

Bad Medicine: Lessons from an Enduring Alliance between Big Pharma and Global Policing

The challenges of tackling international crime with national law enforcement are legion. John Binns, partner in the Financial Crime team at BCL Solicitors considers how Interpol's Operation Pangea illustrates how they can be overcome, in the context of the global fight against illicit medicines.

A World of Problems

What can be done about the sale of illicit medicines? The question illustrates a familiar challenge in the world of law enforcement, in that a problem we as consumers and taxpayers can see as straightforwardly needing tough and enduring action is made harder to solve by two fundamental features of the landscape.

The first of these is legal complexity. The trade in counterfeit and otherwise illicit medicines can be categorised in various ways from a legal perspective, broadly depending on the nature of the harms that are involved. Even where the law clearly provides remedies against conduct, which may result from a combination of civil and criminal law, the overlapping provisions and procedures can be unhelpful.

Controlled Drugs

In the UK, and indeed in most jurisdictions, the starting point for tackling many illicit sales of pharmaceutical products will be controlled drugs offences. The Single Convention on Narcotic Drugs 1953 provides the international framework, while the Misuse of Drugs Act 1971 and its schedules set the domestic framework for prohibited acts and the classification of various substances, with various regulations made under it providing the detailed rules. Where the actions of an illicit trader in medicines constitute prohibited actions under that legislation and are not covered, or insufficiently covered, by licences granted under those regulations, criminal investigation and prosecution may be both possible and appropriate.

Counterfeit Medicines

With respect to counterfeit medicines, these may breach intellectual property

laws, specifically in connection with the infringement of patents (under the Copyright Designs and Patents Act 1988) and the unauthorised use of trademarks (under the Trade Marks Act 1994), which can be enforced using either civil law routes, litigation in the High Court) or criminal law (prosecution in the magistrates' courts or Crown Court.

Significantly, the availability of these two routes of enforcement does not entirely depend on who is doing the enforcing. Increasingly, private companies opt to bring private prosecutions in UK criminal courts against those identified as breaching criminal provisions of intellectual property law. While civil litigation may result in substantial damages and payment of costs by the losing party, and involve the lower evidential standard of civil proceedings, 'the balance of probabilities', as opposed to the criminal standard of 'beyond reasonable doubt', there is substantial deterrent value in obtaining a criminal conviction, with all that implies in terms of the offender's reputation and, in and insofar as individuals rather than corporate defendants can be proved responsible, the threat of imprisonment.

Proceeds of Crime

A significant factor in the growth of private prosecutions in the UK has been the availability of confiscation procedures under the Proceeds of Crime Act 2002 (POCA), under which a convicted defendant can be ordered to pay sums that are equivalent to their benefit from criminal conduct, which in many cases are far in excess of their actual profits from the activity.

Meanwhile, state agencies – including, in the pharmaceutical conduct, the Medicines and Healthcare products Regulatory Agency (MHRA), can now use different provisions of POCA to pursue the proceeds of unlawful conduct (whether that conduct took place in- or outside the UK) without a criminal conviction. Recent changes to those provisions enable a relatively easy route to summary freezing and forfeiture of such proceeds in the magistrates' courts where they are represented by funds in bank or building society accounts, which the MHRA have used to pursue alleged proceeds of online sales of prescription-only medicines.

The provisions of POCA relating to money laundering may also be engaged where there are proceeds of conduct that breaches UK law, or overseas conduct that would do so if it occurred here. In a pharmaceutical context, this has proven problematic in the context of sales of medicinal cannabis, which are, at least arguably, 'criminal conduct' for these purposes.

Consumer Protection

As well as the societal harms that underpin controlled drugs legislation, and the protection for private rights afforded by intellectual property laws, the sale of illicit drugs can engage various laws aimed at protecting the consumer from deception or various other forms of unfair trading. The Fraud Act 2006 prohibits, among other things, the use of active deception (or, in some circumstances, the failure to disclose relevant information) as a means to extract a gain from someone, while the Consumer Protection from Unfair Trading Regulations 2008 (CPUTR), generally enforced in the UK by trading standards departments of local councils, contain specific prohibitions on, among other things, selling medicines based on untrue claims as to their efficacy.

On top of all of that, there are specific provisions that establish bespoke regimes for medicines, including natural and homeopathic remedies, under the Human Medicines Regulations 2012 (the HMRs). Significantly, having previously derived many of these specific rules from EU law, post-Brexit, the UK government can make, amend, and repeal regulations under the Medicines and Medical Devices Act 2012 (the MMDA), which also establishes a civil penalty regime for offences involving medical devices.

Picking Up the Pieces

The second fundamental, and often unhelpful, feature of the law enforcement landscape is the contrast between its international nature and the significance of national borders – a challenge that the MHRA has also taken an effective lead in this sector in overcoming. As is increasingly obvious, the nature of financial crime, of which illicit medicine sales are a prime example, is global, which positively demands that



local, national, and regional agencies join forces to share information and coordinate enforcement efforts.

A Joined-up Approach

We do not, and indeed may never, have such a thing as a global police force. Instead, the role of Interpol is to help coordinate the efforts of national and supranational law enforcement agencies. Since 2006, the MHRA has worked with Interpol and various other agencies, including the EU's Europol, to tackle illicit medicines and medical devices. This includes concerted days or weeks of action against suspected offenders and their assets, which are then publicly announced, most recently this summer. Under the surface, the work to produce this undeniably impressive feat is essentially about tackling those twin challenges of legal complexity and working across national borders. Among other things, this will necessarily involve consideration of data protection and procedural rights for suspects and others involved.

Importantly, the agencies involved are not limited to public-sector regulators and law enforcement. They also include private companies, whose financial interests of course are engaged in a big way, insofar as counterfeit medicines breach their intellectual property rights. Indeed, more broadly, the profits and reputation of the pharmaceutical sector generally are put at risk by those who sell medicines in breach of the rules. Involving them therefore makes sense on a principled basis, and doubtless helps with resourcing the work of agencies that may not otherwise be wallowing in money.

A Global Template?

So, is there anything in Operation Pangea that might point the way for other efforts to tackle financial crime? Are there other industries that might similarly be incentivised to cooperate with and fund law enforcement in this way, other categories of crime that require similar international coordination? Could, for example, the financial sector be brought into international efforts to combat frauds on covid support schemes, or offending that involves crypto assets, or sanctions evasion?

Such comparisons make for interesting thought experiments, with some instructive results. The immediate impact of bounce back loans, controversially handed out with minimal due diligence to businesses at the peak of the pandemic, has been on lending banks, but the government guarantees have made them squarely a public sector problem. The UK's response, so far, has been at a national level, perhaps assuming such crimes do not cross borders – but is this right? Are we doing enough to involve the financial regulators, or to work internationally, on crypto- and sanctions crime?

Conflicts of Interest

We should take care, of course, not to celebrate the contribution of the international pharmaceutical industry to law enforcement without recognising that it is, at least to a large extent, the result of self-interest. Indeed, it might reasonably be asked whether agencies like Interpol and Europol might even be short-changed by the deal, putting public resources into enforcing laws that are largely in place to protect intellectual property rights that might

just as easily be protected by civil litigation, or even by private firms bringing their own prosecutions. In addition to that, might the alliance of national law enforcement agencies (LEAs) and private firms lead to an unhealthy conflict of interests, insofar as private firms, even reputable multinationals, are not above committing offences themselves, including breaches of competition law and the payment of bribes, for example, from time to time?

In the UK, a comparison with the financial services industry is particularly apposite: thanks to many years of banks and other financial institutions being obliged, under yet more provisions of POCA, to gather and submit intelligence to LEAs on suspected money laundering, they have amassed the expertise and authority to enable their CEOs to sit alongside senior ministers in policy-making bodies. Even while this is happening, major banks are investigated, fined, and even prosecuted for money laundering failures by their (industry-funded) regulatory body, the Financial Conduct Authority (FCA).

The Role of Global Britain

The international nature of the problem of illicit medicines is what makes the challenge faced by the MHRA and by Operation Pangea unique. Not only must it tackle the legal complexity involved in multiple legal remedies and enforcement authorities, and the potential for conflicts of interest in public-private partnerships, but it must do so across national borders. To make matters harder, of course, it must do so in the context of a form of Brexit that has, at least potentially, decisively broken from EU regulatory norms, including in the regulation of medicines and the protection of rights

in the context of criminal investigation. Among other things, that has necessitated a new, somewhat hollowed-out relationship between domestic LEAs and Europol, and doubtless created numerous hurdles behind the scenes of Pangea's operations.

Despite all that, the overwhelming logic of converging interests between national law enforcement and international pharmaceutical firms means that the impetus for continuing, strengthening, and deepening the activities of Pangea will surely endure; indeed, there may be potential for offshoots using the same approach. With many jurisdictions now beginning to embrace a more sensible regulatory approach to medicinal uses of cannabis, for example, there are commonalities of interest between national LEAs in regulating the borders between the various jurisdictions and tackling parties that may seek to exploit differences and gaps in these nascent frameworks. As the development and rollout of covid vaccines and treatments continue to expand, the need to police unlicensed or unsafe alternatives, particularly in the developing world, is ever clearer. And, of course, the alarming societal harms

associated with sales of opioids diverted from legitimate supply chains, online or otherwise, continues to present a challenge that cries out for international cooperation, including in tracking and seizing their proceeds.

The approach of the UK to these issues is not necessarily perfect. Cannabis, even in a medicinal context, remains the province of the Home Office rather than the MHRA, with a licensing regime in its infancy and too little thought given to a joined-up approach between the regulatory and law enforcement approaches. Scant attention is paid to fake covid treatments, save for isolated examples of trading standards prosecutions under CPUTRs for so-called cures. UK LEAs' attempts to tackle UK proceeds of illicit sales overseas rarely show signs of real cooperation with their overseas counterparts. On all these fronts, there is surely the potential for the mechanisms created by Operation Pangea to assist. With decades now of experience in tackling the complexities of working with overlapping laws and across national borders, it is a cooperative endeavour that the newly styled, post-Brexit, Global Britain should continue to embrace.



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