

Criminal Enforcement within the MHRA

Introduction

Medicines legislation places a statutory responsibility on the Secretary of State to enforce breaches in regulatory requirements in the UK. In practice, this duty is undertaken by the MHRA in England, Scotland and Wales. In N Ireland this is conducted by the Department for Health and Social Public Services Northern Ireland. Similar arrangements are in place with respect to medical devices. The investigation of criminal acts sits within the Inspection, Enforcement and Standards Division and is the Enforcement Group's primary responsibility; enquiries are conducted taking into account the over-arching agency priority to protect public health.

The purpose of this report is to set out some of the key achievements of the Enforcement Group over the last 12 months, broken down into the main National Intelligence Model (NIM) portfolio areas, along with other key innovation and development that has been pursued to increase impact and effectiveness whilst ensuring efficiency.

Intelligence Teams

To assist in the prioritisation and effective use of resources, all agencies with a law enforcement responsibility pursue an intelligence-led approach described within NIM and the MHRA is no different. The underpinning systems and processes are critical in ensuring threat, risk and harm are appropriately aligned with resourcing.

Implementation of the Intelligence Development Unit (IDU): The IDU was introduced to maximise intelligence received by the Enforcement Group whilst ensuring its legal obligations are correctly discharged. The Unit has responsibility for developing operational intelligence using covert techniques, including covert human intelligence sources (CHIS), covert assets (undercover operatives) – people - and investigations into activities online. The focused tasking of the IDU has delivered positive outcomes in supporting enforcement activity, through the deployment of tactics to identify organised criminal networks engaged in diverted, unlicensed and falsified medicines criminality. The following is a successful example of IDU activity:

A case study: Operation Calla: This operation commenced following a referral from industry partners relating to a mail forwarding company who were acting as an importer and distributor of medicines entering the UK illegally. A criminal network was identified involving individuals residing outside the UK, fulfilling demand from European customers via overseas websites. The UK aspect of the operation involved five individuals who were arrested in 2016. Trials were held at Southwark crown court in 2018 and 2019 and included the complexity of a number of covert operatives delivering live evidence in court. Following deliberation, four defendants were found guilty of offences of importation, sale and supply of unlicensed medicines, including controlled drugs. These defendants were subsequently sentenced to imprisonment totalling nine years.

Alternative interventions and disruption: The ever-growing and innovative usage of the internet brings criminal opportunity for a few. The Enforcement Group has developed alternative ways of responding to identified criminality to both manage the demand upon its resources and ensure a proportionate response to the wrongdoing identified. One such approach has been the focus upon websites and other on-line methods of advertising and selling medicinal products illegally. The MHRA cannot be responsible for 'policing' the whole

of the world-wide web, however, it has focused upon the UK domain tree (.co.uk) and other online marketplaces, e.g. eBay advertisements, targeting UK consumers. This approach is designed to disrupt the criminal activity by removing the ability to advertise and sell medicines illegally however, the scale of the activity described below (table 1 relates to activity from January to August 2019) highlights the enforcement challenge and also the commitment of the MHRA to adopt a variety of methods to combat criminality.

Website and Social Media Suspensions		Online Market-Place Suspensions	
Domain name (website) suspensions	78	Medicines	429
URL removal (e.g. Facebook page)	322	Devices	113
Websites brought into compliance	16	Overall total	542
Overall total	416		

Table 1: Number of websites, URLs and online market-place advertisements suspended following enforcement intervention.

Expansion of intelligence sources: Since 2014 the Enforcement Group has provided a designated agency whistle-blower service for those employed within the pharmaceutical industry to report concerns. This work is critical in providing an anonymous and secure method for those wishing to report concerns and responding to those concerns, whilst strategically, gaining a greater insight into the complexities of the regulated supply chain. Figure 1 below highlights the ever-increasing number of reports received through this process with the red dotted trend line displaying the year on year trend direction.

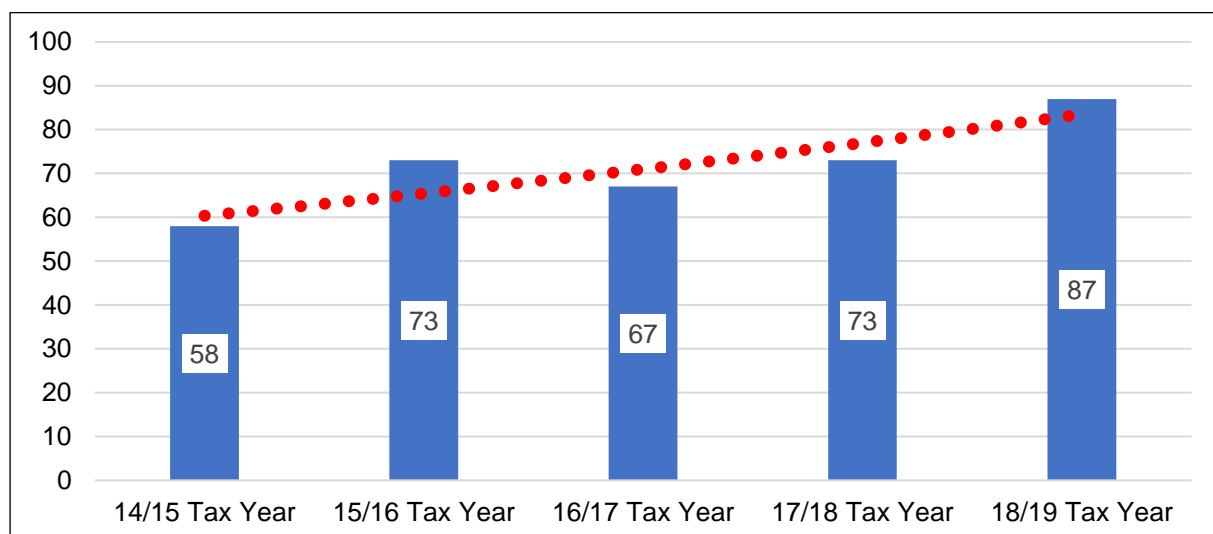


Figure 1: Number of external whistleblowing allocations by tax year.

Operations Teams

The Enforcement group's criminal investigations are progressed by the operations teams with defined areas of responsibility: Legal Supply Chain, Complex Case, High Volume/High Risk and Financial Investigations. As part of the Enforcement Group's strategy of targeting criminality that poses the greatest threat to public health, greater use has been made of alternative interventions and disruptions to ensure highly skilled investigative resources target the highest risk matters. The impact of this approach is clearly displayed below:

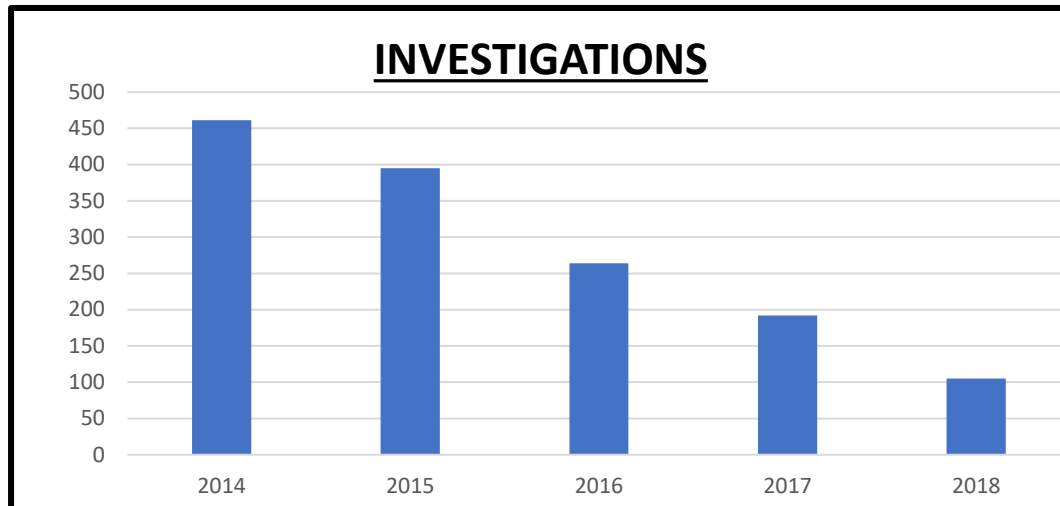


Figure 2: Number of criminal investigations raised per calendar year.

As can be seen in figure 2 above, the number of investigations raised for full investigation each year has decreased from a high in 2014 of over 450 criminal investigations. The allegations that historically resulted in criminal investigations continue to be reported to the agency and responded to. However, where the threat and risk allow, proportionate alternative interventions are adopted. Targeting investigative resources to the most serious allegations has allowed increasing effectiveness and thereby an ever-increasing number of prosecutions being pursued at the most serious threat, risk and harm end of the criminal spectrum. Although the number of criminal investigations has decreased the Enforcement Group has delivered significant year on year increases in prosecutions targeting the most serious and complex matters, as displayed in figure 3 below.

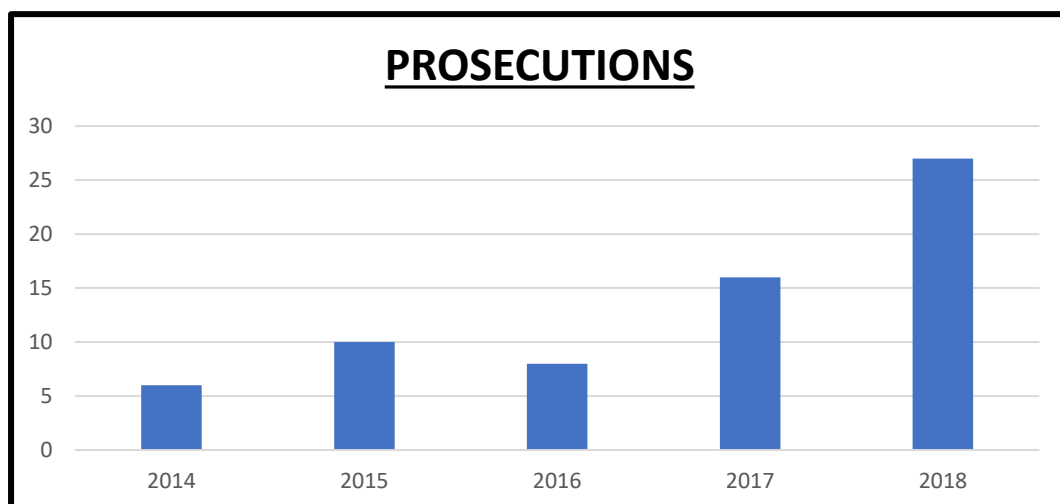


Figure 3: Number of prosecutions conducted per calendar year.

The following two examples highlight both the variety of investigations and challenges faced by enforcement investigators:

Problem - The diversion of medicines to the illegal market: In 2015 the MHRA became aware that large volumes of Prescription-Only Medicines (POMs) were being diverted from the legal healthcare supply chain and sold on the criminal market. The diverted medicines were mainly being sold via illegally operating websites controlled by organised crime groups, in effect offering highly addictive medicines to be bought with a credit card with no prescription required. To protect public health, the MHRA instigated a series of investigations to identify the source and extent of the diversion. These investigations uncovered organised criminality collaborating with wholesale dealers and pharmacists which has resulted in the diversion of up to 5.6 million packs of medicines with a street or internet value up to £200 million.

In combating this emerging issue:

- 32 criminal investigations have been initiated, 86 suspects have been either arrested or interviewed under caution and criminal convictions have been obtained.
- 13 wholesale dealers have had their licences discontinued or terminated and 8 pharmacists have been suspended, some of whom are facing prosecution. Several cases are with the Crown Prosecution Service and prosecutions are expected in 2019 and beyond.

In 2017 the Enforcement Group embarked upon its most ambitious data analysis project collecting millions of lines of medicines sale data for the commonly diverted medicines. The purpose of this activity was to understand the impact of MHRA and partner enforcement activity. Analysis revealed that bulk trading by wholesale dealers has dramatically reduced:

- top strength diazepam reduced by 73%,
- nitrazepam reduced by 30%,
- temazepam and zolpidem both reduced by 18%.

As a result of MHRA and partner activity illegally operating websites, a key enabler, have been observed moving their operations to non-cooperative jurisdictions and are now selling mostly unlicensed generic brands rather than diverted regulated supply chain UK stock.

Case Study: Operation Tocantins: The MHRA concluded a 3-year investigation into the unlawful manufacture and supply of an unlicensed medicine called GcMAF, which the manufacturer claimed cured cancer, HIV Aids, autism and many other serious illnesses by a company called Immuno Biotech Ltd. The starter material for this medicine was a blood product (GC Globulin) that was not intended for human consumption and was not to be used in medicinal products. The investigation showed that the company owner, David Noakes, had generated over £10 million from sales across the world and claimed to have treated over 8,000 patients, both remotely and in several unlicensed clinics in European countries.

Noakes and others were subsequently charged with Human Medicines Regulations 2012 and Money Laundering offences, four defendants including Noakes pleaded guilty and a 5th defendant was convicted following a short trial at Southwark Crown Court in November 2018. In December 2018 David Noakes was sentenced to a total of 15 months imprisonment. There remains a Proceeds of Crime process and the MHRA and police are seeking to confiscate a significant amount of assets that are restrained by the court.

The Financial Investigation Unit (FIU) support Enforcement Group activity through the use of powers provided by The Proceeds of Crime Act 2002 (POCA). Criminal and regulatory investigations often rely on the support of an Accredited Financial Investigator (AFI) assisting

to support the investigative plan, securing evidence in pursuit of prosecution and driving the confiscation process. During 2018-2019 the FIU obtained:

- 279 investigative orders, e.g. Production Orders
- maintained 19 restraints
- obtained 7 confiscation orders

Utilisation of new legislation: In 2019 the FIU initiated a project (Operation Galileo) designed to disrupt criminality where a full investigation was not deemed viable. The project aims to remove the proceeds of criminality utilising new powers (Account Freezing Orders) created by The Criminal Finances Act (2017). AFOs allow AFIs to freeze, and ultimately forfeit, the contents of bank accounts which can be shown to facilitate pharmaceutical based crime. The project also aims to disrupt crime by taking down websites hosting illegal activity and the identification of ultimate beneficiaries. This will be achieved through partnership working with the National Crime Agency (NCA) and financial institutions based overseas.

In addition, this year the FIU has secured direct access to the NCA hosted Suspicious Activity Report (SAR) database which will provide a rich, financially based, picture of criminality linked to pharmaceutical crime. It is anticipated that this will inform enforcement activity including those that support Op Galileo.

Prosecutions Unit

Over the last year the Enforcement Group has been engaged in several highly complex prosecutions. Because the focus at the operations level has concentrated upon the highest risk and harm, this work has progressed through into the prosecution's arena. The complexity of prosecution cases reflects this ongoing change in the profile of investigations which have moved towards organised crime groups and networks who have sought to diversify their criminality. Historically it was rare for the agency to be engaged in criminal trials where defendants pleaded not guilty, however, this is now the norm and impacts significantly upon resources.

MHRA Prosecutions August 2018 to July 2019 – A 12-month snapshot			
Number of MHRA trials	Number of defendants	Number of defendants convicted	Cumulative total of imprisonment
12	24	21	29 Years

Table 2: Key prosecution statistics August 2018 to July 2019.

Despite such a challenging environment table 2 above sets out the agency's prosecution achievements over the last 12 months.

Prevention

Annually millions of doses of medicines enter the UK illegally from overseas and flood the criminal market impacting upon public health. Pursuing the old adage 'prevention is better than cure' the Enforcement Group has adopted a problem solving approach to the underlying issues that contribute to criminality. One of the successful approaches adopted has seen the development of a strategy of engagement with countries where medicinal products are sourced for the UK criminal market with the long-term goal of seeking intervention in those countries prior to illegal entry into the UK. As a result significant progress has been made including:

- sharing of actionable intelligence

- operations conducted overseas based upon MHRA intelligence
- joint communication and media messaging with UK and key countries

Case Study - International collaboration: Through MHRA and Border Force joint working a new large source of unlicensed diazepam was identified illegally entering the UK targeting a small geographic area. The Enforcement Group developed this intelligence and shared it with the local police force working with them to focus their activity. Continued work with Border Force allowed for the seizure of further consignments of diazepam entering the UK illegally. Communication was initiated with the source country to identify and respond to the root causes. Coordinated activity both within the UK and overseas resulted in:

- arrest and conviction of 3 individuals for conspiracy to import controlled drugs
- the seizure of over 1 million doses of diazepam and removal from criminal circulation
- Regulatory action being taken by the source country against the manufacturer
- Customs activity in source country seizing consignments preventing arrival in UK

This strategic approach, led and coordinated by the MHRA, resulted in the dismantling of an organised crime group, removal of the enabling factors allowing the movement of illegal goods through borders and the focus upon the root cause of the illegal supply problem. This has provided the basis of a model for future operational activity.

Partnership

The Enforcement Group's approach to combating criminality recognises that their mission cannot be accomplished alone and therefore it is critical to work in partnership with a range of national and international partners. By adopting such a rounded approach greater benefits can be achieved for the UK. Embedded partnerships continue to deliver positive outcomes in 2018 including:

The MHRA is the lead UK agency for Interpol's Operation Pangea, the single global operation targeting the illegal sale and supply of medicines, and now medical devices, online. Working with UK partners, in particular Border Force, the MHRA again achieved significant results some of the highlights being:

- 10,008,826 doses of medicinal products were seized globally – the UK contribution was 1,037,860 doses over 10% of the global result
- two linked search warrants executed relating to an ongoing dark web investigation resulting in one arrest and significant seizures of medicines in excess of 300,000 doses
- noteworthy seizures working with Border Force, an example being, around 1KG of methamphetamine secreted within tubes of skin lightening crème.

The success of Interpol's Operation Pangea has assisted in influencing the focus of Europol. As a result, Europol initiated an operation (Mismed) targeting illegal activity involving medicines. The MHRA joined this operation as one of the founding members and participated in Operation Mismed2 2018 which overall seized more than €165 million of illegally trafficked medicines.

Working at a national level the Enforcement Group seek to share their experiences around the criminal exploitation of health provision to aide the tightening of systems and processes to enhance public health whilst reducing criminal opportunity. Such work includes:

- collaborating with partner healthcare regulators to review digital healthcare provision including identifying legal gaps and developing appropriate solutions

- working with Vigilance and Risk Management of Medicines (VRMM) on an opioid addiction review to contribute, in particular, to online sales and electronic prescribing to counteract abuse
- participating in the National Controlled Drugs Working Group to share intelligence on misuse of controlled drugs/ POMs, including diversion issues.

Due to the global aspect of the illegal trade in medicines an international approach is also required to our partnership working. The Enforcement Group continue to make a significant contribution to the international development of coordinated approaches to the challenges we all face. Over the last year members of the Enforcement Group continued to participate in:

- Working Group of Enforcement Officers (WGEO) – a sub-group of the European Heads of Medicines group providing an operational forum for joint working, sharing of best practice and the development of coordinated approaches to operational challenges.
- Permanent Forum on International Pharmaceutical Crime (PFIPC) – a global group, including several the countries seen by the UK as the source of medicines illegally entering the UK, focused upon collaboration and joint working.
- European Directorate for the Quality of Medicines and Healthcare (EDQM) Expert Working on Illegal Activity with Medical Products – A number of work groups are managed through the Committee including Communications, Training, Single Points of Contact (SPOCs) and more recently Digital Health. Training is a focus, of particular importance in countries outside EU where regulatory controls are not as robust. The group promotes the Council of Europe's (47 member states) Medicrime Convention, the Council of Europe's multilateral convention on the counterfeiting of medical products and related threats.

Conclusion

Whilst small in the number the Enforcement Group conducts wide ranging activities to provide a balanced and rounded approach to combating criminality. This report has set out some of the key headline achievements over the last year which, in light of the changes the agency will face in the coming months, places our enforcement approach in a positive place to continue to deliver on our core mission of protecting public health.