# Progress Report after one year on the MHRA and DH response to the recommendations of the Howe Review into Poly Implant Prothèse (PIP) Breast Implants

## Introduction

In January 2012 Earl Howe commissioned a review of the activities of the Medicines and Healthcare products Regulatory Agency (MHRA) into its involvement and handling of the PIP breast implant investigations. This review was published in May 2012[1], making fifteen specific recommendations for the MHRA and Department of Health (DH) to act on.

This report outlines the substantial progress achieved by the MHRA and DH in addressing the recommendations of the Howe Review, as of the end March 2013. A summary of these recommendations is at Annex A.

In response to the Howe Review, the MHRA Devices Division established eleven projects, commencing in September 2012, covering a range of initiatives to specifically address the recommendations and, also, to introduce a range of measures required to enhance the performance of the Devices Division over the next five years.

The MHRA plans to strengthen its role in medical device regulation in a number of ways. For example, it will enhance the clinical advice it brings to bear on major issues and introduce increased scrutiny of the performance of notified bodies.

The timescales associated with these projects ranged from short-term activities, for example, introducing changes to adverse incident handling procedures and associated administrative tasks, to long-term projects to tackle the more complex issues identified in the review.

Consequently, the progress achieved by the projects varies in accordance with the magnitude and nature of the tasks. Some have delivered "quick wins" through the introduction of enhancements to existing procedures for adverse incident investigation and data trending, whereas others, such as the UDI (Unique Device Identification) programme, have been started, but will take longer to complete and involve commitments and actions from others involved in both the delivery of care and evolution of the regulations.

For the purposes of this report the recommendations of the Howe Review, and the MHRA activity implemented to address these, have been grouped into five broad headings of activity. The last of these groupings covers recommendations

[1] Poly Implant Prothèse (PIP) silicone breast implants. Review of the actions of the Medicines and Healthcare products Regulatory Agency (MHRA) and Department of Health. Published 14 May 2012.

directed towards the DH, although many others require action by DH and NHS England in order to be implemented effectively:

i) Adverse incident reporting and investigation

Enhancing the effectiveness of adverse incident reporting and the appropriate level of investigation by the MHRA, coupled with an effective analysis of reporting trends and the detection of signals from the incident database, should prevent the recurrence of a situation where problems with a particular medical device or manufacturer remain undetected for long periods.

ii) Regulatory activity and engagement with Europe

The revision of the European Union (EU)Medical Devices Directives is a major undertaking in which the MHRA is fully engaged, leading negotiations for the UK Government and working closely with other Member States and the European Parliament in this process. Key issues being addressed include the oversight of notified bodies throughout the EU and the collaboration across all member states over safety issues relating to medical devices.

iii) Communications and stakeholder engagement

The importance of communication with all stakeholders over medical device regulation and safety issues is recognised as a key priority for the MHRA, and is highlighted in the Agency's Communications Strategy. A major programme of engagement is under way, utilising novel means of communication to supplement the more traditional channels such as the broadcast and print media.

iv) Records management

The necessity of maintaining comprehensive records of all adverse incident investigations has long been recognised by the MHRA. In addition, the need to keep detailed and accessible records for all forms of correspondence was highlighted in the Howe Review.

v) Other recommendations

The review included a number of other, general recommendations not directly within the remit of the MHRA.

## Background

In March 2010, the MHRA was informed by AFSSAPS (Agence Française de Sécurité Sanitaire des Produits de Santé, the French regulator of medicines and medical devices) that it had suspended the marketing, distribution, export and use of silicone gel filled breast implants manufactured by Poly Implant Prosthèse (PIP), as it had been established that implants manufactured since 2001 had been filled with an unapproved silicone gel.

The MHRA issued a Medical Device Alert advising UK clinicians not to implant these devices within two days of receiving this notification, following a much accelerated consultation process (an 18 day target for the issue of Medical Device Alerts was in force at this time).

In April 2010, AFSSAPS initiated testing of affected implants to look at the genotoxicity, cellular toxicity and irritation to biological tissues. At the end of June 2010, the MHRA decided to commission its own limited testing to obtain an early indication of genotoxicity, due to delays with the AFSSAPS testing.

In early September 2010 the MHRA announced the results of the UK testing, which found no evidence of safety issues associated with the filler material. These results were then confirmed by the AFSSAPS tests later in the same month.

In October 2010, the MHRA issued a further Medical Device Alert advising UK clinicians on the clinical management of women implanted with PIP silicone gel filled breast implants.

In April 2011, AFSSAPS published the results of additional tests on the filler material that did not show any genotoxic effects.

On 23 December 2011, the French Government announced that it was recommending that all women who had been implanted with PIP breast implants should have them removed as a preventative measure. This generated considerable media interest across Europe.

On 31 December 2011, the Right Hon. Andrew Lansley MP, the then Secretary of State for Health, asked Professor Sir Bruce Keogh, the NHS Medical Director, to launch a review into PIP breast implants. Sir Bruce chaired an Expert Group charged with providing advice about whether further steps needed to be taken and whether there were wider lessons to be learnt for regulation of safety and quality in cosmetic surgery.

This Expert Group published an interim report on 6 January 2012. This report concluded that PIP implants were not associated with a higher risk of breast cancer or other forms of cancer than other breast implants. Toxicological tests carried out in the UK, France and Australia showed no evidence of cytotoxicity or genotoxicity. However, due to the uncertainty of the results, the report recommended that further testing should be carried out.

In January 2012 Earl Howe, the Minister with responsibility for medical drugs and devices commissioned a review of the activities of the Medicines and Healthcare products Regulatory Agency (MHRA) into its involvement and handling of the PIP breast implant investigations. In May 2012, the Howe Review of the MHRA's actions in relation to PIP breast implants was published.

In January 2013 the MHRA published the final toxicology test results, which confirmed previous testing and concluded that there was no evidence of cytotoxicity or genotoxicity of the PIP breast implant filler.

## Adverse incident reporting, investigation and analysis.

**Recommendation i:** *There is a system-wide responsibility for maximising reporting of adverse device incidents and for ensuring that reports are of high quality. The MHRA should continue to work with health providers, professional bodies, regulators and patient groups to promote the best possible understanding of the role of the reporting system and to ensure that professionals in particular understand what they have a duty to report – and why.*

The MHRA saw an unprecedented rise in adverse incident reporting levels in calendar year 2012 (25%). Increased reporting by manufacturers and, encouragingly, from the private sector primarily drove this increase. There was also increased reporting by members of the public. However, incident reporting levels from the NHS continued to decline and the MHRA has been working hard to understand the reasons for this in order to reverse the trend and further improve reporting in all areas. Several techniques were employed to research this issue. These included a survey of trust policies regarding adverse incident reporting available on-line; telephone interviews with a number of trusts, in-depth interviews with key staff from a single trust, external surveys of adverse incident reporting practices and consultation with an MHRA convened group of external experts. A number of reasons for this decline in adverse incident reporting were identified, ranging from a lack of awareness amongst healthcare professionals of how to report and, in some cases, the need to report incidents to the MHRA.

This research has led to several strands of work. The MHRA is working in partnership with the NHS England to improve medical device governance at Trust Board level within the NHS and support this with an enhanced Medical Device Liaison Officer role. This partnership will also seek to improve and link the NRLS (National Reporting and Learning System) and the MHRA medical device reporting routes to increase quality and quantity of reporting to both the MHRA and the NRLS. This work will encourage and provide a framework for an open and fair reporting culture and improved local medical device governance designed to establish best practice for compliance with CQC Outcomes 11 and 16[2]. This will also involve the MHRA developing new types of aggregated device information to feedback to Trusts

The MHRA has made significant progress towards developing a reporting culture. Working alongside the NHS Medical Director and his Cosmetic Review team the MHRA has persuaded the General Medical Council to include improvements to their Good Medical Practice and Prescribing guidance, such that it includes reporting medical device adverse incidents to the MHRA. The MHRA will extend this work to include Nursing and Midwifery Council, General Dental Council and Health and Care Professions Council.

In order to increase clinical engagement with adverse incident reporting, the MHRA has initiated a new programme of work with professional bodies to create

[2] CQC Outcome 11 is concerned with the safety, availability and suitability of equipment; Outcome 16 relates to the assessment and monitoring of the quality of service provision.

and promote device specific reporting webpages for key procedures involving implantable devices. In particular, the MHRA is working with the British Cardiovascular Intervention Society, the British Society of Interventional Radiologists, the Vascular Surgical Society and the British Society of Urogynaecology to create reporting guidance on coronary stents, transcatheter heart valves, stent grafts, and transvaginal meshes and tapes. In this way the MHRA is focusing its efforts on those implants used in the highest risk surgery. These societies will include, or link, to this guidance on their own websites. Collaborative work with the Association of Surgeons of Great Britain and Northern Ireland has also begun with a similar aim. At the same time, the MHRA is continuing to improve general reporting guidance on its website and place more emphasis on the reasons for reporting, including recent examples. Work has begun with NHS Choices to improve information on medical device safety and reporting.

**Recommendation ii:** *The MHRA should work with partners to explore the potential for strengthening the network of Medical Device Liaison Officers, and emphasising the importance of the role within health care providers. In particular, it should work with the main private health care providers to encourage the establishment of a network of Medical Device Liaison Officers in that sector to complement that which exists in the NHS.*

The MHRA has taken on board earlier comments from Medical Device Liaison Officers (MDLO) and undertaken a new survey. Survey findings have been used to support development of a new guidance manual setting out a strengthened and expanded role for MDLOs. The MHRA has held initial discussions with the Independent Healthcare Advisory Service (IHAS), and directly with some large private provider organisations, on establishing a Medical Device Liaison Officer role in that sector. The Agency will also discuss creating similar roles within social care with representatives of both local government and private providers of social care.

The launch of this MDLO guidance and an associated conference late in 2013 will be dovetailed to fit with broader work on medical device governance at Trust Board level (see Adverse Incident reporting section above for details of joint working on medical device governance). Launching these initiatives in unison is designed to maximise the impact on clinician and institutional behaviour in the public and private healthcare sectors. A change of name for the role to Medical Device Safety Lead (MDSL), to emphasise the change and increased focussed responsibilty of the role, is also being considered.

**Recommendation iii:** *The MHRA should press ahead with planned work to improve its periodic trend analysis of data on adverse device events, including a more systematic focus on analysis of the rate of reported incidents relative to sales. This work should incorporate provision for periodic expert, external statistical input to support analysis of the available data on adverse device events and help identify what other data are needed. It should include consideration of how best to use additional sources of information alongside incident reporting to assist in the early identification of issues.*

The MHRA has continued to improve its trending systems to manage the increasing adverse incident workload. This has included the development of a Medical Device Specialist toolkit to set best practice expectations for medical device specialist work with industry and best practice templates for periodic summary reporting. The toolkit seeks to improve the use of denominator sales figures and distribution data for trending. Adverse incident triggers for review and possible action have also continued to be refined. This workplan has been reviewed and agreed with Dr David Spiegelhalter (Winton Professor for the Public Understanding of Risk at Cambridge Univesity) as an independent expert in statistics and the communication of risk, who will continue to review the MHRA programmes on a periodic basis.

The MHRA has continued to prepare for future EU reporting integration by ensuring that its trending systems utilise internationally agreed nomenclature.. Nomenclature for describing adverse events in compliance with TS19218[3] has already been adopted and similar nomenclature for concluded incidents will be implemented during 2013, following the adverse incident workflow system upgrade.

The MHRA is developing programmes to increase awareness of external sources of information and these have advanced significantly:

- the MHRA now has presence on the safety committees of the Royal College of Surgeons, Association of Anaesthetists and the College of Radiologists. The MHRA will seek to attend other key professional safety committees, where they exist, and encourage key societies to create them, if they do not exist;
- the MHRA has introduced and trained staff in the use of Pro-quest™ (electronic archive search system) to identify and review new medical device safety research literature;
- the MHRA is currently reviewing the findings of a trial of Skills for Health monitoring of: Trans Aortic Valve Inserts (TAVI), dermal fillers, cranial flow diverters for aneurysms;
- the MHRA now monitors several twitter channels of representative groups.

**Recommendation iv:** *While acknowledging that a "one size fits all" approach to consideration of cumulative vigilance information will never be appropriate given the wide diversity of medical devices on the market, the MHRA should ensure that it has clear operating procedures for the periodic review of ongoing series/categories/types of device incident reports, particularly for higher risk products, including appropriate involvement of external experts. Plans to involve members of the Committee on Safety of Devices in such activity should be implemented without delay.*

The MHRA implemented a trending system covering all types of medical devices in April 2011. Adverse incident triggers for review and possible action developed

[3] ISO/TS 19218-1:2011 specifies requirements for a hierarchical coding structure for describing adverse events relating to medical devices.

as part of this system have continued to be refined, and all are reviewed on an annual basis, as a minimum.

The MHRA has developed new procedures for triggering the engagement of external experts with periodic summary reporting and when trend reports or emerging themes give cause for concern. When such concerns arise the MHRA will seek an expert opinion from appropriate Committee on the Safety of Devices (CSD) and/or Register of Expert members on the significance of these signals. The CSD has reviewed our trending system in plenary session and also as part of a specific audit and was reassured by the progress that had been made.

The MHRA is currently revising the way that it engages with the clinical community in order to enhance the flow of information both to and from the Agency and to facilitate better collaborative working in an era of ever more complex interventions involving the use of medical devices. This includes ensuring that the role and contribution of the CSD is both clear and offers maximum benefit to the Agency's role in overseeing the resulting system.

The MHRA is reviewing the functioning of its Committee for the Safety of Devices to look at whether its existing clinical engagement and advice arrangements can be improved and modified to take further advantage of the best clinical expertise available and improve information exchange with the clinical community.

The MHRA has made significant strides in acquiring new software to support enhanced information systems for trending. These systems will allow the MHRA to integrate and analyse data (including manufacturers' sales figures) from multiple sources in innovative ways.

## Regulatory activity and engagement with Europe

**Recommendation vi:** *The MHRA should review the processes and governance it uses to ensure that timely and appropriate action is taken in pursuing responses from manufacturers, notified bodies or others, and in ensuring appropriate regulatory actions take place in a timely manner.*

One of the key responsibilities of the MHRA is to minimise the risk of members of public receiving medical devices that are not compliant with legislation. To improve effectiveness in this area the MHRA has reviewed internal processes and looked to increase cooperation between devices and medicines cross-agency teams in the area of compliance enforcement. Notable successes in the last six months have been:

- two joint medicines/medical device operations in known problem locations – seizing goods from Soho establishments where many unlicensed medicines and counterfeit medical devices were being sold;
- four pro-active operations on specific product types – seizing goods such as portable x-ray machines, dental equipment, counterfeit condoms and digital thermometers;

- collaboration with Customs Authorities at ports (Felixstowe) and airports (Heathrow) to develop joint guidelines and good practice for border controls and develop cross agency training;
- work with Police and Trading Standards to target on-line internet sellers and seize goods from traders operating from private addresses.

Extensive proactive publicity has been generated on these issues, including, for example, a front-page story in the Daily Mirror relating to dental scanners and coverage on Radio 1 relating to counterfeit condoms.

No operational activity can be efficiently executed unless it is supported by an effective IT system. With this in mind, over the last 18 months, the MHRA has adapted an IT system, which is currently being used by a number of police and other government departments carrying our similar roles, in order to fit in with the role and objectives of the Agency. The functionality includes:

- online investigation software, which offers real time (date/time stamp) recording of investigation notes, processes and activities for all Agency compliance and enforcement activities;
- an 'Intellicase' function to support trending information for proactive exercises;
- a single cross-agency solution to record, review and report this type of process and activity.

Following a review of thresholds for triggering risk-based audits of companies, the MHRA has completed five manufacturer audits in response to concerns about both regulatory systems compliance and effective implementation of quality systems.

**Recommendation xi:** *The MHRA and Government should fully support efforts initiated by the European Commission to improve the operation of the regulatory system, with particular regard to higher risk devices, within the current legal framework and in advance of any specific legislative proposals the Commission brings forward. In particular, they should press for early adoption of proposals for a single European reporting portal to provide a central repository for information on device adverse incidents, accessible to all EU competent authorities. They should also press for the establishment of frequent routine teleconferences, facilitated by the Commission, to make it easier for EU competent authorities to discuss specific areas of concern regarding medical device safety and regulation on an ongoing basis, in order to improve European Co-ordination.*

**Recommendation xiii:** *The Department should ensure that a focus on continual improvement in device vigilance is an explicit component of the MHRA's annual business plan, and that arrangements are in place to monitor the delivery and impact of agreed improvements.*

The MHRA led the task force to develop proposals for an EU monthly vigilance teleconference. From the summer of 2012, these EU vigilance conference calls have been held under the facilitation of the European Commission. These calls have been well supported and have been the basis for a very good exchange of intelligence about specific product performance concerns. Beyond the exchange

of information there is an emerging pattern of work-sharing with informal rapporteur roles being adopted by individual member states to the benefit of all.

The MHRA is leading on the development of the first EU device specific vigilance reporting guidance for manufacturers. Such documents will be useful for developing common EU reporting expectations in advance of an EU vigilance reporting portal.

The MHRA has developed proposals and pushed for the early development of an EU vigilance reporting portal at European level. It has won support from many other EU member states, included Germany and France. However, the European Commission has informed Member States that it does not have funds agreed for early implementation of IT systems, even on a trial basis, and so the MHRA is beginning to pursue joint funding by Member States and, possibly, industry.

The MHRA business plan for 2013-14 includes the following objective in relation to device vigilance:

> *Continue to improve risk-based approach to device vigilance including the development of enhanced signal detection methodologies.*

In order to maximise the effectiveness of working practices within the Devices Division, one of the project teams was tasked with the review of current and anticipated workloads for the staff engaged in adverse incident investigation. The long-term objective of this project was the identification of resource needs to optimise the adverse incident investigation processes in the future.

In connection with this objective, the MHRA will conduct a full review of adverse incident management processes and the necessary supporting information technology.

**Recommendation xv:** *All parties - healthcare professionals, providers and patients, as well as industry - must be involved in the vigilance system as equal partners with the single aim of reducing the risk of harm to patients from medical device incidents. MHRA should therefore continuously review its activities to ensure that everything it does is consistent with this aim, and that it promotes this shared aim amongst all those involved in medical device vigilance.*

The UK has supported an initiative introduced under the Irish Presidency of the EU to review all working groups and, in conjunction with the European Commission, rationalise and focus the governance of such groups in order to substantially enhance collaborative work amongst member states and with the Commission. The group will also work to maximise the impact of Commission investments at the Food and Veterinary Office and Joint Research Centre in support of better coordination within the EU regulatory system. The UK will chair this working group.

The MHRA has taken additional leadership responsibility as chair of the In-Vitro Diagnostics Working Group and co-chair of the Compliance and Enforcement Working Group (COEN). This is in addition to extensive pre-existing active representation in key steering and working groups.

With regard to efforts to improve the performance of Notified Bodies the following actions have been taken. The Agency has:

- reviewed the competence of UK Notified Bodies designated for Class III devices and informed the Commission of the results.

- obtained confirmation that there is a contract in place to ensure that all Notified Bodies receive copies of vigilance reports from their clients.

- established an extensive programme of joint audit of Notified Bodies designated for Class III devices. This involves staff from a number of national authorities and the European Commission. The goals of the programme are to ensure that consistently high standards operate across all Notified Bodies throughout the EU and other states that operate under the European regulations. The MHRA has been a key contributor to the task force set up to progress these audits. A full programme of joint audits is in place for the whole of 2013 and the first joint audit took place in the UK during January 2013.

In order to improve the performance of UK Notified Bodies in their review of clinical evaluations the MHRA has taken, or will take, the following actions:

- a training workshop for Notified Bodies took place in March 2013;

- additional surveillance audits of Notified Bodies with regard to clinical investigations are scheduled throughout 2013;

- the MHRA has attended individual Notified Body training events to provide clarity on expectations for clinical investigations;

- an MHRA led conference in the area of clinical evaluations for manufacturers is planned for the autumn of 2013.

The MHRA has also been active in the International Medical Devices Regulators Forum (IMDRF) preparing a requirements document for Conformity Assessment Bodies, such as Notified Bodies. These requirements incorporate best practice from around the world and it is envisaged that these will be incorporated in European guidance, when published.

**Recommendation xii:** *The MHRA and Government should endeavour to ensure that future reform of devices regulation at European level is based on a rigorous and transparent assessment of the evidence. Any implications for the work of the MHRA should be carefully costed and the Agency supported to ensure that it can discharge its functions effectively.*

The MHRA set out the UK's high-level negotiating position on revision of the medical devices directives in a ten-week public consultation that opened in November 2012. This position was developed based on initial discussions with key stakeholders, other Government departments and the devolved

administrations, with the aim of the wider public consultation to challenge and strengthen the Government's position.

This consultation was promoted through a variety of channels and included producing an online video explaining the EU legislative decision-making process. The MHRA was very pleased to receive over 100 responses to its public consultation, which provided a rich evidence base to test and challenge the UK's negotiating position. An analysis of the evidence received was published in April 2013[4].

An impact assessment on the proposals is now being put together, drawing on evidence from the public consultation, to ensure that the UK's negotiating position takes into full consideration the costs and benefits and to ensure that the MHRA can plan for its additional responsibilities when the new legislation comes into effect. The MHRA is being held to account on this work through the Parliamentary scrutiny process by the European Scrutiny committees in both Houses.

Ongoing stakeholder meetings ensure that the MHRA continues to take into account the implications of the policy options arising during the negotiations. Specifically, the MHRA will ensure that the key medical device manufacturers are kept informed of the proposed changes and the likely impact on their businesses through engagement with the Trade Associations, such as the Association of British Healthcare Industries (ABHI), the British Healthcare Trades Association (BHTA), the British In Vitro Diagnostics Association (BIVDA) and Surgical Dressings Manufacturers Association (SDMA).

The changes in the regulations are still subject to debate in the European Parliament and substantial negotiation in the European Council, so the full extent of changes in obligations remains to be determined. What is certain is that the scope of the legislation will expand (for example, to cover specific categories of devices with no medical purpose in the cosmetic enhancement area) and there will be increased statutory requirements and stakeholder expectations on the MHRA. The action plan initiated by former Commissioner Dalli and committed to by all member states, has resulted in more intense management of Notified Bodies and enhanced market surveillance activity under an umbrella of increased collaboration by Competent Authorities across Europe. Against this backdrop there is a general tightening of public funding for regulation across Europe as a result of austerity measures in response to the financial crisis. This has led several member states to introduce fee-based funding regimes. The MHRA is working with other member states to explore the possibility of consistent and equitable bases for such fees across Europe and as a potential means to provide incremental funding to reflect the increased demands being placed on the MHRA. A full costing exercise will take place once there is a greater degree of certainty around the precise provisions to be included in the new legislation.

## Communications and stakeholder engagement

[2] http://www.mhra.gov.uk/Publications/Consultations/Deviceconsultations/CON205361

**Recommendation ix:** *The MHRA should review and further develop its communications capability to ensure they can rapidly establish and provide centralised communications regarding device alerts and related issues on an ongoing basis. This should be a proactive capability serving the needs of patients, professionals and the press / public. It should regularly and simply update interested parties around progress and current information on specific safety concerns, anticipating areas of anxiety or uncertainty and managing the information and misinformation that can circulate around safety concerns. It should also constitute a source of information for concerned individuals which is easy to access and to understand.*

The Agency carried out a comprehensive review of its web pages relating to the regulation of medical devices and the provision of technical information to healthcare professionals and patients has been completed. These pages have been reviewed and rewritten, where appropriate, in preparation for the transition to the Gov.uk web site.

The Agency also took forward a strategic review of device communications at the start of this project and identified a number of initiatives to facilitate the rapid and clear distribution of key messages to the range of stakeholders for medical devices. The review highlighted the use of social media as an important adjunct to the more conventional means of disseminating information, particularly safety information relating to devices used by the general public. The MHRA launched a new medical device safety Twitter feed in January 2013, which now has some 500 followers, building on the success of the press Twitter channel, which currently has over 3,000 followers.

This complements the MHRA's well-established email alerting system, one of the most successful such systems in the UK, where subscribers can sign up to receive relevant alerts on devices issues.

Much of the MHRA's communications needs to be carried out in partnership with others across the health landscape, particularly when giving advice to patients. Many messages are complex and partly involve safety issues, but also involve the need to advise clinicians and patients. For example, communication of PIP involved the MHRA, the Department of Health, the NHS and professional bodies.

The MHRA instigated discussions on the need to effectively co-ordinate communications across these different bodies through the DH/Arm's Length Body (ALB) Communications Directors' forum, and convened a workshop involving DH and its ALBs to look at how cross-system issues could be communicated more effectively. A number of actions were identified for DH to take forward, including training and awareness for press officers of who does what in the new landscape, and a comprehensive directory of communications staff across the new health system. It was also agreed that a cross-system communications protocol and scenarios were needed for the launch of the new system on 1 April 2013, and this was taken forward by DH and NHS England.

A separate workshop was convened by DH to consider policy and communications links, and identify areas where these could be strengthened,

particularly in terms of horizon scanning. The MHRA has convened an initial meeting to progress this further in May 2013.

## Records management

**Recommendation v:** *The MHRA should review the way in which it manages records and knowledge on ongoing device issues so that they can be retrieved and analysed more easily for the purposes of retrospective review and learning, and the construction of narrative information to support the periodic review procedures mentioned above.*

All staff in Devices Division have been trained in the use of the Documentum document management system and a comprehensive folder structure has been set up to enable all routine correspondence to be filed electronically. This, coupled with an effective search facility, will enable records to be retrieved efficiently in the future.

The existing adverse incident database (AITS) already has a sophisticated search engine to permit the retrieval of information from both active and archived data on adverse incidents.

## Other recommendations

**Recommendation vii:** *Sir Bruce Keogh's review should examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery. Routine incident reporting and review of outcome data by individual surgeons and providers should be the norm.*

**Recommendation viii:** *The Breast Implant Registry was closed in 2005 because the majority of women registered declined to participate in follow-up research, presumably in part because of concerns about confidentiality, meaning the information generated was of low value. Yet if it is of good quality a registry system can, as other work has shown, generate valuable information to support a detailed understanding of the safety profile of medical devices over time. Sir Bruce Keogh's review should investigate the potential for re-establishing a breast implant registry in a more effective form, including an assessment of likely cost-effectiveness, and consider its applicability to other kinds of higher-risk medical device that are not currently covered by such arrangements.*

Sir Bruce Keogh's review has investigated the need to re-establish the Breast Implant Registry in a more effective form and has made the following recommendations:

- a system should be set up to link the Unique Device Identifier of all implants to the patient's electronic record, enabling routine collection through Hospital Episode Statistics data. This information would enable assessment of implant performance, and the tracking and tracing of patients in case of a safety alert. Patient-anonymised aggregated data should be made available.

- until such a system is developed, a National Breast Implant Registry should be established and be operational within 12 months. It should be extended to other devices as soon as possible, to allow better monitoring of patient outcomes and device safety. All cosmetic surgery providers should keep, as a minimum, data on the patient, breast device, surgeon, provider and outcome and this data should be held locally until the registry is operational.

- people who have undergone implant surgery should be able to compare their own personal data, with aggregated data from the registries on the implant, surgeon and provider.

- full participation in the registries should be an essential component of the Care Quality Commission (CQC) registration and assessment process of providers, and an essential part of the annual appraisal and revalidation.

The MHRA will assist the Department of Health with the re-establishment of the National Breast Implant Registry and with consideration of how the system can be extended to cover other types of high risk devices. The MHRA is already an active participant in the work of the England and Wales National Joint Registry (NJR). Information from the NJR forms a key element of the post-market surveillance data, which is regularly used by the Agency, manufacturers and healthcare professionals to monitor the safety and performance of hip, knee and ankle implants. Experience gained from the successful operation of the NJR will be of value in the further extension of implant registries.

Looking further ahead, the MHRA has been working to develop systems to incorporate Unique Device Identifiers (UDIs) into patient electronic records and Hospital Episode Statistic data. Once in place, this system will significantly enhance post-market surveillance of high risk devices by enabling assessment of implant performance, and the tracking and tracing of patients in case of a recall or safety alert, without the need for multiple device registries. It will also allow patient-anonymised aggregated data to be made available to inform patients, healthcare professionals and health researchers.

The MHRA has met a number of Trusts to explore the feasibility and practicalities of collecting UDIs within the hospital records. The Agency has begun to set-up pilot programmes and has thus far received commitment to participate from four Trusts. We have also had exploratory discussions with the NHS Information Centre about how this information can best be collated and integrated into centralised Hospital Episode Statistics records.

**Recommendation x:** *While we found no evidence of a direct impact in this case, the MHRA Board and Department of Health should ensure that key strategic posts in the organisation do not remain unfilled for long periods of time.*

The Department is working closely with the Agency to ensure that key posts are filled promptly.

## Ongoing activities

Although much has been achieved during the past eight months, there is still a great deal of activity required, both within the MHRA and the community of healthcare professionals, to take forward the various work streams in key areas.

Specifically, the areas where work will need to continue are:

The MHRA intends to further strengthen its role in regulation and support of safe use of devices in a number of ways. These include working with fellow European member states to make expectations on industry more precise and ensure consistent application of the regulations across the whole of Europe, including supervision of notified bodies. The MHRA will enhance both internal capability to provide clinical advice and establish well structured processes and links to ensure that the very best expert clinical input is available to support all of the Agency's activities. This advice is needed to support our every-day activities as well as in cases when major public health issues arise.

Developing the capability to both ‘track and trace’ implantable devices, as well as gather information on long-term performance of devices using the Clinical Practice Research Datalink (CPRD) is a key strategic goal. Central to this will be the implementation of a UDI system at European level and the outcomes of the pilot studies conducted at the four NHS Trusts, once assessed, will feed into a longer-term programme to introduce the system throughout the NHS.

The engagement with other EU Competent Authorities will continue to address such issues as the sustainable funding of the regulatory agencies and the establishment of a European single-portal for adverse incident reporting.

Enhancing the oversight of Notified Bodies across the EU by adopting a unified approach to audit and regulation, in order to ensure effective control of this vital aspect of medical device regulation.

The strengthening of the MDLO network and the engagement with healthcare professionals to promote the reporting of adverse incidents to the MHRA is an ongoing programme. The MDLO conference planned for later in 2013 will herald the start of an ongoing campaign to enhance activities in this area and will be supported by a communications strategy to increase awareness of the MHRA’s role amongst key stakeholders.

The Agency will continue to build on links with professional bodies in order to ensure a consistent and high quality exchange of information around the use of devices in clinical practice and, where necessary, collaborate in addressing specific areas of concern around performance.

**Recommendation xiv:** *The Department of Health should ensure that the actions and lessons from the events surrounding PIP breast implants are taken into account and acted on by the MHRA. This should be assured through routine sponsorship arrangements and in the Department's Performance and Capability Review of the MHRA.*

The Department of Health has conducted regular review meetings with the MHRA to ensure satisfactory progress with the work programme designed to address the recommendations of the Howe review. The Department will continue to monitor implementation of the Review through regular accountability meetings between the Department and MHRA.

## Annex 1 – Recommendations of the Howe Review

**Recommendation i:** *There is a system-wide responsibility for maximising reporting of adverse device incidents and for ensuring that reports are of high quality. The MHRA should continue to work with health providers, professional bodies, regulators and patient groups to promote the best possible understanding of the role of the reporting system and to ensure that professionals in particular understand what they have a duty to report – and why.*

**Recommendation ii:** *The MHRA should work with partners to explore the potential for strengthening the network of Medical Device Liaison Officers, and emphasising the importance of the role within health care providers. In particular, it should work with the main private health care providers to encourage the establishment of a network of Medical Device Liaison Officers in that sector to complement that which exists in the NHS.*

**Recommendation iii:** *The MHRA should press ahead with planned work to improve its periodic trend analysis of data on adverse device events, including a more systematic focus on analysis of the rate of reported incidents relative to sales. This work should incorporate provision for periodic expert, external statistical input to support analysis of the available data on adverse device events and help identify what other data are needed. It should include consideration of how best to use additional sources of information alongside incident reporting to assist in the early identification of issues.*

**Recommendation iv:** *While acknowledging that a "one size fits all" approach to consideration of cumulative vigilance information will never be appropriate given the wide diversity of medical devices on the market, the MHRA should ensure that it has clear operating procedures for the periodic review of ongoing series/categories/types of device incident reports, particularly for higher risk products, including appropriate involvement of external experts. Plans to involve members of the Committee on Safety of Devices in such activity should be implemented without delay.*

**Recommendation v:** *The MHRA should review the way in which it manages records and knowledge on ongoing device issues so that they can be retrieved and analysed more easily for the purposes of retrospective review and learning, and the construction of narrative information to support the periodic review procedures mentioned above.*

**Recommendation vi:** *The MHRA should review the processes and governance it uses to ensure that timely and appropriate action is taken in pursuing responses from manufacturers, notified bodies or others, and in ensuring appropriate regulatory actions take place in a timely manner.*

**Recommendation vii:** *Sir Bruce Keogh's review should examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery. Routine incident reporting and review of outcome data by individual surgeons and providers should be the norm.*

**Recommendation viii:** *The Breast Implant Registry was closed in 2005 because the majority of women registered declined to participate in follow-up research, presumably in part because of concerns about confidentiality, meaning the information generated was of low value. Yet if it is of good quality a registry system can, as other work has shown, generate valuable information to support a detailed understanding of the safety profile of medical devices over time. Sir Bruce Keogh's review should investigate the potential for re-establishing a breast implant registry in a more effective form, including an assessment of likely cost-effectiveness, and consider its applicability to other kinds of higher-risk medical device that are not currently covered by such arrangements.*

**Recommendation ix:** *The MHRA should review and further develop its communications capability to ensure they can rapidly establish and provide centralised communications regarding device alerts and related issues on an ongoing basis. This should be a proactive capability serving the needs of patients, professionals and the press / public. It should regularly and simply update interested parties around progress and current information on specific safety concerns, anticipating areas of anxiety or uncertainty and managing the information and misinformation that can circulate around safety concerns. It should also constitute a source of information for concerned individuals which is easy to access and to understand.*

**Recommendation x:** *While we found no evidence of a direct impact in this case, the MHRA Board and Department of Health should ensure that key strategic posts in the organisation do not remain unfilled for long periods of time.*

**Recommendation xi:** *The MHRA and Government should fully support efforts initiated by the European Commission to improve the operation of the regulatory system, with particular regard to higher risk devices, within the current legal framework and in advance of any specific legislative proposals the Commission brings forward. In particular, they should press for early adoption of proposals for a single European reporting portal to provide a central repository for information on device adverse incidents, accessible to all EU competent authorities. They should also press for the establishment of frequent routine teleconferences, facilitated by the Commission, to make it easier for EU competent authorities to discuss specific areas of concern regarding medical device safety and regulation on an ongoing basis, in order to improve European Co-ordination.*

**Recommendation xii:** *The MHRA and Government should endeavour to ensure that future reform of devices regulation at European level is based on a rigorous and transparent assessment of the evidence. Any implications for the work of the MHRA should be carefully costed and the Agency supported to ensure that it can discharge its functions effectively.*

**Recommendation xiii:** *The Department should ensure that a focus on continual improvement in device vigilance is an explicit component of the MHRA's annual business plan, and that arrangements are in place to monitor the delivery and impact of agreed improvements.*

**Recommendation xiv:** *The Department of Health should ensure that the actions and lessons from the events surrounding PIP breast implants are taken into account and acted on by the MHRA. This should be assured through routine sponsorship arrangements and in the Department's Performance and Capability Review of the MHRA.*

**Recommendation xv:** *All parties - healthcare professionals, providers and patients, as well as industry - must be involved in the vigilance system as equal partners with the single aim of reducing the risk of harm to patients from medical device incidents. MHRA should therefore continuously review its activities to ensure that everything it does is consistent with this aim, and that it promotes this shared aim amongst all those involved in medical device vigilance.*

**Glossary**

ABHI – Association of British Healthcare Industries (Trade association)
AFSSAPS (now ANSM – see below) - Agence Française de Sécurité SAnitaire des Produits de Santé
AITS – Adverse Incident Tracking System (MHRA database)
ANSM - L'Agence Nationale de Sécurité du Médicament et des produits de santé
BHTA – British Healthcare Trades Association (Trade association)
BIVDA – British In Vitro Diagnostics Association (Trade association)
CAMD - Competent Authorities for Medical Devices
COEN - Compliance and Enforcement Group
CPRD - Clinical Practice Research Datalink
CSD – Committee on the Safety of Devices
Documentum – MHRA document storage system
HES – Hospital Episode Statistics
HMA – Heads of Medicines Agencies
IMB – Irish Medicines Board (Irish Competent Authority)
IMDRF - International Medical Devices Regulators Forum
MORE – Manufacturers' On-line Reporting Environment
NHS IC – NHS Information Centre
NRLS – National Reporting and Learning System
SDMA – Surgical Dressings Manufacturers Association (Trade association)
UDI – Unique Device Identifier