ROUNDTABLE: PHARMACEUTICAL COUNTERFEITING

Is the pharmaceutical industry winning the war against counterfeiting? Our panel of experts discuss whether recent legislative moves and co-operation are improving traditionally troubled marketplaces, and offer their suggestions on how to make things better.

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The counterfeiting of medicines and pharmaceutical products has been an accepted evil in the marketplace for too long. Legislative measures introduced across the US, Europe and Australasia have sought to address the problem, but there is still a vacuum between what looks like a workable law in a statute book and one that can be proactively policed and enforced on the ground. Arguably, some economies have turned a blind eye to the problem and, mistakenly, have viewed counterfeits themselves as a contributor to the local economy.

In recent times, we have seen shocking examples of what happens when controls are not in place or are badly enforced. China, in particular, has been made to focus its mind on the problem in the wake of the melamine milk scandal. The health risks are real and this is the message that is finally coming through. What is clear is that there is greater need for co-operation between countries, and co-ordinated and concerted lobbying by companies to force through more change.

For this special report, *World Intellectual Property Review* has brought together a panel of experts in this field to assess the impact of recent changes and experiences from various jurisdictions, and to offer their insight into what more can be done to ensure the war against counterfeiting can shift from an enduring crusade to a more convincing win. We asked them the following questions:

How will improved cross-border co-operation on counterfeiting prevention help alleviate the problems of counterfeit medicines and pharmaceuticals?

Baker & McKenzie:[1]

Effective border control by Customs authorities and the global co-ordinating role taken by the World Customs Organisation are critically important in addressing the problem, but in reality, enforcement authorities, legal regimes and pharmaceutical companies around the world are playing catch-up and have only recently begun to grapple seriously with the issues.

The EU has, in part, harmonised its measures to combat this through the Counterfeit Goods Regulations, allowing Customs recordations to be filed throughout the EU and, further, by way of harmonisation of legal remedies through the EU Enforcement Directive, although more needs to be done, on the ground, to make this cross-border co-operation really effective. Also, recent European Court of Justice (ECJ) decisions (such as Class International, which held that goods merely transiting through an EU country are not liable to be injuncted on the grounds of trademark infringement) militate against a zero tolerance policy trend and are sending a message that the EU is a safe harbour for trans-shipment of counterfeit goods. This cannot be what was intended, and there needs to be a more rigorous review of EU policy in this respect.

IACC:

Cross-border co-operation is essential to addressing the problem of counterfeit pharmaceuticals for a very simple reason—counterfeiting is a global problem. It's not a US problem, or a European problem, or a problem for developing nations; it's a problem for everyone.

Last year, US Customs and Border Protection seized over $100 million worth of counterfeit products coming into the United States. The total estimated value of counterfeit goods bound for the US market though, across product sectors, is estimated at 2,000 times that number. The global trade in counterfeit goods has grown to proportions that far exceed the ability of any country to address it single-handedly.

Cross-border co-operation, whether in the case of multi-jurisdictional investigations that seek to dismantle international counterfeiting operations, or assistance with capacity building, can have a far greater impact than the individual efforts of any one government.

Eli Lilly:

Although most countries now recognise counterfeit medicines as a threat to consumer health and safety, many lack the comprehensive framework of laws and controls necessary to safeguard the drug supply chain against counterfeit sales and exports. Several common deficiencies contribute to the growing incidence of counterfeit medicines. Weak enforcement, due to inadequate remedies, penalties, resources and commitment, is a significant problem. In certain countries, law enforcement does not prioritise drug counterfeiting as a serious crime. In other countries, drug safety regimes lack the investigative and enforcement authority to properly address counterfeiting. Evidentiary rules serve as hurdles to proper enforcement, or counterfeiting does not carry appropriate administrative or civil penalties.

To address these deficiencies, a comprehensive regulatory and enforcement framework is needed that: (i) subjects drug counterfeiting activity to effective administrative and criminal remedies and deterrent penalties; (ii) adequately regulates and controls each link in the counterfeiting supply chain; (iii) trains, empowers and directs drug regulators, law enforcement authorities, and Customs to take effective and co-ordinated actions, including against exports and online activities; and (iv) educates all stakeholders about the inherent dangers of counterfeit medicines.

Is a drive towards greater co-operation and awareness of IP protection filtering through to Asia, and are there any particular initiatives that would help prevent counterfeiting in this region?

NanoGuardian:

Japanese pharmaceutical companies have a long-standing awareness of the value of IP protection, particularly as they are globalising their blockbuster brands and building a marketing presence outside of their home borders. And even when Japanese pharmaceutical companies seek growth via marketing partners, patent rights and licences are a key component of what the larger global players will pay for in a relationship. So it benefits the Japanese to have as much protection outside of Japan as possible.

Indian-based pharmaceutical companies are also beginning to better appreciate the value of IP protection as they seek to become legitimate global players. It is not a consistent appreciation across this market, but the major Indian players are reaching out to the large global pharma companies, and international rules of IP protection and business conduct are core to being seriously considered as legitimate. Certainly, the takeover of Indian pharma companies by larger global players, most recently Ranbaxy by Daiichi Sankyo, will continue to move that region towards international compliance.

It is less clear with China and the rest of Asia. Probably the best way to move this region towards international compliance is for the governments in these countries to enforce existing laws and to standardise with the rest of the world as much as possible. This enforcement needs to be increased significantly beyond the political posturing that has been the norm with China. Actions speak louder than words and, thus far, China's actions against counterfeiters have been abysmal.

Eli Lilly:

Growing awareness of intellectual property among Asian-based companies and governments is critical to getting government sector support for additional anti-counterfeiting intervention. There are a number of important awareness, reform and enforcement initiatives that are occurring in this region, ranging from Interpol programmes to APEC educational training meetings. Important reforms are occurring around trademark and intellectual property protection, as well as export controls and customs authorities, but many of these reforms are slow and not universally recognised among all countries in the region. Patient groups and various government agencies are also becoming more aware of the impact of counterfeit medicines on the local healthcare systems—the recent events in China exemplify the significant and tragic consequences of a breach in the integrity of the supply chain.

Baker & McKenzie:[2]

Hong Kong continues to be a growth market for counterfeits, and the counterfeiting of pharmaceuticals in China has grown in scope and scale over the last decade, with a widening range of drugs being exported and sold domestically. The central government has introduced a range of new measures in response to the fact that both Chinese drug companies and consumers are victims, with the level of fakes in the market sometimes rising as high as 30 percent, and to the recent international attention generated by reports of defective pharmaceutical exports. Despite these measures, the scale of pharmaceutical counterfeiting appears to be increasing, and pharmaceutical companies are encouraging the implementation of a wider range of initiatives.

To what extent are contentious issues concerning pharmaceutical IP in Latin America being addressed, and what do you consider to have the greatest potential impact on counterfeiting in this sector in the region?

Eli Lilly:

Let's be clear, counterfeit medicines pose a direct and immediate threat to patient health, regardless of whether there are any violations of intellectual property. The counterfeiter is falsely and fraudulently misrepresenting the medicines as something that they are not. The counterfeiter is not just copying the original marketing approval holder's medicine, but it is also committing fraud against both the patient and the government. The patient, the caregiver and the healthcare provider have no recourse against the counterfeiter. The availability of strong intellectual property rights enforcement, especially trademark rights, with deterrent penalties, is an important tool in combating counterfeiting.

Baker & McKenzie:[3]

Since Brazil has participated in the World Trade Organization, pharmaceutical IP rights have been controversial, being highlighted in the national news and legal debates. The Brazilian government tends to be aligned with international trends regarding IP protection, adopting international rules, but there has been considerable debate about compulsory licences of patented pharmaceuticals. This mainly affects anti-viral drugs, and especially those used in the treatment of HIV, with pharmaceutical companies announcing losses of R1 billion ($615 million) from compulsory licences. On the other hand, under the patent pipeline system, drugs protected by overseas patents may be protected in Brazil without thorough analysis by the Brazilian National Institute of Industrial Property. Pipeline patents can be used to attack counterfeit medicines, but given the current controversy, it is hard to predict the actual effect on the incidence of counterfeit drugs.

PICA Corporation:

Latin America is a growth market for counterfeiters. The combination of a large population base, the worldwide economic crisis, the high cost of many pharmaceuticals, the lack of governmental controls in many countries, and the reliance on loose supply chains even in first-tier channels, presents a daunting problem for brand owners. We are also seeing that the increase in anti-US governmental regimes throughout Latin America has begun to impact US and other western companies that are operating in those countries. In the pharmaceutical industry in particular, many of these governments are supporting (both overtly and covertly) the widespread availability of lower-priced generic (or equivalent) products. This is often despite IP rights to which the brand owner is entitled.

The key to addressing these issues is to closely interact with government representatives on a localised basis. This should involve the implementation of robust, localised government outreach programmes designed to stress the negative effects that counterfeiting has on the nation.

Is the ability to prosecute for counterfeiting adequate?

IACC:

In a word, 'no'. While the legal remedies available to rights holders are certainly adequate in many countries, in many jurisdictions, we still see structural deficiencies that inhibit effective and deterrent action against counterfeiters.

For several years, the IACC has noted in its Special 301 recommendations to the US Trade Representative that China relies too heavily on administrative enforcement measures, largely to the exclusion of criminal prosecution of counterfeiters. In addition, when cases are brought, whether via the administrative or criminal route, the penalties handed down are often so minor that they serve no real deterrent effect. It would be hard to characterise the ability to prosecute counterfeiting as adequate.

Eli Lilly:

Many, if not all, countries have some form of regulatory or legal framework that addresses counterfeit medicines. However, in many of those countries, the agencies tasked with fighting counterfeit medicines do not have the expertise or the resources to properly fight the counterfeiters. In many instances, the penalties remain low relative to other serious crimes, sentences can be deferred or avoided altogether, and fines are not sufficient to deter future counterfeiting.

To adequately prosecute counterfeit activity, enforcement agencies must have adequate powers and resources to investigate, seize and destroy both the illegal products and the manufacturing equipment. Improved cross-border co-operation and common definitions of counterfeit crimes would contribute greatly to law enforcement efforts in this area.

Baker & McKenzie:[4]

Due to limited resources, the US Attorney's Offices are often interested in large and important targets at or near the top of the criminal enterprise. Counterfeiting investigations by their nature, however, often must begin with street-level violators, and substantial time and resources are required for a brand owner to proceed up the supply chain to identify larger, more lucrative targets. It is often the case that federal prosecutors have neither the budget nor the manpower to assume the prosecution of the lower ranks, thereby limiting action against the more important defendants.

What brand protection considerations need to be made when licensing pharmaceutical manufacture to third parties?

Authentix:

Intellectual property owners and marketing companies should conduct a full risk assessment of their manufacturing processes to determine vulnerabilities and appropriate points of focus for brand protection measures. By mapping out the upstream supply chain for chemical precursors, raw materials and packaging components, and downstream distribution channels for finished product, various risks can be identified and quantified. Once a proper risk assessment exercise has been completed, it is then possible to select and implement relevant technologies, procedures and processes designed to mitigate identified risks, and increase visibility at key points across manufacturing and supply chain nodes.

Eli Lilly:

The real threat for counterfeiting does not come from licensed third-party manufacturers. Rather it comes from illegal manufacturing, packaging and distribution operations. Occasionally, legitimate third-party licensed manufacturers might be involved in counterfeiting, but more often the counterfeiting of medicines occurs through illegal manufacturing operations that operate outside the regulatory framework.

A related, but extremely important, issue is the unregulated manufacture of bulk chemicals and API (Active Pharmaceutical Ingredients) in certain countries. In many cases, these bulk manufacturers (legitimate or illegitimate) are the source of the API used in illegal counterfeit medicines. These unregulated chemicals are knowingly manufactured, advertised and even exported for use in making illegal and counterfeit medicines, without regulatory oversight and in contradiction

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to the health regulatory requirements of the local country. Often these illegal bulk products can be found on business-to-business websites or are advertised at chemical trade shows.

Baker & McKenzie:[5]

Quality control is paramount in any licensing situation, to ensure that the quality of the product is consistent and retains the values associated with the brand. In a pharmaceutical manufacturing licence, it is a given that the manufacturing processes must be tightly controlled. But also necessary are controls over the packaging and distribution of the product, to ensure that the product does not become available outside the legitimate supply chain. The makers of fake products need supplies of genuine goods to legitimise their operations and sell alongside counterfeits, and even surplus or discarded packaging can be misappropriated and put to use by counterfeiters. Therefore, all involved in the manufacture and distribution of product need to be vigilant to avoid loopholes for the unscrupulous.

Do you believe that the industry is winning the war against counterfeiting?

Eli Lilly:

This is a growing, international threat with implications for the entire global healthcare system. The only way to fight this menace is to have meaningful, comprehensive and consistent intervention across both private and public organisations. This means that all players in the supply and distribution chain and relevant regulatory and enforcement agencies throughout the world need to work together. The industry cannot take on this issue alone.

IACC:

I'd be reluctant to say that the industry is winning the war against counterfeiting, though primarily because the question seems to imply that there may be a day in the future when the industry will not have to concern itself with the counterfeiting of its products—i.e. a day when the war against counterfeiting has been won.

Unfortunately, individuals have been trying to pass off their goods as others for about as long as individuals have been using trademarks. I think this is unlikely to change—there will likely always be unscrupulous individuals who will try to make a quick buck off of the good name of another.

Baker & McKenzie:[6]

Statistics published by a wide variety of sources confirm that brand owners are not currently winning the war against counterfeiting. The estimated volume of counterfeits as a percentage of legitimate trade has not materially declined in recent years, despite the dramatic increase in overall global trade, and counterfeit medicines appear to be on the increase. Border agencies such as US Customs and Border Protection have not increased the volume of seizures to substantially reduce the overall levels.

Realistically, the battle for supremacy over counterfeiters will probably never be won, but more priority is clearly needed from governments for action to tackle counterfeit medicines and pharmaceuticals. Measures now being taken in various jurisdictions are helping firms to navigate the hurdles in an industry constantly jeopardised by the fraudsters. The catch-up game must continue.

NanoGuardian:

Given projections that the estimated $38 billion in counterfeit medications in 2007 will grow to $70 billion in 2010, I would think not. However, there is certainly a greater awareness of the issues of counterfeiting and diversion among manufacturers, authorities, industry groups and governments, but we have a way to go before anyone can say we are winning the war against the criminals who counterfeit and illegally divert.

The recent legislation here in the US that put some teeth into anti-counterfeiting laws is definitely a step in the right direction. But more is needed. I would like to see the US and EU governments work collaboratively to establish comprehensive mandates requiring drug manufacturers to provide product security features on the packaging (such as ePedigree) and on the actual doses of all products. So as not to financially burden the industry or the supply chain participants, these mandates could be accompanied by government-sponsored rebates or tax incentives for the manufacturers and other key supply chain constituents. The faster they move to meet the mandate, the greater the incentive. This would effectively reduce pressure from pharmaceutical companies, which are each independently and inconsistently attempting to identify the best approach, refocus analyses away from time-intensive and costly assessments of the risk and benefit of applying security measures on a product-by-product basis, and instead focus decisions on which technologies to apply.

Authentix:

The industry is still in the early days of the war against counterfeiting. Some progress has been made by the more proactive companies; however, the industry as a whole requires a much more co-ordinated and industry-wide effort. The rewards for dealing in counterfeit and grey market drugs and medical devices still far outweigh the penalties for getting caught. From a deterrent standpoint, I would dramatically increase the penalties for counterfeiting and unauthorised distribution of medicines and medical devices.

As a first step, I believe the path that EFPIA is pursuing, focusing on product serialisation with digital verification at the point of dispensing, is both realistic and represents an approach that could be expanded globally. In addition, I also believe the industry should establish minimum standards and requirements for physical authentication of products and their packaging. This capability should become a component of product quality such that every manufacturer can quickly and definitively authenticate its product and its packaging.

If there was one thing you could do to improve the situation, what would it be and why?

Eli Lilly:

If there was one primary area that could be changed, it would be the level of awareness of this threat to patient safety among government officials and consumers. Unfortunately, too many patients see the attractiveness of buying products at prices that are "too good to be true" without asking where the product came from. In addition, too many health regulatory agencies are looking for an easy "magic bullet" to solve this complex issue—often in the form of a track or tracing technology solution. This is a complex issue that needs to be attacked on multiple fronts, at its source, its funding and its distribution network.

Authentix:

We believe that use of serialisation to uniquely identify items at the unit level, and associated data management systems to verify product in the supply chain, will certainly be a step forward and an improvement; however, it will not provide the panacea solution that some people believe. In association with serialisation efforts, it will also be important to engineer physical authentication systems into both the products and their packaging. It is inevitable that counterfeiters will continue to copy and mass-produce whatever they can see on a product and its packaging, including serialised information. As serialisation and digital verification become more routine and proactive processes, larger numbers of exceptions will be identified and set aside for rapid follow-up and dispensation. The ability to authenticate suspect samples through quick confirmation of physical security characteristics will be an essential component of an effective authentication/serialisation system.

PICA Corporation:

Track and trace technology (by itself) is of limited value in combating counterfeiting. Overt authentication systems will deter some wholesale and retail sales if the brand holder aggressively commits to educating its supply chain and consumers on the authentication of its products. However, the primary market for counterfeit pharmaceuticals sits outside the traditional supply chain (e.g. smaller retail and Internet vendors, third-world economies concerned with cost, etc.). Since counterfeiters tend to focus on

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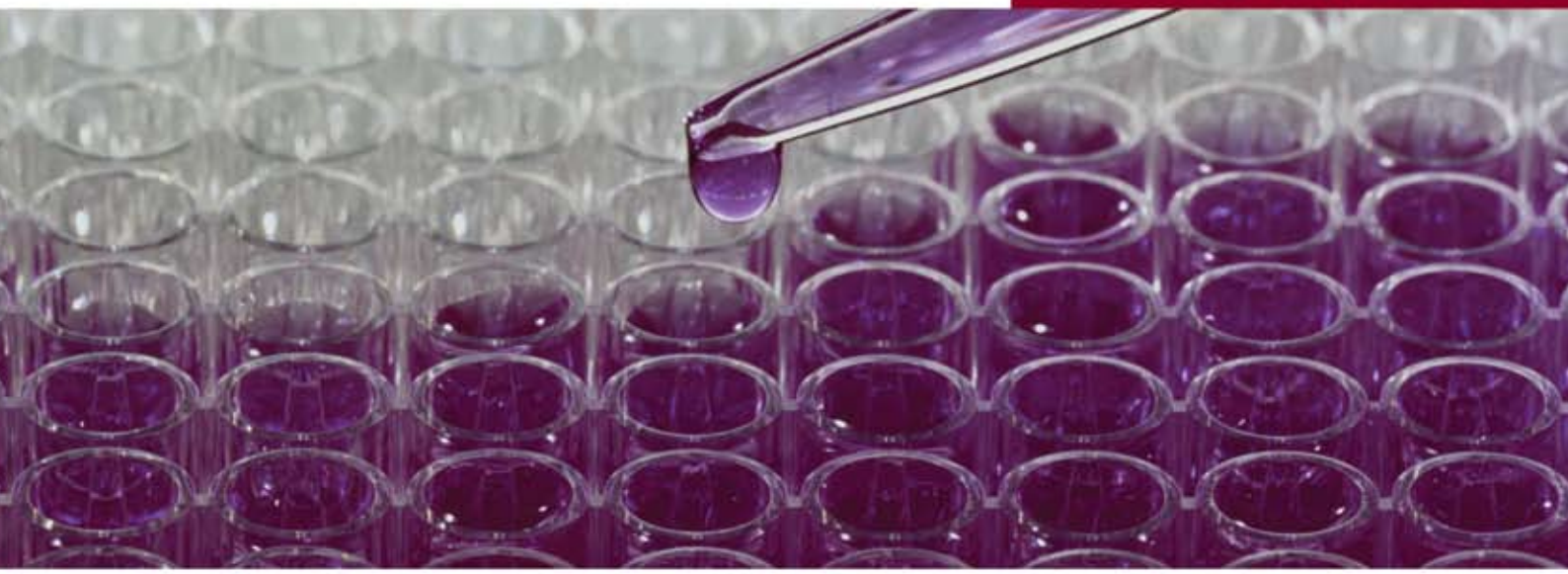

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the non-traditional supply chain, these customers (both retail and wholesale) are less likely to know or even care about authentication solutions, let alone traceability technology.

Eli Lilly:

Lilly believes that the use of technologies deployed in the right manner and with the right resources will result in improved supply chain integrity and enhanced patient safety. However, the inherent success of any such measure largely depends on the ability of all segments within the supply and distribution chain to employ the same technologies, read and process the data in real time, and share data without restriction—otherwise, the use of such systems is simply an added cost of production to the manufacturers.

Importantly, there are limitations to what traceability systems can provide. Such systems must be part of a larger, more comprehensive anti-counterfeit framework if they are to succeed. Track and trace systems only track the packaging of a product and not the product inside. In addition, no one technology solution can be a magic bullet. These technologies can be replicated or compromised by counterfeiters. These measures also do little to address the flood of illegal products entering countries through Internet sales.

NanoGuardian:

First and foremost, any additional security features added to the supply chain will most likely make the chain more secure, but I do not believe there is a 'silver bullet' technology or approach that will bring an end to counterfeiting and illegal diversion.

The most fundamental element in any security strategy is the layering of security features—both overt and covert. For example, some are arguing that on-package ePedigree initiatives, such as RFID and data matrix bar codes, are indeed the silver bullet that will end counterfeiting and illegal diversion; however, RFID and 2D matrix bar codes fall far short of a complete solution. First, studies show that they can be copied, hacked or reused. Second, they are applied to the package only, and once a product is repackaged, even legitimately, the protection provided by these package-level technologies is lost. Only by combining together on-package and on-dose security features that can provide field-level authentication and dose-level tracing will pharma manufacturers take a significant step towards protecting each and every dose from plant to patient.

PICA Corporation:

There needs to be closer day-to-day interaction between public health and safety/police agencies and brand owners to combat the problem. Both have a significant vested interest in solving the problem, but each lacks what the other has. Brand holders have industry and channel knowledge, resources, and authentication capabilities, but must rely on the government for meaningful enforcement. The government can create a deterrent through enforcement, but lacks the resources and knowledge to start and build cases. Linking these two is vital to the success of any ACF campaign in the pharmaceutical or medical products industry.

What improvements in supply chain management are most helpful in helping to avoid fakes?

NanoGuardian:

The ePedigree requirements that are being discussed and legislated, such as those in California, will ultimately benefit the consumer by improving the security of the pharmaceutical supply chain. However, this is only a starting point. The current lack of clear standards with respect to ePedigree will make establishing a uniform process in the US a very difficult task. This is likely to be a situation in which government mandates, fully vetted with the pharmaceutical stakeholders, will be helpful to all constituents of the supply chain.

Beyond ePedigree, implementing brand protection security features that link each dose to the bottle or box, which in turn is linked to the larger packaging and shipping pallet, including the transportation source, will greatly impact counterfeiting and illegal diversion, and allow for rapid and accurate authentication of each individual dose. Anything less will not serve the best interests of the most important component of the supply chain—the patient.

IACC:

I do think the industry is heading in the right direction by taking steps towards ensuring its supply chains, by using track-and-trace technologies and, perhaps most importantly, by taking steps to engage and educate the public about how to identify and avoid counterfeit drugs, and the dangers of purchasing pharmaceutical products outside the normal retail channels.

Authentix:

Strong agreements with authorised distributors that clearly define allowable sources for purchase of product are an important tool in controlling the entry of fake and substandard product through secondary channels. These distribution agreements need to carry stiff penalties that remove the incentive for a distributor to cheat. In addition, the use of authentication and serialisation technologies enable efficient and effective supply chain monitoring to be conducted both proactively to provide an early warning of problems and reactively to quickly investigate known problems. The combination of both digital verification of serial codes against an industry data management system, and physical authentication of the product and packaging are necessary components for ensuring a secure supply chain.

PICA Corporation:

The key to containing a counterfeiting problem is to monitor and control the secondary market. If the secondary market is flooded with authentic grey market product or sell-off products, consumers and wholesalers are being trained that your product can be routinely obtained on the cheap. This creates a fertile breeding ground for the later introduction of counterfeits.

Baker & McKenzie:[7]

Ideally, a manufacturer would be able to control every stage of the supply chain between the manufacture of the product and its delivery to the end user. Any breaks in the chain allow opportunities for entry of counterfeits. Parallel imports (grey goods) provide a route into the supply chain that can be exploited by counterfeiters, particularly where repackaging of the product is permitted to allow entry into a different market. To this end, the EC Commission's recent consultation on counterfeiting of medicines goes so far as to consider whether a ban on repackaging is needed. Given that counterfeit products have been found in the legitimate supply chain via wholesalers and pharmacies in the UK and elsewhere, a tightening of controls is clearly needed. The use of sophisticated labelling and tracking devices can help, but not if the relevant materials can be removed during repackaging.

Eli Lilly:

Again, the fight against counterfeit medicines must take a multidimensional approach. The existing legal framework should ensure that: (i) drug counterfeiting activity is subject to effective administrative and criminal remedies and deterrent penalties; and (ii) each link in the counterfeiting supply chain is adequately regulated. Distributors, wholesalers, traders, brokers and retailers must be held to the same level of accountability as manufacturers in the handling and shipment of prescription medicines. Certain commercial measures, such as creating authorised wholesalers, or contractual requirements that require wholesalers to purchase only from the approved manufacturer, where appropriate and legal, can add additional protection in the supply chain. Additional measures such as limitations or bans on unauthorised repackaging for resale, can also improve the integrity of the supply chain and prevent the infiltration of counterfeit products.

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[1] Richard Gough and Elisabeth Coffey in Sydney and Paul Rawlinson in London
[2] Joe Simone in Hong Kong
[3] Esther Flesch in Sao Paulo
[4] Kevin O'Brien in Washington DC and Esther Flesch in Sao Paulo
[5] Stephen Jones in London
[6] Kevin O'Brien in Washington DC
[7] Stephen Jones in London

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