MHRA response to the Independent Review on access to clinical advice and engagement with the clinical community in relation to medical devices

The MHRA warmly welcomes the independent report *Expert Clinical Advice – MHRA Medical Devices* and would like to thank Professor Terence Stephenson, the chairman, and other members of the Review Panel. MHRA takes careful note of the findings of the Review Panel and welcomes the Review's recommendations. The Review highlighted wider concerns which are not just the responsibility of MHRA, but the Agency wants to work in partnership with others to improve patient safety in relation to medical devices and to help drive solutions.

The Agency accepts all of the recommendations. This paper outlines activities already underway and the plans to work better with others to improve patient safety.

The MHRA will review progress with taking forward the recommendations, making best use of the resources available, in line with the new Regulator's code (a framework for how regulators should engage with those they regulate). A cross-Agency group has been formed to oversee progress with implementation of the recommendations, with a view to formally reporting on progress on the anniversary of publication of the report. Prioritisation and timing of the required tasks (some of which are interdependent) will need to 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.

Organisation of clinical advice input, resources and leadership

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.

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.

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.

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 it's ability to contribute to broader patient safety issues. Work in this area will inform the numbers and configuration of Agency staff in the future.

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.

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.

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.

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.

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.

Collecting and using device incident data

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.

Communications and partnerships

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.

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.

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.

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.

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.

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.

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.

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.

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.

Accepted:
The Agency views collaboration as a critical element of supporting patient safety, and is committed to ensuring is 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 that our links to the Devolved Administrations are well structured and consistently used. 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.

Future developments and emerging challenges

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.

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.