

Tackling pharmaceutical crime: initiatives at multinational, EU and national level

Lisa Peets and Victoria Hanley, Covington & Burling LLP

www.practicallaw.com/6-500-9988

With sales of counterfeit pharmaceuticals predicted to increase at nearly twice the rate of sales of legitimate products, it is not surprising that tackling pharmaceutical crime is high on the agendas of both global policymakers and pharmaceutical manufacturers. The US-based Center for Medicine in the Public Interest estimates that in 2010 alone counterfeit medicine commerce will generate US\$75 billion (about EUR51.2 billion) in revenues - a 92% increase from 2005. Worryingly for patients, it is anticipated that many of these counterfeits will come through the legal supply chain.

Against that background, this chapter considers:

- The global trends in pharmaceutical crime.
- Various policy-related initiatives that are being advanced to fight pharmaceutical crime. In particular, this chapter covers:
 - multinational initiatives;
 - initiatives from the EC.
- The responses of policymakers at the multinational, national and industry level to the particular problems raised by the internet.
- New technologies which may assist in tackling pharmaceutical crime.

THE GLOBAL LANDSCAPE

The following trends are apparent in the rise of counterfeit medicines:

- A rise in the number of counterfeit medicines.
- Increasing diversity in the types of medicines counterfeited.
- The role of the internet in aiding the counterfeiters.

These trends have led to new approaches from policymakers (see below, *New approaches from policymakers*).

Rise in counterfeit medicines

The EU's Directorate General for Tax and Customs Union (DG TAXUD) published a report in July 2009 which showed that European customs authorities had detained 126% more goods suspected of infringing IP rights in 2008 than in 2007. This was a rise from 79 million to 178 million articles.

This was replicated in the pharmaceutical sector, with the report demonstrating a 57% increase in the volume of counterfeit and patent-infringing medicines seized. The report identified India as the main source of infringing medicines, followed by Syria, the

United Arab Emirates and the Ukraine. The statistics presented in DG TAXUD's report take into account the 2008 EU-wide *Medi-fake* action, where customs authorities targeted illegal medicines entering the EU, stopping over 32 million medicinal products.

EU statistics are consistent with global trends. The WHO estimates that counterfeit pharmaceuticals represent over 30% of pharmaceuticals in some developing countries. In many of the former Soviet Union countries, for example, the rate of counterfeit pharmaceuticals is estimated to exceed 20%. Counterfeit medicines can also be found in markets that are looked to for best practice policies; for example:

- Between 2005 and 2008, there were at least nine recalls of counterfeit medicines that reached pharmacy and patient level in the UK.
- The US Food and Drug Administration (FDA) opened over 50 cases of counterfeit medical products in 2006.
- In 2006, the Dutch Healthcare inspectorate warned consumers not to buy a particular flu medication through the internet. This was after counterfeit capsules containing lactose and vitamin C and lacking any active substance were found in The Netherlands.

Expansion in types of medicines counterfeited

In the past, counterfeiters restricted their activities to expensive anti-cancer medicines or lifestyle drugs such as Viagra. DG TAXUD's report demonstrated that counterfeiters are now targeting a far wider variety of medicines, however, ranging from:

- Medicines which treat life-threatening conditions, such as malaria, tuberculosis, HIV and AIDS.
- Simple painkillers and antihistamines.

The role of the internet

The internet provides convenience and savings to patients who choose to purchase medicines from legitimate online pharmacies. However, the wide reach and anonymity that it provides have made it possible for counterfeiters and others dealing in illegitimate medicines to reach a global audience quickly, cheaply and with relative impunity. Consumers are often confused as to which offerings are legitimate and which are not.

The World Health Organisation (WHO) estimates that over 50% of medicines purchased over the internet from sites that conceal their physical address are counterfeit. Research by the Royal Pharmaceutical Society of Great Britain (RPSGB) reveals that 2.25 million people buy prescription medicines online; one-third of these medicines are estimated to be counterfeit. Almost 60%

of spam sent via the internet relates to medicines. A recent study by the European Alliance for Access to Safe Medicines (EEASM) found that:

- 62% of medicines purchased online are fake or sub-standard, including medicines indicated to treat serious conditions such as:
 - cardiovascular and respiratory disease;
 - neurological disorders; and
 - mental health conditions.
- 95.6% of online pharmacies researched are operating illegally.
- 94% of websites do not have a named, verifiable pharmacist.
- Over 90% of websites supply prescription-only medicines without a prescription.

The particular problems that the internet and new technologies pose have led to a variety of initiatives (*see below, Initiatives concerning the internet*).

NEW APPROACHES FROM POLICYMAKERS

Faced with these challenges, policymakers have taken varying approaches. Significantly, many of these initiatives reflect a shift from a focus on “counterfeit medicines” to “pharmaceutical crime”. This recognises that the problem is not confined to trade mark infringing medicines but also covers a far broader range of products, including:

- Mislabeled or misidentified medicines.
- Grey market products (that is, legal products supplied through unauthorised distribution channels).
- Medicines diverted from the legitimate supply chain.

This chapter summarises multinational and EC initiatives to fight pharmaceutical crime. Relevant policymakers include:

- The WHO.
- The Council of Europe (COE).
- The EU.
- Certain key countries, such as the US and the UK.

MULTINATIONAL INITIATIVES

The following multinational initiatives are considered:

- The Anti-Counterfeiting Trade Agreement (ACTA).
- The COE’s Convention on Pharmaceutical Crime.
- The WHO’s International Medicinal Products and Anti-Counterfeiting Taskforce (IMPACT).

ACTA

In April 2007, a group of countries began negotiations on ACTA. The US trade negotiators stated that it will represent “a new, state-of-the art agreement to combat counterfeiting and piracy”.

The negotiations now include:

- Australia.
- Canada.
- The EU.
- Japan.
- Korea.
- Mexico.
- Morocco.
- New Zealand.
- Singapore.
- Switzerland.
- The US.

Documentation published by the negotiating parties and stakeholders consultation meeting confirm that ACTA will focus on enforcement measures and not address:

- Substantive law.
- Sector-specific provisions specifically dealing with pharmaceutical crime.

However, ACTA will include mechanisms that pharmaceutical companies can rely on to tackle pharmaceutical crime, particularly in markets whose legal regimes may not be as robust as those in the US or EU. Provisions under discussion include:

- **Civil enforcement.** Negotiations are ongoing over:
 - the definition of adequate damages and how to best quantify damages;
 - remedies, including the circumstances in which infringing goods should be destroyed or disposed of outside the channels of commerce;
 - the extent of national authorities’ powers to order injunctions; and
 - provisional measures, such as the seizure of goods without necessarily hearing both parties.
- **Border measures.** These include provisions:
 - allowing both rights holders and customs authorities to suspend the entry of goods suspected of infringing IP rights at the border, and customs to determine whether the suspended goods infringe those rights;
 - strengthening the position of rights holders in relation to the release, forfeiture and destruction of goods that have been seized;
 - concerning the capacity of competent authorities to require rights holders to provide reasonable security;
 - increasing co-operation between customs authorities and rights holders by permitting customs authorities to disclose to rights holders key information about infringing shipments.

- **Criminal measures.** These include provisions to:
 - criminalise trade in stand-alone labels. This could help pharmaceutical manufacturers to prevent counterfeiters from using these labels to legitimise counterfeit product;
 - clarify the scale of infringement necessary to qualify for criminal sanctions in relation to counterfeiting. However, the European Commission's DG Trade has confirmed that ACTA's criminal enforcement measures will not apply to patent infringement;
 - allow national authorities, in certain circumstances, to take enforcement action *ex officio* (that is, on their own initiative).
- **The internet.** Japan and the US are responsible for drafting ACTA's provisions on IP rights enforcement in the digital environment. The negotiating parties have primarily focused on remedies including those relating to:
 - the circumvention of technological protection measures;
 - the protection of rights management information;
 - third party liability; and
 - infringing material online.
- **International co-operation.** ACTA will seek to improve international co-operation and enforcement practices. However, the negotiating parties have confirmed that ACTA is not intended to bypass the WTO's dispute resolution process. It does not appear that there will be formal arrangements put in place to police compliance with the agreement.

Negotiations will continue in Mexico in January 2010. The negotiating parties intend to conclude the agreement as soon as possible in 2010. However, given that the initial target was to finalise the agreement in 2008, it remains to be seen whether the 2010 deadline will be achieved.

The COE Convention on Pharmaceutical Crime

The Council of Europe (COE) brings together 47 countries with the aim of developing common principles based primarily on the European Convention on Human Rights. The COE has been working, since 2006, on a proposal for an international agreement to facilitate co-operation among its member states in combating pharmaceutical crime.

In February 2009, a COE-organised group of specialists on counterfeit pharmaceutical products published a first draft, entitled the Draft Convention of the Council of Europe on counterfeiting medical products and similar crimes involving threats to public health (Draft Convention).

As currently drafted, the Draft Convention seeks to tackle pharmaceutical crime in general, not just counterfeit pharmaceuticals. It applies to:

- Medicinal products.
- The ingredients or components of medicinal products.
- Medical devices.

The Draft Convention seeks to prevent and combat threats to public health by:

- Introducing new offences and related criminal sanctions.
- Protecting the rights of victims of those offences.
- Promoting national and international co-operation.

It also provides for a dedicated monitoring mechanism to ensure the Convention is implemented in an effective manner.

The Draft Convention criminalises the following acts, if committed intentionally:

- The manufacturing of counterfeit medical products, including their adulteration.
- The falsifying of any document related to a medical product.
- The supplying or offering to supply counterfeit medical products.
- The promotion of counterfeit medical products.
- Illicit trafficking in counterfeit medical products.

The Draft Convention also renders it a criminal offence to intentionally possess a counterfeit medical product or related documents for the purpose of committing any of the above offences. In addition, it requires member states to establish corporate liability (civil, criminal or administrative) for these offences. They have discretion whether to criminalise attempts to commit these offences.

Member states must introduce measures to ensure that criminal and/or other sanctions are applied to those manufacturing or supplying non-counterfeit medical products that have not been authorised by or are in breach of their rules.

Any criminal sanctions that the member states introduce should:

- Be effective, proportionate and dissuasive.
- Include penalties involving the deprivation of liberty that may give rise to extradition.
- Take into account any aggravating circumstances, such as whether the offence:
 - caused death or damage to the physical or mental health of the victim;
 - was committed by persons in a position of confidence; or
 - was committed by several people acting together or in the framework of a criminal organisation.

Sanctions for corporate liability may include:

- Fines.
- Temporary or permanent disqualification from exercising commercial activity.
- Placing under judicial supervision.
- A judicial winding-up order.

The Draft Convention also requires member states to provide for the:

- Destruction of any medical products resulting from the criminal offences established under the Draft Convention.
- Seizure and confiscation of items used to commit the offences or any proceeds.
- Total or partial closure of any establishments used to commit the offences.

The Draft Convention requires member states to introduce other measures to promote enforcement, including to:

- Provide adequate resources, information-exchange mechanisms and co-ordination among the relevant authorities in the investigation of offences established by the Draft Convention (*see above*).
- Take preventative measures, such as:
 - establishing standards for the manufacture and supply of medical products;
 - introducing tracking systems;
 - implementing public awareness campaigns;
 - training healthcare professionals, providers, police, customs authorities and regulatory authorities; and
 - developing agreements with internet service providers (ISPs) and domain name registrars to facilitate action against websites illegally promoting or supplying counterfeit medical products.

The European Committee on Crime Problems (CDPC) adopted the Convention on 16 October 2009. The text will now be considered by the Parliamentary Assembly and the Committee of Ministers. An established Convention text is expected to be ready for signature by February 2010. Five signatories are necessary, including three COE member states, for the Convention to enter into force. The Convention will then bind the states that proceed to ratify the agreement.

The COE is also working with the IMPACT group to review the responsibilities of stakeholders in the distribution chain, such as ISPs and other service providers (*see below, IMPACT*).

IMPACT

In 2006, the WHO established IMPACT to mobilise awareness in the fight against fake medicines. All 193 WHO member states participate in IMPACT on a voluntary basis. IMPACT brings together:

- International organisations.
- Enforcement agencies.
- National medicine regulatory authorities.
- Customs and police organisations.
- Non-governmental organisations.
- Associations representing:
 - pharmaceutical manufacturers and wholesalers;
 - health professionals; and
 - patients' groups.

IMPACT's immediate goal is to:

- Eradicate all counterfeit medical products from developed world supply chains.
- Reduce counterfeit medical products by two-thirds in the developing world by 2020.

IMPACT's five key areas of focus are:

- Legislative and regulatory infrastructure.
- Regulatory implementation.
- Enforcement.
- Technology.
- Communication.

A hotly debated topic (inside and outside the WHO) has been the revised definition of a "counterfeit medical product". Currently, the WHO definition is confined to medicines "deliberately and fraudulently mislabelled with respect to identity and/or source...". As an initial step, the IMPACT group has sought to improve and expand the WHO's definition to capture all medical products (not just medicines).

The IMPACT Group's proposed revised definition is as follows:

"The term counterfeit medical product describes a product with a false representation of its identity and/or source. This applies to the product, its container or other packaging or labelling information. Counterfeiting can apply to both branded and generic products. Counterfeits may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging."

The definition also makes express what is not covered by the definition of counterfeit medical products:

- Violations or disputes concerning patents.
- Medical products (whether generic or branded) that are not authorised for marketing in a given country but authorised elsewhere.
- Substandard batches of, or quality defects or non-compliance with good manufacturing practices/good distribution practices (GMP/GDP) in legitimate medical products.

The revised definition, like the existing definition, makes clear that the primary characteristic of counterfeiting is consumer deception as to "identity and/or source". This deception can (and often does) occur even in the absence of a trade mark infringement (although these infringements remain an important subset of counterfeit medical products because their essence is consumer deception).

IMPACT has achieved substantial consensus around the revised definition. However, it has encountered opposition from Brazil, India and other developing countries. They fear that it could be used to limit parallel trade and access to generic medicines. This is despite the explicit disclaimers in the definition's explanatory text to the contrary. In addition, given the WHO's current focus on the swine flu pandemic, further consideration has

been delayed until at least 2010. IMPACT is also discussing other definitions including those that identify the:

- Manufacturer.
- Operator in the distribution chain.
- Other operators involved.
- Retailer.

IMPACT plans future initiatives covering:

- A review of strategies regarding the exportation of pharmaceuticals.
- Adapting pharmacovigilance systems for counterfeit reporting.
- Updating the 1999 WHO guidelines on measures to combat counterfeit drugs.

IMPACT is also working to prepare a guidance to combat internet trade of counterfeit medical products (*see below, Initiatives concerning the internet: IMPACT's internet guidance*).

EC INITIATIVES

Recent months have seen a flurry of activity in Brussels resulting in a concerted effort to tackle pharmaceutical crime, from the following institutions:

- The European Parliament. In November 2008, the Parliament adopted a report on the impact of counterfeiting. Although not specifically concerning pharmaceuticals, the report:
 - acknowledges the increase in the counterfeiting of medicines;
 - recognises that combating pharmaceutical crime is an EC priority;
 - expresses support for the WHO definition of a counterfeit medical product.

Worryingly, the Report calls for a distinction to be drawn between generic medicines and counterfeit medicines. This may potentially mislead by implying that generic medicines cannot be counterfeited.

- The European Commission (Commission) and its Directorate Generals of:
 - Taxation and Customs Union (DG TAXUD);
 - Enterprise and Industry;
 - Internal Market (DG MARKT);
 - Trade;
 - Justice, Freedom and Security (DG JLS).

The Commission has made various proposals, including:

- a proposed Directive amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source (*COM(2008)668, 10 December 2008*) (Proposed Falsified Medicines Directive);

- an EC Customs Action Plan to Combat IPR Infringements 2009-2012 (EC Customs Action Plan);
- a review of Regulation 1383/2003/EC (Border Control Regulation);
- the potential re-opening of Directive 2004/48/EC on the enforcement of intellectual property rights (IP Rights Enforcement Directive);
- various non-legislative initiatives.

These initiatives are described in turn below.

Proposed Falsified Medicines Directive

The Proposed Falsified Medicines Directive (which forms part of three proposals introduced in the Commission's update of the "Pharmaceutical Package" adopted in December 2008) seeks to amend existing EC legislation aimed at preventing the entry into the legal supply chain of falsified medicinal products destined for human use. It proposes a harmonised European response to deal with pharmaceutical crime and the severe threat it poses to public health.

The key changes include:

- **Obligatory harmonised pan-European safety features for prescription-only medicinal products.** This concerns the requirement that medicinal product packaging include safety features that make it possible to identify, authenticate and trace medicinal products. The scheme contemplates a risk-based approach; the implementation of safety features would:
 - be prioritised according to the threat a medicinal product presents to patients or other users' health and safety;
 - adapt to changing risk-profiles in response to evolving counterfeiting activities.

After the Directive's adoption, the Commission will enter into a comitology procedure with committees of representatives of member states. This procedure will result in detailed implementing measures and the precise safety features to be required.

The proposal also contemplates pharmacists and wholesale distributors being able to verify the authenticity of medicinal products by, among other things, assessing these mandatory "overt, covert or forensic devices."

- **Responsibility and liability for repackagers.** The Commission originally proposed a ban on repackaging. This was seen as an attempt to ban parallel trade in medicines, and encountered resistance, particularly from DG MARKT and some member states.

The Commission's final proposal allows repackagers to partially or fully remove, or cover-up safety features, provided that the:

- authenticity of the product is verified;
- safety feature is replaced with an equivalent safety feature, without opening the immediate packaging; and
- competent authority supervises the replacement.

This is intended to enable parallel importers to make necessary changes to comply with rules in different member states (such changes to outer labelling, pack sizes, or inclusion of leaflets in the local language) while ensuring safety features put in place to protect patients are present throughout the supply chain.

The Commission also proposes to make “manufacturing authorisation holders” generally responsible for any damage caused by products whose identity is falsified, unless they can prove that the defect arose further down the distribution chain.

- **Obligatory audits and strengthened inspections.** To strengthen the legitimate supply chain, the proposal introduces:
 - obligatory audits of wholesale distributors;
 - audits of manufacturers of active pharmaceutical ingredients (APIs) and strengthened requirements on the import of APIs from third countries. This is as a result of medicines found to contain counterfeit APIs;
 - stricter rules for inspections; and
 - increased transparency through the publication of inspection results.
- **Effective sanctions.** Member states must impose “effective, proportionate and dissuasive” penalties for infringements of national provisions that implement the Directive.

The Parliament, Council and industry stakeholders have called for three further elements to be added to strengthen the Commission’s proposal:

- **Inclusion of a deadline for the completion of the comitology procedure.** This is to avoid the risk of patients being denied the protection envisaged under the proposed regime if the procedure is not completed in a timely manner.
- **Inclusion of a definition of a “falsified medicine”.** The majority of member states support the introduction of a definition, but as with the IMPACT initiative, there is disagreement (see above, *Multinational initiatives: IMPACT*). Some member states support using the current WHO definition (as opposed to the wider definition proposed by the IMPACT group). Others prefer one based on the COE’s definition, or one which could be refined in the comitology procedure.
- **Provisions addressing falsified medicines sold over the internet.** Currently, individual member states are left to determine how to address this major threat to public health. Harmonised principles at EC level will introduce more robust patient protection.

Before implementation of the Directive into national law, the Parliament and Council will first review the Commission’s proposal under the co-decision procedure. The new legislation is expected to come into force in the second half of 2010.

Customs Action Plan

In March 2009, the Council of the EU adopted a resolution endorsing the Customs Action Plan, intended to combat infringements of IP rights. It identifies four main counterfeiting challenges:

- Dangerous counterfeit goods.

- Organised crime.
- The globalisation of counterfeiting.
- The sale of counterfeits over the internet.

DG TAXUD and the member states will implement the Customs Action Plan. It contains the following initiatives:

- A review of the EC legislation establishing the border control rules relating to counterfeits, the Border Control Regulation, and the relevant implementing provisions included in Regulation 1891/2004/EC (see below, *Border Control Regulation*).
- The development and introduction of a database for recording customs seizures and related statistics.
- The organisation of pan-European activities specifically focused on dangerous products, such as pharmaceuticals, representing the highest risks to the:
 - health and safety of consumers; and
 - environment.
- The creation of a working group of experts to examine the growing problem of trade in counterfeit goods via the internet. Among other initiatives, the group will:
 - seek to promote co-operation between the member states on this issue;
 - organise seminars for customs and stakeholders with a special emphasis on identifying best practices in this area.
- The promotion of agreements between right holders and other stakeholders (such as ISPs) intended to facilitate:
 - co-operation;
 - the exchange of information.
- Training for enforcement officials and rights holders.
- Support for EC-China customs co-operation and to enhance co-operation with other key partners such as Japan (see below, *Non-legislative initiatives*).
- Campaigns to better communicate the results achieved by customs in the IP rights area. This is to raise consumer awareness of the risk associated with purchasing counterfeit goods (including pharmaceuticals), specifically in relation to internet sales.

Review of the Border Control Regulation

The Commission’s review of the Border Control Regulation and relevant implementing provisions is aimed at clarifying and harmonising the application of the customs rules across the member states. To this end, DG TAXUD is currently undertaking an internal review that will result in a proposal to be submitted to the Council.

There is no fixed timetable for the review and no formal public consultation is planned. However, DG TAXUD has asked relevant stakeholders to provide input and welcomes ideas from those with whom it has not already informally consulted. On completion of the review, a proposal to modify EC customs legislation in accordance with the findings will be submitted to the Council.

The issues DG TAXUD is considering include:

- **The Regulation's application to the transshipment of goods.** The preliminary ruling by the European Court of Justice (ECJ) concerning the interpretation of Directive 89/104/EC as updated (Trademark Directive) in the case of *Montex (Case C-281/05)* has cast doubt on whether rights holders can rely on the Border Control Regulation to detain IP right-protected goods that are merely transported through the EU. The UK Court of Appeal and the Belgian Court in Antwerp are both poised to refer questions to the ECJ on this point. The ECJ's consideration of this question should provide clarity for rights holders following its preliminary ruling proceedings; however it may also delay the Commission's review as the average duration of such proceedings in 2008 was over 16 months and can be considerably longer.
- **The simplified procedure.** DG TAXUD is considering the Regulation's rules under which EU member states can set up a simplified procedure enabling the customs authorities to have seized goods destroyed without the need to determine whether an IP right has been infringed under national law (*Article 11, Regulation*). The simplified procedure is subject to:
 - the IP right holder's agreeing to its use;
 - the right holder informing the customs authorities that the goods infringe an IP right;
 - the person completing the customs declaration (declarant), the holder or the owner of the goods agreeing to destruction; and
 - the destruction being carried out at the expense and under the responsibility of the right holder.

In June 2009, the UK customs authorities published a letter stating that they intended to revise their policy in this area by implementing a simplified procedure, to bring UK practice fully in line with the Regulation. This represents a dramatic change in the UK approach which will make it more difficult for pharmaceutical rights owners and others to stop counterfeit and diverted shipments into the UK. (Until that time, UK practice had been to seize items based on a witness statement from the right holder as confirmation that the goods are infringing that could then be later challenged by the owner through judicial proceedings. Now, however, the right holder must confirm the infringing nature of the goods by filing legal proceedings, ordinarily within ten (or, at the latest, 20) working days of the rights holder receiving notification of detention of the allegedly infringing goods.)

It is not clear, at this stage, how the Commission's review will affect the procedure in other member states.

- **Grey market goods.** DG TAXUD is discussing the possible extension of the scope of the Border Control Regulation to cover parallel imports, which are currently excluded from the Regulation's scope. The Regulation currently does not apply to:
 - parallel goods imported into the EU;
 - goods manufactured under conditions different from those agreed to by the right holder; and

- goods contained in travellers' personal luggage.

There are also limits to the types of actions that legitimately fall under the Regulation. For example, breach of contract issues generally do not justify grant of a border detention order.

Potential re-opening of the IP Rights Enforcement Directive

The IP Rights Enforcement Directive harmonises the rules for the civil enforcement of IP rights across the EU, including provisions relating to:

- The preservation of evidence.
- Search and seizure orders.
- Injunctions.
- Damage awards.

Member states had to submit a report on the Directive's implementation to the Commission by April 2009. DG MARKT is currently drawing up a report on the effectiveness of measures taken by member states to be shared with the Parliament and Council. If necessary, it will follow this report with proposals to amend the Directive itself.

Due to the late implementation of the Directive by a number of member states, however, the Commission is still awaiting receipt of some national reports. DG MARKT expects to complete its implementation report in the first quarter of 2010, followed by a second report evaluating of the Directive's impact on innovation and the development of the information society in 2011. On the basis of these reports, the Commission will then decide whether or not to propose amendments to the Directive.

While the civil enforcement rules are harmonised in the EU, the criminal rules are defined at national level. To address this gap, in 2005, DG JLS adopted proposals to supplement the Directive with harmonised criminal rules concerning IP infringement. This includes:

- Making it a criminal offence EU-wide to:
 - intentionally infringe IP rights on a commercial scale; or
 - attempt, aid, abet or incite such an infringement.
- In relation to pharmaceutical crime, increased fines and extended powers of confiscation for offences that carry a health and safety risk.

Many stakeholders (particularly the member states) have criticised the proposals, questioning the Commission's competence to initiate legislation concerning criminal enforcement. At the end of 2005, the ECJ passed judgment in *Commission v Council (Case C-176/03)*. The ECJ stated that the Commission can propose legislation requiring the criminalisation of certain acts, but cannot establish criminal penalties in any degree of detail. The controversy surrounding the Commission's proposal later led to its withdrawal.

The Commission has recently indicated that it will revive the draft legislation. If it does, it could provide pharmaceutical manufacturers with an opportunity to enhance the tools available EU-wide to tackle pharmaceutical counterfeiting.

Non-legislative initiatives

These include:

- **EU-China customs co-operation.** DG TAXUD's report identifies China as being the primary source of counterfeit goods detained by EU customs in 2008. In an effort to tackle this problem, on 30 January 2009, the EC signed an agreement with China to develop a customs action plan on IP rights enforcement. The plan will concentrate on four areas:
 - the exchange of statistical information;
 - the creation of a network of customs experts in key ports;
 - the enhancement of co-operation with other enforcement administrations; and
 - the development of partnerships with business communities.
- **The European Observatory on counterfeiting and piracy (European Observatory) and enhancement of the enforcement of IP rights.** In 2008, the European Council asked the Commission to create a European Observatory. The Observatory was launched in 2009 with the principal aims of:
 - improving the available statistics relating to counterfeiting and piracy in the internal market;
 - identifying and disseminating best practice strategies and enforcement techniques; and
 - helping to raise public awareness.
- **DG MARKT co-ordinates the Observatory.** It brings together policymakers and experts from the:
 - EU member states;
 - industry representatives; and
 - consumer organisations.

The Observatory's efforts should enable policymakers to better understand trends in pharmaceutical counterfeiting, helping to shape future legislative responses and enforcement efforts.

The launch of the Observatory was followed in September 2009 by a Commission Communication on enhancing IP enforcement, focused on non-legislative measures to support the EU's existing regulatory framework. The specific measures proposed include:

- fostering administrative co-operation across member states; and
- promoting voluntary arrangements between stakeholders.

Among other things, the Commission has offered to act as a facilitator for a stakeholder dialogue on the sale of counterfeit goods over the internet. This dialogue, which is already underway, may lead to a memorandum of understanding dealing with prevention, identification and removal of infringing offers. If voluntary arrangements cannot be agreed in this respect the Commission will consider legislative solutions.

INITIATIVES CONCERNING THE INTERNET

Policymakers, medical authorities and industry are well aware of the need to take action against the growing impact of the internet on pharmaceutical crime (*see above, The global landscape: The role of the internet*). Initiatives are underway at international and national level, such as:

- IMPACT's proposed internet guidance.
- RPSGB's internet pharmacy logo scheme.
- The accreditation programme of the US Verified Internet Pharmacy Practice Sites (VIPPS).
- The upcoming Anti-Counterfeiting Strategy of the UK's Medicines and Healthcare Products Regulatory Agency (MHRA).
- Proposals of the European Parliament.

IMPACT's internet guidance

This is intended to combat the internet trade of counterfeit medical products, specifically:

- The legal framework governing internet trade of counterfeits.
- The legal responsibilities of ISPs.
- Regulatory aspects of advertisement and sale of medical products through the internet.
- Investigation, identification and prosecution of illegal sites and activities.
- Monitoring the internet to collect information on practices to build appropriate advocacy and information activities and campaigns.
- Developing and implementing a communications strategy to warn internet users about the risks of purchasing medical products from unknown and unreliable sources.

The group also plans to develop consumer education campaigns to warn consumers of the potential risks of buying medical products online. A draft text is due to be circulated for comment.

RPSGB's internet pharmacy logo scheme

Some pharmaceutical societies have launched online logo schemes to aid patients in verifying the legitimacy of online pharmacies. For example, the RPSGB has introduced a logo which is displayed on the front page of participating online pharmacy sites. It allows patients to identify whether a website offering to sell medicines or provide other pharmacy services is connected to a registered pharmacy. Each logo includes a pharmacy premises registration number, which is unique to that pharmacy. By clicking on the logo visitors are linked to a page on the RPSGB website where they can verify that the site of their intended purchase is that of a registered pharmacy. If a pharmacy is registered with the RPSGB, a patient knows that the pharmacists and technicians should comply with the high standards of conduct, practice and performance laid down in the RPSGB's code of ethics, including the professional responsibilities set out for those involved in the sale and supply of medicines via the internet.

VIPPS' accreditation programme

VIPPS is an information and verification site operated by the National Association of Boards of Pharmacy. Similarly to the UK system, before being permitted to display the VIPPS hyperlink system, the pharmacy must comply with the licensing and survey requirements of:

- Their state.
- Each state to which they dispense pharmaceuticals.

In addition, pharmacies displaying the VIPPS seal have demonstrated compliance with criteria that can reassure patients in making online purchases, including:

- Patient rights to privacy.
- Authentication and security of prescription orders.
- Adherence to a recognised quality assurance policy.
- Provision of meaningful consultation between patients and pharmacists.

MHRA's upcoming anti-counterfeiting strategy

The UK's MHRA is also taking steps to tackle online distribution of counterfeit medicines. Among other things, the MHRA employs specialist internet investigators to monitor products that are on the MHRA's "watch list" and take action as appropriate. This is part of a broader, formal MHRA anti-counterfeiting strategy, which encompasses:

- Intelligence gathering.
- Communication to both the public and healthcare professionals.
- Collaboration with international and domestic stakeholders, including government officials and industry.

The MHRA is currently updating this strategy.

Through its "Internet Days of Action" programme, the MHRA has showcased its online enforcement activities to other European medicines agencies to raise awareness of the increased risk of obtaining substandard medicines from unlicensed websites.

European institutions

Members of the European Parliament have identified the internet as the main point of entry for counterfeit medicines into the EU's legal supply chain and have formally asked the Commission how it will protect Europe's consumers. Among other things, MEPs have proposed certifying internet websites as a way of hindering illegal internet trade.

The Commission considers that its opportunities for preventive action are limited by divergent national rules governing the distance-sale of prescription medicines; some member states have chosen to prohibit such sales while others permit sales under differing conditions. The Commission has, therefore, taken the view that this is a task for member states and points to actions taken at a national level including in Germany and the UK (*see above*).

NEW TECHNOLOGIES

A variety of long-standing and newly emerging technologies also offer useful solutions to tackling pharmaceutical crime. These technologies include:

- More traditional solutions such as:
 - stickers;
 - holograms,
 - radio frequency identification (RFID); and
 - 2-D Bar codes.
- Emerging nanotechnologies that, for example, allow the authentication and tracing of medicinal products at the level of individual dosage forms (the capsule, tablet or tamper-evident packaging of liquids).

Such technologies can also assist in identifying fake medicinal products that are packaged in genuine packaging or expired products that can pose health and safety risks to patients.

The Commission's proposal on falsified medicines (*see above, EC initiatives: Proposed Falsified Medicines Directive*) requires that medicinal product packaging include safety features that make it possible to ascertain the identity, authenticity and traceability of the product. This will doubtless push some of these solutions to the foreground of the fight against pharmaceutical crime.

THE OPPORTUNITIES TO TACKLE PHARMACEUTICAL CRIME

Pharmaceutical crime continues to ascend the global political agenda, with efforts to address the problem being taken at international, regional and national levels. As a result, industry has a broad variety of opportunities to promote regulatory and enforcement regimes that will minimise pharmaceutical crime and protect the health of the world's population.

CONTRIBUTOR DETAILS

Lisa Peets and Victoria Hanley

Covington & Burling LLP

T +44 20 7067 2031

+32 2 549 5239

F +44 20 7067 2222

+32 2 549 1039

E lpeets@cov.com

vhanley@cov.com

W www.cov.com