures to discourage and/or to identify and punish the deliberate sale of illegally produced, deliberately falsified, medicines. Nevertheless, uncertainties and disputes surround this area. As indicated in the introduction, this may in part be because it is not at present possible to describe either the scale or the health impact of medicines counterfeiting in validated quantitative terms.

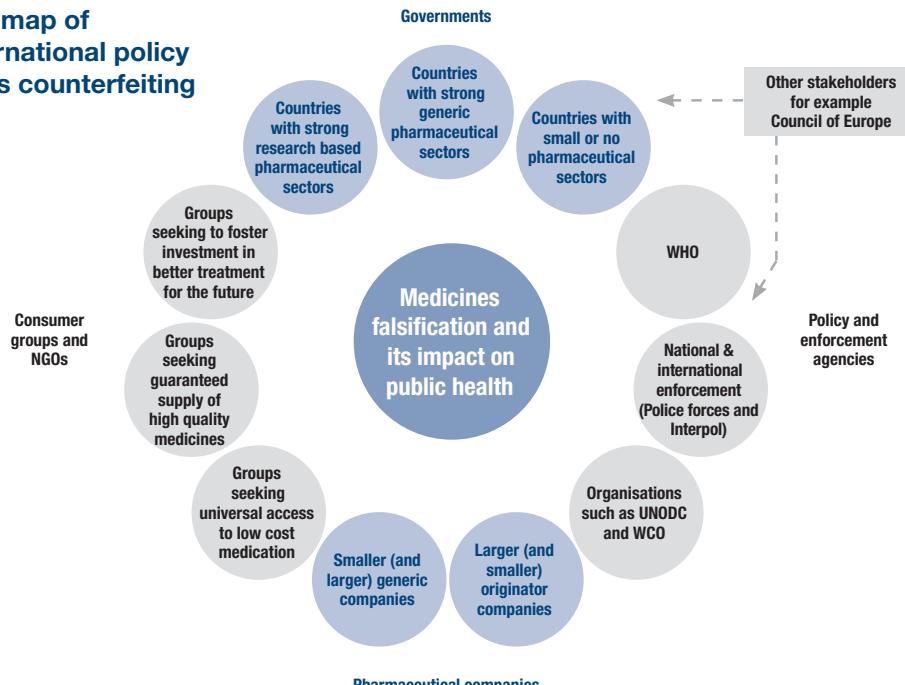
Disputes may also arise as a result of confusion between medicines falsification and a number of other undesirable practices. These include the deliberate or careless provision of poorly produced or adulterated drugs, which may on some occasions be fit for purpose despite their defects but can on others be so substandard that their supply might in itself be seen as a criminal act. The manufacture and sale of products in ways that infringe intellectual property rights is another practice which can be controversial and may be judged reprehensible, but does not in itself constitute falsification. As incidents like the highly contentious Dutch police seizure of a shipment of medicines in transit from India to Brazil described in Box 1 indicates, such confusions have – rightly or wrongly – been associated with concerns about initiatives such as IMPACT.

Defining the threat

Various authorities have sought to clarify the terminology employed in this area in order to make the distinctions between medicines counterfeiting/falsification and other problem areas absolutely clear (Clift, 2010). Such interventions will be fruitless if participants in policy debates are not motivated to accept rational analyses. But it is worth emphasising that from the perspective of this brief report medicinal drug counterfeiting is a process which involves both:

- deliberately misrepresenting a pharmaceutical product's characteristics and/or provenance; and
- deliberately circumventing relevant regulatory processes.

Figure 2. Illustrative map of stakeholders in international policy relating to medicines counterfeiting



Source: the authors

Box 1. Protecting public health, or erecting unfair barriers to trade?

In 2008 and 2009 Dutch customs authorities seized a number of shipments of generic medicines in transit from India to countries such as Brazil, Peru and Nigeria via Schipol airport. For example, in early December 2008 570 kgs of losartan, which is used to lower blood pressure and was destined for Brazil, was taken following a request from the European patent holder. The consignment was held for a month and then returned to India. Subsequently, a shipment of anti-HIV medicines intended for Nigeria, which had been paid for by the Clinton Foundation on behalf of UNITAID, was also impounded.

The latter event took place shortly before a TRIPS Council meeting. Both India and Brazil made protests and complained to the WTO. These countries, together with UNITAID, pointed out that the medicines in question were not counterfeit, and were legal in both India and at their point of destination. These and related incidents were also raised by India and Brazil with both the World Economic Forum and the WHO Executive Board in 2009.

Since then it has been widely agreed that these seizures were inappropriate. Many commentators believe that actions of this sort can be construed as threatening to form unfair barriers to international trading in low cost versions of medicines available in more expensive IPR protected presentations in regions such as the EU. However, this is not to say that any customs authority should be discouraged from attempting genuinely to prevent falsified or otherwise illegal medicines from entering the territory it is charged with defending.

There may appear to be little scope for misunderstanding in relation to this definition of pharmaceutical falsification. But to clarify it further, preventing pharmaceutical counterfeiting does not involve:

- curbing the supply of poor quality or even frankly dangerous medicines² that have been produced in legally regulated circumstances. Some recent tragedies in countries such as Nigeria and China have (as did similar events in the US in the 1930s, which strongly influenced the development of the FDA) involved human medicine production errors like the use of (toxic) diethylene glycol as a solvent. But although mistakes of this nature, which have reportedly resulted in many hundreds of deaths, may in some circumstances be considered to be criminally careless they are not examples of falsification, except in instances in which there is additional deliberate deception and regulatory avoidance;
- limiting the supply of generic or non-original branded medicines produced by regulated manufacturers, whether or not they are regarded by third parties as failing to respect legitimate intellectual property rights; and

² The term sub-standard is sometimes used to differentiate between counterfeit and poor quality but nevertheless licit medicines. However, this too can lead to disputes, because all counterfeit pharmaceuticals are, regardless of their actual material quality, sub-standard in the sense that they have not been subject to appropriate regulatory and allied agency oversight and approval.

- stopping the ‘parallel trading’ (or in US terminology re-importation) of licit medicines within the European Union or across the internal borders of other regional groupings operating ‘single market’ agreements. Parallel trading in the EU has occurred when a patented or branded medicine (or any other product) is sold at a low officially controlled price in a country such as, say, Greece, and is then repackaged and sold on by traders to purchasers in other Member States that have higher medicine prices.

The latter may lead to more limited savings for health care funders than is sometimes suggested, and has on occasions been linked with problems like local drug shortages. As with any other legitimate business, parallel trading can sometimes be associated with criminal activities such as thefts from warehouses. ‘Fake parallel trading’ has also sometimes been used as a device to deliberately insert falsified medicines and other health products into legitimate supply chains (see below). But there is nothing illegal or wrong about properly conducted parallel trading. It certainly should not be confused with medicines counterfeiting, even if companies that lose revenues as a result of it on occasions question its desirability.

Likewise, although causing avoidable physical harm may be judged morally wrong as and when culpability is involved, it is not by itself a relevant differentiator in the context of defining counterfeiting. Only a conscious misrepresentation of a medicine’s characteristics and the mindful circumvention of legally mandated regulations (*a mens rea*, or guilty mind, is the key factor) constitutes falsification in the sense that this term is used here.

However, having established this, the production and supply of sub-standard medicines of any type should not, of course, be tolerated if it presents a threat to public well-being. Rather, the argument presented here is that (except in extreme circumstances) remedies distinct from those used to discourage criminal offenses like counterfeiting are normally required when errors have occurred due to ignorance, incompetence, carelessness or genuinely unfortunate accident. Similar points apply to minimising and learning from prescribing and dispensing errors. Experience gained in the world of pharmacy illustrates the fact that it can be highly counter-productive to criminalise non-intentional professional errors during the course of attempts to assure quality.

Quantitative and qualitative evidence of counterfeiting

It is unfortunate that there is not adequate evidence of the volume and value of appropriately defined medicines counterfeiting taking place globally. Estimates that 10 per cent of the world market for medicines by value takes the form of trading in falsified products have, despite sometimes being wrongly attributed to WHO research, no robust basis in fact. Such figures cannot be substantiated and may well be inflated. But there is evidence indicating that in some parts of Africa and Asia

between 15 and 50 per cent of the market for medicines such as artesunate based treatments for malaria caused by *Plasmodium Falciparum* takes the form of (often inactive) counterfeits (Bate and Attaran, 2010; Newton et al., 2011; Bate, 2012).

With the wisdom of retrospect it would probably have been desirable to have invested in more substantive evaluations of the extent of medicines counterfeiting and its consequences in the 1980s, when the WHO first expressed an interest in this area. However, it is perhaps most important to note here that previous academic and business driven analyses conducted in other areas of trade appear to have generated relatively robust estimates of the total value and volume of counterfeiting. The same is true for illicit leisure drug production and consumption, where a variety of proxy indicators and sampling-based surveillance techniques are in use by international agencies to track the manufacture and use of substances like cannabis, cocaine and ecstasy. The quality of herbal medicines is also monitored relatively well in regions such as Europe, despite it being in some respects a regulatory ‘grey area’ – see Box 2.

Hopefully, better quality global information will in future become available as to the extent of medicines falsification and its health impacts. But for the present it is salient to note that data such as those recently presented by the United Nations Office on Drugs and Crime (UNODC, 2010) were derived in part on the basis of the number of counterfeiting incidents recorded annually by the Pharmaceutical Security Institute.³ Figures 3a and 3b are updated versions of statistics used by UNODC. This and other sources could be taken to suggest that the value of ‘genuinely counterfeit’ medicines provided to the world public each year is in the order of one per cent of the current annual world pharmaceutical sales total of approaching \$US 1,000 billion calculated by IMS Health (IMS Institute for Healthcare Informatics, 2011). Nevertheless, there is considerable uncertainty surrounding this estimate.

In addition to the limited quantitative data available, the case studies briefly outlined below offer robust qualitative evidence of the capacity of medicines falsification to harm public health across all of the WHO’s regions. Viewed from this last perspective the argument for taking a precautionary, wherever possible anticipatory, approach is not critically dependent on the scale of the existing harm being caused by medicines falsification. It rests more on its potential to harm and to undermine public confidence in both pharmaceutical sector regulation and health care quality. Counterfeiting is unlikely to cause identifiable mortality in well regulated and policed communities, albeit that harmful events may occasionally occur despite the best of systems. Yet there is clearly a large material trade in falsified pharmaceuticals in less advantaged settings, and people living in both rich and poor settings expect to be able to take medicines with confidence.

Box 2. Herbal medicines and ‘fake’ Heparin in the United States

Many people believe that because they are ‘natural’ herbal medicines are inherently safer than modern synthetic drugs. This is not, however, the case, in part because ‘natural’ substances can even if pure be just as poisonous as man-made ones, as and when taken in sufficient quantity. It is also because throughout history there have been problems with assuring the quality of herbal products. The latter range from the difficulties inherent in identifying and sourcing rare (and on occasions relatively common) plants through to the risks of accidental adulteration during unregulated production processes.

The introduction of more rigorous quality controls in modern societies such as those of People’s China, the EU and the US have, in licit settings, made herbal drug treatments safer than ever before. But like allopathic (western pharmaceutical science based) medicines, herbal products can be counterfeited and/or deliberately adulterated during both poorly regulated and unregulated manufacturing processes. For example, a ‘genuine’ herbal mixture might have an undeclared analgesic drug added to it to increase its perceived effectiveness. Whether or not this should be classified as a form of counterfeiting or as a different pharmaceutical crime is debateable.

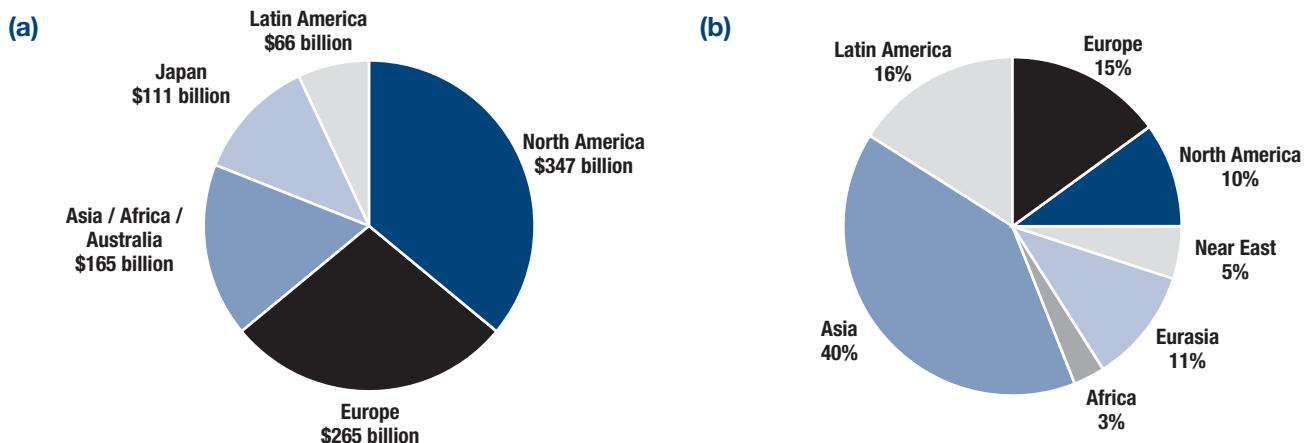
Another example of ‘grey area’ activity on the borderlines between falsification, adulteration, negligence and other forms of crime or incompetence was provided by the supply of ‘fake’ heparin based medicines that caused both deaths and serious morbidity in the US and elsewhere in around the Spring of 2008. The active pharmaceutical ingredient (API) of this drug is extracted from pig intestines. Because of cost saving opportunities linked to raw material shortages Chinese producers, from very small scale operators upwards, had added a potentially toxic substance called ‘over-sulphated chondroitin sulphate’ to the product they sold on to the end-point providers of pharmaceutical quality heparin.

The apportionment of fault in such a circumstance is inevitably controversial, as is the use of the term counterfeit to describe a product ultimately supplied in good faith by a trusted, legally regulated, producer. But whether or not medicines containing an ingredient that has been secretly adulterated before its purchase should be said to be falsified as opposed to being of unacceptably poor quality is not the key issue. Rather, what requires most emphasis is the need for both effective regulation and systematic quality assessment at every stage in the pharmaceutical manufacturing and supply process.

A final point to make before considering examples of contrasting local experiences in more detail is that despite the attempts of regulatory agencies and organisations such as customs and police forces to contain this public health hazard, the technology available to criminals involved in activities such as illicit pill making and forging medicinal product delivery systems and packaging is becoming progressively more sophisticated. In this sense, the underlying threat from medicines counterfeiting will increase in coming decades. The extent to which this is manifested in the shape of increased levels of tangible harm will depend on the success or otherwise of the defensive measures in place.

3 The PSI, which is financed by the research based pharmaceutical industry

Figures 3a and 3b. The geographic distribution of (a) pharmaceutical sales (IMS, 2012) and (b) counterfeiting incidents recorded by the Pharmaceutical Security Institute (2011).



Source: Figure 3a: IMS 2012. Figure 3b: PSI 2011

Note: Current IMS projections indicate that the relative value of the North American pharmaceutical market is declining against that of emerging markets such as China. The proportion of total global pharmaceutical expenditures attributed to the US will probably fall from 36 per cent in 2010 to 31 per cent in 2015. The paucity of data relating to counterfeiting in Africa is likely to be illustrative more of the global problems still to be overcome than it is of the effective protection of people living in less economically advantaged settings.

Selected case studies

Kevin Xu

Kevin Xu led a major counterfeiting operation based in China towards the end of the last decade. He supplied falsified medicines to a number of countries, including the US. It is known that around 72,000 medicine packets containing counterfeit Casodex (indicated for prostate cancer), Zyprexa (primarily prescribed for the treatment of schizophrenia) and Plavix (used to reduce vascular disease related risks) were introduced into the legal UK supply chain in 2007. Of these 7,000 packs were successfully recalled and 40,000 were seized by the regulatory authority (the MHRA).

The counterfeit drugs supplied by Xu were air-freighted from China to Singapore and from there to Brussels, where they were picked up by a British pharmaceutical wholesaler named Peter Gillespie. Gillespie subsequently falsified documentation and presented the medicines concerned as having been parallel-traded into the UK from France. But inconsistencies were identified by a British pharmaceutical re-packager. The original manufacturer of Zyprexa (Eli Lilly) was contacted, and staff in this company in turn contacted the MHRA. Gillespie was convicted in the UK and Xu is in prison in the US because of other counterfeiting convictions. It is not possible to quantify the health related harm caused by their activities. But sampled Zyprexa tablets were found to contain only 55-80 per cent of the active ingredient (Securing Pharma, 2010; Siva, 2011).

Falsified erectile dysfunction (ED) treatments

Dutch national Christiaan Winkel (who is said to be a former University College London employee) worked

with his girlfriend Yuly Sandoval-Moro and an associate called Safa Issoto Ba Sedi to establish a medicines counterfeiting operation in a central London flat in 2010. They focused on producing a falsified version of the erectile dysfunction drug tadalafil (Cialis), with a production run estimated to have a street value of £1.6 million/\$2.6 million.

This provides an illustration of a small-scale, somewhat amateur, attempt at counterfeiting. The fact that the manufacturing was conducted (with equipment purchased from a Chinese source, the Minhua pharmaceutical machinery company) in a European country makes it a relative rarity (Taylor, 2011b). Due to early interception and cooperation between the MHRA and the police no harm to public health was caused, and the counterfeit drugs produced did not enter the supply chain.

On occasions, ED medicines are regarded as leisure drugs rather than 'serious treatments'. The fact that falsified versions may, along with look-alike products and legally made but improperly supplied drugs, be purchased without prescription via the internet or in places like clubs, can add to this impression. However, erectile dysfunction is potentially indicative of serious underlying disorders, and the medicines used to treat it can themselves have unwanted effects.⁴ Falsification should be taken as seriously in this field as in any other therapeutic context. Beyond the immediate context of sexual health/lifestyle related factors rather than exposures to infectious disease are now key determinants of health and illness in much of the world.

⁴ In 2008 there were deaths amongst men taking counterfeit ED medicines in Hong Kong and Singapore, because of contamination with glibenclamide (glyburide in the US). The latter is used in the treatment of type 2 diabetes.

Counterfeit Avastin and Tamiflu in the US

The presently (as of late 2012) ongoing counterfeit Avastin (a high unit cost, specialist use, anti-cancer medicine) case in the US provides an instance of a complex wholesale infiltration, the details and origins of which are as yet not entirely clear. In April 2012 the US FDA announced (following other incidents it had tracked) that a counterfeit batch of Avastin had been seized and that it contained no active ingredient. The supply line involved reportedly linked Turkey and the US via Switzerland and the UK. Innocent or knowingly involved actors in this and related incidents may also have been located in Egypt and Denmark (Faucon and Whalen, 2012).

If medicines such as falsified anti-cancer treatments can enter legal supply pathways in the US it is probable that they can do so anywhere in the world. They are especially likely to harm the health interests of people seeking to access treatment in countries which lack the resources to support regulatory agencies as capable as the FDA. Similar concerns exist in other fields. For example in October 2009 the Food and Drug Administration issued a warning on counterfeit Tamiflu pills for H1N1 flu (swine flu) treatments, alerting consumers to the need to exercise extreme caution when purchasing any alleged H1N1 treatment over the Internet.

FDA staff had previously bought five products over the Internet, advertised as Tamiflu. They were counterfeit. One of the orders was supplied from India in an unmarked envelope. The pills inside contained only talc and acetaminophen (paracetamol – a pain reliever). Other orders contained amounts of oseltamivir, the correct active ingredient, but not in the right dose (FDA, 2009; itWire, 2009).

The Jebel Ali Free Zone, United Arab Emirates

The Jebel Ali Free Zone in Dubai is one of the world's biggest free trade zones. It functions with limited regulatory oversight, albeit that the relevant authorities take action when problems such as medicine counterfeiting are drawn to their attention. In late 2007, a large cache of drugs was seized from a warehouse operated by a company called Euro Gulf Trading. A year earlier, on May 22nd, 2006, British customs officials had intercepted over 800 lbs (some 400 kgs) of mostly counterfeit drugs at Heathrow airport. Some contained traces of metallic contaminants.

The products concerned were for the treatment of conditions such as high blood pressure, raised cholesterol levels and acid reflux. The shipment originated in another free trade zone in Sharjah, one of the Gulf Emirates, and was intended for the Bahamas. From there the '*Personal Touch Pharmacy*', which was subsequently found to be linked with Euro Gulf Trading in Dubai, supplied medicines to individual patients in the US and possibly elsewhere via Canada (where another internet pharmacy was involved) and the UK. This routing was designed to misrepresent the drugs as being appropriately sourced from well regulated suppliers. They were in

fact manufactured by low cost Chinese producers. This complex case illustrates the potential scale of well-organised counterfeiting. It also demonstrates how free trade zones can be used to market or transfer falsified medicines, and those on the borderline between being counterfeit and of poor quality (Bogdanich, 2007).

Counterfeit medicines supplied from India and intended for Togo

In late 2008, customs officers at Brussels' Zaventem Airport confiscated three shipments of counterfeit drugs in transit from Mumbai in India to Togo on the West African coast, via Morocco. They contained 2.1 million tablets of two falsified medicines – Fansidar, an antimalarial made under license from the Swiss company Roche, and Tramal/tramadol hydrochloride, a painkiller originally manufactured by the German pharmaceutical company Grünenthal. It is likely that had they reached Togo they would have been circulated in several countries in the region.

The packages were initially identified as being counterfeit through simple spelling mistakes. This again illustrates the potential risk to public health associated with the supply of falsified drugs. A shipment of this scale could have resulted in the wide distribution to a vulnerable population of medicines produced in unregulated circumstances and containing toxic ingredients (Pharmaletter, 2008).

Lebanese counterfeit production connected to a network of complicit pharmacies

In 2010, a counterfeit drug trafficking and production operation in Lebanon was uncovered by the Lebanese customs department. The drug primarily concerned was Plavix. This raid took place after investigations had found that counterfeit Plavix was readily available on the domestic market. Demand for such products may have increased due to earlier interventions that had reduced pharmacies' profit margins and so helped to create a demand for unusually 'cheap' supplies, albeit that other reforms had been intended to introduce counter-balancing restraints. Reports indicate that pharmacies had been warned that if they were found selling counterfeit drugs they would have to cease trading.

A large scale international criminal organisation was originally suspected. But in the event the source proved to be a single corrupt factory owner. Only 40 per cent of the relevant API was found in tested samples of the counterfeits, indicating that they posed a significant threat to patients with cardiovascular disease (Rizk, 2010). However, attributing specific events such as myocardial infarctions to the use of under-strength medicines is not possible at the individual (as opposed to the population wide, statistical) level.

Counterfeit medicine vendors in Nigeria

A Nigerian pharmacy staff member and a patent medicine dealer were arrested in Owerri, Nigeria, in July

2011 for selling fake antibiotic, anti-malaria and anti-diabetic medicines. The products concerned originated from local factories, which were also targeted during interventions coordinated by the Nigerian regulatory agency NAFDAC (Nwosu, 2011).

As described in the section below, the most populous African State (Nigeria now has a reported population of over 150 million people) has taken important steps towards curbing medicines falsification and improving pharmaceutical quality in recent years. But it still faces major challenges in these fields, along with – in some respects even more importantly – that of providing its population with affordable access to reliable health care. In such circumstances there are always likely to be both provider and purchaser incentives that serve to promote the counterfeiting of even relatively low unit cost medicines.

Controlling medicines falsification – world progress

Populations living in the European Union and the United States, together with other more affluent nations like Canada, Australia and Japan, are – as has already been highlighted – comparatively well protected with regard to not only health care access and medicines quality, but in most other fields of social and physical security. In the specific context of medicines falsification the UK Medicines and Healthcare products Regulatory Agency (MHRA) has, for example, recently produced its second anti-counterfeiting strategy – see Box 3. The policing undertaken in order to identify and facilitate the punishment of counterfeiting is different in nature from the MHRA's regulatory work, which is not directed against criminal behaviour. Yet taken together they form an integrated set of activities aimed at maintaining medicines quality and the safe and effective functioning of the overall UK medicines supply chain.

In national settings such as the UK pharmaceutical companies work constructively with the MHRA and other stakeholders to help achieve such ends. As some of the evidence offered above shows, counterfeit medicines can enter the legal pharmaceutical delivery system even in countries like Britain. Yet people living there and in similar environments are normally only exposed to falsified medicines via illegal websites and other illicit vendors which they have little incentive to use because of their funded access to health services.

Unauthorised websites are difficult to monitor, and typically quick to disappear if pursued. It is fortunate there have in recent decades been no recorded fatalities in the UK due to falsified allopathic medicines, although this is not to say that none have occurred.⁵ The drugs most typically available through illicit internet outlets

5 There has been one relatively recent UK death recorded as being due to the ingestion of an adulterated herbal medicine. But it is difficult to identify harm done to individuals by falsified medicines which may, for instance, have inadequate amounts of the correct active ingredients. The potential impact on large populations can be estimated, but the extent of personal harm in such instances can never be precisely known.

Box 3. The UK MHRA's anti-counterfeiting strategy

Britain's Medicines and Healthcare products Regulatory Agency (MHRA) recently (in May 2012) released its second anti-counterfeiting strategy. This, the organisation claims, demonstrates its continued commitment to '*combating the real and present threat posed by falsified medical products*' (MHRA, 2012). The overall aim of the new strategy (which builds on the first, released five years previously in 2007) is to reduce the risks to patients and other medicine consumers posed by the supply of counterfeit pharmaceutical products, while simultaneously increasing the risks to those responsible for such illegal activity. The MHRA seeks to achieve its goals via:

- **prevention** – reducing the number of falsified medicinal products entering the UK supply chain involves threat communication to the public, healthcare professionals and other stakeholders; market surveillance and product testing; promoting customs and allied vigilance at UK ports; pharmacovigilance; and establishing national and international networks in order to facilitate information exchange and cooperation. These may involve both public and private sector partners, ranging from pharmaceutical companies and wholesalers to, for instance, police forces and the WHO;
- **incident management** – if falsified medicines enter the supply chain incident management teams are responsible for minimising the public threat by seizing/quarantining suspected products in a timely manner and executing medical and availability assessments, product recalls and effective risk communication programmes; and
- **investigations** – identifying products' origins (which can be determined by tracing falsified medicines back through the supply chain to the point of insertion) and finding payment routes are amongst the key techniques used to facilitate successful prosecutions. The latter serve as deterrents to others. Thorough investigations can also provide the necessary evidence to drive ongoing legislative change.

The majority of falsified medicines reach UK consumers via illegal websites, rather than high street pharmacies. The MHRA has been involved with the successful investigation and prosecution of people taking part in illegal internet sales on many occasions. It in addition played a key role in the setting up of Interpol's operation Pangea (see main text). However, the Agency does not believe that enforcement activities alone can remove the threat of falsified medicines being provided via the Internet. A second element in its strategy is therefore to raise further public awareness of the hazards associated with (knowingly or unknowingly) using unregulated websites to obtain medicines of any type. This is an attempt to reduce demand for drugs that could be met by illicit sources. It complements measures like 'test purchasing' exercises and pro-active internet monitoring programmes.

can be described as ‘life-style’ medicines, including those for the treatment of conditions such as obesity and depression. The Agency’s commitment to reducing illegal internet-based drug sales led to its founding participation in Interpol’s Operation Pangea in 2008. By 2011 this had grown into a global multi-sector operation involving 80 countries.

In America responsibility for instituting anti-counterfeiting measures falls to the US Food and Drug Administration (FDA). As with the UK, the US has one of the most secure drug distribution systems in the world (FDA, 2011). The Agency works with partners such as the Drug Enforcement Administration, US Customs and Border Protection and the US Postal Service to ensure that America’s complex drug supply chain is secure. Nonetheless, instances of counterfeiting occur (FDA Counterfeit Drug Task Force, 2006). Relevant fields of interest for the FDA include:

- securing product ingredient and packaging integrity and monitoring the movement of drugs through the supply chain;
- securing business transactions involving APIs as well as finished medicines supply;
- ensuring regulatory oversight and enforcement at all stages of manufacturing and supply;
- promoting appropriate penalties for medicines falsification;
- heightening public and professional vigilance and awareness; and
- improving international cooperation, in order to defend shared public interests in limiting and discouraging pharmaceutical counterfeiting.

Pharmaceutical product authentication measures introduced and tested by manufacturers in the US include the use of ‘colour shifting’ inks, holograms and chemical markers embedded in drugs. It has also for some time (see FDA, 2004) been intended that a ‘track and trace’ system should be developed to provide accurate ‘electronic pedigrees’ for all medicines. However, in California – the first US State to in principle require such a record for each prescription drug pack – the implementation deadline has already been delayed twice⁶. The current target introduction date is July 2017 (Barlas, 2011).

In Europe, the Falsified Medicine Directive of 2011 has, in addition to measures intended to strengthen oversight and control of active pharmaceutical ingredient manufacturing, wholesalers’ record-keeping and inspection processes, paved the way for the Union-wide serialisation and checking of the authenticity of medicinal products (European Union, 2011). It is hoped that –

⁶ Since some pharmaceutical products are supplied for subdivision into smaller containers by pharmacists in the US, a track and trace system would even when implemented not be able to provide full product information all the way to delivery to the patient. In Europe medicines are normally supplied to patients in their original packs. This should allow more complete monitoring of the supply chain (Killick and Strelzyk Herzog, 2007).

notwithstanding the costs to the stakeholders involved (EFPIA, 2012) – all Europe’s 130,000 community pharmacies will have the equipment needed to verify the medicines supplied to them within the next three to five years.

However, the global significance and reproducibility of this example should not be overstated. One concern is that such an approach would not be affordable or otherwise viable in those parts of the world where people are at most risk of harm from, for instance, falsified malaria treatments. The least developed countries are particularly vulnerable to externally and internally driven pharmaceutical counterfeiting because they normally lack both the physical infrastructure and human capital based technological expertise needed to regulate their pharmaceutical sectors well, and to police criminal activity when it threatens public health.

At the same time it is important to recognise that today the proportion of the world’s people living in and the volume of manufacturing undertaken in emerging economies like those of China, India, Brazil and Turkey is in aggregate far greater than the combined populations of the EU and the North American Free Trade Agreement nations. The ‘BRIC’ and associated emerging markets have a growing consumer base. Relatively large numbers of individuals and families living there may be prepared to risk illicit prescription drug purchases, and are in close geographical proximity to counterfeit medicine producers (Mackey and Liang, 2011).

It is also likely that as governments seek to improve health by increasing publicly funded medicines access, they will on occasions be exposed to criminal attempts to profit from such policies. These may include not only diverting publicly purchased medicine supplies into the private sector in disguised forms, but also the insertion of falsified products into the State funded health sector. The remainder of this section therefore offers selected ‘system level’ outline descriptions of regulatory system development in emergent economies.

Chinese action

China is now one of the world’s largest suppliers of in the main good quality and legally produced pharmaceutical products. Yet in the near past a significant proportion of counterfeit medicines identified globally have (along with some other hazardously poor quality products) been traced back to China (Lewis, 2009).

The relatively recently re-established Chinese State Food and Drugs Administration (SFDA) is responsible for regulating the quality and safety of all pharmaceuticals and allied products, as well as for supplying quality and safety information on drugs and medical devices. The SFDA has, like the US FDA, recognised the prevention of medicines counterfeiting as one of its key objectives. Inspection teams at the state, provincial, municipal and country levels have during the past decade been strengthened, and new funds have been allocated to support an increased frequency of sampling and

inspections. So-called 'third shift'⁷ production has been targeted by measures introduced by the Government in 2011 to enhance the regulation of contract manufacturing organisations.

In addition, regulatory enforcement has been strengthened via a number of amendments and supplements to the 1984 Drug Administration Law of the Peoples Republic of China. Penalties for crimes such as medicines falsification have been increased and definitions of counterfeiting expanded. Importantly, a Criminal Law Amendment Act abolished the requirement for such offences to be harmful enough to seriously endanger public health in order to result in prosecution. In April 2009 the Chinese Government also established an inter-ministerial cooperative taskforce for combating drug counterfeiting⁸. Action stemming from this last initiative has led to websites providing falsified medicines being taken down, underground factories being closed, illegal distribution networks being disrupted and public education programmes aimed at raising awareness of the hazards of unregulated and otherwise poor quality pharmaceuticals being established (Sun, 2010).

Moreover, the SFDA has introduced e-coding. This is a track and trace system providing patients with a way of verifying the origin of medicine packs. To date it has been used to assure products on the National Essential Drugs List, but it will be extended in the coming year to cover most other products. Manufacturers are required to print an e-code on the smallest unit of sale and on the shipment case. Each party within the supply chain (at minimum the manufacturer and distributor) is required to send a 'signal' to confirm receipt and/or dispatch of the items to the SFDA central system where all events associated with each unique e-code are collated. Patients/consumers can enter the e-code into the SFDA online database to check the origin of the medicines they receive.

Many commentators believe that these initiatives demonstrate high level Chinese Government recognition of the importance of preventing medicines counterfeiting and controlling related problems like food and drug adulteration, and its determination to respond effectively to public concerns about pharmaceutical and other product quality. In a nation of the size and at the present development stage of China it would be foolhardy to suggest that significant challenges do not remain. Yet the positive progress made deserves recognition.

Indian pharmaceutical sector policies

India is another of the world's largest manufacturers and exporters of in the main high quality generic/off-patent pharmaceutical products. Some observers and policy makers are therefore concerned that it is also said to be one of the world's largest producers of falsified medicines (Lakshmi, 2010). All nations need to guard against corruption of all types. But it appears that India faces particular challenges, some of which exist in the field of pharmaceutical sector regulation (Parliament of India, 2012).

Expressed as a proportion of GDP, India also has a very low level of public spending on health. It is home to several hundred million of the poorest people on earth. These factors, together with the large volume of in the main relatively low cost branded (as opposed to 'true generic') drugs supplied in its domestic market, help to explain why medicines falsification may have evolved as a special problem in the Indian setting.

Implementing regulations and rules governing the manufacture, sale and distribution of medicines and taking action against counterfeiting has traditionally been the responsibility of the local authorities in each of the 35 Indian States, many of which have populations comparable in size to those of European nations like France and Germany. While some States have very high standards of pharmaceutical regulation, others have lagged behind. Inconsistent interpretation and enforcement of relevant national legislation like that embodied in the Drug and Cosmetic Act has led to a degree of fragmentation and has been regarded as a root cause of inadequate control and prevention of medicines falsification (Indian Ministry of Health and Family Welfare/Government of India, 2003).

Notwithstanding this situation, the formation in 2008 of the Indian Central Drug Agency was part of the nation's attempt to remedy such problems. It bears overall responsibility for approving new drugs and clinical trials, the establishment of regulatory standards and the appropriate coordination of State level regulatory activities. An example of the latter involves local regulatory agencies carrying out tests of drug samples to evaluate their quality every six months.

In an effort to increase the level of deterrence, the death penalty has been introduced for the manufacture and/or sale of counterfeit medicines that cause grievous harm or death. Alongside this, the minimum prison term for related crimes has been increased from 5 to 10 years. However, there have been recent criticisms of the Central Drug Agency's performance.

Relatively low cost Indian company produced 'branded generic' medicines have conferred benefits in contexts such as increasing access to anti-HIV treatments in sub-Saharan Africa and elsewhere (Box 4). Yet there have also been claims that Indian products have on occasions been responsible for harm in vulnerable importing nations. In response to the latter export regulations have recently been changed. The Indian Directorate General of

7 'Third shift production' is a term used to describe contracted manufacturers making unauthorised batches of their customers' products outside normally regulated conditions. These are channelled into the counterfeit drugs market. It can also involve other illicit forms of production in licit facilities.

8 The Ministry of Health, SFDA, Ministry of Industry & Information Technology, Ministry of Public Security, Ministry of Supervision, Ministry of Finance, Ministry of Commerce, Chinese Customs, State Administration of Industry and Commerce, Administration of Broadcast & Television, the Bank Supervision Committee, Legal Office of State Council and the Chinese Postal Office.

Foreign Trade is implementing a serialised coding system similar to the track and trace technologies referred to above. This involves pack codes and the use of barcode technology, and is now being extended to the domestic supply chain. However, as with the proposed American system, there have been delays, and implementation will not now take place this year (Taylor, 2011a).

In future such innovations should help further to reduce the likelihood of medicines falsification in India. They could play a useful part in wider efforts to ensure uniformly high quality nationwide supply of affordably priced treatment and care. For the moment, however, there appear to remain risks of product misrepresentation, alongside problems such as poorer people not being able to access products and services to which they should be entitled in publicly resourced health facilities.

The Russian system

Russia has long been a great military and scientific power. To classify it as an emergent economy is therefore in some ways questionable. However, the living standards and access to health care enjoyed by a significant proportion of its population are not high by the standards of regions such as Western Europe and North America, and questions have in the past been raised in relation to medicines falsification in the Russian Federation and the Soviet Union before it.

The control and prevention of drug counterfeiting in the Russian Federation is the responsibility of the Federal Agency for Monitoring Health and Social Development (Roszdravnadzor). In parallel with action taken elsewhere in the world, recent Government initiatives have given Roszdravnadzor more power and resources. The available reports indicate that this has resulted in increased surveillance capacity and improved regulatory and associated law enforcement in relation to medicines falsification prevention and punishment.

In 2010 a new Federal Law on the Circulation of Medicines was passed. It is now, for example, mandatory in Russia for counterfeit and other substandard medicines to, immediately on discovery, be destroyed by organisations specifically licensed for the collection, transportation and disposal of this kind of waste at the expense of the owner of the products concerned (Taylor, 2010). Such measures ought to further discourage activities such as 'third shift' production runs undertaken out of hours in otherwise legitimately owned and run factories. At the international level, Russia has been one of the strongest advocates of the recently approved Medicrime Convention.

Russia nevertheless remains on the US Trade Representative's 'priority watch list' for counterfeiting. Some sources have suggested there has been Russian criminal involvement in areas such as supporting the international networks involved in illegal medicines supply via the Internet (Satchwell, 2004). Nevertheless, Roszdravnadzor has a highly competent staff, members of which have recently been involved in learning activities related to international best practice in pharmaceutical regulation.

The Agency has been praised for its efforts in relation to the control and policing of pharmaceutical counterfeiting, and there is no significant evidence of illicit Russian made medicinal products penetrating licit supply chains outside the established Russian sphere of influence.

Improving health and pharmaceutical care in Brazil

Brazil today has a per capita GDP (expressed in exchange rate terms) of about \$US 10,000 per annum. This is similar to that of other fast developing economies like Turkey and Mexico. Although there are large poor rural and peri-urban poor populations, Brazil is in overall terms significantly more affluent than emergent nations such as China and India. The latter is, for instance, in addition to being home to some of the world's richest individuals and families a country with an average income per head of little more than \$US 2,000.

Box 4. The impact of HIV/AIDS on pharmaceutical sector policies and practices

The emergence of AIDS as a threat to public health in the US and parts of western Europe in the early 1980s initially concentrated many policy makers' minds on the needs of relatively affluent populations. It was only later that the scale of the developing pandemic in sub-Saharan Africa and other less advantaged areas became properly understood, and the vital importance of enhanced access to effective medicines fully recognised.

In the period between the 1940s and the 1980s the processes of demographic and epidemiological development had – notwithstanding the relative neglect of many specifically 'tropical' conditions – typically created new health care needs associated with the growing prevalence of non-communicable disease in richer populations before they became highly prevalent in less affluent settings. More advantaged communities are naturally best placed to pay for medicines while they are patented, and hence expensive as compared with generic versions. But the advent of AIDS dramatically highlighted the need for new approaches, designed swiftly to provide innovative products to the least advantaged sections of the world community.

More satisfactory arrangements for anti-HIV medicines funding have now evolved, as have financing systems for the development and timely supply of products such as vaccines. But as the world community continues to live longer and age, and experience a growing burden of diseases such as cancer while still living with historic 'plagues' such as TB, malaria and the various forms of infectious hepatitis, there will almost certainly continue to be problems with new medicine affordability in vulnerable communities. If and when access to 'free or affordable at the point of care' health services is universally available then consumers' incentives for seeking treatment from unreliable sources will be reduced. But for the foreseeable future large and often chaotic private pharmaceutical markets for low cost and other medicines will continue to exist in many countries. Unless adequate regulatory capabilities are developed these could in future be penetrated by counterfeit products to an increasing degree.

Brazilian policy makers have recently initiated a number of measures aimed at improving public access to appropriate pharmaceutical care. In the case of community pharmacy, for instance, Government and other bodies have led targeted attempts to extend low cost access to good quality medicines in poorer areas. Measures to improve the traceability of medicines and supply chain transparency are also being explored. The National Health Surveillance Agency (ANVISA), which regulates all medicinal products in the country and is responsible for pharmaceutical surveillance, pharmacovigilance and the prevention of medicinal counterfeiting, recently published guidelines on the printing of serialised 2D matrix codes onto drug packaging (ANVISA, 2011). ANVISA has also increased its human resources.

Brazilian legislation recognises medicinal counterfeiting as a criminal activity, punishable by up to 15 years imprisonment. Cooperation between ANVISA and the Federal Police has resulted in joint operations in this field and in a substantial increase in the volume of illegal medicines seized. The available literature suggests a volume of 18 million doses in 2010, in contrast to 500,000 in 2008 (Interfarma, 2011). Most of the products seized were classified as lifestyle drugs. Brazil is now looking to cooperate with other Mercosur countries (Argentina, Paraguay and Uruguay) to develop a coordinated regional anti-counterfeiting strategy.

Brazil and India have played key parts in the expression of concerns about the WHO's IMPACT initiative. These existed in part because of the involvement of global research based pharmaceutical companies in its governance, and seemingly because of fears that this might lead to developments that would restrict the development of locally owned generic and 'branded generic' pharmaceutical manufacturing and supply. But whether or not this is the case the progress outlined here indicates an acceptance of the undesirability of medicines falsification, and the importance of preventing it as an integral part of assuring overall medicines quality. The most important immediate opportunity appears to be to build on this emerging consensus on medicines counterfeiting and its prevention.

Nigerian developments

Nigeria is still in a relatively early stage of its demographic and epidemiological transition, and the regulatory and other social evolution stages characteristic of human development during the associated period of rapid population growth. There are presently said to be 150 million plus Nigerians, compared with under 40 million at the start of the 1960s. Infections such as malaria and TB remain relatively common, while age specific mortality and disability rates from conditions such as strokes and heart disease are also higher than in more developed countries. In the face of this double burden of communicable and non-communicable disease the access to health care enjoyed by less affluent people is often very limited.

Nigeria has in recent decades been particularly exposed to counterfeit drug imports, as well as to their local production and supply. This is generally what development theory would predict in the context of access to pharmaceutical care during 'early-to-mid transition'. But Nigeria is atypical in that, through the work of individuals such as Professor Dora Akunyili and the National Agency for Food and Drug Administration and Control (NAFDAC), it has taken vigorous regulatory action to control this problem.

NAFDAC was born out of the 1993 Nigerian Food, Drugs and Related Products Decree. During her period in office Dr Akunyili⁹ (whose sister died as a result of being supplied with fake insulin) identified corruption amongst public officials as one of the key barriers to establishing a more-effective anti-counterfeiting regime. She consequently dismissed many of the men involved and replaced them with women, who she believed would in the cultural setting of the day be more resistant to bribery. Incentives for honest behaviour were introduced and a key open air market was closed for three months after her officers had confiscated some \$US 200,000 worth of falsified drugs (Frenkiel, 2005).

Despite violence that involved Dora Akunyili being shot at and another public official being killed, the criminal vendors' operations were successfully disrupted. Because Indian sources had been identified as key suppliers of counterfeit drugs to Nigeria NAFDAC also set up three offices to facilitate cooperation with the Indian authorities (Securing Pharma, 2009).

NAFDAC is now headed by Dr Paul Botwev Orhii, who succeeded Professor Akunyili in 2009. In addition to serving as vice-chair of WHO's IMPACT Dr Orhii has taken forward the work of the Agency in a variety of important directions. For example, the maximum sentence for medicines counterfeiting in Nigeria has been increased to 15 years and NAFDAC has more recently led bids to replace this with a compulsory life term. Its policy proposals also include measures to allow the confiscation of assets from criminals found guilty of participating in the falsified medicines trade.

As in Europe and the Americas, the adoption of modern technology is seen as having an important future role to play in the prevention of pharmaceutical counterfeiting in Nigeria. For example, there has been a limited introduction of a mobile authentication service (MAS) to validate medicines via the telephone transmission of original pack identification codes to a central database. This should allow purchasers to determine whether or not they are in possession of a genuine product. NAFDAC has also employed scanners which enable border control agencies to validate the authenticity of drugs without having to send them to a central testing laboratory. This avoids drug confiscations based on mere suspicion, which might impede public access to genuine medicines.

⁹ Dr Akunyili is a pharmacist who studied in London. Following her work on medicines falsification and other aspects of pharmaceutical sector corruption she became the Nigerian Minister of Information.

Turkish pharmaceutical sector regulation

Turkey has the sixth biggest pharmaceuticals market in the WHO's European region. With the single exception of China it enjoyed faster economic growth than any other country in the world during the period 2000-2010, and has in recent decades seen dramatic improvements in fields such as maternal and infant mortality. Life expectancy at birth in Turkey is now about 75 years, ten years more than in India and some twenty years longer than in Nigeria. Under the (to date) ten years of leadership by Health Minister Dr Recep Akdağ the country is seeking to continue the transformation of its health care system via the establishment of a family doctor led primary care service, coupled with better population wide access to effective, rationally prescribed, drug treatments.

Nevertheless, there have during the past few years been instances of abusive claims for medicines reimbursement involving pharmacists and the illicit repackaging of original products resulting in the *de facto* creation of falsified drug products. Turkey's geographical position has meant that in the past it has served as a gateway to the European Union's internal market in ways which made it a hub for trading in counterfeit goods of many types, including falsified medicines (Arslan and Albayrak, 2012). The existence of free trade zones throughout the country is also relevant to such concerns.¹⁰

To protect public health interests, regulatory interventions have included measures such as the banning of internet drug sales. In addition a number of major police raids on suspected purveyors of counterfeit drugs located in offices, houses, warehouses and pharmacies have been conducted. Examples of these have included 'operation Elixir' in 2007, 'Dermann 33' in 2008 and operation 'Aci Recete' (Bitter Prescription) in 2009. Turkey has also cooperated with Interpol in contexts such as the Pangea operations against illegal internet trading in counterfeit and other medicines – see below. For reasons of both internal security and external responsibility the country has played a leading role in combating pharmaceutical sector crime.

A serialised medicine pack coding system is currently being implemented, primarily to combat reimbursement fraud. However, its potentially positive impact on counterfeit medicines trading has resulted in its being used as an 'example to follow' by a number of other States, including Brazil. Such illustrations underline the point that Governments across the world have become increasingly united in their desire to curb medicines falsification and prevent harm from illicitly manufactured pharmaceuticals as it might affect the communities they serve.

The case for globally co-ordinated public protection against medicine falsifiers

There is already considerable convergence in the measures being adopted at national and regional levels to safeguard public health interests against the consequences of using illicitly produced and improperly supplied medicinal products. Some observers may therefore argue that nothing further needs to be done to promote effective international action against medicines falsification. But there is a logical case for believing that additional, surveillance based and systematically supported, global co-ordination could add extra value through, for instance, providing an early warning of emergent hazards and disseminating good practices. (See, for instance, *The Lancet*, 2012).

Stronger inter-governmental partnerships, coupled with the positive involvement of other public and private stakeholders in public health improvement and effective pharmaceutical care, could help to protect particularly vulnerable populations from neglect and abuse by criminals operating without the restraints normally imposed in more affluent contexts.

Such aspirations are not new. The World Health Organisation began addressing the issue of medicines counterfeiting in the 1980s. It was, for instance, raised at the 1985 Conference of Experts in the Rational Use of Drugs in Nairobi. In 2003, the WHO offered an analysis of falsified medicines risks differentiated by therapeutic class. It recommended that Member States should establish strong national regulatory bodies to prevent counterfeiting and related pharmaceutical sector crimes and malpractices. It was against the background provided by these developments that the formation of the International Medical Products Anti-Counterfeiting Taskforce was announced during a WHO conference in 2006. (See Box 5 and Taylor and Craig, 2009).

IMPACT's goals included improving collaboration among various stakeholders in combating counterfeit medicines; raising public, professional and political awareness of relevant hazards and opportunities; establishing mechanisms to assist agencies concerned with the control of medicines falsification; and bridging between different anti-counterfeiting initiatives. The Taskforce produced several resources related to these goals, including, for instance, a collection of draft principles to inform national legislation. It in addition brought expert groups together to discuss technical issues and undertook a range of other creditable activities. The efforts that IMPACT made in this regard were acknowledged by the recent WHO Working Group on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit (SSFFC) Medical Products.

However, for the reasons already discussed the IMPACT initiative was from the start subject to criticism (Shashikant 2010). As an illustration of the opposition which emerged, a letter drafted in 2009 by the Small and Medium Enterprise Pharmaceutical Confederation

10 As already described, free trade zones allow for a low tax environment that can boost exports and foreign currency earnings. This generates benefits consistent with a variety of public interests. But as a result of light regulation free trade zones can be used illicitly as transit points for counterfeit goods.

Box 5. The origins of IMPACT and the pursuit of enhanced public health protection

The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) was launched at a WHO meeting in Rome in 2006. It was at that time endorsed by 57 national drug regulatory authorities and a wide range of international agencies, patient and professional associations, and pharmaceutical manufacturers and wholesalers, and described as '*the latest initiative in a long campaign*' against medicines counterfeiting. Its primary aims were to raise awareness of pharmaceutical product falsification as a part of the WHO's overall mission to improve health care quality and public health world-wide.

The positive achievements of IMPACT in areas such as professional education have been welcomed by the major stakeholders involved. There is good reason to believe that its foundation was principally motivated by a shared desire on the part of all those participating to protect public health. Yet as argued in the main text, there is also good reason for clearly separating issues relating to the criminal falsification of medicines from other aspects of maintaining high standards of drug manufacturing and supply and/or the protection of commercial and intellectual property. Rightly or wrongly, some observers have felt that IMPACT and/or groups linked to it did not always achieve this goal. In moving forward it will be important to allay such concerns, while retaining a strong and urgent focus on further reducing both the risks and actual occurrence of harm to people caused by medicines falsification.

One example of an area where a strengthened international approach to regulation might in future significantly enhance public health protection is that of internet sales of prescription and other medicines. Some sources suggest that in the order of 50 per cent of medicines supplied via illegal sites that disguise their true addresses are falsified, and that more could and should be done to prevent this form of trading. Uncontrolled access to medicines via self-purchasing on the internet and postal supply across international borders can, even when products are genuine, also permit harmfully inappropriate self-treatment. The types of problem resulting range from addiction to psycho-active treatments through to increased rates of resistance to anti-microbial medicines.

of India to the Indian Prime Minister called for the '*total rejection of the work of IMPACT*', seemingly because it was thought to threaten exports from India to other countries. It was argued by the interests involved in that initiative that, despite the positive aspects of IMPACT, research based pharmaceutical industry representatives were too heavily involved in its functioning.

At the 2010 World Health Assembly Brazil and India favoured bringing the IMPACT initiative to a close because of the involvement of groups that '*represent the interest of pharmaceutical firms*' (Kaiser Daily Global Health Policy Report, 2010). WHO Member States subsequently established a Working Group on SSFFC Drugs. It was charged with reviewing WHO's definition of counterfeit medicines and IMPACT's role, mandate and membership. The consensus decision finally taken was to propose establishing a new mechanism '*to promote,*

through effective collaboration among Member States and the Secretariat, the prevention and control of SSFFC medical products and associated activities'.

This way forward was recommended to the 2012 World Health Assembly by the WHO Executive Board in January 2012 (WHO, 2012). It is presently envisaged that such an inter-State initiative will be explicitly health interest focused and avoid offering permanent roles for stakeholders such as NGOs or pharmaceutical company groups. However, expert representatives of such stakeholders may be invited to give advice, collaborate and to be consulted with on specific topics.

Provided such an approach is proactively managed and adequately funded there appears every reason for taking it forward. Medicines counterfeiting, like the supply of adulterated or very poorly made medicines, is clearly a threat to global public health. Future health gains are arguably more than ever before likely to be dependent on all sections of the world community having affordable access to appropriately prescribed or otherwise correctly selected preventive, ameliorative and curative pharmaceutical products of a quality fit for purpose.

Achieving progress

Figure 4 offers a suggested outline of the type of mechanism that might successfully foster closer international collaborations against medicines falsification and appropriately allow the WHO to go on developing its role in this field in a manner consistent with its globally defined accountabilities on the one hand and sensitive to specific regional and national level governmental requirements and local public interests on the other. It would be inappropriate to attempt to offer here a detailed prescription of how WHO or other specialised UN agency member States such as UNODC¹¹ should seek to proceed. However, key points relating to the model proposed in Figure 4 include:

- at the 'top' level, horizon scanning and surveillance activities should be led in a way that is accountable to the World Health Assembly, and focused on identifying not only emergent problems but also good practices and commonly agreed values. The global group's aim should be to facilitate the prevention of medicines falsification and its unwanted consequences whenever possible, without attempting to 'micro-manage' how this is done in practice;
- at the intermediate or regional level, developing shared local strategies for achieving agreed world-wide goals, and practically overcoming barriers to progress such as poor public awareness of the hazards associated

¹¹ UNODC has been given a unique mandate to assist Member States in the fight against trafficking in fraudulent medicines. To implement this resolution, UNODC is in the preparatory stages of developing a phased strategy (UNODC, 2012). It defines fraudulent medicines as including all those where the contents are inert, less than indicated, more than indicated, different than indicated, misbranded, or expired, which is broader than that of falsified medicines employed here, and has argued that the global death toll associated with the supply of such products may be in the order of 200,000 per annum.

- with medicines falsification or inadequate cross border and allied policy enforcement arrangements; and
- at the nation State (or large internal state) level(s), the formation of policy implementation groups, focused on delivering agreed goals and ensuring that effective action is taken to manage identified threats to public health and protect the interests of communities.

In the final analysis the WHA should, via the global and regional groups, be able to have an overview of the strengths and weaknesses of anti-falsification and wider medicines quality management programmes across the world, and be able to positively influence their performance as and when opportunities arise. Non-governmental stakeholder groups with special knowledge of, or responsibilities relating to, medicines falsification (which include not only pharmaceutical companies but also pharmacy and the other health professions involved in drug supply, and agencies such as police forces and customs organisations) should be involved as judged appropriate at each level. From a public interest standpoint it would appear reasonable to argue that any group that can demonstrate special knowledge of the causes, occurrence, consequences or potential means of controlling falsification ought to be able to participate at any level, subject to open disclosures of interest and transparent discussion of any feared conflicts with those of the public being served.

Other aspects of the mechanisms by which more consolidated global action to prevent medicines falsification are touched on briefly in the conclusion of this report. However, before that two other areas are briefly outlined. The first relates to the enforcement of laws designed to prevent and punish medicines falsification. At the global level the work of Interpol is critically important in this context, alongside that of bodies such as UNODC and the World Customs Organisation.

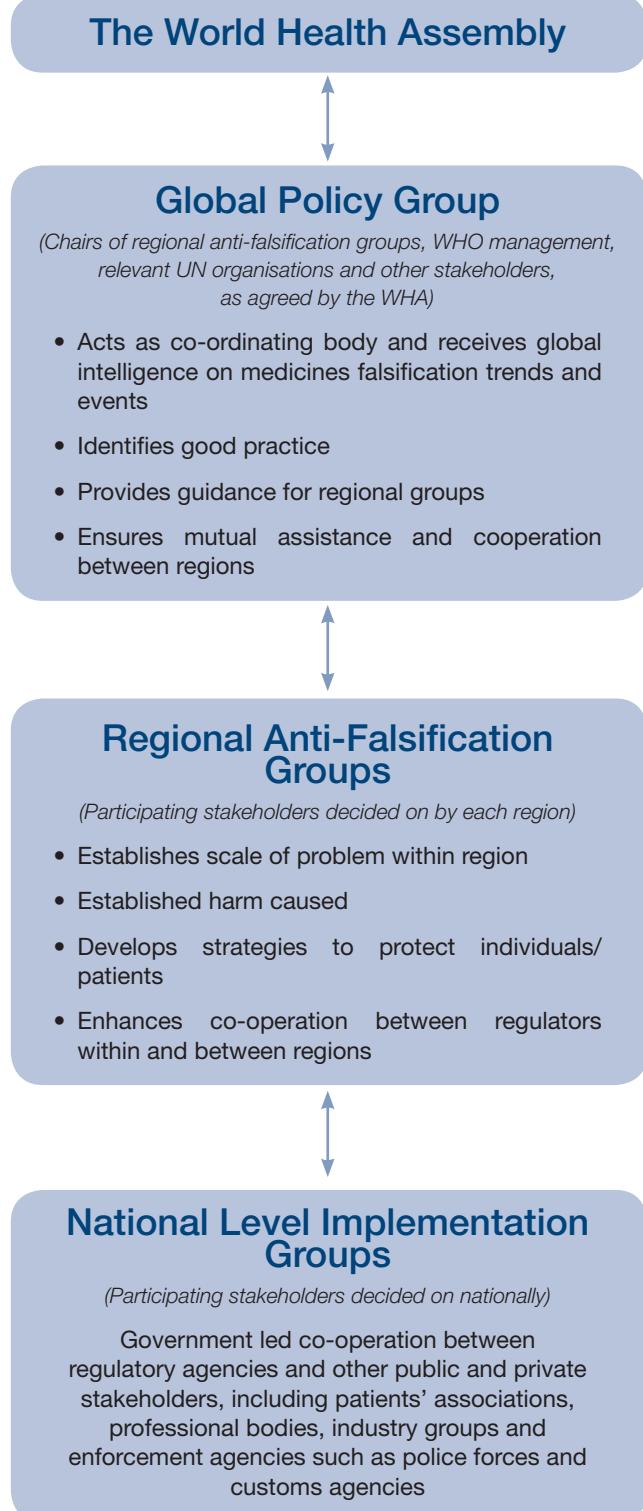
The second links to the work of the Council of Europe in drawing up and garnering support for its Medicrime Convention. The latter has possible limitations, but is open to non-European signatories and might, in the event of further progress under the auspices of the WHO not proving as successful as might reasonably be hoped, provide an alternative path towards establishing better world-wide (or at least regional and selected inter-regional) collaboration against medicines counterfeiting.

Well organised and appropriate policing

The International Criminal Police Organisation (INTERPOL) was originally established in 1923 as the International Criminal Police Commission (ICPC). It is today heavily involved in the international enforcement of counterfeit medicines controls. Its mission is to facilitate cross-sector international action to identify, investigate and prosecute the criminals behind falsification. It does this by:

- coordinating field operations to disrupt illegal transnational networks;
- training to build relevant skills and knowledge in the agencies fighting pharmaceutical crime; and
- building partnerships across sectors.

Figure 4. An illustrative mechanism for WHO led international cooperation against medicines falsification



Source: the authors

INTERPOL's partners in tackling pharmaceutical crime have included the WHO, the Permanent Forum on International Pharmaceutical Crime (PFIPC)¹² and bodies such as Singapore's Health Sciences Authority (HSA). A recent example of an activity involving the latter was an 'Operation Storm' Enforcement Network 'train-the-trainer' course held in Singapore early in 2012. Its objective was to disseminate the expertise needed to combat medicines counterfeiting.

INTERPOL primarily coordinates and conducts international enforcement operations. But it also provides public information on the dangers of medicines falsification and associated crimes in Africa and elsewhere. There are currently four 'flagship' anti-counterfeiting initiatives, run on an annual basis. As previously indicated, operation Pangea (which was first launched in 2008) is aimed at curbing online illegal medicine sales. Pangea IV (20 – 27 September 2011) involved police forces based in 81 countries. The available reports indicate that it resulted in 2.4 million 'illicit pills' being confiscated and 55 individuals being placed under arrest or under investigation.

Operation Mamba targets eastern Africa. It aims to disrupt organised crime there and to promote public education and awareness of drug counterfeiting and allied offenses. Mamba in addition fosters capacity building and investment. While Storm is focused on south east Asia, operation Cobra – the first phase of which took place in 2011 – targets western Africa. Seven countries have so far been involved. It has been reported that 10 tons of falsified or otherwise illicit medicines were seized, and over 100 arrests made.

Yet important though such cross-national law enforcement efforts are, some observers argue that they have not sufficiently deterred illegal online medicine sellers and the organising groups behind them, or kept up with the creativity of these and other illicit drug vendors. (See Mackey and Liang, 2011, and Box 5.) As with any challenge that involves a constant underlying threat, sustained high level attention needs to be paid to maintaining and where necessary strengthening control measures. Law enforcement agencies alone cannot be expected to succeed in ensuring protection from medicines falsification and allied hazards.

This is especially so in environments in which there may be problems associated with corruption, and/or where there may be uncertainties as to the extent to which authorities are committed to regulating all aspects of domestic and international medicines supply to the highest realistically affordable standards. There is also an important need not to inappropriately criminalise activities that would be better regulated via alternative mechanisms, such as politically and managerially led service interventions, professional codes or civil law provisions.

12 The Permanent Forum on International Pharmaceutical Crime (PFIPC) is an international enforcement initiative tasked with protecting public health through exchanging information and improving cooperation. The members of the PFIPC include regulatory agencies from South Africa, Singapore, Australia, New Zealand, Belgium, Germany, Ireland, Israel, Italy, Netherlands, Spain, Switzerland and the UK. They attend regular PFIPC conferences.

The Medicrime Convention

The Council of Europe was founded in 1949 and today has 47 member countries, covering virtually the whole continent. It is committed to advancing democratic principles and human rights, and has funded extensive research into medicines counterfeiting (Harper and Gellie, 2006). This work led the Council to conclude that the potential for harm in Europe and elsewhere is sufficient to demand a more coherent international approach, and to formulate the Medicrime Convention. There are presently 21 signatories as of October 2012, including Israel and Turkey. The Convention is open to all States, and others which have expressed interest included Benin, Canada, Japan, Mexico and the USA. It will come into force after five countries have formally ratified it and will obligate States to criminalise:

- manufacturing counterfeit medical/medicinal products;
- supplying, offering to supply and trafficking such counterfeit products;
- falsifying relevant documents; and
- the unauthorised manufacture and supply of medicinal products and/or the marketing of medical devices that do not comply with appropriate requirements.

In addition, Medicrime offers a framework for national and international cooperation across different sectors of public administration; measures for national level coordination; preventive measures; and the establishment of a monitoring body to oversee Convention implementation. (Council of Europe, 2012). As a novel attempt to build further international consensus on the measures required to curb drug counterfeiting it has been widely welcomed. Were in future sub-Saharan nations like Nigeria (which is by far sub-Saharan Africa's most populous nation) and its neighbours to decide to join the Convention it may help defend not only the populations of richer countries but also the people of poorer communities in Africa and perhaps elsewhere.

Yet the Medicrime Convention has faced criticisms. As what is regarded as a primarily European initiative it may, for instance, lack credibility in societies which were in the past negatively affected by colonialism, and whose citizens may – rightly or wrongly – to a degree associate the latter with provisions such as patents for medical innovations. Exaggerated or not, reports such as those of European authorities seizing drugs being transported from nations in which they were legally manufactured (like India) to destinations in which they can be legally sold (like Brazil) have, unsurprisingly, fostered resentments and tensions.

It has also been suggested that the definition of counterfeit products contained within the Medicrime Convention's clauses could risk criminalising unintentional mistakes. Commentators have noted that the Convention might require criminal law remedies in cases where, thus far, civil prosecution has been the vehicle used to prevent intellectual property infringements (Bate and Attaran, 2010). In as much as this is actually the case it has

significant implications which may well take a decade or more to be fully resolved. This is not to say that any such failings could not be remedied. But it underlines the desirability of, to the fullest extent possible, strengthening international efforts to rapidly and effectively control medicines falsification via WHO co-ordinated, regionally guided and agreed and nationally implemented collaborations.

Conclusions

The safe and effective supply of established and new pharmaceuticals will become an increasingly important global priority as the 21st century progresses. But realising the promise of better pharmaceutical care will involve overcoming many obstacles. Maintaining the funding needed to support genuinely high risk innovation is one challenge. Ensuring that the world's poorest people have timely and affordable access to good quality established and new pharmaceuticals and the often more costly professional advice and support needed to use them effectively is another. Historically transient conflicts between countries and different parts of the global pharmaceutical industry should not be allowed to obscure common interests in either of these important fields – see Box 6.

Many more people die or are disabled as a result of not being able to obtain good health care than are harmed by counterfeit treatments. Nevertheless, providing effective protection against medicines falsification is a third global goal, the achievement of which is in the interests of individuals and communities all over the world.

The actions of governments across the world show that the importance of assuring medicines quality and preventing their falsification is now widely understood at a national level. The World Health Organisation can claim some credit for the progress already achieved with respect to the prevention of pharmaceutical counterfeiting. It will in future contribute even more if the good intentions underpinning current proposals for a new mechanism to facilitate more co-ordinated action prove demonstrably effective in fostering greater international co-operation, and further reducing the public health hazards linked to the supply of drugs produced in unregulated environments.

The analysis presented here indicates that the future prevention of medicines falsification is likely to demand complementary actions to improve performance at three main levels. They in summary are:

- global surveillance and world-wide intelligence gathering, information sharing and policy formation. This high level governmental leadership function should arguably be coordinated by the World Health Organisation working in partnership with other appropriate organisations and individuals. The latter include, for instance, UNODC and regional level representatives. At the world wide level attention should be focused on recognising common values and long term world-wide objectives;

Box 6. Pharmaceutical sector evolution

Discovering effective medicinal substances and the collective means of employing them to good effect has been a part of the human story for at least five millennia. But the period between the late 1940s and the start of this century saw a fundamental discontinuity. Many new pharmaceutical treatments for common conditions were developed and marketed. They have contributed successfully to reducing mortality and morbidity in all parts of the world, and are now in the main available as low cost generic medicines.

This latter shift created the conditions in which generic pharmaceutical companies could prosper alongside those primarily focused on fundamental innovation. However, since the late 1990s the rate of pharmaceutical innovation appears to have slowed. Perhaps more importantly, the average potential market size for new more precisely targeted medicines has reduced. Companies involved in innovation are more likely than in the past to be serving 'orphan' or near orphan patient groups, as opposed to the general population.

Such developments should in time herald a new era of better targeted 'personalised' medicine. But they are also creating wider gaps between the prices of intellectual property law protected medicines and other 'true generic' or off-patent branded products. They may also be creating tensions between generic (and emergent innovative) pharmaceutical producers and the nations which host them, as against more established research based companies and their major hosts.

This can be seen as an inevitable part of the overall process of early twenty first century human development. Yet at the same time it should not be allowed to disrupt common efforts to prevent harm to public health everywhere in the world due to the supply of falsified medicines. Nor should it draw attention away from the common interests that all pharmaceutical manufacturers share, along with the world public and regulatory and allied agencies, in assuring medicines quality, safety and access.

- regional groups, constituted to determine tailored collective priorities and strategies and to foster national level co-operation and action in ways that anticipate and counter possible conflicts of economic and related interests between States; and
- national programmes, delivered in ways consistent with global goals and standards, tempered by regionally agreed approaches and ends. It is at this level that practical efforts aimed at the effective enforcement of anti-falsification policies must in practice be achieved.

The involvement of other stakeholder groups, ranging from international agencies such as Interpol or the World Customs Union to major NGOs and individual regulatory agencies, consumer and patient organisations, professional and industry bodies and/or local police forces and customs organisations will need to be flexible, and appropriate to local conditions. It should be decided in a manner designed progressively to build development capacity and wider inclusiveness, and to

ensure the uncensored flow of validated information within and between communities.

During the first decade of the twentieth century IMPACT was helpful in terms of information sharing and technical support. But the conclusion offered here is that in future the WHO should readjust its activities to focus more on monitoring and coordination activities, where it is uniquely equipped to work, and to leave the day-to-day regulation of pharmaceutical manufacturing and supply chain management and the enforcement of both criminal and civil law to government and other agencies working at the regional and national levels. This will allow it to be better placed to help resolve disputes relating to global public interests in all aspects of medicines development and supply when there is a need for it to do so.

This is not to say that the WHO should pull back from educating political, professional and wider audiences about medicines falsification, as and when it has opportunities and responsibilities to do so. Nor should it fail to address matters relating to the rational and affordable use of medicines, or any other matter that can be shown to have important public health implications. Yet in the final analysis the impact of medicines counterfeiting on public health will be best addressed independently from other concerns, including assuring the financial and allied property arrangements needed to maintain ongoing public and private investment in high risk research. Examples of the latter include seeking to develop medicines for the prevention and treatment of Alzheimer's Disease in ageing populations, alongside treatments for previously neglected parasitic disorders in less advantaged communities.

Failures to achieve an effective framework for organising collaborative action against medicines falsification may well serve to perpetuate disputes that at best do nothing to benefit world health. At worst, they could in future – if not laid to rest – cost significant numbers of lives which responsible global action would otherwise have saved.

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