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Combatting illegal pharma trade

Combatting black and grey markets for the pharmaceutical industry



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What's the challenge?

Focus I: International black market trade

Among the industries that suffer most from black and grey market activities, the pharmaceutical sector sadly holds one of the top positions. The World Health Organization (WHO) estimated the annual damage resulting from trade in counterfeit pharmaceuticals at approximately 75,000,000,000 Euro.

On a global scope today's illegal pharma trade is largely operated via the Internet. The WHO estimates that more than every second medical product sold online is a counterfeit. The anonymity of the Internet and the fact that perpetrators regularly operate from countries with weaker rights enforcement-, mechanisms makes it even harder to effectively fight black market trade.

Focus II: Grey market activities

Besides combatting conventional counterfeiting, the pharmaceutical industry has to cope with another related issue: illegal grey market trade in original products.

In this context, manufacturers must, on the one hand, identify and stop operations which bypass regulations on international parallel imports and parallel distributions. On the other hand, unlawful practices which infringe domestic, drug-related provisions, such as pricing or labeling provisions, can also significantly damage the legitimate business of pharmaceutical manufacturers, and therefore have to be eradicated.



One-Stop-Shop

Whatever the infringement scenario, EFFICIENCY and EFFECTIVENESS are the key elements behind any meaningful enforcement activity. How the best possible results can be achieved with the least possible investment of corporate time and money is predetermined by a few vital decisions:

- Which infringements are worth pursuing?
- Where is the best place to take action?
- What is the best enforcement procedure: out-of-court, civil, criminal, customs or online enforcement?
- Is the information up-to-date or is further evidence required?
- Are multiple procedures aligned and do they fit into the overall strategy?

In order to allow you to fight grey and black markets as effectively and economically as possible, our strategy is based on a one-stop-shop-approach, that considers product piracy issues from every relevant angle. In a nutshell, we help pharmaceutical companies with taking the right steps for **fighting product piracy**.

In all its manifestations

- Counterfeits and lookalikes
- Illegal third party trade in original products (non-exhausted rights to trademarks, patents, etc., and violations against other distribution restrictions, such as pricing regulations)
- National trade and cross-border activities (reimports, parallel imports, parallel distributions)
- Stationary trading and online retailing (e.g. rogue internet pharmacies)

By all available means

- Enforcement of civil law claims (in and out of court)
- Capitalizing on the criminal and customs authorities for investigative and enforcement measures (filing criminal complaints, examining suspects and witnesses, performing raids and seizures)
- Getting regulatory/supervisory authorities and the relevant professional association involved

Think outside the box

Having in place a comprehensive solution for fighting grey and black market activities also includes the ability to spot where stereotype enforcement actions are less promising. For us, this particularly means:

Where you cannot hit perpetrators directly, target their business by proceeding against their service providers and cohorts

It is not unusual to be aware of an infringement but to not know the perpetrator or those who pull the strings in the background. Especially in cases of illegal trade via the Internet, this is an enormous problem that has to be faced when planning enforcement measures. One key to overcome this problem is identifying the services upon which the perpetrators' illegal business relies and depends. Easily identifiable services of this kind might often be Internet providers that host the perpetrator's illegal online presence, or payment service providers which keep the perpetrator's cash flow going. Including these parties in your enforcement plan can generate information about the backers which will be your primary targets. It can also directly damage the perpetrators' illegal activities by eliminating the technical and financial infrastructure behind them.

Where your investigations are less effective or practical, consider outsourcing forensic work to the authorities

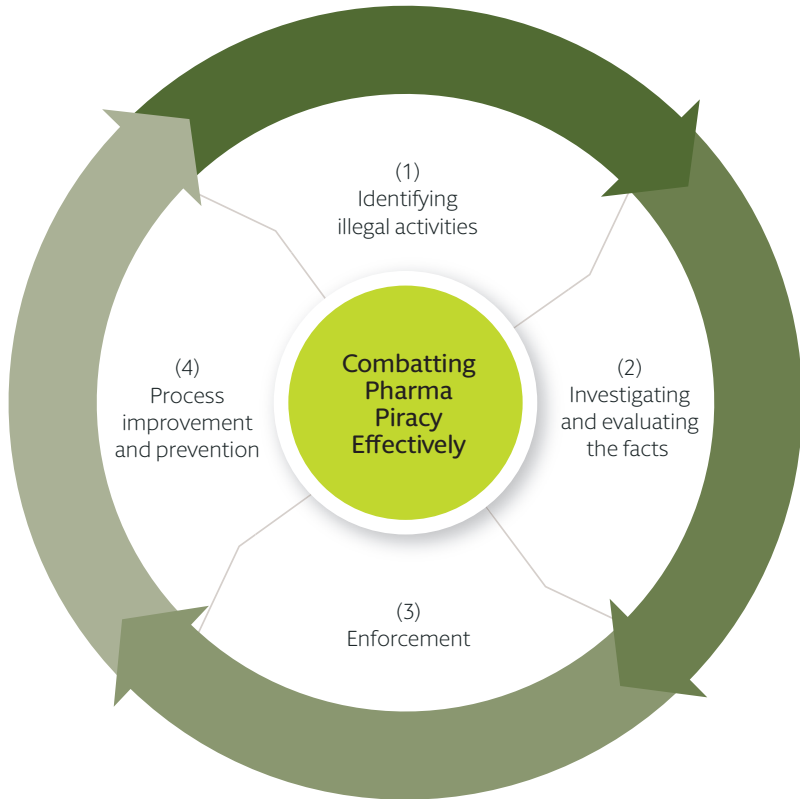
In almost every case, illegal trade in pharmaceuticals is subject to criminal charges. Thus, we can make use of the criminal authorities and their resources. Involving these prosecution agencies can be an important trump card in many ways: Having the support of the police when examining a case, of course, reduces the resources you have to put into investigations. Beyond that, the criminal authorities can take action – interviewing suspects and witnesses, performing raids or tracing and seizing assets – which may not be achievable through other means of enforcement. Last but not least, assistance by the prosecution agencies can provide a key time advantage wherever illegal trade poses imminent threat to your corporate assets or the safety of customers. In such cases, criminal enforcement can deliver the necessary immediate results – raids and seizures often can be carried out within hours after filing the initial criminal complaint.

No enforcement strategy would be fully functional, if it did not make use of the most advanced information technology

Technology practically plays a role in every aspect of enforcement work. Data we can make use of for our enforcement work, is literally everywhere. However, a major task is screening and filtering information to avoid drowning in a data overload. With this in mind, our IT-solutions help us firstly to collect just the right data and evidence needed for identifying infringements. Then we prioritize entry and classification of all information relevant to the infringement according to certain categories (infringement types, infringers, infringing patterns and/or locations) to enable a prioritization of further enforcement action. In this context, choosing a specific database program is less relevant than having a good system for analyzing and categorizing the information obtained.



Fighting illegal trade in four steps



Knowing the backgrounds and the sources of piracy activities significantly enhances our chances to tackle the problem at its root. Thus, any effective strategy for combatting illegal trade in pharmaceuticals has to start with tracing (1) and clarifying the relevant facts and circumstances (2) as early as possible. Building on this initial fact-finding-stage, your strategy should include a systematical prosecution of detected infringements (3). Infringers commonly tend to look for "easier victims", the harder and more rigorously your enforcement work hits them. In many cases, implementing the aforementioned steps can reveal existing weak points – potential gateways for product piracy – within one's own corporate organization. Knowing and optimally eliminating such weaknesses again often allows you to track and counter future infringements even at an earlier stage (4).



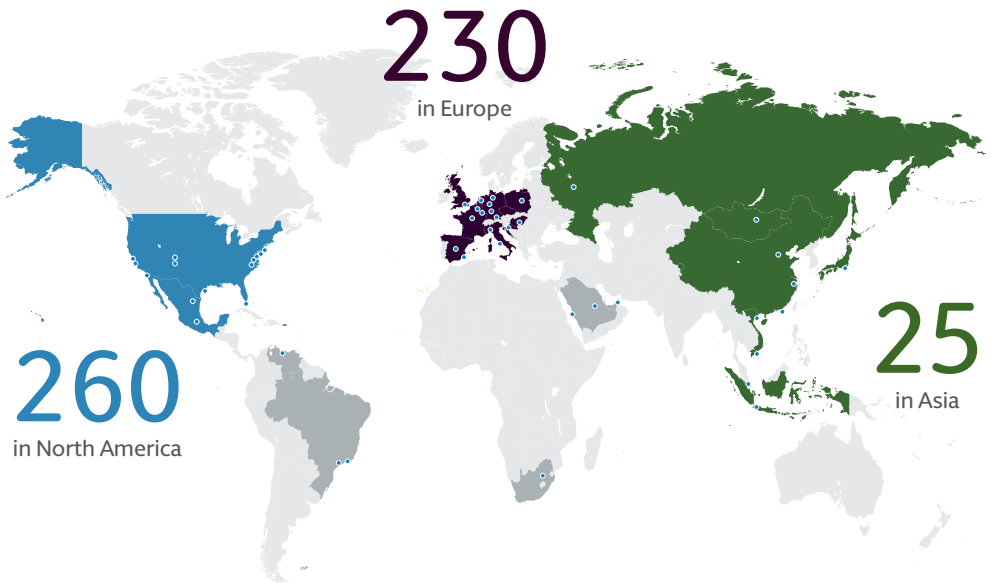
Our network

Local Roots, Global Reach

With more than 500 life sciences lawyers across the globe, we work closely with you and each other to tackle tough issues and difficult-to-enter markets – no matter where you are today or want to be tomorrow. Because we know what makes your industry tick, we have a deep understanding of the issues you face – helping you stay ahead of the curve and on top of your opportunities.

Whatever your challenge, wherever the issue, Hogan Lovells has you covered. It's that easy.

Over 500 life sciences practitioners worldwide



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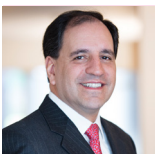
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