



Medicines and Healthcare products Regulatory Agency

Enforcement Strategy

MHRA Enforcement Strategy

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1.0 Introduction

This document sets out the MHRA strategy for the enforcement of medicines and medical devices legislation. Our strategy reflects Government Better Regulation initiatives and the recommendations contained in the Hampton Review¹ and the Regulators' Compliance Code², which sets out the principles and characteristics to be applied in the enforcement of regulations. It should also be read in conjunction with the Regulation and Accreditation Proposal (RAMS) Sectorial Market Surveillance Programme for Medical Devices³.

The MHRA is also actively considering extending its existing toolkit of sanctions in line with the recommendations of the Macrory Review⁴. Macrory found that the range of sanctions available to regulators was too limited and predicated on criminal prosecution. Core criminal offences were drafted in restricted terms and had to cope with an enormous range of sanctions that aimed to change behaviour, eliminate the financial gain of regulatory breach, deter future non-compliance and were proportionate to the offence.

The MHRA believe that the new sanctions (listed in appendix B) represent a substantial benefit to public health. We are actively exploring options to consult on the proposed use of sanctions in more detail.

The primary aim of the MHRA is to safeguard public health; this is achieved through the compliance of those involved in the development, manufacture, placing on the market and distribution of medicines and medical devices. The United Kingdom is one of the safest environments in which to conduct these activities and the MHRA is committed to preserving the confidence of all stakeholders involved.

¹ Hampton Review 2005, Reducing administrative burdens effective inspection and enforcement

² Regulators Compliance Code 2007

³ Regulation and Accreditation Proposal (RAMS) Sectorial Market Surveillance Programme for Medical Devices, 2009

⁴ Macrory Review 2006, Making sanctions effective

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In most cases compliance is achieved without the need to resort to enforcement action or the need to apply sanctions. The MHRA will continue to work hard with all of its stakeholders to achieve and maintain high levels of compliance. However, in a minority of cases the MHRA will take action against those who fail to comply with the recognised standards or seek to operate outside of the licensed and regulated regime.

In serious cases the MHRA will use its full range of powers to prosecute those responsible.

In all cases where enforcement action is deemed to be the appropriate course, the MHRA will ensure it is applied in a fair, consistent, transparent and proportionate manner.

2.0 Medicines and Healthcare products Regulatory Agency

The MHRA is an Executive Agency of the Department of Health responsible for the regulation and control of medicines for human use and medical devices for human use on the UK market.

The MHRA was established in April 2003 from the resultant merger of two former Executive Agencies of the Department of Health, namely the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA). The MHRA carries out the functions of the licensing authority under section 6 of the Medicines Act 1968 as the Competent Authority for medicinal products for human use in the UK. The MHRA also carries out the Secretary of state's functions as Competent Authority for medical devices in the UK.

2.1 Mission

To enhance and safeguard the health of the public, by ensuring that medicines and medical devices work and are acceptably safe.

2.2 Values

In pursuing our mission we will strive to act with:

- Integrity
- Openness
- Courtesy
- Responsiveness
- Timeliness
- Professionalism
- Impartiality
- Consistency

2.3 Aims

- Protecting public health through regulation, with acceptable benefit-risk profiles for medicines and devices
- Promoting public health by helping people who use these products to understand their risks and benefits

- Improving public health by encouraging and facilitating developments in products that will benefit people

2.4 Strategic Objectives

- Protecting public health through our primary role in ensuring that the products we regulate meet required standards that they work and are acceptably safe
 - Carry out our communication role through the provision of accurate, timely and authoritative information to healthcare professionals, patients and the public
 - Support research, ensuring through the application of better regulation principles that regulation does not stifle innovation
 - Influence the shape of the future regulatory framework through use of our effective European and International relationships
 - Run an organisation with a skilled and equipped workforce that is fit for the future
-

3.0 Which laws do we enforce?

3.1 Medicines

The relevant legislation⁵ that controls the manufacture, clinical trials, importation, wholesaling ongoing safety and sale of medicines in the UK is the Medicines Act 1968, and all its supporting regulations. It is illegal to engage in these activities except in accordance with appropriate licenses, registration, certificates or exemptions. The maximum sentence imposed under this legislation is a maximum 2 years imprisonment and/or unlimited fine.

The legislation has undergone numerous amendments and parts of it have been superseded by subsequent European regulations. Consequently, a consolidation and review project is currently underway to ensure that any future legislative framework for medicines is comprehensive, comprehensible and remains fit for purpose.

Herbal Medicines

Herbal medicines are medicines in their own right; they are currently available as unlicensed, registered traditional herbal medicines,⁶ or licensed herbal medicines. They are subject to the provisions of the Medicines Act 1968.

Homeopathic Medicines.

Homeopathy is a system of complimentary medicine in which disease is treated by minute doses of substances that enlarge quantities would produce symptoms of the disease. Guidance on the manufacturing, supply, enabling and registration is available on the MHRA website.

⁵ The Medicines Act 1968

The Medicines for Human Use Regulations (Marketing Authorisations) 1994 SI 3144

Medicines for Human Use (Clinical Trial Regulations) 2004 SI 1031

The Medicines (Advertising) Regulations and Medicines (Monitoring advertising) Regulations 1994

⁶ EC Directive 2004/24/EC, Traditional Herbal Medicine Products

3.2 Devices

There are currently three main European medical devices Directives which have been transposed into UK law by the Medical Devices Regulations 2002 (as amended). They place obligations on manufacturers to ensure that their devices are safe, of an acceptable quality and are fit for their intended purpose as specified by the manufacturer before they are CE marked and placed on the EU market. Devices regulations are made under the European Communities Act and the Consumer Protection Act 1987. The regulations and the Act provide a range of powers including entry to business premises, inspection of procedures, examine records and seize or detain goods. The maximum penalty for a conviction under any of these regulations is 6 months imprisonment and/or £5000 fine. The Agency is also the Enforcement Authority for 'consumer' medical devices under the General Product Safety Regulations⁷. Non-compliance under these regulations carries a maximum penalty of 12 months imprisonment and/or £20,000 fine.

3.3 Blood

Blood regulations⁸ are designed to ensure safety and maintain quality in blood establishments and hospital blood banks. They impose a licensing and inspection regime and extend regulation to reporting adverse incidents, traceability and record keeping requirements to other facilities which may receive blood or blood components. Breaches of this legislation attract a maximum sentence of 2 years imprisonment and/or an unlimited fine.

⁷ General Product Safety Regulations 2005

⁸ Blood Safety and Quality Regulations 2005 SI 50

Blood Safety and Quality (Amendment) Regulations 2005 SI 2898

Blood Safety and Quality (Amendment) Regulations 2006 SI 2013

3.4 Good Laboratory Practice

Good Laboratory Practice regulations⁹ (GLP) embodies a set of principles that provides a framework within which laboratory studies are planned, performed, monitored, recorded, reported and archived. These studies are undertaken to generate data by which the hazards and risks to users, consumers and third parties, including the environment, can be assessed for pharmaceuticals, agrochemicals, veterinary medicines, industrial chemicals, cosmetics, food and feed additives and biocides. GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied upon when making risk/safety assessments. Breaches of the requirements of GLP attract a maximum penalty of 2 years imprisonment and/or unlimited fine.

⁹ Good Laboratory Practice Regulations 1999 SI 3106

Good Laboratory Practice (Codification amendments) 2004 SI 994

4.0 Where can we enforce?

4.1 Jurisdiction

The Medicines Act 1968 confers on the Secretary of State for Health a statutory responsibility to enforce, or secure enforcement of the provisions of that Act and any subordinate legislation in relation to England. In practice this function is undertaken by the MHRA.

Enforcement of Medicines legislation in Wales¹⁰ is the responsibility of the National Assembly for Wales, but their enforcement functions are performed on their behalf by the MHRA pursuant to an agreement with the devolved administration.

Enforcement of Medicines legislation in Scotland¹¹ is the responsibility of the Scottish Parliament and their enforcement functions are also performed by the MHRA pursuant to existing agreements.

The MHRA has no enforcement responsibility for medicines in Northern Ireland. This falls to the Department of Health, Social Services and Public Safety Northern Ireland (DHSSPSNI)

The enforcement of Medical Device legislation extends throughout the UK and is the responsibility of the MHRA.

4.2 International Investigation

Where allegations are referred to the MHRA which feature cases not within our jurisdiction those matters will be directed to the appropriate agency within the relevant jurisdiction for consideration of enforcement activity. An extensive network exists amongst Drug Regulatory Authorities throughout the world and collaboration in protecting public health through enforcement activity is common and encouraged.

¹⁰ Government of Wales Act 1998 S.41 (1) (a) and (b)

¹¹ The Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc) Order 1999 (S.I. 1999 / 1750 Schedule 1)

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The MHRA is able to secure evidence from outside its jurisdictional boundaries through existing mutual legal assistance treaties currently in place with a number of countries.

5.0 Why do we enforce?

The MHRA undertakes enforcement activity as part of its responsibility to safeguard public health.

The manufacture, clinical trials, importation, wholesaling ongoing safety, advertising and supply of medicines and medical devices are practices which demand, by their very nature, high standards enforceable by law. The MHRA regards as essential the need for patients and consumers to maintain the highest degree of confidence in the products legally available in the UK, which extends to those engaged in their production and supply and to those, responsible for their regulation. That confidence is maintained through taking appropriate action against those who are operating outside of prescribed acceptable standards

Sometimes enforcement action is required to achieve compliance, maintain standards and deter others from non-compliance with existing legislation. On occasions it is necessary to prevent persons in serious or repeated non-compliance from continuing to operate in the business of the manufacture and supply of medicines and medical devices through regulatory action, including the suspension or revocation of licences and registrations.

The principle aim of the MHRA is to achieve compliance through the provision of advice and guidance and to maintain standards of quality and safety through a robust risk based inspection programme and a well established regulatory regime. However, when this process fails, or there is no intention to adhere to a regulatory model, the MHRA will use the available powers conferred by the relevant legislation to protect public health.

6.0 How do we enforce?

The MHRA aims to achieve compliance with regulations in the first instance through the provision of advice and guidance and an inspection programme to determine levels of compliance. In most cases only when this cannot be achieved or it is impracticable to attempt to do so, will enforcement activity and the subsequent application of sanctions be commenced. This will be carried out in a proportionate and consistent manner, with a clear focus on the desired outcome of safeguarding public health and maintaining future compliance.

However, in accordance with recommendations proposed by Government Better Regulation initiatives, and to protect public health, the MHRA will strive to ensure that those who persistently contravene regulations, or where there is evidence to suggest significant criminal activity has taken place, that those responsible will be identified quickly and face proportionate and meaningful sanction. The MHRA can, and will, use all available powers to take action against those who are responsible for the most serious breaches of legislation.

6.1 Definition of Enforcement

Enforcement activity is defined within the Regulatory, Enforcement and Sanctions Act 2008 to include,

- Action taken to secure compliance with a restriction, requirement or condition in relation to a breach or supposed breach
- Action taken in connection with imposing a sanction for an act or omission
- Action taken in connection with a statutory remedy for an act or omission

6.2 MHRA Approach to Enforcement

The MHRA method of achieving compliance is separated into 5 distinct stages,

1. Prevention of non-compliance
2. Identification of non-compliance
3. Investigation of non-compliance
4. Use of sanctions for non-compliance

5. The outcome of enforcement action

6.2.1 Prevention of non-compliance

The prevention of non-compliance is a key desired outcome of the MHRA. The Agency is clearly focused on achieving compliance amongst those that hold medicine licences and registrations issued by the MHRA or place medical devices on the UK market and, in order to achieve this aim an extensive range of current and specific advice and guidance is made available. Most of the guidance has been issued following consultation with stakeholders and is frequently reviewed to ensure it is up to date, reliable and authoritative.

Advice and guidance is delivered through publications available either through the MHRA website or in hard copy. The MHRA also hosts and presents at a number of conferences and seminars throughout the year aimed at specific areas of regulation and tailored to relevant audiences where guidance on the interpretation and application of regulations can be obtained.

Examples of published guidance include the Orange Guide which relates to good manufacturing and distribution practice, the Good Pharmacovigilance Guide and the Blue guide relating to the advertising and promotion of medicines in the UK. The Devices compliance unit has published a range of guidance, including a document on its enforcement responsibilities and manufacturers rights which is sent to manufacturer's subject of enforcement activity.

The MHRA publishes the most common deficiencies encountered during the inspection process, and the outcomes of complaints about advertising licensed medicines, on the MHRA website in an effort to assist others in achieving compliance.

Meetings with stakeholders are frequently held where advice and clarification can be sought from specialists within the Agency.

6.2.2 Identification of non-compliance

The MHRA is committed to putting in place processes which will encourage the reporting of non-compliance and rapid identification of persistent and repeat offenders.

Reporting Schemes

It is a fundamental requirement to provide the public and other stakeholders with an efficient and effective method to report suspected breaches of medicines legislation to the regulator. The MHRA Information Centre is a central point of contact. In addition a Case Referral Centre within the Enforcement Group has been established to receive all referrals of alleged breaches of medicines legislation. The Case Referral Centre can be contacted by telephone or email and out of hours contact can be made in urgent circumstances (See appendix A).

The Case Referral Centre will acknowledge receipt of the referral, assess the referral in terms of risk and, if it falls within MHRA's responsibilities, allocate it to a member of the Enforcement Group for investigation. Cases not falling within the responsibilities of the MHRA will be referred to the relevant agency.

All reports of suspected non compliant medical devices are reported direct to the compliance unit where again a risk assessment process is applied before allocation of the referral for investigation.

In addition, a number of MHRA website based and other mechanisms have been put in place to facilitate fast and efficient reporting, these include reporting counterfeit medicines / medical devices, blood related adverse incidents, adverse reactions to medicines/devices and complaints about the advertisement of medicines.

Specific policies exist within the MHRA to receive and handle reports from whistleblowers either associated with or previously associated with licensed entities or medical device manufacturers.

Risk Based Inspections

The MHRA has implemented a risk based inspection programme throughout the manufacturing, distribution, laboratory, clinical trials and pharmacovigilance inspectorates. This process primarily focuses medicines inspectorate resources on the areas that will maximise protection of public health while reducing the overall administrative and economic burden to stakeholders. The risk based approach is sharply focused upon determining that compliance is being achieved and where necessary providing the support to achieve satisfactory levels of compliance. Where compliance cannot be achieved or an unacceptable risk to public health exists this process can trigger appropriate enforcement action. Close co-operation between the Inspectorate and the Enforcement Group can lead to the early identification and action against those entities that are persistently in breach.

The medical device compliance unit has close working ties with the Medical Devices Clinical team and the Device technology and safety branch which help identify areas of public health risk where they relate to medical device compliance. This helps focus activity upon the devices demonstrated to be most at risk.

Market Surveillance

A testing scheme of medicines assessed as being most at risk of being counterfeited is operated throughout the UK supply chain. This scheme operates through the sampling of high risk products from wholesalers and retailers and is a method of identifying the presence of counterfeit products within the supply chain which would trigger both the appropriate action to protect public health and enforcement activity.

Compliance Visits

Where a company or individual has been the subject of enforcement action, follow up un-announced compliance visits will be conducted at pre-determined periods to establish if compliance is being maintained. Non-compliance would be likely to stimulate further enforcement action.

Internet Vigilance

The MHRA configures web crawling software to monitor the internet for websites engaged in the illegal advertising, supply and distribution of medicines and medical devices. The software searches for sites that appear to be hosted managed or located in the UK. Products are then purchased, tested and where appropriate enforcement action is taken to remove the site and prosecute those responsible. The MHRA is working together with the Police, internet service providers, credit card companies and other relevant stakeholders to disrupt and dismantle illegal internet operations including those based overseas, to help protect UK consumers and prevent their exposure to dangerous medical products.

6.2.3 Investigation of non-compliance

Several Divisions within the Agency have responsibility for taking initial action where non-compliance is identified, for example following a complaint, inspection or pro-active monitoring. Action is usually taken by correspondence to seek voluntary compliance but may also include statutory action. Where compliance is not achieved within a reasonable timescale depending on the breach, where there is a history of non-compliance or if there is a significant concern for public health the case may be referred for enforcement action at any point. The Enforcement Group may also refer cases to other Groups for initial action where appropriate.

The MHRA will ensure that referrals which result in a criminal investigation will be conducted diligently, thoroughly, fairly and consistently. Investigators will

be properly trained, qualified and experienced in the relevant law, procedure and the proportionate use of powers.

Specialists are employed by the Agency who are experienced and where necessary qualified in investigative practice, financial investigation, test purchasing, internet investigation, disclosure, intelligence analysis and the use of other specialist investigative techniques. Expert advice is sought from colleagues in other parts of the Agency as required.

Legislative Powers

The Medicines Act 1968, Consumer Protection Act 1987, and associated legislation¹² have set out a range of powers conferred upon MHRA enforcement officers and inspectors.

S.111 of the Medicines Act 1968 confers a power of right of entry at any reasonable times to any premises or vehicle for the purposes of ascertaining if there is or has been any contravention of the Act. Under certain circumstances a warrant of entry may be applied for from a Magistrate to authorise entry without notice, and the use of force to effect entry if necessary.

S.112 of the Medicines Act 1968 confers a power to inspect, take samples and seize goods and documents for the purposes of ascertaining if there is or has been any contravention of the Act.

S.29 of the Consumer Protection Act 1987 confers the following powers as far as medicines and medical devices investigations are concerned:

- Enter premises and inspect goods
- Examine manufacturing procedures and testing arrangements

¹² Medical Devices Regulations 2002

General Product Safety Regulations (Devices)

- Require the production of any records and take copies
- Seize or detain suspect records or goods which may be required as evidence
- Issue prohibition notices
- Issue suspension notices
- Issue notices to warn
- Obtain test purchases

Regulation 15 of the General Product Safety Regulations 2005 confers the power to issue recall notices for consumer medical devices.

Regulation 62 of the Medical Devices Regulation 2002 confers the power to issue notices for non-compliance (Compliance Notices). In addition Regulation 63(1) confers the power to issue a restriction notice where the Agency is of the opinion that it is necessary to restrict the availability of a product on grounds of public health or safety.

The MHRA is authorised under the Regulation of Investigatory Powers Act 2000 to conduct Directed Surveillance, authorise the conduct and use of Covert Human Intelligence Sources, and acquire certain categories of communications data. The Agency is regularly inspected by the relevant Commissioners to ensure appropriate use of these powers.

Under the Proceeds of Crime Act 2002 the MHRA is authorised to access specific financial information in connection with a criminal investigation or confiscation hearing. Properly trained, experienced and authorised personnel seek to identify and retain the assets of those that are suspected or have been convicted of breaches of medicines legislation which have led to financial gain.

All enforcement officers are trained in the proportionate use of the powers conferred upon them. This training is underpinned by policies and procedures to ensure the fair and appropriate use of those powers at all times.

Investigators will also ensure, wherever possible subject to legal constraint that those referring cases, witnesses and the victims of breaches of medicines and associated legislation will be regularly updated on the progress of the investigation.

6.2.4 Use of sanctions for non-compliance

Sanctions imposed by the MHRA can include;

- Warning letter / notice
- Caution
- Criminal Prosecution and asset confiscation
- Civil Action (Injunction)

The MHRA also has powers conferred under the Medicines Act 1968 to suspend, revoke and vary licences. Established procedures exist within the MHRA for both Medicines and Medical devices in terms of regulatory sanctions for changes to licences or to restrict the availability of non compliant devices that are placed on the market. Advice in relation to these procedures can be found on the MHRA website together with details of the appeals procedures.

Those engaged in the imposition of sanctions examine each case on its own merits and the preferred approach would be to apply an incremental escalation in terms of the severity of the sanction, however this decision would be based on a number of factors and take into consideration the criteria set out below.

Administrative Penalties

At present the MHRA has no power to impose administrative sanctions. These new sanctions include Monetary Administrative penalties, (fixed or variable), Statutory notices and Enforceable undertakings, (The Macrory sanctions are attached at appendix b).

However, as referenced above, we are actively considering the usefulness and the applicability of the extended toolkit of sanctions recommended in the Macrory review. Our initial view is that such sanctions are an opportunity for the Agency to deal with

minor breaches in a more proportionate and effective way. The detail of which sanctions would be applicable to which offences is still to be worked up, and once established will require consultation with stakeholders before any drafting of empowering regulations. If and when the MHRA obtains the power to impose these civil, administrative sanctions, we will use them in a proportionate, transparent and equitable manner and will be subject to an appeals process and tribunal

Although the MHRA has not yet got Macrory sanctioning powers, any sanctions imposed by the MHRA will endeavour to be consistent with the recommendations set out in the Macrory review namely,

- Aim to change the behaviour of the offender
- Aim to eliminate any financial gain or benefit from non-compliance
- Be responsive and consider what is appropriate for the particular offender and regulatory issue, which can include punishment and the public stigma that should be associated with a criminal conviction
- Be proportionate to the nature of the offence and the harm caused
- Aim to correct the harm caused by regulatory non-compliance where appropriate
- Aim to deter future non-compliance

6.2.5. Criteria for the application of sanctions

Criteria for the application of a sanction would include the following,

- Actual or potential adverse impact on public health
- Adverse reaction caused to a patient
- Seriously undermines confidence in public health systems
- Seriousness of the non-compliance (critical or major)
- Was non-compliance committed intentionally
- Was non-compliance committed negligently or recklessly
- Should the offender have known about the non-compliance
- Repeated non-compliance
- Attempt to cover up the non-compliance

- Steps to correct the non-compliance
- Had the non-compliance been reported
- The duration of the non-compliance
- Was false or misleading information submitted to the Agency
- Were false or misleading statement(s) made to the Agency
- Falsification of documentation
- Has the non-compliance led to the recall of a medicine from the market
- Has the non-compliance led to the withdrawal of a device from the market
- Level of co-operation received by the Agency during the investigation
- Was there any wilful obstruction
- Extent of financial gain
- Extent of financial loss to others
- Level of public interest
- Previous compliance history

6.3 Outcomes of Enforcement Action

The key outcomes from conducting enforcement action and applying sanctions are as follows,

- An increase in maintaining standards and compliance within licensed entities following enforcement activity
- The cessation of illegal activity by unlicensed entities following enforcement action
- A reduction in the number of repeat offenders

These outcomes will be measured through examining the compliance history and follow up compliance visits to individuals and companies subject to enforcement activity.

7.0 When do we prosecute?

The MHRA Enforcement Group includes a Prosecutions Unit whose responsibility it is to quality assure the submission of potential prosecutions to Government solicitors. The Prosecutions Unit is also responsible for the management of witnesses.

The Department of Health Legal Services (Prosecutions) Department consists of a team of lawyers and support staff who are responsible for assessing evidence, making decisions concerning prosecutions and are responsible for the conduct of the case.

Prosecutions undertaken in Scotland for medicines or medical device offences are referred to the Procurator Fiscals office.

7.1 Code for Crown Prosecutors

In order to decide if a case should progress to the criminal court, prosecutors apply the Code for Crown Prosecutors¹³ which sets out the general principles Crown prosecutors should follow when they make decisions concerning cases.

The code contains a 'full code test' which has two stages,

- The Evidential stage

Prosecutors must be satisfied that there is sufficient evidence to provide a realistic prospect of conviction against each suspect on each charge. They must consider what the defence case may be, and how it is likely to affect the prospects of a conviction. They will also consider if the evidence is admissible and reliable. A case which does not pass the evidential stage must not proceed, no matter how serious or sensitive it may be.

¹³ Code for Crown Prosecutors, 2010

- The Public Interest Stage

Once prosecutors are satisfied that sufficient evidence exists to support a prosecution they will then consider the public interest. Each case will be considered on its own facts and merits. A prosecution would normally take place unless there were factors tending against prosecution that outweighed those tending in favour. The more serious the offence or the offender's record of criminal behaviour, the more likely it is that a prosecution will be required in the public interest.

The MHRA has prosecuted between 5-10% of all criminal investigations conducted since 2006. Cases are normally disposed of by way of warning, caution, and in respect of devices through a range of compliance notices, in the future administrative penalties will be considered. However, in some cases alternative means of case disposal are inappropriate and the matter sufficiently serious to be referred immediately to court.

The MHRA is not restricted to only prosecuting cases involving medicines legislation. Successful prosecutions have been conducted in relation to counterfeit medicines and devices which have been brought under trademark and money laundering legislation. The MHRA will use the appropriate legislation to reflect the full range of illegal activity being undertaken.

In some cases the MHRA will pursue confiscation proceedings where the evidence suggests that significant financial gain has been accrued by those convicted. This can involve the restraint and subsequent realisation of assets.

The MHRA actively collaborates with other law enforcement and regulatory bodies to bring joint prosecutions, most commonly with the Police and Trading Standards.

7.2 Civil Action

The MHRA will resort to civil remedy when necessary. Injunctions have been granted against those persons operating websites illegally to prevent the illegal advertisement and supply of medicines

7.3 Publicising Sentencing Outcomes

The MHRA may wish to publish the outcome of any sentence passed following a successful prosecution. The purpose of this publicity is to;

- Provide re-assurance to the public
- Encourage reporting of non-compliance
- Increase confidence in the regulatory and criminal justice systems
- Discourage offending and/or re-offending.

The publication of results of cases on The MHRA website is not designed to provide a permanent record and reference of Agency prosecutions, but to draw attention to the conviction and sentence as they are handed down. Information concerning convictions will be removed from the MHRA website 1 month after sentence.

Any publicity will be conducted in line with the relevant guidance issued by the Ministry of Justice¹⁴.

¹⁴ Publicising Sentencing Outcomes, Criminal Justice System, 2009

8.0 Review

A report detailing MHRA enforcement activity will be published annually including statistics concerning referrals and the use of sanctions including prosecutions.

This enforcement strategy will be the subject of a two year review period to ensure that it remains specific relevant, up-to-date.

Appendix A

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Email: counterfeit@mhra.gsi.gov.uk

Case Referral Centre

Telephone: +44 203 080 6701 (09:00 – 17:00)

Fax: +44 208 754 3968

Email: casereferral@mhra.gsi.gov.uk

Appendix B

MACRORY SANCTIONS

Monetary Administrative Penalties (MAPs)

Monetary Administrative Penalties are monetary penalties that are applied directly by a regulator. Criminal courts do not play a part in the MAP process, and are generally not involved in issuing or enforcing such penalties. The recipient of a MAP would have a right to appeal through an administrative appeals mechanism.

Fixed Monetary Administrative Penalties (FMAPs)

Fixed Monetary Administrative Penalties (FMAPs) are fines for a relatively low fixed amount that are applied in respect of low level, minor or high-volume instances of noncompliance. They can be applied directly by the regulator, where a business has been found to have failed to comply with regulations. Legislation will need to specify both the nature of the offence as well as the maximum amount of the fine.

Variable Monetary Administrative Penalties

Variable Monetary Administrative Penalties (VMAPs) are sanctions applied by the regulator where the amount is at the discretion of the regulator. Instead of being for a relatively small fixed amount whose maximum is pre-determined by legislation (as with FMAPs above), a variable penalty can, where appropriate and proportionate, be for a more significant amount initially determined at the discretion of the regulator in accordance with a published scheme. Relevant mitigating or aggravating factors, the specific circumstances of the offence and the means of the non-compliant business must be taken into consideration by the regulator when determining the amount of the penalty in any particular case.

Level of financial penalty

In the case of FMAPs, these should have a statutory maximum level which should be set out in the relevant underlying legislation. By definition, FMAPs are for low level breaches and the financial penalty should be for a relatively low amount. Macrory suggests a maximum figure of £5,000

Macrory suggests no upper limit for VMAPs, but suggests that regulators attempt to capture the financial benefit a business may have acquired through a regulatory breach, and reflect this where possible in the VMAP.

Statutory Notices

In some instances of regulatory non-compliance, regulators can decide to issue a Statutory Notice. These notices require the recipient to do or refrain from a particular behaviour. They specify the steps a business must take in order to be compliant and the timescale for these changes. Depending on the statutory provision, a Statutory Notice may also include remediation provisions relating to the damage caused by the failure to comply with regulations. Failure to carry out the actions laid out in the notice may also be a criminal offence.

Regulators may decide that non-compliance with a Statutory Notice always justifies prosecution because an intentional act is implied, or that this should be reserved, say, for repeated non-compliance. There may also be circumstances where the use of a MAP will be a more appropriate and effective sanctioning tool to ensure compliance with a statutory notice. For example, where a business has clearly saved money by delaying compliance but the behaviour does not justify a criminal prosecution, or where a business has complied with most of the requirements of a notice, with the knowledge that a regulator is unlikely to consider that the costs and time of a prosecution is justified to deal with a small proportion of outstanding issues.

Enforceable Undertakings (EUs)

Enforceable undertakings are flexible sanctions that enable regulators to tailor their enforcement response to individual circumstances taking industry considerations and resources, such as management capacity and willingness to restore harm, into account.

EUs are legally binding agreements between the regulator and business, under which the business agrees to carry out specific activities to rectify its non-compliance. An EU could include a commitment to future regulatory outcomes, including steps to ensure that a specific type of incident does not re-occur. EUs would be most effective when monitored closely by the regulator and where non-compliance with an EU is not tolerated. EUs could be more effective in cases where a financial penalty or criminal conviction is likely to be absorbed by the business with a limited impact on the culture or management of the firm. They are also likely to be more effective in securing a change in businesses' behaviour when compared to warning letters or other means of persuasion currently available to the regulator. Warning letters and advice are imposed by a regulator and specify what actions need to be taken by a business. The business may not have bought into the actions required. With EUs, it is the businesses who would apply for an EU and come up with their own list of conditions, and take ownership of the regulatory solution presented. Conditions that form part of the EU would be proportionate to the underlying breach and would hold business to account for their non-compliance.

Undertakings Plus

While an undertaking offered by the business may be appropriate, the circumstances of the breach may also be such as to require the payment of a financial penalty. Macrory proposes that EUs should be sufficiently flexible to incorporate this. This might be appropriate where, for example, the business has made a clear financial gain from noncompliance. The financial element of an Undertaking Plus would be based on the same principles as Fixed and Variable Monetary Administrative

Penalties, and any revenue from the penalty would not go direct to the regulator. The Undertaking Plus would also be a voluntary but legally binding agreement. Both the financial element and the conditions of the EU would need to be agreed upon by the company and the regulator. If a company did not agree with the level of the financial penalty, then it would choose not to enter into the EU and the regulator would decide what, if any enforcement action should be taken.

Restorative Justice (RJ)

Restorative justice is a philosophy that views harm and crime as violations of people and relationships. It is a holistic process that addresses the repercussions and obligations created by harm with a view to putting things right. When compared with current models of punishment, RJ requires a paradigm shift in thinking about responses to harm. Macrory recognises this paradigm shift, and limits his proposals to recommending that Government introduce pilot schemes involving the use of Restorative Justice techniques in addressing cases of regulatory non-compliance. This might include RJ as a pre-court diversion; instead of a Monetary Administrative Penalty; and within the criminal justice system – as both a pre or post sentencing option. So any use of RJ by the MHRA would be determined by the outcome of these – yet to be initiated – pilot schemes.
