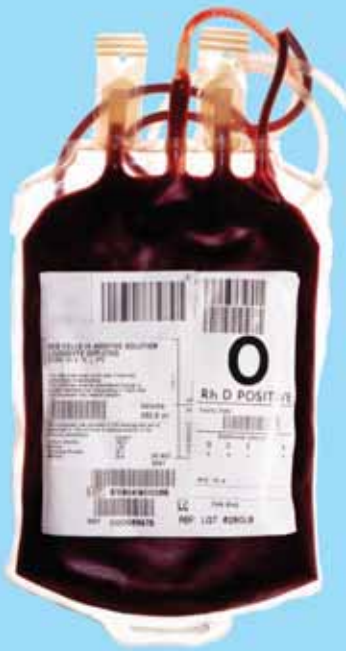
Safeguarding public health

MHRA

05/06

Annual report and accounts 2005/06



Medicines and Healthcare products Regulatory Agency

MHRA at a glance

Mission

The MHRA's mission is to enhance and safeguard the public's health by ensuring that medicines and medical devices meet acceptable standards of safety and that they work.

Values

In pursuing its mission, the Agency will strive to act with:

- integrity;
- openness;
- courtesy;
- responsiveness;
- timeliness;
- professionalism;
- impartiality; and
- consistency.

Aims

MHRA aims to safeguard public health by:

- ensuring, through regulation, that medicines and devices have an acceptable balance of risks and benefits;
- helping people understand the benefits and risks of medicines and devices; and
- encouraging and helping the development of medicines and devices that will contribute to health.

Objectives

The Agency's key objectives are to:

- maintain rigorous authorisation and inspection programmes;
- maintain and develop pro-active surveillance and enforcement programmes;
- communicate authoritative and reliable information and advice to improve public and professional awareness;
- engage with and influence other government bodies and European and worldwide regulators concerned with medicines or medical devices;
- support innovation and product development, offering constructive and impartial advice to scientific communities and health services;
- minimise the cost of regulation so far as is compatible with our public health role; and
- run a successful business with a skilled and equipped workforce dedicated to the Agency's aims.

Activities

The Agency's main activities are:

- assessing the safety, quality, and efficacy of medicines sold or supplied in the UK for human use;
- overseeing the UK Notified Bodies which audit medical device manufacturers;
- operating post-marketing surveillance and other systems for reporting, investigating and monitoring adverse reactions to medicines and adverse incidents involving medical devices, and taking any necessary action to safeguard public health, for example through safety warnings, removing or restricting the availability of products, or improving designs;
- operating a proactive compliance programme for medical devices;
- operating a quality surveillance system to sample and test medicines and to address quality defects, monitoring the safety and quality of imported unlicensed medicines and investigating Internet sales and potential counterfeiting of medicines;
- regulating clinical trials of medicines and medical devices;
- monitoring and ensuring compliance with statutory obligations relating to medicines and medical devices through inspection, taking enforcement action where necessary;
- promoting good practice in the safe use of medicines and medical devices;
- managing the General Practice Research Database (GPRD) and the *British Pharmacopoeia* (BP) and contributing to the development of performance standards for medical devices;
- offering scientific, technical and regulatory advice on medicines and medical devices; and
- providing the public and professions with authoritative information to enable informed dialogue on treatment choices.

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Accounts, prepared pursuant to section 4(6) of the Government Trading Funds Act 1973 as amended by the Government Trading Act 1990, of the MHRA Trading Fund as at 31 March 2006 together with the Report of the Comptroller and Auditor General thereon

Presented pursuant to Act 1973, c.63, s.4(6)

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Professor Kent Woods
Chief Executive Officer

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O ice s e o t

Welcome to this year's Annual Report of the MHRA. I am pleased to have this opportunity to reflect on the Agency's performance in the last year. This has been a busy year for us and the Report celebrates some of our successes, but also highlights some issues which have presented problems.

This Annual Report enables us to demonstrate how effectively we are meeting our objectives and also indicates to our stakeholders how we are dealing with more difficult issues. As well as offering an opportunity for looking back, it also looks forward to the year ahead.

We are still a young Agency, although we have built on the strengths of the two agencies which preceded us, and the scientific, social, political and regulatory landscape is changing significantly around us. Many of the issues faced last year, the successes and the challenges, were influenced by these two facts. To many people this has been a year of change but I see it as having been a year of investment in our future, and reaction to the changing environment. This investment, of time, money and resource, has been in both our information technology and in the way that we are organised. While the pace of this investment may slow in the coming years, I also acknowledge that we must face further changes as the Agency matures.

The implementation of our new information management system, Sentinel, has been dominated by the work we have been doing to ensure that the systems introduced meet our required standards in terms of searchability, user friendliness and response time. There is no doubt that the long term investment will pay off but I do recognise that there has been a short term impact on service delivery and on our ability to manage certain aspects of our work. I have taken a personal interest in ensuring that these issues are addressed. I am confident that there will be benefits to public health, increased efficiency in the way that we work and a better standard of service when this change is completed.

Coinciding with the changes in the Information Technology which underpins our work, we have also invested a great deal of time and energy in an internal reorganisation of two of our largest divisions. In the medicines licensing field, we have introduced Product Lifecycle Assessment Teams aligned by

therapeutic areas which will actively manage licence and variation applications over a product's lifecycle, the cradle to grave approach'. This will be coupled with a dedicated service management team to handle licensing enquiries from industry and provide a professional external face for our customers. We have also reorganised our safety operations to allow us to carry out proactive and targeted activities better across therapeutic groups of medicines and our ongoing vigilance activities will allow us to monitor the risk-benefit of marketed medicines.

We can look forward to a year of consolidation in which we get a return on the investments made; but there is more work to be done. For example, although the regulatory environments for devices and medicines are quite different, I am conscious that we need to work harder to unify the culture of the Agency, developing further the one team concept. Looking ahead, I intend to devote more time to developing ways that medicines and devices staff can learn from one another, identify best practice and build bridges for the greater protection of public health. We can achieve this through more joint working on specific projects, such as the creation of a vigilance priorities board to promote a more joined up approach to medicines and device safety and the forthcoming twinning project with the C ech Republic which will involve both devices and medicines staff. As the regulation of advanced therapies becomes a reality with the negotiation of legislation establishing a regulatory framework, we have also seen a coming together of medicines and devices expertise to ensure that UK interests are properly represented in the negotiations. This will continue.

None of this would be possible without the dedication and hard work of our staff. Their commitment to the role of the Agency in the protection of public health is striking, and it is vital to the recruitment and retention of high quality staff. This is not enough on its own and it is a key part of my role, and one that is shared by my Executive Board, to ensure that staff feel empowered and enabled to carry out their tasks efficiently and effectively. This year we have taken steps to ensure that our staff feel able to complete their tasks by offering training in a wide variety of hard and soft skills at all levels of the Agency. However, I attach particular importance to the management and leadership training which has been introduced and which I and the entire Executive Board have participated in. I see it as key to the development of the one team concept. To demonstrate its commitment to its staff, the Agency recently underwent its second Investors in People (IiP) assessment. While many areas of good practice were identified, the assessor found we did not meet all of the indicators but felt that there was evidence of progress and that the Agency should be afforded Retaining Recognition Status. Achieving full recognition will be a priority next year.

I would like to close this report by thanking not only the staff of the Agency, but also our non-executive directors and the members of the medicines and devices advisory bodies and their working groups, for their contribution to the life of the Agency over the past year.

Professor Kent Woods
Chief Executive Officer

Professor Sir Alasdair Breckenridge
Chairman

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In the business of medicines and devices regulation, there are many stakeholders and it is an ever changing environment. Every organisation needs to take stock of its stakeholders' needs and expectations on a regular basis, and examine its approach to meeting their expectations.

I regard this report as a key part of this on-going cycle of communication and feedback. I am pleased to be offered this opportunity to look at some of the interactions with our stakeholders during the year, and briefly examine the changing landscape.

The mission of the Agency is to enhance and safeguard the public's health by ensuring that medicines and devices work and are acceptably safe. A key partner in this is the Department of Heath (DoH). Under the terms of the trading fund, they are our main customer for our devices operations. Promoting the reporting of adverse events and their subsequent analysis is a major contribution to patient safety in the UK. For example, we recently wrote to all manufacturers in the UK and the relevant trade association recommending improved labelling of unpackaged devices following the death of a patient in which the difficulty in distinguishing between male and female urinary balloon catheters was a contributory factor.

It is also important that we continue to use our regulatory tools to promote the Department's broader public health aims, and this year we have continued to ensure access to more medicines over the counter and the availability of innovative treatments. With DoH colleagues, we worked on the government response to the Health Select Committee Report, The Influence of the Pharmaceutical Industry. We continue to build the detail of our responses into our internal planning, operations and policy development.

We continue to operate in a European legislative and regulatory framework and this year the Agency played a key role in the successful delivery of the UK Presidency programme. As well as steering regulation on paediatric medicines through to political agreement, we hosted two meetings of the Heads of

Medicines Agencies and a series of informal scientific meetings. We also participated in the Chief Medical Officer's Patient Safety Summit and welcomed the heads of Competent Authorities for devices to London. Outside the Presidency, we continued to participate actively in the European regulatory regimes for medicines and devices. Our staff contributed to the development of policy initiatives (such as the European medicines agencies benchmarking project, leading the development of a European counterfeiting project and promoting the more effective regulation of Notified Bodies), carried out scientific work on behalf of the EMEA, and were responsible for driving forward regulatory science at European level (for example, by chairing the Pharmacovigilance Working Party of the Committee on Human Medicinal Products).

We have a variety of other stakeholders. Balancing their needs, while taking into account the wider interests of public health, is at the heart of our work. Since the creation of the new Agency, for example, we have engaged more directly with patients and patient groups. Building on direct patient reporting of adverse events involving devices, we have now introduced direct patient reporting of adverse drug reactions. The new Commission on Human Medicines now incorporates better ways for getting lay views on regulatory issues. We have recently initiated research into public and professional perspectives on risk-benefit and regulation in medicines and devices which will feed into policy development. We are also seeking ways to engage better with healthcare professionals and launched an education programme for devices users in conjunction with The Royal College of Surgeons.

We have also been working with industry on a variety of issues. This includes working with the devices and pharmaceutical industry on the development of the regulatory regimes. For example, we have, together with the DoH and other government departments, worked with the Ministerial Industry Strategy Group (MISG) to develop the long term potential of the pharmaceutical industry in the UK. We are also helping deliver the recommendations of the Healthcare Industries Task Force (HITF), aimed at improving the competitiveness of the medical devices industry.

Science leads regulation and there is no doubt that, in scientific and in regulatory terms, ours is a changing environment. For example, the Agency is now leading the negotiations for the UK on the new Community legislation for advanced therapies and we are keen to ensure that there is a correct balance between the needs of public health and the need for innovation. The recent incident involving healthy volunteers in clinical trials for a new product designed to treat chronic inflammatory conditions and leukaemia, TGN1412, may also have implications for the future of clinical trials which will need to be investigated further. The regulator must also react to social change and I was very pleased that the 2006 annual lecture addressed the issue of patient choice and patient involvement in the regulation of medicines and devices.

This brief overview of the last year's activity helps illustrate the variety of our stakeholders and some of the steps we have taken to engage with them. ou will read about some of these activities in more depth elsewhere in this report. I would like to acknowledge the hard work and sustained effort that takes place in order to ensure that the regulatory environment meets the needs of all stakeholders in a balanced way.

I would particularly like to thank my non-executive board members for the role that they play in influencing the strategic direction of the Agency and ensuring we meet the tasks set for us by Ministers.

Professor Sir
Alasdair Breckenridge
Chairman

1 Communicate

2 Regulate

3 Cooperate

4 Investigate

5 Participate

The year in review

6 Educate

7 Legislate

8 Innovate

1

Promoting and expanding our adverse reporting systems to help identify new safety issues more efficiently and effectively

Communicate

Patient-centred regulation – where increased and easier reporting really does help make a difference.

Adverse drug reporting

One of the highest priorities for the Agency is to allow patients to report their adverse drug reactions (ADRs) directly, helping to ensure an outward facing approach to regulation, putting the patient at the centre. This helps the Agency tap into patient's perspectives, allowing us to better reflect their views in decisions affecting their health.

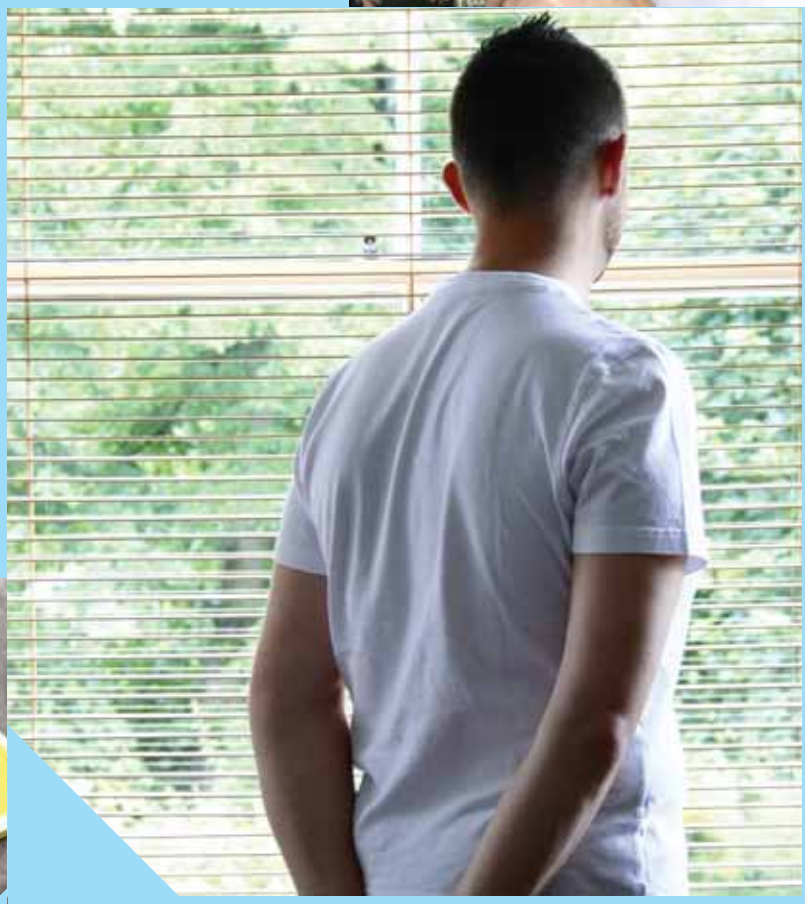
To help patients directly report suspected ADRs, the Agency launched a pilot in January 2005 and expanded UK-wide in October 2005. Patients can report suspected ADRs both electronically, through our website (www.yellowcard.gov.uk), and via a purpose designed Yellow Card. Since October 2005, patients have also been able to report via the Yellow Card hotline on a freephone number (0808 100 3352). Patient and health professional reports are handled in the same way and patient reports have been included in the current signal detection process to identify new medicine safety issues.

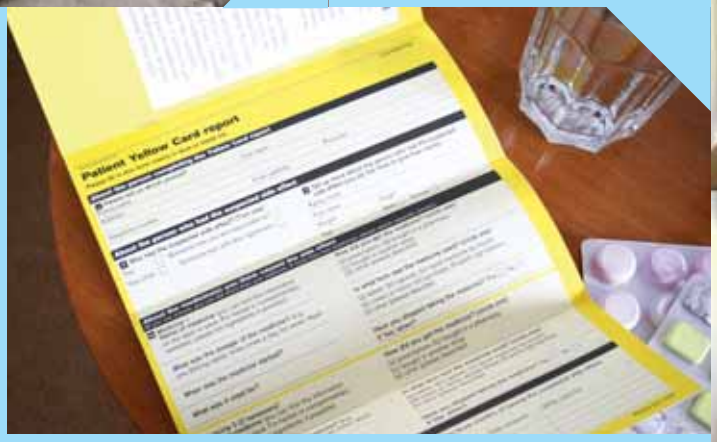
July 2005 saw the publication of the Committee on Safety of Medicines (CSM) Patient Information Working Group report *a s rea the ea et*. The report included recommendations to improve the quality of patient information. The Agency also funded the production of the leaflet *a i me ici es*, launched at the NHS Live national event, with over 14,000 issued across the UK.

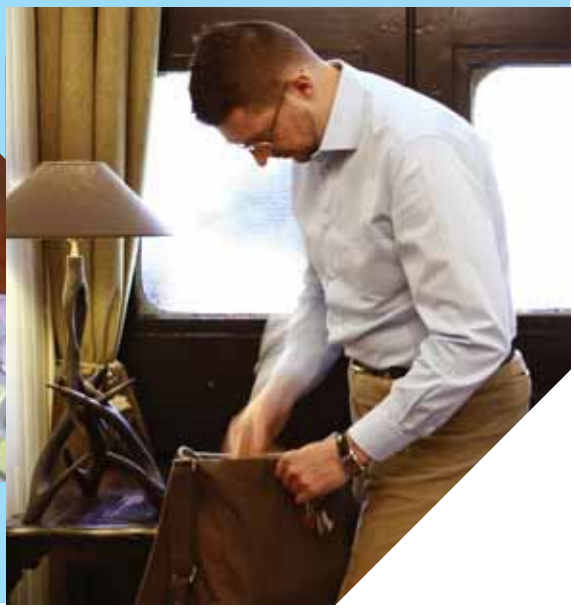
Reclassification

The Agency remains committed to expanding the range of medicines available to patients without prescription. The most notable reclassification this year was chloramphenicol 0.5% eye drops for acute bacterial conjunctivitis, the first antibiotic which can be obtained without prescription. The Agency has also consulted on the reclassification of the antibiotic trimethoprim for the treatment of cystitis, and on sumatriptan and zolmitriptan for the treatment of migraine. All these possible switches have potential to have a significant impact on public health.


Yellow Card
Taking medicines
- some questions & answers about side effects
MHRA
YellowCard
A side effect from your medicine?
Report it on this Yellow Card




Patient Yellow Card report



Wider availability

Other important developments include support for the White Paper *hoosi ea th*, in making Nicotine Replacement Therapy (NRT) more widely available. It is recognised there could be great potential for public health by making NRT more accessible. In December 2005 the Agency announced that the use of all forms of NRT should be widened, with minimum restrictions, in adolescents over 12 years, in pregnant or breast feeding women and in others such as those with heart, liver and kidney disease and those with diabetes. This was in recognition of the fact that these are patients where stopping smoking as soon as possible is especially important.

Adverse incident reporting

This year we received 7,954 adverse incident reports relating to medical devices, a decrease of 11 per cent. However, the current volume of incident reports submitted is still over 8.5 per cent higher than five years ago.

Whilst the overall number may have decreased, the proportion of incidents involving serious injury or a fatality has increased. As a direct consequence the number of in-depth investigations undertaken by our medical device specialists rose by 4.4 per cent to 2,075.

Actions taken to safeguard the public and improve device safety

The great majority of incidents investigated involved actual or potential harm to patients; we will act to protect anyone involved however, including users or carers. As a result of our investigations we:

- issued 71 safety warnings;
- shared 77 safety notifications with authorities in other EU member states;
- monitored 589 manufacturer's field safety corrective actions; and
- 232 other manufacturer's field actions;
- issued advice in 455 cases on safer device use or improved staff training
- got 635 manufacturer undertakings to improve designs, manufacturing processes and quality systems.

ommunicate

We issued all but one of the 71 safety warnings to prevent direct or indirect harm to patients or the device user (e.g. wheelchair user). These included 15 requiring patient follow-up actions for actual or potential implantable device failures and three that included important safety information to help stop harm to healthcare professionals.

Easier reporting and increased efficiency from on-line reporting

MHRA operates and encourages use of its two online medical device adverse incident reporting systems, for device users and for device manufacturers. They have proved easy to use for reporters and offer efficiency and accuracy advantages to the Agency. The user reporting system includes a simple form for patients and members of the public to report directly.

The success of the user online reporting system is evident in the significant growth in the numbers of reports now submitted through this route. This has risen from just under 900 in 2002 to over 2,500 this year. The current level is 64 per cent of the total number of reports received from device users. Similarly, since its launch in October 2003, the manufacturers' route for reporting online, MORE (Manufacturers' Online Reporting Environment), has grown steadily in activity to 22 per cent of the total number of reports received.

Regulate

New system introduced for regulating blood, including adverse reporting and inspection.

Regulations became effective on 8 November 2005 that implemented the European Blood Safety and Quality Directives and laid down requirements for the collection, testing, processing, storage and distribution of human blood and blood components. Any facility responsible for the collection and processing of blood and blood components must have a Blood Establishment Authorisation (BEA). This also includes the collection of pre-operative autologous blood, the collection of granulocytes and irradiation of blood components. The Agency has authorised the four national blood authorities in the UK and seven Hospital Blood Banks as Blood Establishments. The blood authorities were previously licensed and regularly inspected under the Medicines Act and so no further additional inspections were necessary. However the Hospital Blood Banks required inspection before the Agency could grant the authorisation.

Hospital Blood Banks do not need to be authorised or undergo routine inspections under the Regulations. However, the Regulations require that the Competent Authority, currently MHRA, assures itself that they comply with the relevant regulations. To achieve this, the Agency specified a report which all hospitals with blood banks must complete annually. Hospital Blood Banks must provide details on their current accreditation status, staffing levels and their Quality System. Following review, an on-site inspection takes place if compliance is considered a problem. Inspectors are now trained to review the 369 reports received and inspect both Blood Establishments and Blood Banks. We have completed some, but 66 Blood Banks will need inspection before the end of March 2007. All other reports reviewed were compliant although some will need inspection if improvements are not seen in the next one.

New regulations implemented setting out requirements for collection, testing, processing, storage and distribution of human blood and blood components

There is also a legal requirement to report blood related serious adverse reactions and serious adverse events to the MHRA as the interim UK Competent Authority. The Agency therefore established, by 8 November 2005, a system for reporting and recording of these incidents. SABRE, an innovative online reporting system, was developed for this purpose.

Its development and design process involved close working with many key organisations such as the Department of Health's Operational Impact Group, representatives of Serious Ha ards of Transfusion (SHOT), the national blood services and the National Patient Safety Agency, as well as the system developers.

SABRE was also developed to help reporting to SHOT by incorporating their existing haemovigilance questionnaires. This provided a single reporting route for UK haemoviligance and incorporated facilities for SHOT to review and then extract data for their own detailed manipulation and analysis.

The design and function of SABRE allows the reporting of an annual summary from each reporting establishment of all their serious adverse reaction and serious adverse event reports. SABRE will therefore help us to send these reports to the EU Commission.

Before launch we ran a UK-wide series of conferences and practical training workshops and published two guidance documents. The first described the legislation and the associated reporting responsibilities and requirements. The second was a user guide, explaining, for example;

- how to register as a SABRE user;
- how to complete the simple online report forms; and
- how to get the best from SABRE with existing local reporting arrangements.

Over 300 reporters across the UK have registered to use SABRE in the first five months of its operation, with over 800 reports submitted online to MHRA and SHOT. This total includes over 350 reports of serious adverse reactions and events submitted to MHRA.

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Helping host the UK Presidency, MHRA concentrated on the patient safety theme.

The lack of medicines developed specifically for paediatric use has been a concern for many years. The Agency has played a key role in formulating legislation to address this.

This year the Agency has continued a high level of activity in European Union (EU) business, including participation in a wide range of expert working groups and committees, and has had a significant programme of work flowing from the UK Presidency of the EU. Also during the year two key pieces of EU medicines legislation came into force, following significant input from MHRA to their negotiation over the preceding two to three years. Important progress was made in a Council Working Group under our chairmanship on draft European Commission proposals for a regulation on medicines for paediatric use. The Agency also participated in EU discussions before the launch of negotiations on a draft EU regulation on tissue engineering in January 2006.

Between 1 July and 31 December 2005 the UK held the Presidency of the EU. The Department of Health developed two headline themes, patient safety and health inequalities. All the events organised by the Agency fell within the patient safety theme.

MHRA organised and hosted twelve meetings of European Member State representatives during the six months of the Presidency, ran a successful conference on nanotechnology and contributed to the Department of Health's patient safety summit. This extensive programme of work meant that the UK Presidency was probably a more demanding time for the Agency than for any other part of the Department of Health.

Regulation for both medicines and medical devices is based on European legislation that requires close working between the various Member States. There are a number of committees and groups established that bring the Member States together to agree on the terms in which medicines and medical devices are marketed, such as the Committee on Human Medicinal Products (CHMP). In addition, a number of other, non-statutory, groups have also been established to bring experts together. These groups consider wider aspects of European legislation and its application, rather than taking product-specific decisions.

During the UK Presidency the Agency successfully organised and hosted informal meetings of experts dealing with a wide range of issues, such as counterfeiting of medicines and medical devices, homoeopathic products, information technology and medical devices. At the invitation of the Scottish Executive, two of these meetings were held in Edinburgh, the others held at venues close to London.

Highlights from the programme of meetings included:

- two successful meetings of the Heads of all the EU medicines agencies, one in Edinburgh and one in Dorking, where counterfeiting of medicines and a strategy for cooperation between the national medicines agencies (the European Medicines Network Strategy) were discussed;
- Discussions by the CHMP on patient involvement in decision making, the forthcoming paediatric regulation, transparency and communication, industrial innovation versus regulation;
- discussions on various aspects of the new medicines legislation which came into force during the Presidency, including improvements to patient information, labels and leaflets and new rules for user testing the content and quality of patient information with patient groups, ensuring that guidelines were published in time;
- setting up the first meeting of a new group established by the review of medicines legislation (the Co-ordination Group for Mutual Recognition);
- a meeting to consider how to improve harmonisation in regulation of homoeopathic medicines;
- a meeting of medicines enforcement officers who agreed to develop strategies for tackling medicine and device counterfeiting and Internet selling of non-compliant medical devices;
- demonstrations of Member State IT systems, including our Sentinel system;
- a meeting of communications experts who agreed to develop a good practice toolkit for communications on medicines matters.

One of the key tasks was to chair formal working groups of Member State representatives to undertake detailed negotiations of draft European proposals for legislation. The lack of medicines authorised and formulated specifically for paediatric use has been a concern for many years. The Agency has always considered that a pan-European solution is required to address this issue. The proposed regulation helps address this with both incentives and requirements to ensure that new medicines for children and medicines already on the market meet the specific needs of the paediatric population while ensuring that children are not subjected to unnecessary clinical trials, and that the needs of children do not delay the authorisation of medicines for adults. The Regulation has been long awaited and will be key to addressing the current unacceptable situation whereby more than 50 per cent of all medicines used to treat children have not been tested for this specific use.

Greater access to information for blind and partially-sighted patients will soon become a reality. New legislation addresses the need for some Braille labelling on all medicines.

The legislative proposal was a key health priority for the UK Presidency and the MHRA successfully chaired the working group negotiating the draft and steered it to a key stage in the negotiations at the Health Council in December 2005. This is an important step in the process of gaining overall agreement to the Regulation under the procedure that requires Member States, the European Commission and the European Parliament to develop legislation that has the support of all three institutions. The legislation is now under further discussion and is on track to come into force before the end of 2006.

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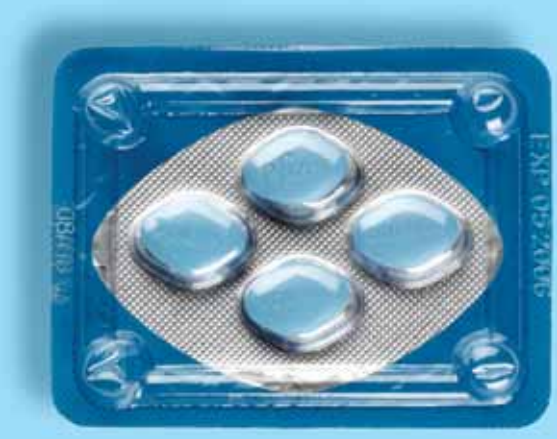
Enforcing medicines and device legislation counterfeiting and Internet sales provide us with two of our greatest challenges.



The Agency is responsible for enforcing medicines and device legislation throughout the UK, drawing on powers of entry to sei e goods and materials. Cases are referred from within the Agency, from the pharmaceutical industry, healthcare professionals and the public. They include regulatory breaches, Internet related investigations, clinical trials and counterfeits.

Which one is the counterfeit?

The Agency has stepped up its activities to help combat the challenges of counterfeiting and illegal Internet sales

Medical devices

Although not a major issue in the device sector, we have seen an increase in the sale of counterfeit devices. These are mainly low cost devices sold directly to the public, for example condoms, rather than high cost items sold to healthcare professionals or institutions. Nevertheless, there is still a clear public health concern where, as is often the case, the counterfeit is not of an adequate standard. To counter this the Agency actively investigates all reported cases of suspected counterfeiting. These can be very complicated cases to resolve because of the complicated distribution chain such products frequently go through before reaching the UK market and the fact that the counterfeiter may well be based outside of the UK. In such cases we focus on the importer or distributor that brought the product into the UK. Supplying non-compliant devices on the UK market is a criminal offence and a recent prosecution resulted in fines of several thousands of pounds for a UK distributor importing counterfeit condoms. Companies buying devices to sell on the UK market are therefore advised to check the validity of the products and their sources and inform us if they have any suspicions the devices being sold are not genuine.
(020 7084 3184)

Medicines

Counterfeit medicines are a global problem becoming an important issue both in developed as well as developing countries. Within the UK counterfeit medicines rarely get into the regulated supply chain; with 700 million prescriptions dispensed last year, only one instance was reported. Despite these low statistics, and increased market surveillance, there is no room for complacency. There is clear evidence to suggest that those engaged in organised crime are moving into the supply of counterfeit medicine, attracted by the combination of high returns and the perception of a low risk of getting caught.

Over the past 12 months the MHRA has actively investigated international counterfeiting rings, from which 12 defendants are currently awaiting trial for conspiring to introduce counterfeit medicines into the UK supply chain. We have sei ed medicines valued at 2 million and restrained assets valued at 2 million.

However, the existence of counterfeit medicines is more commonly found within the unregulated supply chain, often through websites offering lifestyle medicines, including those for obesity, impotence and hair loss.

Increased risks of buying medicines from unknown websites?

Medical devices

Medical devices for sale on the Internet must comply with the regulations where there are concerns and where the server or the company are based within the European Union. We will liaise with the appropriate country to take action. In the UK we do this ourselves. Outside the European Union certain countries will take action, such as the USA, Canada and Australia, but some areas of the world are more problematic. However, we have successfully taken action on all complaints received so far.

Unlike medicines, the Medical Devices Regulations do not actually control the advertising of medical devices. eBay has caused us concerns in the past, for example, and we have now arranged with them that any complaint brought to our notice about medical devices is dealt with through a single point of contact to ensure consistency.

nvestigate

MHRA regularly monitors this website for products that may be illegally advertised. eBay also require sellers to sign an agreement that the product concerned meets its policies, which stops the sale of certain medical devices, and that goods must be in clean good condition with any instructions for use and a labelled box.

Medicines

The Internet has encouraged a culture of self diagnosis and treatment with the wealth of health related information available and the provision of a global distribution channel. The proliferation of lifestyle medicines is feeding a huge market that can be supplied easily over the Internet. However the risks are significantly increased when buying medicines from unknown websites, with no guarantee of their safety, quality or efficacy. There is rarely any proper medical consultation; in most cases none at all.

We monitor the availability of medicines through websites. It is illegal to supply a prescription only medicine without a prescription, an unlicensed medicine or counterfeit. We use search tools to concentrate on those medicines most frequently counterfeited and available in the UK. The MHRA has jurisdiction over websites hosted within the UK or when orders are fulfilled from within the UK.

Intelligence officers conduct test purchases of medicines which are then analysed to determine the precise ingredients of the product. We have found too little or too much active pharmaceutical ingredient or even no active ingredient at all. We have also found cases where no product has been supplied or credit card details misused. We refer such cases to the relevant Trading Standards office.

We seek compliance where breaches of legislation are found and, where appropriate and proportionate, will vigorously pursue those responsible through the criminal and civil courts.

The investigation of counterfeits and Internet sales requires international collaboration; both issues are global in nature and require a global co-operative response. We helped in World Health Organisation initiatives to combat the availability of counterfeit medicines, and lead European-wide initiatives to co-ordinate strategies to reduce the risk and harm caused by these. This work will continue.

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The Agency has started several initiatives to help us listen, understand and respond to suggestions, particularly from the general public.

During the year the Agency undertook a major exercise to restructure the independent scientific bodies that advise the UK Licensing Authority (Ministers) on medicines regulatory matters. Changes were made to the legislation, abolishing the Medicines Commission and creating a number of statutory committees with equal status, with the ability to create Expert Advisory Groups to advise the statutory committees on specific issues. The new structure comprises the Commission on Human Medicines (CHM), which replaced the Committee on Safety of Medicines (CSM), and which also has a statutory obligation to undertake certain tasks previously the responsibility of the Medicines Commission, the Herbal Medicines Advisory Committee (HMAC), the British Pharmacopoeia Commission (BPC) and the Advisory Board for the Registration of Homoeopathic products (ABRH).

The Agency also revised the Code of Practice on Interests for the chairmen and members of the statutory committees and their Expert Advisory Groups. The chairmen and members of the CHM, HMAC and ABRH may not hold any personal interests in the pharmaceutical industry, and revised rules have been established governing the disclosure and publication of interests by them and their Expert Advisory Groups, and for attendance at conferences and scientific meetings. A revised Code of Practice on Interests for the chairman and members of BPC was also drawn up, although different rules apply to them because of their distinct role and remit.

The MHRA has helped deliver key outputs identified by the joint government and medical device industry HITF. It helped identify areas that would benefit patients, service users, health and social care services and industry by stimulating innovation, procurement, research and development capacity and by improving the regulations, supporting export strategies and raising awareness and public understanding of the safety and value of medical devices.


MHRA

Working with industry, healthcare professionals, EU partners and other key stakeholders, MHRA has helped maximise UK influence in regulatory matters and developed a strategy for communicating with patients and public to improve understanding of the benefits and risks of medical devices. The Agency was also involved in work helping improve training and education on medical devices for NHS staff.

The Agency's mission to safeguard public health can only be fully achieved if the Agency listens to, understands and responds to the expectations of the general public. This means that the Agency needs to communicate effectively with the public, both by sharing information and by being able to access and respond to public views about its activities. Over the last few years, the Agency's activity has been the subject of detailed scrutiny by, for example, Parliament and the National Audit Office. At the same time, it has taken steps to open up its work to patients and the public in novel ways.

Last year the House of Commons Health Select Committee issued its report into the influence of the pharmaceutical industry. Although this was not specifically about the MHRA, a number of its recommendations are focussed on, or at least have a bearing on, the Agency's work. The government's response accepted many of the recommendations which related to areas including the regulation of advertising and promotional materials and the communication of information about medicines to patients.

The report and response have underscored the importance of taking forward the Agency's programme of work on communications, which was given a new focus on 1 April 2005 with the creation of the Communications Division. For the first time, the Agency now has a published communications strategy, its own in-house press office, and an integrated website allowing healthcare professionals and the public ready access to information about medicines and medical devices.

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The communications strategy sets as one of its key priorities the need to engage more effectively with patients and the public. A key part of this has been the creation of a new panel of expert advisory groups on medicines, all with lay representation. The Agency regularly hosts consultative committees in which industry trade associations, non-commercial organisations and other government bodies discuss inspection activities. For medical devices, the Committee on the Safety of Devices (CSD) also has lay members, and the plan over the next year is to build mechanisms by which all of the Agency's lay representatives can maintain contact with each other, provide support and share expertise.

And it is not just a question of bringing stakeholders into the Agency staff are also regular speakers at outside events where industry, healthcare professionals and lay people attend. This provides an important opportunity to present the work of the Agency, and to discuss the work of the Agency with those affected by our decisions. Over the coming year, we are planning our first MHRA conference which will be open to all of our stakeholder groups, and will build on this programme of work.

On certain issues, the Agency has a responsibility to consult formally for example, on the setting of fees, or on decisions to switch medicines from prescription-only to over-the-counter status. The Agency has an established process for doing this, and has run a number of consultations over the year with a variety of stakeholders contributing.

However, the Agency is also exploring new ways of seeking consultation input, particularly from patients and the public for example, last year the MHRA commissioned a special survey of patient and consumer groups to help inform changes to ways of working in relation to patient information, and in particular the regulation of advertising. It is also in the middle of a large market research programme to establish public and healthcare professionals' perceptions of the risks and benefits of medicines, and their regulation. During the course of the year, the Patient Information Working Group, a specialist group including lay representatives, concluded its deliberations on the user-testing of patient leaflets, and published its report *a s ea the a e*, providing advice on how best to undertake such testing.

Finally, the advent of the Freedom of Information (FOI) Act in January 2005 has provided another opportunity for increased openness and transparency. The Agency has received several hundred requests under the FOI Act, and in early 2006 has set up a dedicated section on its website for the publication of responses to FOI requests. Members of the public can now see what FOI requests have been made to the Agency, and how it has responded.

The Agency has continued to develop more effective education, training and communications to its various stakeholders

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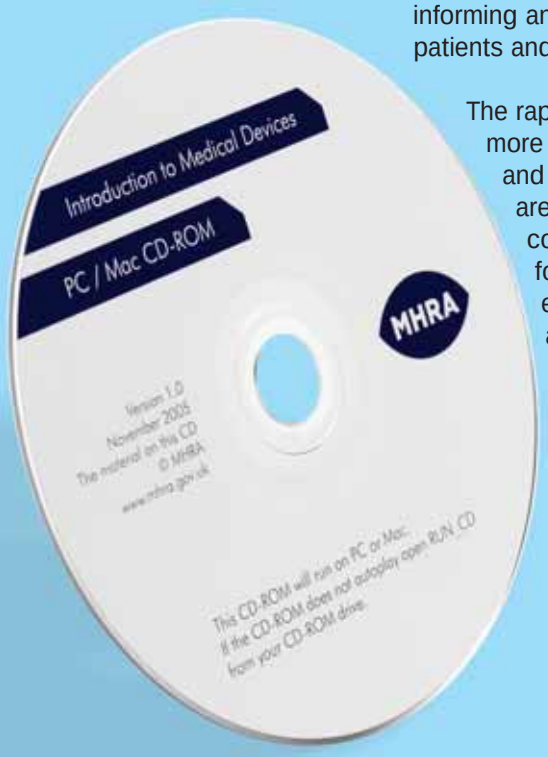
Providing a range of education and training packages to help the safe and effective use of medicines and medical devices.



The Agency has been actively involved in education and training in the safe and effective use of medical devices across all healthcare sectors for many years now. Medical Device Alerts, One Liners, Device Bulletins and a range of other supporting publications play an important role in informing and educating both patients and staff.

The rapid development of ever more sophisticated devices and their appearance in all areas of modern healthcare continues to drive this need for widespread and effective education and training.

In the past essential information about the safe use of medical devices was mainly disseminated through written publications and presentations. The rapid rise in the use of the electronic learning programmes, either delivered from CD ROM or via the Internet, gives an exciting opportunity to get this kind of educational material to a much wider audience.

Over the last year the MHRA has started a bespoke e-learning program covering the principles of the safe use of medical devices. Using high resolution images, sound effects and a Flash-based interactive platform the Agency has produced a CD ROM and Internet-based learning programme aimed at all users. So far feedback about the programme is good with nearly 5,000 CD copies distributed. The Committee on the Safety of Devices (CSD) fully supports this with a second enhanced version published later this year.

In response to the HITF recommendations the MHRA has proposed the introduction of a modular training programme along the lines of the European Computer Driving Licence. Extensive discussions were held with a range of interested parties including the Royal Colleges, the General Medical Council, Postgraduate Medical Education and Training Board, Modernising Medical Careers and industry. The CSD also gave this its unanimous support. Three modules are scoped covering electrosurgery, operating tables and anaesthesia workstations, with the intention to be ready by the end of June 2006.

We now have in-house expertise to provide high quality images, video material and 3D animations to support the project, as well as expertise in the use of state of the art rapid e-learning development tools. This produces high-quality e-learning materials cheaper than external commercial alternatives. It also allows rapid response to user feedback.

This fourth conference, Making Connections', took place in November 2005 in Bristol.

More than 200 delegates from all areas of the NHS, social care and the private health sector attended. Speakers included the Department of Health's Patient Safety Team, the MHRA and the CSD. The Chief Executive gave the Keynote Address highlighting the need for effective connection with our various stakeholders to allow the Agency to perform its functions effectively.

Other topics included:

- the MHRA's communication strategy;
- the new Blood Safety Directive;
- the launch of the new education programme for device users;
- communication with device users in the community; and
- an update on the Safety Alert Broadcast System.

Delegates had plenty of opportunity to network and an electronic audience response system was used for the first time. This helped provide feedback at what was one of the most successful Liaison Officers' Conferences ever.

Many symposia have been arranged to provide stakeholders with an opportunity to discuss the variety of challenges they face and understand their interactions with the MHRA.

The Agency continues to take a lead role in Europe by providing training for inspectors from many countries.

Last year the Agency provided regulatory and drug safety input to medical student teaching programmes in four UK Medical Schools with input to curricula and examination questions in a further three. We have also provided regulatory curriculum development and examination input for postgraduate Higher Medical Training in Pharmaceutical Medicine and proposals suggested for Royal College of Physicians' lectures.

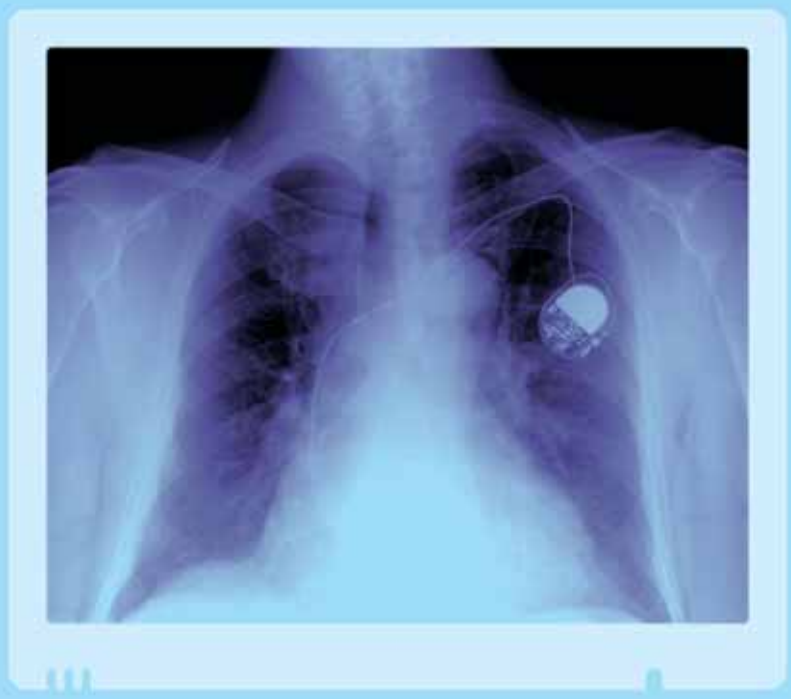
70 delegates from a range of leading UK academic research centres attended a successful symposium at MHRA to launch a new collaborative project with academia. This project will lead to closer links between academia and research groups and improve the Agency's ability to proactively investigate drug safety issues.

The Agency also issued new prescribing advice on suicidal behaviour associated with Strattera (atomoxetine), the safety of salmeterol and formoterol, the cardiovascular safety of traditional non-steroidal anti-inflammatory medicines (NSAIDS) and the safety of paroxetine in pregnancy.

Information was added to our new website to coincide with the launch of the new COX-2 inhibitor, Prexige (lumiracoxib) in December 2005. This included the full licensing assessment reports for this medicine, summaries of the key data relating to the safety of the COX-2 inhibitors and traditional NSAIDs and the Risk Management Plan for Prexige.

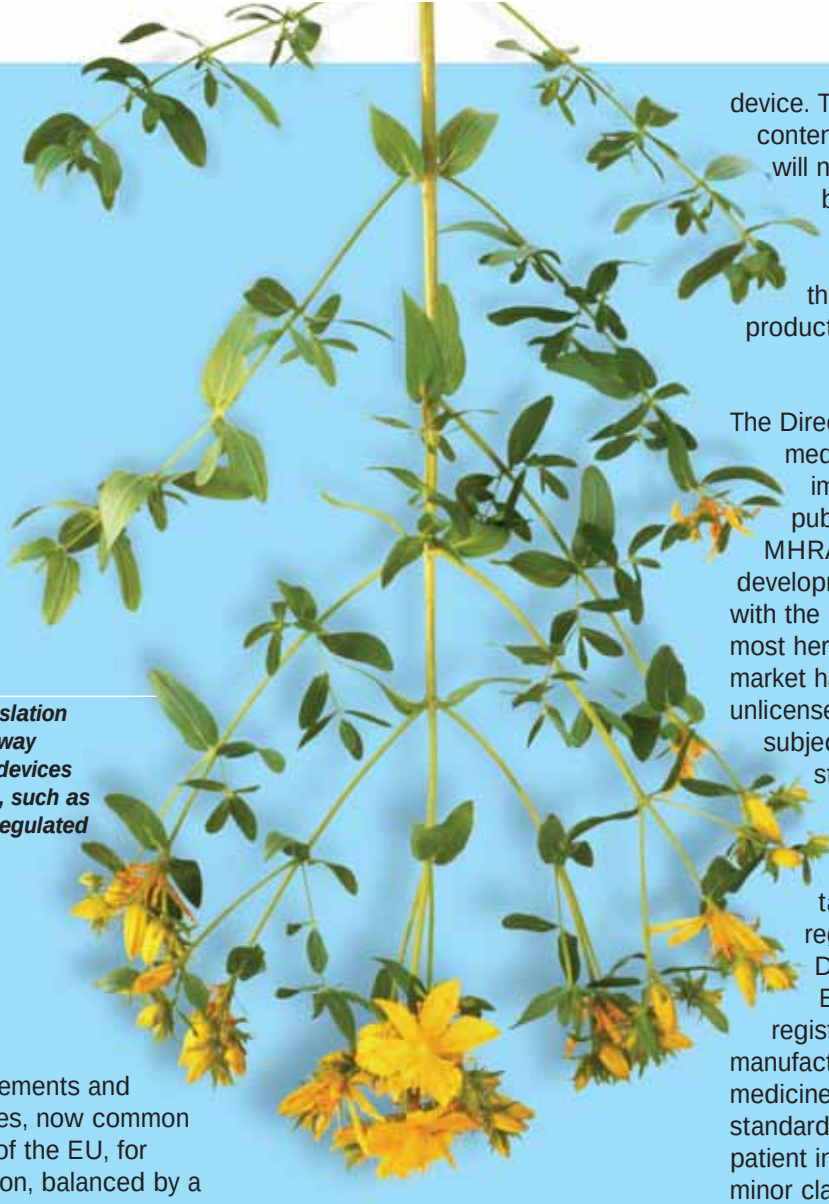
egislate

The introduction of new legislation has helped promote and protect public health in medicines, medical devices and herbal products.



In October 2005 new legislation came into force in the UK making significant and wide ranging changes to the way medicines are regulated. The European Commission proposed these changes in their 2001 review of medicines legislation. However it took three years for the European Commission, the Member States and the European Parliament to reach agreement on the new provisions.

The Agency played a leading role in these negotiations and was broadly successful in ensuring the outcome met UK government's overall objectives for the review. The revised medicines legislation has produced the most comprehensive set of changes to the regulatory framework since European law was first introduced just over forty years ago. It addresses the entire lifecycle of the medicine, and makes some fundamental changes, including extending the range of products that must apply to the European Medicines Agency (EMEA) for a marketing authorisation, strengthening post-marketing



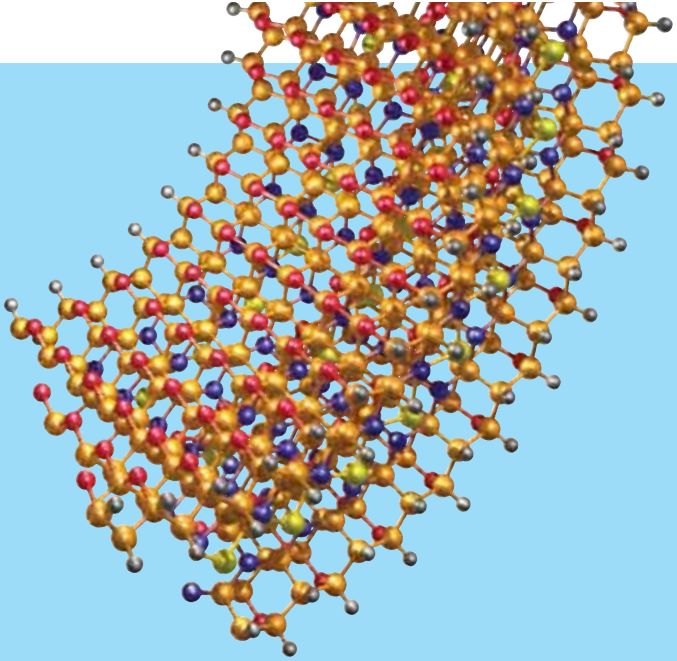
Introducing new legislation to help improve the way medicines, medical devices and herbal products, such as St. Johns Wort, are regulated

surveillance requirements and providing clear rules, now common across the whole of the EU, for rewarding innovation, balanced by a range of benefits to encourage development of generic products. There are some significant improvements to the transparency of procedures, including public access to databases. It recognised the increasing globalisation of medicines regulation and the need to ensure that the regulatory system can handle emerging new technologies.

As a result of the review, the regulatory system is now better, faster and stronger than before. It is better able to protect and promote public health through more effective safeguards in relation to pharmacovigilance; faster, to the benefit of patients and their access to important new medicines; stronger, because of the increased transparency of the system in relation to the evidence base for decisions and the confidence that the public can have.

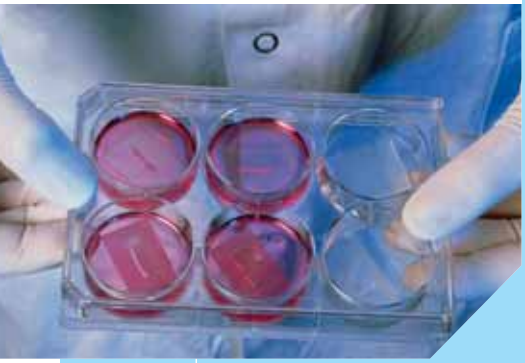
Work also began, in early 2006, in negotiating the EU Commission's proposals to revise the main Medical Devices Directive and the Implantable Medical Devices Directive. These broadly reflect the findings of the 2002 Review into the functioning of the medical devices directives and are aimed at helping to improve the consistent interpretation and implementation of the existing regulatory regime rather than fundamentally changing it. The UK was active and influential in that review and, accordingly, believes that most of the proposed revisions should be broadly acceptable. However, the Commission has also suggested changing the scope of the Directive to include elements of human tissue engineered products that act in an ancillary manner to the device. This is likely to prove a more contentious area and the Agency will need to ensure close liaison between work on the devices Directive and that concerned with negotiating the new tissue engineered products Regulation.

The Directive on traditional herbal medicinal products is an important step forward in public health protection and the MHRA played a major role in its development, in close collaboration with the UK herbal sector. Historically most herbal medicines on the UK market have been supplied as unlicensed herbal remedies and subject to few regulatory standards. There is continuing evidence that the public has been put at risk by unsafe, low grade, herbal products taking advantage of this weak regulatory regime. The Directive now requires each EU Member State to set up a registration scheme regulating manufactured traditional herbal medicines. Products will have to meet standards of safety, quality and patient information and can make minor claims on the basis of their traditional usage. The Directive was transposed into UK law in October 2005, when the MHRA also established the UK registration scheme. The UK herbal sector includes many small and medium si ed businesses. To help them meet the challenge of these systematic new requirements, and so maximise choice available to consumers, the MHRA has worked closely with the industry, providing extensive guidance and help about the requirements of the registration scheme.



nnovate

MHRA is working at ways to encourage innovation, like tissue engineering and nanotechnology, while still achieving a proportionate regulatory framework to ensure public health.



Supporting innovation without stifling development while still helping ensure patient safety – meeting the challenges

At the beginning of 2005 a group of senior pharmaceutical industry executives and Ministers from Departments of Health and Trade and Industry agreed that for a Long Term Leadership Strategy, a group was needed to identify critical actions that would improve the effectiveness of medicines regulation and help both the promotion and protection of public health. This project is part of an overall initiative that follows on from the Pharmaceutical Industry Competitiveness Task Force (PICTF) set up by the Prime Minister which reported in March 2001. Whilst recognising the benefits that PICTF had brought, it was agreed that some four years on, and following a similar initiative in Europe, it was time for the UK to re-examine the way medicines regulation operates to both promote and protect public health and to foster a climate of innovation in the UK. The group is looking at new methods for the safe introduction of medicines and the safety of licensed medicines, whilst maintaining patient access to innovative medicines and if possible reducing the burden of development costs of a pharmaceutical product through to approval. There will be a need to focus on both UK and Europe.

In March 2006, a serious and tragic incident occurred in a clinical trial for a new monoclonal antibody (TGN1412), which was being conducted at the Parexel clinical trials unit in north London. All six of the healthy volunteers involved in this study experienced very serious adverse reactions as a result of cytokine storm' following administration of the medicine, and were admitted to the intensive care unit at Northwick Park hospital.

The MHRA immediately suspended the trial authorisation, and sent a team of inspectors to investigate the incident. At the time of writing, findings from the investigation indicated that there was no evidence of contamination of the product, nor was there anything in the running of the trial which contributed to the outcome.

This suggests that there is something about the way this particular product works which was not predicted in extensive pre-clinical testing, and this in turn raises complex and important scientific issues for the future. The Secretary of State for Health has set up an expert working group to consider these issues, and the Agency will be studying the group's recommendations carefully once published.

The Agency has participated in a number of groups brought together from across government to address the emerging issues associated with nanotechnology, in particular those examining the potential risks posed by engineered nanoparticles, identifying the extent of potential gaps in medical devices regulation with regard to nanotechnology and participation in the BSI Nanotechnology Standards Committee.

Nanotechnology conference: Impact on Health and Regulation

The recent report by The Royal Society and The Royal Academy of Engineering made a number of recommendations on nanotechnology, highlighting the need for research to address uncertainties about the health and environmental effects of nanoparticles and regulation to control exposure to nanoparticles. The MHRA took the opportunity of the UK Presidency to hold an event highlighting the relevant health, safety, regulatory, consumer and environment issues.

The event attracted over 120 delegates from both the UK and overseas, from a variety of organisations including academia, medical device manufacturers, pharmaceutical industry, trade associations, the insurance industry, regulatory groups, healthcare professionals and government. Speakers came from a wide range of organisations including the US Food and Drug Administration, the Netherlands Centre for Biological Medicines and Medical Technology and the European Commission, Greenpeace and the Office for Science and Technology.

The conference confirmed that there is a need for further understanding of the potential unknown and undesirable consequences of this technology; but also, that this technology offers potential benefits, particularly in the healthcare environment.

Tissue engineering is an emerging technology combining aspects of medicine, cell biology, science and engineering for the purpose of regenerating, repairing or replacing damaged tissue. The use of tissue engineering has already led to the development of products that are used clinically for the treatment of burns or ulcers and cartilage repair systems. More complex products are currently being developed which could have significant potential for future healthcare treatments.

Currently, there is no specific European regulatory framework for tissue engineering. Achieving an appropriate and uniform one will help this important area of bioscience to develop.

In November 2005, following several public consultations, the European Commission adopted formal proposals for a regulation on advanced therapy medicinal products, including tissue engineering. Negotiations started under the Austrian Presidency in January 2006 and are expected to continue through the coming year. MHRA objectives are to achieve a proportionate regulatory framework which not only protects public health but also fosters innovation and gives industry the regulatory clarity required to attract investment. The Agency also wants to ensure that the medicines and medical devices regulatory regimes fit in well with this area. Work will continue with stakeholders, including representatives of industry, the NHS, academic researchers and consumers as negotiations continue.

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Agency Board

Executive Board

Executive Board
Top row, from left to right

Bottom row, from left to right

Corporate Governance

Agency Board
From left to right

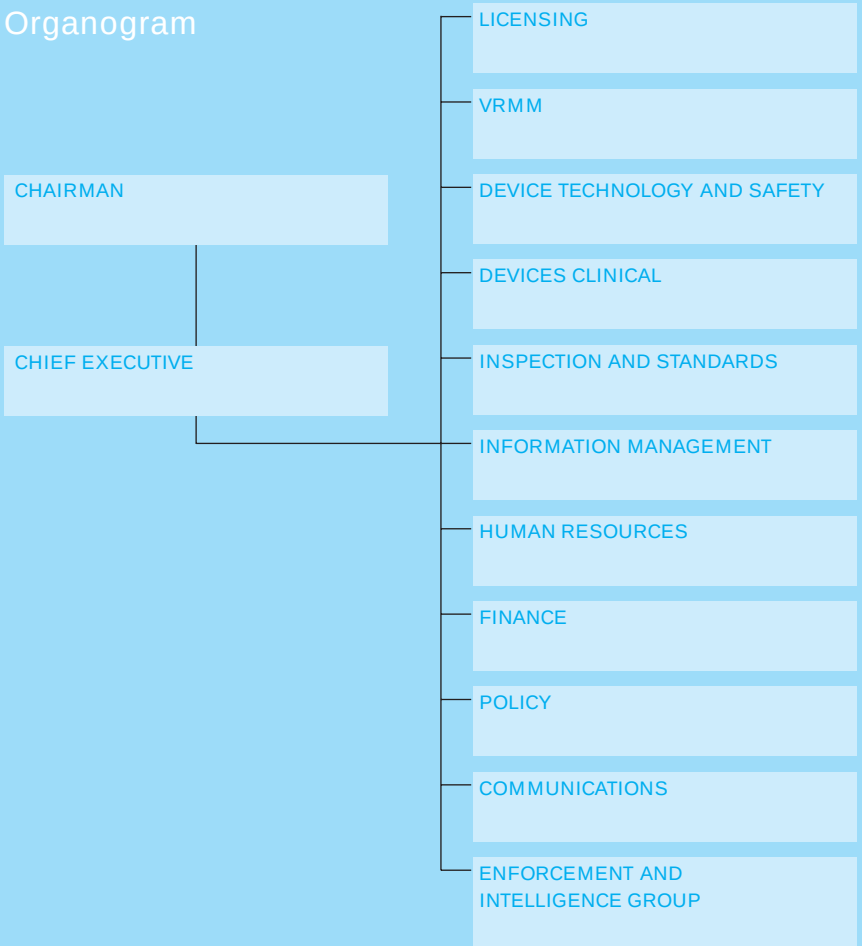
MHRA has an Agency Board, an Executive Board and a Risk and Audit Committee. Together these three entities oversee the Agency's corporate governance and risk management systems to ensure that the highest standards of integrity, accountability and operational capability are maintained.

The Agency Board consists of a Chairman, six non-executive members and the Chief Executive Officer of the Agency. The Agency Board's role is to monitor the Agency's strategic direction and to take action as appropriate. The Chairman is directly accountable to Ministers for the performance of the Agency and its decisions.

The Executive Board comprises the Chief Executive Officer and the Heads of Divisions, who take executive responsibility for the strategy, operational management and service delivery of the Agency, including risk management. As the Accounting Officer, the Chief Executive Officer also has responsibility for the Agency's resources.

The Risk and Audit Committee reports independently to the Accounting Officer and the Agency Board on the effectiveness of the operation of the Agency's corporate governance and risk management systems. The Committee is chaired by a non-executive Agency Board member.

Organogram



Performance against key targets 2005/06

Implement proposals for a new medicines advisory body structure, and introduce revised codes of practice on interests in the pharmaceutical industry for committee members and staff by October 2005.	Achie ed
Promote and demonstrate wider use of the GPRD and Yellow Card database in the interests of medicines safety and reduced medication error with measured increased usage in both databases.	Achie ed
Capture more promptly the reports of adverse drug reactions and device adverse incidents, initiating timely and appropriate action to protect public health, particularly for those reports in which medication error is suspected. Maximum number of working days between receipt of reports and making them available for evaluation and analysis: • three for fatal and serious device adverse incidents; • three for fatal adverse drug reactions and five for serious reactions; • seven for identification and transmission of suspected medication errors to the National Patient Safety Agency (NPSA).	ot achie ed for the first bullet point but achie ed for the second and third

To provide health professionals with greater knowledge about the regulation and safe usage of medicines and devices, produce and pilot at least two new postgraduate level education programmes or tools for assessment which are acceptable to relevant professional bodies and, at undergraduate level, secure agreement for the introduction in 2006-07 of examination questions relating to medicinal products in at least four medical school curricula.	ot achie ed though agree ent for one ore edical school curriculu ould ha e secured achie e ent
Engage proactively with the public and healthcare professionals, in particular promoting understanding of risk and drawing attention to the dangers of Internet sales, positioning this work in the development and agreement by July 2005 of a wider two-year communications strategy containing actions that will be completed by March 2006.	Achie ed
Improve the transparency of decision making within the Agency and accountability to the public by publishing UK Public Assessment Reports for medicinal products licensed from October 2005, by providing summaries of the evidence supporting major safety decisions, and by ensuring that all requests under the Freedom of Information Act are replied to within 20 working days, with internal reviews showing 90 per cent of them complying with the principles contained in the Act and guidance issued by Department of Constitutional Affairs and the Information Commissioner.	ot achie ed in respect of reedo of nfor ation replies though the other t o parts of the target ere achie ed
Implement the new UK legislation for improving patient information leaflets (PILs), including through user testing with target patient groups. By 30 October 2005 issue practical guidance for company initiated applications as developed through Europe. Arrange for user testing of PILs for ten priority medicines, taking into account medication error, other safety concerns, specific target populations such as children, and/or widespread usage.	Achie ed
Within one month of receiving the European Commission's expected legislative proposals on the regulation of tissue engineered products, and of its expected draft amending directive on medical devices, agree timetabled plans for the launch and conduct of negotiations during the UK Presidency; and fulfil those plans.	arget superseded at the re uest of Ministers since hat as e pected fro the o ission as not recei ed until the residency as nearly o er Actions subse uently agreed ith Ministers ere ho e er co pleted
a) Assessment of clinical trial authorisations for medicines: • Phase I (normal volunteer) trials: 100 per cent in 21 calendar days with an average of 14 calendar days or less; • All other trials: 100 per cent in 30 calendar days. b) Assessment of clinical investigation notifications for medical devices • 100 per cent in 60 days with an average of 54 days or less.	ot achie ed in respect of part a though part b as achie ed
Increase the number of appropriately labelled medicines for children, including in at least two new therapeutic classes, and ensure relevant and up to date advice for paediatric medicines is available for health professionals and patients.	Achie ed

Key targets 2006/07

1 Before each quarter, agree a risk-based plan for Good Practice inspections in the medicines sector; during the quarter, inspect 95 per cent of the sites in that plan, including all those deemed to be of high risk.

2 Promptly capture reports of adverse drug reactions and device adverse incidents, initiating timely and appropriate action to protect public health, particularly for those reports in which medication error is suspected.

Maximum number of working days between receipt of reports and making them available for evaluation and analysis:

- three for fatal and serious device adverse incidents;
- three for fatal adverse drug reactions and five for serious reactions;
- seven for identification and transmission of suspected medication errors to the National Patient Safety Agency (NPSA).

3 Issue timely drug alerts, medical device alerts and other safety warnings which identify clear and appropriate action which recipients can achieve within realistic timescales, reviewing the effectiveness of these alerts through feedback monitoring and their quality through independent assessment.

4 Develop by September an anti-counterfeiting strategy aimed at disrupting those enterprises engaged in the importation, wholesale, distribution and supply of counterfeit medicines, through public awareness, targeted market surveillance, international co-operation between regulators, and co-ordinated and focussed investigations and prosecutions. Implement all actions in the strategy that are designated for the remainder of 2006-07.

5 Continue to improve the transparency of decision making within the Agency and accountability to the public by:

- publishing UK Public Assessment Reports for medicinal products licensed;
- providing summaries of the evidence supporting major safety decisions, and
- ensuring that all requests under the Freedom of Information Act, where the balance of public interest does not apply, are replied to within 20 working days, with internal reviews showing 90 per cent of them complying with the principles contained in the Act and guidance issued by Department of Constitutional Affairs and the Information Commissioner.

6 Consult with patients, healthcare professionals and other stakeholders to refine the Agency's model for weighing risks against benefits in its regulatory decisions, and publish the resulting model in language accessible to the public.

Financial statements 2005/06

7a Assessment of clinical trial authorisations for medicines Phase I (normal volunteer) trials:

- 100 per cent in 21 calendar days with an average of 14 calendar days or less;
- All other trials: 100 per cent in 30 calendar days.

7b Assessment of clinical investigation notifications for medical devices:

- 100 per cent in 60 days with an average of 54 days or less.

8 Achieve an expenditure and income out-turn for 2006-07 in line with the published budget; and set a balanced budget for 2007-08 which would allow the Agency to deliver HM Treasury's requirement for a 3.5 per cent return on capital employed over the first five years of its life.

9 Realise the expected benefits for the medicines sector of the investment in the Sentinel IT system and the restructuring of the organisation, achieving the savings set out in the business case for Sentinel and improving the service to industry stakeholders, to be measured in a survey of them.

10 Repeat the staff satisfaction survey of two years earlier to measure progress and to establish new priorities for action and new targets for achievement.

11 Continue to improve the management and development of people in the Agency, taking full account of the results of the Investors in People assessment of March 2006.

12 Create a cross-divisional, public-facing Medicines and Devices Vigilance (MDV) Group within the Agency which will develop a strategy to improve knowledge of risk-benefit relationships and to present risk-benefit information to patients more effectively.

The Management Commentary has been prepared solely to provide additional information to stakeholders as an entity, to assess the Agency's strategies and the potential for those strategies to succeed. This Management Commentary should not be relied on by any other party or for any other purpose.

The Management Commentary contains forward-looking statements which:

- have been made by the Chairman and Chief Executive in good faith based on the information available to them up to the date of this report, and
- should be treated with caution due to the inherent uncertainties, including political, economic and business risk factors, underlying any such forward-looking information.

The Management Commentary comments on the following areas:

- Strategy and business objectives
- Corporate governance
- Risk management
- Review of operations
- Future outlook
- Performance targets
- Financial review
- Remuneration report
- Social, community and environmental issues

The MHRA's mission is to enhance and safeguard the public's health by ensuring that medicines and medical devices meet acceptable standards of safety and that they work. This is achieved by:

- ensuring through regulation, that medicines and devices have an acceptable balance of risks and benefits;
- helping people understand the benefits and risks of medicines and devices;
- encouraging and helping the development of medicines and devices that will contribute to health.

The MHRA's business objectives are to:

- maintain rigorous authorisation and inspection programmes;
- maintain and develop pro-active surveillance and enforcement programmes;
- communicate authoritative and reliable information and advice to improve public and professional awareness;
- engage with and influence other Government bodies and European and worldwide regulators concerned with medicines or medical devices;
- support innovation and product development, offering constructive and impartial advice to scientific communities and health services;
- minimise the cost of regulation so far as is compatible with the public health role; and
- run a successful business with a skilled and equipped workforce dedicated to the Agency's aims.

The MHRA, an Executive Agency of the Department of Health, and operating as a Government trading fund, came into being on 1 April 2003, from a merger of the Medicines Control Agency and the Medical Devices Agency. The Secretary of State for Health determines the policy and financial framework within which the MHRA operates, but is not involved in the day-to-day management of the Agency. Under the terms of its Framework Document, the MHRA operates through:

- an Agency Board consisting of a Chairman, six non-executive members and the Chief Executive of the Agency, whose role is to monitor the Agency's strategic direction and take action as appropriate. The Chairman is directly accountable to Ministers for the performance of the Agency and its decisions.
- an Executive Board, comprising the Chief Executive and the Heads of Divisions, who take executive responsibility for the strategy, operational management and service delivery of the Agency, including risk management. As the Accounting Officer, the Chief Executive also has responsibility for the Agency's resources.
- a Risk and Audit Committee which reports independently to the Accounting Officer and the Agency Board on the effectiveness of the Agency's corporate governance and risk management systems.

The compositions of the Agency Board, the Executive Board and the Risk and Audit Committee are detailed on page 45.

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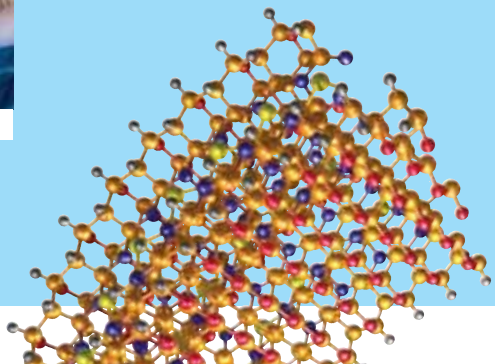

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