



Medicines & Healthcare products
Regulatory Agency

Report on progress with the recommendations of the ‘Expert Clinical Advice – MHRA Medical Devices’ independent review

**Agency progress in response to the independent review on
MHRA access to clinical advice and engagement with the
clinical community in relation to medical devices**

Introduction

The report 'Expert Clinical Advice – MHRA Medical Devices', produced by Professor Terence Stephenson and an independent review team, was published in April 2014. The report made a number of recommendations on how MHRA can improve its access to clinical advice and engagement with the clinical community in relation to medical devices. The Agency published a formal response to the recommendations in July 2014, with a view to giving a progress update after one year of report publication.

A cross-Agency group was formed to oversee progress with implementation of the recommendations, making best use of resources available. Prioritisation and timing of the required tasks (some of which are interdependent) reflect resource constraints, and the relative impact of these activities on the protection of public health. The Agency is currently reviewing options for funding of devices safety activities and consulting stakeholders.

Medical devices is a subject matter which remains within the powers of the central UK Government and Wales, however, for Northern Ireland powers to legislate for medical devices has been handed over to the Northern Ireland Assembly. The Scottish Government acts on devolved matters but regulation on medical devices is reserved to the Competent Authority so in practice, MHRA acts on behalf of the whole of the UK on medical devices. This is because the Northern Ireland Health Minister agreed that the Secretary of State acting through the Agency would act for the whole of the UK. Because the Agency works on behalf of the whole UK, it consults the Devolved Administrations (Scotland, Wales and Northern Ireland) on, and keeps them informed of, proposed changes to legislation, policy and practice that affects them as well as giving advance notice of (and the opportunity to observe) any investigations or inspections of manufacturers based in their country.

Each recommendation, along with the original formal response and a progress update can be found below.

Organisation of clinical advice input, resources and leadership

Recommendation 1. Formal organisation of clinical advice input to MHRA

The field of medical devices is expanding rapidly and there is increasing complexity of both devices and their clinical applications. The MHRA needs to have a high level oversight of devices comparable to that for medicines but designed to reflect the diversity of products, clinical applications and settings, which are more complex than those associated with medicines. A Devices Expert Advisory Committee (DEAC) should be established. The membership of the committee should be limited to the minimum required to cover the broad strategic interests of the Agency whilst being consistent with operating as a cohesive group. The DEAC should be linked to a network of specialist sub-groups and ad hoc groups designed to deliver all specialist advice to the MHRA, as necessary. There should be flexible membership of the sub-groups, depending on the topics.

Agency Response - Accepted:

A new independent Devices Expert Advisory Committee (DEAC) will be established before April 2015. The DEAC will replace the Committee on Safety of Devices (CSD) and will be responsible for providing independent, expert input and advice on a wide range of aspects relating to medical devices to help ensure the safe use and management of medical devices. The DEAC will have firm links with the wider scientific community to facilitate access to specialist expertise. To make the DEAC a responsive and agile forum, it will consist of around 12 members and a Chair, and the membership will be made up of individuals from a variety of specialisms. Once the Chair appointment has been made (recruitment processes have commenced), they will input into the recruitment of the new committee members. The DEAC will be linked to a network of specialist sub-groups and ad-hoc groups to deliver specialist advice to MHRA as necessary. There will be flexible membership of any sub-groups, depending on the topics and where possible, existing specialist groups within professional bodies will be used.

Until the new DEAC has been created, an 'Interim Committee on the Safety of Devices and Transitional Advisory Group' will be in place with some members of the CSD. It will be charged with the duties of the existing CSD plus advising on and supporting the implementation of the Stephenson Review recommendations, including making suggestions on the design and establishment of the DEAC, whilst consulting major stakeholders on the structure, form and functions of the DEAC.

Progress Update

The interim CSD had a number of meetings and has been helping tremendously with the design and establishment of the DEAC.

Working with the Department of Health (DH) Appointments Team, Dr Peter Nightingale was appointed as the first DEAC Chair and took up post for three years from 1st January. Dr Peter Nightingale attended the final interim CSD meeting and the first DEAC meeting will be held in July 2015. Dr Peter Nightingale has started meeting with the Royal Colleges and other key stakeholders to further establish best ways of working.

The final meeting of the Interim Committee on the Safety of Devices took place on 19th March 2015, proposals were endorsed to configure the new advisory structure lead by the DEAC. Following extensive discussions with stakeholders, it was decided that the DEAC should be comprised of representation from the following stakeholders:

- Royal College of Surgeons
- Royal College of Physicians
- Royal College of Radiologists
- Royal College of Anaesthetists
- Royal College of Obstetricians and Gynaecologists
- Royal College of Ophthalmologists
- Faculty of Intensive Care Medicine
- Royal College of Nursing/Nursing and Midwifery Council
- Health and Care Professionals Council
- British Toxicology Society
- Institute of Physics and Engineering in Medicine
- National Institute for Health and Care Excellence
- Clinical representation from each of the Devolved Administrations
- Lay representation

While this group is slightly larger than that envisaged in the report, it is seen as encompassing the major device-intensive clinical disciplines, as well as ensuring that there is appropriate technical and geographic representation. The Devolved Administrations will be invited to put forward nominations and they will also be kept involved with DEAC activities, for example, through sharing of minutes of meetings. The Agency will discuss with the Devolved Administrations whether they can particularly focus on areas that would complement the expertise listed above, for example including a paediatrician and dentist. Contributing stakeholders will be asked to nominate two or three appropriately experienced and qualified candidates so allowing the chair to select the best possible mix of committee members to serve the purposes of the committee with reference to such factors as specialism, experience, linkages to other organisations, gender and the like. Nominating stakeholders will also be asked to ensure that nominees are well equipped to represent the full spectrum of interests within their field, being subject to the nominating organisation's governance in this respect. The DH Appointments Team has confirmed that it is happy with this approach to recruiting members.

It is recognised that there are, and will increasingly be, areas where focussed engagement with complex stakeholder groups is required. It is proposed to support the working of the MHRA by further developing specialist liaison and working groups in such areas. Currently these groups are working in a relatively ad-hoc way in the following areas:

- **Dentistry:** Continuing the Agency's work with the British Dental Association, the Faculty of Dentistry of the Royal College of Surgeons, the General Dental Council and the Chief Dental Officers.
- **Pathology:** Continuing the Agency's work with the Royal College of Pathologists, UK quality assurance networks, NHS England and the devolved administrations. This work involves both the regulatory centre of the MHRA and NIBSC, as emerging issues arise out of the proposed new legislation, stratified medicine and genomics.

It is envisaged that other sub groups will need to be established, either on a fixed-term basis or longer, to address complex issues in areas such as child health and plastic, reconstructive and aesthetic surgery. The drivers for these include the provisions anticipated in the new legislation and the Review of the Regulation of Cosmetic Interventions chaired by Professor Sir Bruce Keogh. These sub groups will be accountable to the main committee.

It is proposed that the DEAC will be supported in conjunction with the Agency's Expert Committee Support function, with Devices Division providing the Expert Committee Support team with the necessary resource in terms of staff and close links being established with the staff in the Devices Clinical team.

Recommendation 2. Review the MHRA resources needed

The Agency needs to be staffed and configured to maintain strategic and operational relationships with a defined list of clinical organisations (Royal Colleges and specialist societies) in order to maintain a proactive dialogue about patient safety issues and to ensure that the MHRA, industry and the regulatory system are visible and better understood by the professions.

It is important that the Agency is configured and resourced to ensure that those providing clinical advice from external bodies are regularly updated regarding changes in regulations and updated on activities related to the Agency's work. The Agency should be explicit to its advisers about the value of their contributions.

Agency Response - Accepted:

The Agency is currently working with existing partners in Royal Colleges and specialist societies to help determine the most effective way of working together to maintain proactive dialogue about patient safety issues and reviewing existing relationships with professional bodies as a first step in mapping out future needs. The interim CSD and DEAC will be instrumental in helping the Agency establish and maintain these relationships. There is a plethora of existing committees and the Agency needs to determine how best to work with and build operational relationships with those most closely linked to our work, with clear links and contacts points and people identified for the wider clinical community.

In consultation with the Colleges and specialist societies, the Agency will be establishing the best way to improve dialogue and ensure they are regularly updated on activities related to the Agency's work. This dialogue will include pathways to ensure emerging and active issues are brought to MHRA without delay. Contributions from experts and advisors are hugely appreciated by the Agency and are vital to the effective performance of the MHRA and its ability to contribute to broader patient safety issues. Work in this area will inform the numbers and configuration of Agency staff in the future.

Progress Update

The Agency has been giving further thought as to how it will keep external bodies regularly updated, and has been establishing the most effective ways of working with existing partners in Royal Colleges and specialist societies. Once established, DEAC will help to consider this further, with the Agency preparing a proposal for discussion.

The Agency has well-established and mutually beneficial relationships with a large number of professional bodies. The strong relationships usually arise out of a history of working together to resolve specific product and clinical practice issues in relation to devices. It is recognised, however, that there is scope for a more pro-active approach to building relationships and exchanging information that would be relevant to the Agency's responsibility to support high levels of patient safety. A programme of meetings has commenced with professional bodies.

The DEAC will help the Agency identify and prioritise which organisations the Agency should build stronger relationships with and advise on the mechanisms which will need to be developed in order to enhance the productive exchange of information on patient safety. These need to be effective but not so onerous as to discourage participation.

A new member of staff has been recruited to co-ordinate the management of DEAC and help broaden the clinical expert network and relationships with professional bodies.

Financing of the Agency's activities in relation to devices is currently largely derived from grant-in-aid from the Department of Health. This has been reduced by over 30% in recent years as a result of austerity measures. The Agency is currently preparing proposals for fee-based funding regime designed to address the increasing burden of both statutory and non-statutory activities which are expected of the Agency.

Recommendation 3. Ensure that adequate clinically trained staff are included in the MHRA staff

It is essential that the Agency has clinical leadership within its Devices Division that is capable of peer-to-peer dialogue with leaders of the professions and has the capability to provide strong strategic leadership both within the Agency, across government and in the broader healthcare community in the United Kingdom, Europe, and beyond. In addition to a strong practical clinical background, the clinical team needs to encompass staff who have broad regulatory expertise and experience including audit training.

The Agency should explore opportunities for fellowships, electives and other forms of secondment with training schemes for clinical staff as a means of both bringing expertise to the Agency, as well as increasing knowledge of the role of the regulator in the broader healthcare system when they return to clinical training within the NHS.

Agency Response - Accepted:

A new Clinical Director of Medical Devices was appointed in March 2014, who brings extensive clinical experience drawn from a wide range of settings. He is a senior member of a specialist devices team. The Devices Clinical Team currently has three out of four posts filled and in light of recommendations 1 and 2 we are considering what the correct establishment should be. The increased level of professional engagement indicated in the report will determine the mix and seniority of full time clinical staff employed within the Devices division.

The Agency employs approximately 70 medically qualified professionals and this wider resource has been used to supplement the work relating to medical devices. The Agency is exploring opportunities for broader career development pathways for clinical staff within the MHRA. This would enhance the Agency's flexibility and should enrich the experience of the pool of medics and would also help handle the increasing number of borderline and hybrid products.

With the substantial increase in complexity and volume of devices, we envisage increasing demand for collaborative work with professional bodies and others and will be working more with our professional partners to influence clinical practice. The Agency needs to make better use of the clinical talents of nurses and allied health professionals, particularly given the increasing volume of care delivered in non-acute settings.

We will explore opportunities for secondments and fellowships, particularly with a view to establishing a public health training rotation into the Agency. We will work with the relevant Deaneries to develop this further and will build on the experience of the Agency's previous clinical secondments through the Chief Medical Officer's Clinical Advisors Scheme.

The MHRA is committed to ensuring we have a strong influence in Europe. We have played a leading role in the negotiations in Europe about new legislation for medical devices, specifically recommending improving the oversight of Notified Bodies, the improved surveillance of post-market events and better collaboration between national regulatory bodies. The clinical team is now actively engaged in the key fora in Europe and we are developing and embedding specific training for clinical staff to ensure they are able to bring influence to bear across the full spectrum of regulatory activities.

Progress Update

The Devices Division now has a full complement of clinical staff in the team. This comprises three medically trained posts and one senior nurse who also leads on clinical input into pre-market regulatory processes around clinical evaluation. This is a particular focus of regulators worldwide and promises to remain a focus for several years.

As the team establishes itself, the Agency will need to continue to evaluate the resources required to fulfil its role on a day-to-day basis within the Agency. As well as managing an increasingly demanding stakeholder network and, also, providing strategic and operational support to a rapidly evolving European and global regulatory network which has increasing focus on clinical inputs to both pre-market processes and market surveillance. Resources will be reviewed against these contexts and the funding available to the Agency to fulfil its obligations.

The small size of the team makes recruitment and succession planning challenging although we have demonstrated the capability to share resources with other parts of the Agency during a period of staff shortages. The Devices Division will continue to work with both medicines colleagues and external organisations, including the Scotland Deanery and the London Deanery to seek opportunities for developing knowledge, as well as, and a potential pipeline of clinicians interested in working in this interesting, demanding and challenging environment. This includes approaching the Scotland and London Deaneries to explore opportunities for clinicians to gain experience of working in a patient safety critical agency as part of their development.

A career pathways group has been established at Agency level to address some of the more challenging areas of recruitment and retention and the Devices Division has been fully supportive of this exercise as a complement to a major training initiative that has been established across the whole division. Recruitment, training and development of clinical staff remain critical challenges for the Agency as a whole, as it does for sister authorities worldwide. As a key strategic issue this will be one of the areas that the Agency seeks strategic guidance from the DEAC.

Recommendation 4. Develop and manage the network of clinical advisors

The MHRA has been reliant on advice on an ad hoc basis from a network of clinical advisors. This network needs to be maintained and systematically renewed and appropriately trained with the help of medical and nursing Royal Colleges and specialist societies in order to ensure that it is quality assured and reflects the range of clinical opinion, including clinical scientists. Consideration should be made to developing a training process for those enrolled into the network, to enhance their ability to provide advice which complements the regulatory role of the Agency.

Agency Response - Accepted:

Building on the contributions of our current expert network, which has provided invaluable advice over the numerous years, the Agency is keen to introduce a more structured approach to recruiting and maintaining a network of clinical advisors. This will help to ensure our advice is subject to appropriate governance and that our access to advice is based on most up to date practices. The Agency recognises that advice will be needed from a broad range of both clinical and scientific sources, including nurses and allied health professionals as well as toxicologists, decontamination specialists and the like.

In terms of training clinical advisors, we will develop induction training and guidance in relation to their role and explore the specific provision of input into clinical investigations. We will also consider working with other organisations to develop modules, enhancing professional recognition.

Progress Update

A piece of work to develop and manage the network of clinical advisors is underway and we are currently reviewing the gaps in clinical areas. Royal colleges and safety committees and specialist societies have been written to, with a request to nominate staff, and the recruited member of staff (mentioned under recommendation 2) will be responsible for this work. The MHRA will work with NICE to ensure that the processes for accessing expert advice are complimentary and do not place an undue burden on partner bodies. Once a formal list has been compiled we will then go through the process of sending out application forms and ensuring contracts and conflicts are covered.

Working closely with the Expert Committee Support function, the clinical advisory network will be reviewed formally on a periodic basis, the length of which is yet to be determined, in consultation with the professional bodies which will be nominating and accrediting advisors. Conflict of Interest declarations will need to be made annually, and be available for scrutiny upon request.

The Agency remains committed to developing a number of training tools to allow clinical advisors to sufficiently understand about the regulations and the role of the Agency to perform their responsibilities effectively. Those supporting our role in supervising clinical investigations will require a more detailed set of tools to support this specific activity and the Agency remains committed to developing these, potentially in partnership with other interested parties.

Recommendation 5. Develop the existing collaboration with EU bodies with similar aims to the UK MHRA

The MHRA has a strong record of leadership in the EU and must ensure that this is maintained in order to serve the needs of patients and innovative industry in the UK. The absence of clinical capacity within the Agency has resulted in reduced involvement in the development of EU legislation and collaboration over the past year and this critical area must be covered in future. The quality of clinical studies associated with pre-market approval has been variable and is a key area where both legislation and management of the European system needs concentrated effort.

References to the clinical capability and capacity in 3) above are relevant to this recommendation.

Accepted:

MHRA during 2013/2014 has been building strategic bilateral relationships with other like-minded Competent Authorities, as well as staff at the European Commission, and the UK has chaired an initiative designed to enhance collaborative behaviour across the whole network. We have identified a number of common and joint working areas, these include improved processes and tools for post market surveillance and work to develop EU IT infrastructure to underpin collaborative regulatory work.

Progress Update

The UK has been one of the leading authorities in supporting the design, development and roll-out of the notified body Joint Audit programme. Designation and supervision of notified bodies is a national responsibility under the current legislative umbrella which covers all CE marked products. Implementing legislation under the existing Medical Device Directives introduced mandatory joint audits for all notified bodies (including re-designation audits for all over a three-year timeframe).

These audits are conducted by a team including the designating authority, two other member states and officials from the European Commission. The goal of such audits, supported by more comprehensive procedural guidance, has been to bring about greater consistency of both expectations and performance of notified bodies across the system. The effect has been substantial and will lead to significantly improved consistency and lowered risk of unsafe products finding their way to market. A side effect of the process has been a rapid drop in the number of notified bodies operating in Europe either as a result of de-notification or, as in most cases, voluntary withdrawal from the system.

The Devices Director, John Wilkinson, is now chairing the Executive Group of Competent Authorities Medical Devices (CAMD) group and 2015 priorities have been agreed.

The UK, via its leadership in the CAMD Executive Group and involvement in the Compliance and Enforcement Network, has been instrumental in the development of two Joint-Action proposals which have been placed before the European Commission for funding. The first is at an advanced stage and targeted at a specific area of labelling for re-usable instruments as well as piloting both infrastructure and processes to enhance collaborative working across member authorities. The second, which is at an indicative stage, is much larger and aims to roll out a series of pan-European programmes targeted at perceived areas of weakness in the management of the regulatory system. Both are designed to build on work already completed and designed to build confidence in the system and its management without creating a disproportionate burden of cost.

Ad-hoc meetings with ANSM (France), BfARM (Germany) and SUKL (Czech Republic) European Competent Authorities (CAs) have been beneficial in proposing major changes in the future legislation. Plans are being developed to combine joint visits to major EU Competent Authorities with work developing CAs ideas for a thorough revision of the Vigilance guidance to take best advantage of current initiatives listed below.

On the back of these ad-hoc meetings and existing EU Vigilance Medical Device Expert Group (VMDEG) meetings MHRA has been influential with Competent Authorities, European Commission and European industry in the development of improved EU vigilance systems and coordination through:

- Pushing and winning support for piloting of a new additional Manufacturer Incident Report (MIR) form with transparent similar incident data and new nomenclature useful for future signal detection using an EU pilot repository. It is anticipated that the pilot will finish with the development of a new validated and fully integrated MIR form for Europe. MHRA is Chairing this pilot.
- Pushing and winning European Commission support and initiative for the development of a pilot data repository for Europe to test new signal detection capabilities and early warning systems on pooled EU vigilance data. It is using the same nomenclatures as that being developed for the new MIR form and indeed is the EU test bed for the piloting of this additional MIR form. It is also hoped to use this database to pilot improved member states coordination to grow and take best advantage of distributed analysis and device expertise, possibly through CA buddying on product areas.
- Pushing and winning support for a European Vigilance Transparency working Group which will build upon the earlier work of the UK Vigilance Transparency working group, both of which are Chaired by MHRA. We expect the development of the EU Pilot Repository will present opportunities to pilot a manufacturer final incident release scheme, initially for release to European and national professional clinical associations.
- Leading the initiation and maintaining regular active participation of monthly vigilance teleconferences to coordinate EU competent authority actions on important safety issues.
- Regular proposals to improve EU Vigilance guidance including the introduction of Trend reports and Periodic Summary reports.
- Leading on the introduction of EU device specific vigilance (DSV) guidance to improve manufacturer and CA coordination in specific device areas. Cardiac ablation guidance has been published, and work is continuing in the area of coronary stents.
- Chairing a VMDEG working group on the development of a Field Safety Notice form to introduce greater consistency to manufacturers' primary European safety communications, which was raised by MHRA as a result of MDSO feedback.

MHRA alongside the Swedish CA is leading EU thought and contribution to an International Medical Device Regulators Forum (IMDRF) Registry Working Group which has been created with the purpose of developing essential principles related to linkage of electronic patient, device and outcome registries and/or related data repositories or identifiers (such as Unique Device Identifiers (UDIs), including the principles of data access, security, informatics formats, governance and other key areas related to global regulatory applications for medical device evaluation; and essential principles related to optimal methodologies for analysis of heterogeneous data sources applied to medical device safety, signal detection (identifying potentially serious issues at an early stage), performance and reliability.

Collecting and using device incident data

Recommendation 6. Build links with the Clinical Commissioning Groups to improve the flow of information on the safety and performance of devices

MHRA could build links with the Clinical Commissioning Groups to help improve the flow of information on safety and performance of devices.

Although outside the remit of the MHRA, the Group made an observation that the commissioning of clinical services should include mechanisms to measure relevant outcomes in order to ensure that the quality of interventions is measured over the long-term in order that both clinical practice and product development are informed and driving continuous improvement. These mechanisms need to be proportionate, to be costed realistically and paid for. They should include on the part of clinicians obligations to fully participate in quality assurance systems such as registries where they are appropriate and exist and to report adverse incidents in a systematic and complete manner. The cost of such participation should be factored into the commissioning process and appropriate links to procurement mechanisms should be put in place.

Accepted:

It is essential that the Agency works closely and collaboratively with the nations of the UK in this rapidly evolving environment. The Agency will start a dialogue which will enable MHRA to better understand CCGs and what commissioning levers they have to improve commissioning quality and how we can work with them and improve information sharing. NHS England could be a conduit to this, and the Agency's presence at the NHS confederation conference will help to begin the process of understanding more about CCGs.

MHRA has built a strategic partnership with NHS England to improve the flow of information on the safety and performance of medical devices. In March 2014, two patient safety alerts with supporting guidance were issued; one covering medical devices and the other covering medicines, both with very similar strategic actions.

Informing CCGs should be enhanced by a network of Medical Device Safety Officers and Medicines Safety Officers which MHRA and NHS England will support through developing national medical device and medicines safety networks. Piloting of these networks has already begun and early experience of the use of Webex electronic seminars is encouraging with a small sample of early adopter sites. A Patient Safety First website is being pushed into service as a neutral website to support the exchange of best practice safety information across the medical device safety network.

The Patient Safety Alerts include guidance and recommendations for CCGs concerning ensuring good governance of medical device safety information and engagement with the National Medical Device Safety Network. MHRA will work with NHS England and endeavour to use this network to encourage the development of mechanisms to measure relevant outcomes in order to ensure that the quality of interventions is measured over the long-term. This work will focus on tools and mechanisms to inform clinical practice, guide product development and drive continuous improvement.

The Agency will also work on these areas with the equivalent institutions in the devolved administrations.

Progress Update

The joint Patient Safety Alerts on improving the reporting and learning from medical device incidents (see above for further information) called for Trusts and CCGs to nominate Medical Device Safety Officers and 276 MDSOs have been nominated so far (compared with 364 MSOs). MHRA are setting up a reporting transparency group to help MHRA, alongside NHS England, review and tackle the safety and performance information needs of CCGs and the current barriers to providing them. CCG MSO and MDSOs attended the joint conference in January 2015 and began to explain some of the current needs and barriers. Feedback at the conference identified that a significant issue is the difficulty in obtaining adverse incident feedback from the commissioned organisations. MHRA and NHS England have been meeting to develop workplans in the light of conference and survey feedback. This difficulty is a key area to address.

The first stage is deeper engagement with CCGs to understand their needs and possible solutions in more detail. A list of CCG contacts have been developed this includes contact names and emails of Chief Operating Officers, medical directors and MDSOs (where we have contact details for CCGs). A short questionnaire has been issued to these CCGs contacts on improving the safety and long term monitoring of the performance of devices and inviting respondents to submit their full contact details if they are interested in participating in ongoing dialogue.

In addition we will engage with NHS England in order to help better understand NHS England's operations and strategic planning to find out points of influence (Commissioning Development Directorate, CSUs).

There are no CCGs in Scotland; however, links will be made with the Scottish Association of Medical Directors (SAMd), the Incident Reporting and Investigation Centre (IRIC) and the Equipment coordinators network and Healthcare Improvement Scotland, in particular, to improve the knowledge in Scotland.

Communications and partnerships

Recommendation 7. Improve and simplify the way incidents are reported, aiming to obtain reports on all device incidents

Working with all participants across the healthcare system to improve adverse incident reporting is critical to the early detection and resolution of potential problems. Working with clinicians, in particular, to remove the barriers to reporting adverse incidents and to ensure that those reporting understand that receiving multiple reports is the driver for intervention will be key to the Agency's ability to take timely regulatory action to minimise risk to patients. The review acknowledges that progress is being made in this area with the publication of updated GMC guidance on reporting for device-related events and the consultation on proposals with NHS England and the devolved administrations on improved adverse incident reporting and accountabilities within Trusts.

Without systematic collection, analysis and transmission of data it is impossible for the MHRA and professional organisations to fulfil their role in managing patient safety issues.

A “one-click” reporting system such as a stand-alone, free MHRA app that sits on all the major ‘tablets’, smart phones, pads, PCs, etc, would overcome some of the practical barriers to reporting adverse events in real time and is recommended for consideration of introduction. There must be as few mandatory questions as possible – the minimum information is the event; that the device can be identified; and the reporter is contactable.

Agency Response - Accepted:

During 2013/14, MHRA has undertaken significant amounts of engagement with our reporting partners across the healthcare system including the independent sector using surveys and deliberative workshops. This has identified some key barriers which were reflected in a jointly badged patient safety alert with supporting guidance from MHRA and NHS England issued for implementation by September 2014. This sets out how NHS England and the MHRA are working together to simplify and increase reporting, improve incident data quality, enhance learning, and guide practice to minimise harm from medical device incidents.

The Yellow Card brand is the most well-recognised reporting brand of the MHRA amongst clinicians and it is therefore planned to expand this for reporting of adverse incidents for devices. This will simplify reporting of adverse incidents for users while maintaining the specific evaluation which device incidents require. This change will be closely monitored to ensure that the volume and quality of reports is maintained and improved.

MHRA will explore collateral developments from the medicines EU SCOPE project that would facilitate developing mobile app reporting for devices that links in to local healthcare reporting and governance systems where they exist. MHRA will also explore the potential for improved GP reporting via partnering with System One, EMIS and other GP systems to deliver easy to use GP reporting systems.

Progress Update

MHRA are developing an integrated vigilance strategy for 2015/2016. The following all form part of this strategy.

Integrated Yellowcard reporting

On 25 November 2014 the Yellowcard brand was introduced for reporting medical devices, defectives medicines and counterfeit devices to MHRA via a single Yellowcard front end. This facilitated the introduction of registration for reporters which simplifies future reporting by auto-populating the organisation and contact details of the reporter. Further planned improvements are scheduled which will provide a searchable reporting history for each registered reporter, particularly helpful for demonstrating clinician reporting at annual appraisals.

Mobile App reporting

MHRA is leading a large EU project that will develop a mobile App for ADR reporting. The Yellow Card App was launched at the 50th anniversary conference on 20th March 2015. MHRA will also adapt the App to include reports of incidents with medical devices. This is a major step forward in reporting as it brings the Yellow Card scheme up to date with the technology platforms that stakeholders have advised will help improve reporting rates.

MHRA will need to further develop the App based on user feedback.

GP reporting

In 2014 an electronic version of the medicines Yellow Card reporting form was adopted as an NHS information standard (ISB 1582). The implementation of this standard has been included as a requirement for all English general practice IT systems under GPSoC. The GP system providers are developing their software to include this electronic Yellow card and will be rolling out to their live systems over the course of the 2015. It is anticipated that this will have a very significant impact on reporting volumes and is a major step forward in addressing under-reporting.

During 2015 MHRA will seek to further influence the standard to include incidents with medical devices and reports of defective and counterfeit medicinal products.

MHRA will also keep under review the implementation of the Yellow Card standard and monitor the impact on reporting. The requirements of GPSoC cover England only, however the same IT providers cover the other UK countries so the new functionalities will be available to all, MHRA will monitor reporting to see if the benefits are realised in all UK territories.

Joint working with NHS England

In March 2014 MHRA and NHS England issued a joint Category 3 Patient Safety Alerts for implementation in September 2014.

Implementation of the jointly badged Category 3 Patient Safety Alerts for implementation in September 2014 has so far delivered the introduction of 276 Medical Device Safety Officers (compared with 364 Medicines Safety Officers), and regular monthly webinars with MDSOs. Presentations given during the webinars promote best practice in reporting, and MDSOs are also using them to highlight local good safety practice in a wide variety of areas. These webinars are stored for later use and interest on the Patient Safety First website.

Meetings with Datix and Ulysses local risk management system (LRMS) providers have led to improvements to Ulysses LRMSs systems in December 2014 with further improvements planned for April 2015 for Datix users. Toolkits for local action to deliver integrated reporting are being developed with pilot sites for each of the LRMS systems. The Ulysses local risk management systems toolkit will be developed first, this will cover improving the timeliness and quality of local and national reporting from the site. Once these toolkits have been developed the publication of an addendum to the Patient Safety Alert will be considered, which is likely to inform of the need to move to integrated reporting Trust by Trust.

A joint MHRA/NHS England conference with the MSOs/MDSOs was held on 19th January 2015. This proved popular with 266 attendees filling the venue. Favourable first impressions regarding the impact and reach of the conference were reinforced by formal post conference evaluation feedback. Attendees particularly valued the opportunity to network with their fellow MDSO and MSO and their opportunity to feedback on their problems and issues with the current joint reporting and learning systems in operation. Of the 72 respondees 93% rated the conference overall as good or excellent.

An electronic survey for MDSOs was developed and distributed, to facilitate greater understanding of who MDSOs are, their sphere of influence in their organisations and experience in devices safety as well as how much time they are able to dedicate to the role. 102 responses had been received when the survey closed on 7th February 2015. Responders were mainly identified as clinical engineers, nurses and health/safety and risk managers. 50% of responders were from the NHS Acute sector with the next largest group being from NHS Mental Health Trusts at 11%. 65% of responders had more than 5 years experience in the medical devices safety field. However, 57% reporting spending less than 5 hours per week on the role.

Feedback from the MDSO/MSO has identified several areas for future work to improve reporting and learning, which MHRA and NHS England are beginning to plan for:

- New facilities for large independent healthcare organisations to report to the National Reporting and Learning system need to be introduced
- A single reporting route for organisations has been requested
- Clinical Commissioning Groups have requested access to adverse incidents and medication errors reported within their commissioned organisations
- Common nomenclature should be incorporated within our reporting and the National Reporting and Learning System. This includes assessing the feasibility of introducing new serious harm and potentially clinical and medicines and medical device nomenclatures.
- Much wider access and feedback on the incidents reported

NHS England has been keeping MHRA updated on the future development of a Patient Safety Information Management System (PSIMS) project. This project is to identify the most appropriate option for a successor to the NRLS, to develop a business case for this option, and procure it for delivery to the NHS. It is recognised that MHRA is a key stakeholder in this regard.

Joint working with Scotland

The Agency will work collaboratively with the Scottish Government to improve and simplify the way incidents are reported, aiming for the ideal, one report which feeds a number of requirements with the foremost being local learning. Knowledge on all device incidents is important for Scottish and UK organisations. The Yellow Card reporting for devices is used by some patient groups in Scotland and will be considered as part of the emerging medical device strategy. The Scottish government will work with acute pilots and primary care teams to discuss how to maximize the use of other developing IT systems so both the UDI and incident reporting and learning are captured.

Improved signal detection and signal management

To improve adverse incident management efficiency and operational communications with one off reporters and members of the public, an IT thematic 'signal' report facility has been introduced into MHRA IT systems. The signal reports are reviewed for priority and progress on a regular basis.

Improved analysis tools for signal detection and text analytics are expected to be acquired and built during 2015/2016. The goal for introducing these technologies is to improve the Agency's ability to identify potentially serious issues at an early stage.

Recommendation 8. Develop means by which devices implanted in patients can be identified by their Unique Device Identifiers, and means by which patients with specific devices can be traced

Access to high quality and reliable data about the performance of devices and clinical interventions over the full life of either the device or patient are critical to making effective clinical and regulatory decisions. This is becoming increasingly important because patients live longer and the number and variety of devices is increasing. The Agency must work with the clinical professions to understand the current distribution of registries and their usefulness and develop a coordinated approach that contributes to the development of rational strategies for tracking the long-term performance of devices, possibly drawing experience from other industrial sectors. A key tool for ensuring that product data are captured and linked to patient records and other databases is the adoption of Unique Device Identifiers (UDI). The Agency must push for the development and adoption of UDI and explore mechanisms for effective market surveillance using tools such as Clinical Practice Research Datalink and the similar system used by NHS Scotland. The NHS number is the obvious unique patient identifier to link to the Unique Device Identifier.

Agency Response - Accepted:

The MHRA recognises the key role that implant registries such as the National Joint Registry play in providing information on the long term safety and performance of implantable medical devices and in tracking and tracing patients in the event of safety alerts and recalls.

There are a number implant registries already in existence in the UK, covering cardiovascular, orthopaedic, vascular and bariatric surgery, but the information that they collect is of variable usefulness to the Agency for identifying under-performing medical devices because some of them are set up with a primary focus on clinical audit rather than implant performance. The Agency has already begun work to identify existing UK implant registries and to map the device related information collected in each of these. Where we identify that further changes are required to improve the usefulness of the registry data to support MHRA's post-market surveillance work, we will seek to influence the organisations that oversee the registries to make the necessary changes and to give MHRA appropriate and timely access to the device related information, by participating in registry steering committees etc.

The MHRA also recognises the value of cooperation between national implant registries on a cross-border basis in order to maximise the available pool of information on implant performance. The Agency has already been active in proposing that there should be better coordination of all post-market surveillance activities for medical device across Europe, including implant registries. The European Commission is now in the early stages of setting up a group to improve implant registry co-ordination across Europe and MHRA will actively participate in this.

The MHRA recognises the value of collecting Unique Device Identifiers (UDI) for implantable medical devices in patient electronic records in support of device post-market surveillance and patient tracking and tracing. This has also been recognised in the Government's response to Sir Bruce Keogh's Review of the Regulation of Cosmetic Interventions (13 February 2014), which states that *"NHS England and Trusts will encourage surgeons and nurses to adopt good practice in recording and reporting use of devices to implement registries and roll-out of UDI"* and in the NHS eProcurement Strategy (7 May 2014) which states that *"Once providers of NHS services have implemented GS1 coded patient identification, they should seek to integrate the recording of the use of medicines and implantable medical devices into patient records by means of scanning the patient identity wristband and the unique device identification barcode(s) on the product"*.

The MHRA has recently undertaken a feasibility study to look at recording implant UDIs in patient electronic records and has identified that considerable work will need to be done to encourage healthcare professionals to adapt their current data collection procedures and that significant changes will need to be made to hospital IT systems to allow UDI information to be systematically collected at the point of use. In the light of this preliminary work, the MHRA will work with DH, NHS England, the Health and Social Care Information Centre and the Clinical Practice Research Datalink to encourage NHS Trusts to implement systems for UDI recording and to adapt national data recording and transfer systems so that UDI information can be centrally collated and analysed.

Recent events have highlighted the fact that patients often do not know what implantable devices have been placed in their bodies. One element of the new European regulations includes a provision that all patients should be provided with a card which clearly identifies the manufacturer, model and item number of implanted devices.

Progress Update

The Agency is well positioned to support the building of consensus across the broad stakeholder network needed to realise ambitions for the full exploitation of UDI coding as a support to patient safety and more effective market surveillance. Ian Hudson, the Agency Chief Executive and Janet Valentine, Director of the Clinical Practice Research Datalink (CPRD), both sit on the National Information Board and John Wilkinson, Director of Devices, sits on the GS1 Health Advisory Board. GS1 are the most prominent coding organisation and the NHS in England is already committed to adopting their format for procurement and logistics purposes. The MHRA will work collaboratively with Scotland whilst they develop their UDI framework.

Influencing UK implant registries to collect data and to carry out data analysis which supports MHRA post-market safety surveillance activities

Adverse incident/vigilance reporting gives a limited picture of the post-market safety /performance of implantable devices. It is therefore important to develop other mechanisms for gaining information about this and these include post-market clinical trials and implant registries.

Registries relating to implant procedures can be set-up in a variety of different ways with possible focus upon patients, clinical practice, devices or a combination of these elements. What information can be obtained from a particular registry will depend upon how it is set up, what data are collected and how these data are analysed. If the goal is to obtain information about the safety/performance of particular types of implants (eg hip joints, heart valves, pacemakers etc) then it is important that the relevant registry collects data which includes adequate information about the devices (model name, catalogue number, batch or serial number etc). If an appropriate dataset is not used then it will be impossible to analyse information about model performance at a later stage. Similarly, data analysis systems need to be set up in such a way that key information on device safety / performance (such as implant survivorship or occurrence of particular complications) can be obtained.

In late 2013 the MHRA set up working group to look at UK implant registries and to work out how the Agency can better utilise them as an integral part of our post-market safety work. The group has already identified 18 UK implant registries and it has recently developed a "road map" which it plans to use as a tool for characterising the status of each registry and for planning how we can influence the development of registries and the use of the registry data as they evolve. A key element of this will be to aim to establish a presence on each relevant Registry Steering Committee so that we - in partnership with implanting surgeons (the key registry stakeholders) - can influence what data are collected, what analyses are undertaken and what access the MHRA will have to information about implant safety / performance.

Encouraging better integration of implant registries

In order to obtain maximum benefit from implant registries it is important to encourage better integration of implant registries into post-market safety surveillance on a European / international basis, with the aim of improving communication and collaboration:

- between registries in different countries
- between registries and competent authorities

European coordination

The European Commission has recognised the importance of registry collaboration and in July 2014 they established a new working group which aims to improve implant registry co-ordination across Europe. MHRA took part in the first teleconference meeting of this group in July 2014 and we will continue to participate as this work is taken forward. This will include considering how the European Parent Joint Action on patient registries can be further developed.

International coordination

In late September 2014 the European Commission put out a call to member states for participants in a new international working group (under the umbrella of the International Medical Device Regulatory Forum) to establish "essential principles" for international collaboration / coordination of patient / device registries. The MHRA put itself forward to participate in this work with the aim of promoting:

- better use of common coding systems/nomenclature by implant registries, such as UDI for device identification , GMDN for device nomenclature, SNOMED CT for coding clinical outcomes and ISO TS 19218 for coding device failures
- better collaboration/data pooling between registries in Europe/internationally
- better coordination of registry activities with other elements of post-market surveillance ie vigilance and post-market clinical follow-up.

The Agency has now been nominated as one of the two European members to represent the European Union on this international group, the first teleconference meeting of which took place in January 2015.

Recording implant UDIs in patient electronic records

The MHRA continues to liaise with Portsmouth Hospitals NHS Trust regarding becoming a “beacon” site for UDI recording. Further progress on this project is currently subject to the introduction of new IT systems at Portsmouth.

The Health and Social Care Information Centre (HSCIC) has now recognised the need to develop national standards for the incorporation of UDIs into patient electronic records and has given initial approval to a “Statement of Need” for this work. MHRA and CPRD will liaise with HSCIC to take this work forward.

The MHRA has worked with the DH eProcurement Team and the GS1 standard setting organisation to agree the attributes to be included in the national data pool which will underpin the NHS eProcurement strategy for England with the aim of ensuring best fit between NHS information about devices and future European / international UDI systems and associated publically accessible databases. When used in combination with the proposed implant cards, the European database should give patients access to key information about the implantable devices that have been placed in their bodies.

Recommendation 9. Improve communications about adverse incidents to patients and the public, clinical staff, clinical scientists, hospital managers and professional bodies

It is essential that the information that the Agency and manufacturers hold in relation to adverse incidents should be shared more effectively with professional organisations so that, where appropriate, training and education programmes can be developed to mitigate risk to patients. The relationships and architecture described above will be critical to delivery of this recommendation.

Agency Response – Accepted:

Current legislation restricts the amount of information about adverse incidents that can be put in the public domain. A major thrust of our work at the EU level is to ensure that transparency is the standard approach. As an integral part of the work with NHS England to improve adverse incident feedback, MHRA has begun work to develop a Transparency scheme with UK medical device industry. This would allow medical device manufacturers to volunteer the release of final adverse report data, to incentivise reporting and improve learning.

The medical device safety network will be used along with representative clinical and other healthcare professional groups to optimise reporting feedback for various future uses.

The medical device safety network together with the supporting webinars and Patient Safety First website will be used to share best practice and learning and develop and highlight newly developed training and education materials in a targeted manner.

Progress Update

UK vigilance transparency scheme and NRLS feedback

Five meetings held with industry (ABHI) have now established the purpose of a future UK Vigilance Transparency scheme and the data fields proposed for the scheme. Industry is keen to see an EU scheme initiated. MHRA has thus regularly updated the EU Vigilance MDEG meeting on progress. We gained agreement for an EU Transparency Task Force in March 2015, which MHRA are Chairing.

The project has now engaged clinicians in three clinical areas (interventional radiology, intensive care, and renal dialysis) to help shape the means and format of the incident feedback provided to meet stakeholder needs.

More recently MHRA have engaged NHS England to try to make feedback on reported incidents available at Trust level for piloting of early feedback.

MHRA will then hopefully be able to enhance this with feedback of investigation conclusions from industry once the EU Vigilance Transparency scheme is piloted and ultimately rolled out. Timescales for this have not been determined.

A programme of joint MHRA and NHSE WebEx meetings have taken place (see progress update under Recommendation 7). Feedback is captured after each presentation to ascertain its degree of usefulness, and to inform future planning. Recent meetings have had themes tailored to MSOs and MDSOs, involving patients and the public, and were held in conjunction with the NHSE Patient Involvement Team. Mobile apps and a review of the human factors stakeholder event have also been themes at these meetings.

The MDSO network will be used along with representative clinical and other healthcare professional groups to optimise reporting feedback for various future uses.

The MDSO network together with the supporting webinars and Patient Safety First website will be used to share best practice and learning and develop and highlight newly developed training and education materials in a targeted manner.

Recommendation 10. Develop improved and more frequent communications with clinicians, clinical scientists, hospital managers and the public

There is a widespread lack of understanding of the nature of the devices regulatory system and the role of the MHRA. The review recommends a strategic approach to communication with healthcare professionals, showing why and how clinicians should engage with the Agency. This complements recommendations 6) and 7) above. In addition, targeted messages need to be developed by the Agency for patients and the public. The review strongly recommends greater patient and public involvement with the

Agency in order to ensure that the quality and effectiveness of communications is enhanced. This is particularly important in light of the shift of often quite complex care and associated devices from acute to homecare settings as well as a substantial increase in self-care and cosmetic interventions which sit in the consumer sector.

Agency Response - Accepted:

The Agency Business Plan 2014-2015 identified amongst its strategic priorities the need to develop strategic relationships with healthcare professionals and with patients and the public. Through these work streams we will seek to develop a corporate understanding of what relationship we want with healthcare professionals and patients and the public and what relationship they want with us. Through the workstreams we plan to pilot and evaluate approaches to engaging and involving healthcare professionals and patients and the public.

The Agency will be exploring - what do patients and the public understand by patient safety? What does this mean to them? What are we or should we be doing when we are keeping them safe?

Patient involvement is not just about communications, patient involvement ensures that we are doing the right things in the right ways and ensures that we have robust governance in place. We need to better understand what patient and their carers (which could be healthcare professionals) need from us to enable them to use medical devices safely and what to do when they go wrong.

We will be attending a number of national conferences in 2014 to promote the organisation and the projects we are undertaking such as the NHS England project (RCN Annual Conference, Patient Safety Conference, NHS confederation and the Patient First Preventing Harm Improving Care Conference).

We are exploring opportunities to contribute more proactively to professional publications and increase our output of informative articles targeted at healthcare professionals and other interested groups.

Progress Update

Various activities have been undertaken and initiated through the Corporate Plan Stakeholder engagement work:

Think Patient Safety

We have developed a campaign, Think Patient Safety, to promote both the MHRA and NHS England joint project to increase the quantity and quality of reporting and the work of the MHRA on patient safety more generally. During 2014/15 we promoted our joint working through exhibiting at the Patient First, Preventing harm, improving care conference on 26-27 November 2014 to promote the joint MHRA/NHS England patient safety alerts and supporting guidance on improving reporting and learning with adverse incidents. This was also done at the Patient Safety Congress, NHS Confederation conference, and the Royal College of Nursing Congress. From interactions at these events we learned that understandings of our patient safety role and responsibilities are limited in some areas. We intend to concentrate effort during 2015-2016 on increasing knowledge and understanding of our patient safety role by sponsoring, speaking and exhibiting at key conferences such as the Patient Safety Congress and Royal College of Nursing Congress.

Additional Communications

MHRA have begun to use new social media tools to promote wider engagement. The Joint MDSO/MSO conference and the Human Factors workshop now feature on Storify as #thinkpatientsafety. Storify is a new application now available to us that allows us to harness social media and create a story surrounding our events. The #thinkpatientsafety twitter was registered to MHRA prior to the event, along with several other twitter accounts, that twitter account was publicised for use during the conferences. A link went live during March 2015 which will be added to as MHRA continue to promote reporting and learning to wider audiences.

Initiated dialogue with Dental College

One of the Devices Clinical team is leading a group to review how we communicate key messages and information to patients and the public. The first workshop had representatives from across the devices division and Comms along with an external expert on this subject. The Irish Health Products Regulatory Authority (HPRA) have produced some very good patient and public information and we have invited them along to discuss how effective this is. We hope eventually to have similar information placed on NHS choices website and implement further initiatives as recommended by the workshop as it develops.

A meeting of the patient consultative forum was held on 21st November 2014 (individual patients and patient groups signed up) and the Stephenson report was used to set the context and two specific examples were used for discussion points (device to feed babies being sold in pound shops and glucose monitors for diabetics) to consider what else we should be doing; find out more about where they would go if they wanted information about the effectiveness of a device, discuss what they would do if they had a problem with a device. The meeting was very informative and will form the feedback will form the basis for developing work streams to address these recommendations

The Academy of Medical Royal Colleges' Patient and Public Group met in December 2014 and MHRA attended this meeting to discuss how important it is that patients report adverse incidents to us.

The agency organised a multi-disciplinary stakeholder event on Human Factors in February. 75 people attended from a diverse range of sectors. The evaluation of the event was extremely positive. Professor Ann Blandford, UCL provided a key note speech. Additional speakers included, notified bodies, usability experts, MHRA providing a regulation perspective, patient groups and industry representatives. The event began the discussion on human factors and patient safety and map activity to ensure we are maximising impact and not duplicating effort.

As an action from the event we will be taking forward a time limited 'task and finish' group with key strategic partners to develop a work programme to ensure that there is better understanding of our regulatory responsibilities, work with notified bodies to ensure human factors are adequately addressed.

The Agency Board and Corporate Executive Team have been further discussing whether it is desirable to raise the public profile of the agency and the need for increased patient and public involvement.

Recommendation 11. Develop collaboration with NICE, NHS, devolved administrations, independent sector

Patient safety is the concern of all organisations spanning the healthcare system and the MHRA must develop open and constructive relationships with key partners including NICE, the Academy of Medical Royal Colleges, NHS organisations, Public Health England, the devolved administrations and the independent sector.

Agency Response - Accepted:

The Agency views collaboration as a critical element of supporting patient safety, and is committed to ensuring it has effective relationships with others in the health and social care system. It is currently taking forward work to review its relationships within the system. This aims to build on current arrangements with key partners to ensure clarity of roles and responsibilities and shared positions in relation to key issues.

Devices members of staff already sit on influential NICE advisory bodies and there is a developing strategic dialogue with NICE. The Academy of Medical Royal Colleges will be a key partner in helping the Agency to establish and maintain a set of vital and dynamic relationships with professional bodies. The Agency has initiated a specific programme to ensure effective communication and working relationships with key partners. This includes putting in place quarterly meetings with NICE and, separately, the Devolved Administrations to take an overview of current and potential key work and issues, and agreeing a Partnership Agreement with NICE to support collaboration. It has also taken initial steps to explore strengthening working arrangements with NHS England, Public Health England and the Care Quality Commission.

A specific recent example of collaborative work has taken place between the Royal College of Pathologists, the regulator and NIBSC in the context of the Barnes Review: Pathology Quality Assurance Review.

Progress Update

The Agency has continued with the specific programme to ensure effective communication and working relationships with key partners. This includes putting in place quarterly meetings with NICE and, separately, the Devolved Administrations to take an overview of current and potential key work and issues, and agreeing a Partnership Agreement with NICE to support collaboration. It has also taken initial steps to explore strengthening working arrangements with NHS England, Public Health England and the Care Quality Commission.

A Memorandum of Understanding is in place between MHRA and NICE and regular meetings are being held including devices bi-annual meeting and attendance at IPAC and MTAC. The Clinical Director sits on the NICE Interventional Procedures Committee (IPAC) whilst the Director sits on the Medical Technology Advisory Committee (MTAC). These have been complemented by the establishment of quarterly informal meetings at a senior level between the devices groups in each organisation and a more formal Liaison Meeting at a cross-Agency level. In addition to this and as already described in Recommendation 1, NICE have been invited to hold a seat on the DEAC.

The Devolved Administrations will also be part of DEAC.

Future developments and emerging challenges

Recommendation 12. Support the safe introduction of new and innovative technologies into clinical practice

The MHRA has a broad role in supporting the safe introduction of new and innovative technologies into clinical practice. To fulfil this role effectively the Agency needs access to networks which are operating at the leading edge of product and clinical innovation in order to ensure that future regulations are fit for purpose and regulation does not act as an unnecessary impediment to the introduction of beneficial new technologies.

Agency Response - Accepted:

The MHRA is committed to encouraging innovation in the UK. Whilst our role in the pre-market assessment of devices is limited, we provide extensive guidance on all aspects of the regulatory framework on our website, with our recent guidance on the regulation of mobile apps an example that has received extensive positive feedback from industry. As well as offering general regulatory advice, with over 1,500 queries received in 2013, we also provide contact details for technical specialists by device area, allowing manufacturers to speak directly to relevant staff. The Innovations Office opened in 2013 and has enabled open dialogue with developers. There is also a cross Agency initiative looking at stem cell therapies and regenerative medicines and we anticipate increasing interest in genomics and associated diagnostic and software applications.

We will work closely with industry and notified bodies to address problems identified with the regulatory framework, reducing administrative burdens wherever possible and having regard to economic impact in all aspects of our work. The MHRA will provide more support and communication to companies, particularly considering the regulatory process for novel devices and those that span the regulatory environments for both devices and pharmaceuticals, such as combination products and diagnostics supporting personalised medicine.

We are engaged with the Beyond Compliance initiative with the orthopaedic community and are looking to see where lessons learned could be applied to other areas.

Agency staff sit on a number of consultative and advisory groups supporting academic and translational activity in the sector, such as the London Regenerative Medicines Network. There is need for an enhanced engagement with the Technology Strategy Board and Knowledge Transfer Network about emerging technologies and how our role of the regulator can support industrial development in the sector.

Initial discussions have been held with the Notified Bodies in relation to using them to help identify new and innovative technologies which may challenge the regulatory system and could benefit from discussion at stakeholder forums to ensure regulations are fit for purpose.

We will continue to bring thought leaders into the Agency to educate, stimulate discussion and help shape the Agency's thinking around the regulatory challenges.

Progress Update

Supporting the safe introduction of new and innovative technologies into clinical practice is core to the philosophy and practice of the MHRA. The most pressing work in this area relates to our work to ensure that confidence in the functioning of the regulatory system is enhanced following the PIP breast implant scandal. There are two key elements to this.

Firstly, the Agency and Foreign & Commonwealth Office (FCO) colleagues in Brussels are working assiduously to ensure that the new legislation is both effective and proportionate. To do this we have been engaging in extensive stakeholder consultation to help establish strong well-reasoned UK positions as well as working with like-minded colleagues across the community to develop detailed proposals on a large number of specific issues.

Secondly, much of the criticism levelled at the EU system was as much about management of the system as the legislation itself. The UK has always been mindful of the need for strong coordinating and collaborating mechanisms having been founder members of both the Compliance and Enforcement Network (COEN) and Notified Bodies Operations Group (NBOG). Since the PIP scandal, the MHRA has been a leading player in driving the establishment of a raft of other mechanisms which have the goal of improving the management of the system and enhancing efficiency by collaborating with EU partners. The detail of this is captured in the response to Recommendation 5.

Proportionate legislation which is effectively managed is critical to the creation and maintenance of an environment where innovation can be safely and effectively brought into clinical practice for the benefit of patients without excessive burden on innovators.

Another critical element of the Agency's support for innovation is presence of expertise in emerging areas of science and technology that is able to bridge between the worlds of the innovator and the regulator. Expertise in this area brings two primary benefits. It allows the Agency to provide practical advice to innovators and help them map a course to market whilst ensuring that we are equipped to anticipate and shape future legislation and its implementation. The Agency has been very active in the following areas:

- **Regenerative medicine:** The Agency has created an Advanced Therapies Forum designed to help innovators by establishing a 'One Stop Shop' concept in collaboration with other regulatory bodies.
- **Innovations Office:** The Innovations Office portal is now fully up and running and a large proportion of the enquiries have been for devices and combination/borderline products requiring continuous development of both processes and collaboration between medicines and devices.
- **Software apps/software as a medical device:** There has been a huge increase in requests for advice on software and whether a particular app constitutes a medical device or not. The Agency continues to work through a long list of emerging issues in this area and published guidance to help innovators and developers determine whether their software was a medical device and, if it was, what regulatory steps would be

required. The Agency has been working with the Royal College of Physicians on guidance for medical practitioners who are developing apps. The Agency has been working with NHS England to ensure that their developing guidelines and processes are complemented by consideration of regulatory requirements. The UK have also been active in contributing to the European shadow group supporting the International Medical Devices Forum (IMDRF) work stream which is producing harmonised global guidance in this area.

- **Beyond Compliance:** The Agency continues to support the steering group for the 'Beyond Compliance' initiative designed to enhance the process of safe introduction of orthopaedic implants. This is an important initiative in its own right but also may provide valuable insights into more generic approaches to managing risk and innovation.
- **Genomics:** The Devices Division is actively involved in the cross-Agency group looking at genomics and the impact of emerging technologies on the work of the MHRA. Most of the immediate regulatory work is around the regulatory status of sequencing devices and software used to translate sequencing data into information that may be used by clinicians or individuals.
- **Horizon scanning:** The Agency has a horizon scanning group which is tasked with spotting emerging challenges and the Devices Division is actively involved.

Devices staff are involved in a number of other initiatives which support the safe introduction of innovation and there is a particular focus on building on already strong links with NICE. (See recommendation 11).

The Agency continues to engage with the academic and innovation communities on a limited basis via representation on the MeDe EPSRC Advanced Manufacturing Programme Steering Group and the advisory board of the Healthtech and Medicines Knowledge Transfer Network. This is in addition to attendance on an ad hoc basis with other groups.

The Agency is also working with the Association of Medical Research Charities to establish if there are opportunities to contribute to each other's work. To date this has resulted in MHRA speaking at one of their member meetings and their helping the Agency in work on patient and public involvement. The good will of patients and public is critical to the success of both organisations in promoting research and innovation.

The Devices Team have supported a number of ad hoc trade development exercises over the past year including supporting the Minister for Life Sciences on a visit to the USA, as well as training updates for UK Trade and Investment (UKT&I) staff, and a trade development visit to Canada to attend a thought leading international seminar on the relationship between health technology assessment and regulation.

Notwithstanding the significant impact of the above activity support for innovation remains a challenge and developing and sustaining expertise in emerging areas of science and medicine is something that will be subject to both stakeholder expectations and resource constraints. Current resource constraints severely limit our ability to provide more support and communication to companies, particularly considering the regulatory processes for novel devices and those that span the regulatory environments for both devices and pharmaceuticals, such as combination products and diagnostics supporting personalised medicine.

Annex 1

Draft Terms of Reference for DEAC

In order to improve and inform MHRA's strategies to protect public health and improve patient safety, the DEAC will help the MHRA:

- By providing advice on strategy in respect to devices which aligns to policy across healthcare sectors and UK, EU and global settings
- Provide advice on product-specific issues when required
- Develop clear and focused partnership with decision makers and those who deliver healthcare
- Establish robust and effective network and dialogue with all who carry out device related activity – from a register of experts to professional, patient and public users

More specifically the DEAC will support the Agency in areas including the following:

- Facilitating access to 'ad hoc' expertise when necessary, particularly on emerging safety issues with either a product or general concerns in relation to clinical practice eg off-label use
- Help in further development of the Agency's register of clinicians who can support our role in ensuring that clinical investigations performed in the UK are safe and effective. These include identifying suitably qualified reviewers as well as advice on the development of broader standards/guidance
- Contributing to quality assurance of above processes
- Advising on configuring provision of Clinical Governance through professional bodies
- Signposting/making connections with professional bodies
- Making the Agency aware of emerging issues and help shape strategy to respond
- Brainstorm specific emerging issues to inform policy and operational activity
- Act as an independent reviewer in cases of dispute or facilitate such a review

The DEAC will meet formally on a quarterly basis.

Please note: The draft TOR will need to be ratified at the first DEAC meeting.