Letter from the editor

Welcome to the final edition of the medical devices newsletter for 2014. In this edition, we introduce an article from Dr Fergal McCaffrey on the development of medical device software standards. The article highlights some of the key standards in software development for medical devices and overviews the research being conducted by Dr. McCaffrey’s group in Dundalk Institute of Technology developing tools to apply the software standards to help ensure compliance with the relevant regulatory requirements and best practise.

We also report on our medical devices information day that was held in October with a record turnout of over 250 attendees comprised of industry and trade representatives, health care professionals and other stakeholders. Feedback from the day was very positive and we were delighted to have guest speakers from the European Parliament, European Commission and HSE colleagues with us on the day.

The discussions on the revision of the medical devices legislation are continuing to progress at the European Council Working Party and we provide an update on its progress in this newsletter. The main objective of revising the legislation is to increase the protection of public health and increase patient safety by developing and enhancing the regulatory framework while also considering the need for a regulation that supports innovation in the medical devices sector that affords patients and healthcare professionals timely and safe access to new diagnostic and therapeutic technologies.

In the last edition of the HPRA medical devices Newsletter we introduced our re-developed HPRA medical device information notices and in this edition we provide practical examples of the types of information notices for further feedback including a safety notice on Insulin Infusion Pumps and an information brochure on IVD self tests. We would welcome your feedback on the new format of these notices to devicesafety@hpra.ie.

Additionally, we have included regulatory updates on the recent European working group meetings namely the Medical Device Expert Group, MDEG Vigilance, Competent Authorities for Medical Devices Rome, New and Emerging Technologies (NET) Working Group, COEN working group, International Medical Device Regulators Forum (IMDRF) and Medical Device Expert Group Investigation Working Group (CIEWG).

Finally, the devices team across the HPRA would like to wish you and your families a very Happy Christmas and a peaceful and prosperous New Year.

As always, the HPRA welcomes feedback on the content of our newsletter and encourages readers to submit suggestions for articles that would be of interest by contacting us at devices@hpra.ie.
Bringing Medical Device Software Development Standards into a single model

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The global medical device market continues to experience steady growth, in regions where an increasing aging population is prevalent. The medical device/healthcare software development market is set to grow considerably over the coming years, with remote monitoring and increasing software complexity in hospital based systems.

Software performs an increasingly essential role in the provision of healthcare services, often forming part of the medical diagnosis and treatment process. Therefore, both the proportion of medical device functionality performed using software and the complexity of that software has substantially increased. Consequently, there is a growing need to harmonise and address the regulatory requirements, standards and compliance in the area to prevent the potential harm that can be caused by faulty software. In 2011, the FDA reported that ‘software failures were behind 24% of all the medical device recalls’1. In Europe, the medical device regulatory environment has been extended to include more focus on software. For example, the 2007/47/EC amendment to the Medical Device Directive recognises that standalone software can also be classified as a medical device in its own right if it fulfils the definition of a medical device. As a result, a significantly increased proportion of software applications, including ‘Mobile Apps’ are now classified as medical devices and must be developed accordingly in order that they are compliant with the applicable regulation. Over the coming years, this development will have a significant impact on the large number of software development organisations that are operating within the medical device domain, therefore it is necessary to increase awareness of the medical devices regulations, the applicable requirements and standards to ensure these developers are prepared.

Another growing trend in global healthcare is electronic medical records management. The use of Electronic Medical Record (EMR) systems in the USA by physicians increased from 18.2% in 2001 to 48.3% in 2010 and this is set to continue. The adoption of EMR systems could produce efficiency and safety savings of $81 billion annually and improve prevention of medical diseases2. While EMR systems are not currently classified as a medical device, other regulations such as data protection and security provide a challenge to the global adoption of interconnected medical systems.

The use of mobile devices in healthcare is rapidly increasing – ‘By 2017, mobile technology will be a key enabler of healthcare delivery reaching every corner of the globe’3. Mobile applications are perhaps the largest source of standalone software that is now classified as a medical device and ‘App’ developers must comply with the associated regulatory requirements for medical devices.

Medical device software development organisations may develop either standalone medical devices or devices that will be interconnected. Additionally, the software developed may be either embedded software as a component of a medical device or standalone software which may itself be classified as a medical device. Regulatory obligations require that highly effective software development practices are defined and adopted within medical device companies. In the EU, regulatory requirements are outlined in the general Medical Device Directive 93/42/EEC, the Active Implantable Medical Device Directive 90/385/EEC, and the In-vitro Diagnostic Medical Device Directive 98/79/EC, the first two of which have been amended by 2007/47/EC. Although slightly different to the US FDA’s safety classifications that are based on the clinical safety of the device, the EU classifications essentially embody similar classifications and limitations, where Class I corresponds to US FDA Class I, Class IIa and IIb to US FDA Class II, and Class III to US FDA Class III. A further safety classification applies to the software in the medical device as outlined in IEC 62304 – ‘medical device software life cycle processes’ - which defines the lifecycle requirements for medical device software.
Adherence to the various medical device regulations may be demonstrated through the implementation of international standards and guidelines. In accordance with the EU medical device regulatory framework, conformity is often based on full quality assurance assessment of a quality management system and technical documentation. EN ISO 13485 can be used as part of the basis for an organisation’s quality management system and to assess an organisation’s ability to meet both customer and regulatory requirements. In addition to other specific requirements of the EU Directives, EN ISO 13485 does not offer specific guidance on software development. IEC 62304, which can be used in conjunction with EN ISO 13485, offers a framework for the lifecycle processes necessary for the safe design and maintenance of medical device software.

IEC 62304 is designed to complement not just quality management systems, but also the risk assessment process (which is further outlined in EN ISO 14971). EN ISO 14971 is responsible for establishing sufficient levels of risk management (with respect to product safety) in the development of medical devices. Many further standards also exist in the medical device development domain, including usability requirements described in IEC 62366, and performance requirements for safe electrical equipment detailed in IEC 60601-1. In addition, guidance from other regulatory regions although it may not be directly applicable may be used to help inform the software development process.

The Regulated Software Research Centre (RSRC) in Dundalk Institute of Technology performs medical device software engineering research and has developed tools to assist with the development of medical device software. This work has required that RSRC have significant engagement with international standards development and part of this work led to the development of IEC 80002-3 (Process Reference Model for IEC 62304), published in May 2014. IEC 80002-3 represents the culmination of many years of work, creating important new standards within the working groups of both the ISO and the IEC. Through working with international standards working groups such as IEC SC62A/ JWG3, IEC SC62A/ JWG7 and ISO/IEC JTC1 SC7 WG10, the RSRC has also advanced other standards, including IEC 80001-1-7 (Process Assessment Model for IEC 80001-1) and IEC 80001-2-8 (Guidance on standards for establishing Security Capabilities identified in IEC/TR 80001-2-2).

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References:


3. Interview with Jeanine Vos, Executive Director, mHealth at the GSMA. 2012
Software and mobile applications that fall under the definition of a medical device or an in vitro diagnostic (IVD) medical device are regulated by the respective Directives 93/42/EEC or 98/79/EC.

To complement Dr Fergal McCaffery’s article on software development standards we have provided a brief recap on the qualification criteria for medical devices and IVDs.

The MEDDEV Guidance 2.1/6, entitled ‘Guidelines on the qualification and classification of stand-alone software used in healthcare within the Regulatory Framework of Medical Devices’ published by the Commission services in January 2012, is the most relevant document which provides practical advice to manufacturers, organisations and public authorities on how to determine when a software falls under the definition of a medical device or of an in-vitro diagnostic medical device. Such criteria also apply to mobile applications.

In December 2013, the International Medical Device Regulators Forum (IMDRF) published ‘Software as a Medical Device (SaMD): Key Definitions’ focusing on a common definition for when software is considered to be a medical device. The term SaMD is defined as ‘software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device’. The working group established by the IMDRF continued to develop guidance and in September 2014 published ‘Software as a Medical Device: possible framework for risk categorisation and corresponding considerations’. The objective of the document is to introduce an approach, harmonised vocabulary and general and specific considerations for manufacturers, regulators and users alike to address the unique challenges associated with the use of SaMD. The IMDRF working group recognises the need to develop the foundational approach further with respect to classification and regulatory requirements. It is anticipated that this group working at international level will have a significant impact on the terminology, definitions and provisions relating to standalone software.

With the ongoing revision of the medical devices legislation significant discussion is necessary to ensure that the proposed Regulation deals appropriately with the different type of medical device software. This includes ensuring the definitions, classification and conformity assessment provisions are appropriate to effectively handle the ever growing area of medical device software. A more proportionate risk-based classification system for standalone software is required. Member States are continuing to discuss the provisions of the Regulation, such as the classification rules in Annex VII. It is important to ensure that guidance in the area of software as a medical device is harmonised and reflected in the text of the European Regulation.

References:
5 http://www.imdrf.org/docs/imdrafinal/technical/imdraf-tech-131209-samd-key-definitions-140901.pdf
Standalone software qualifies as a medical device when:

- The software is considered as a computer program.
- It is not incorporated into a medical device at the time it is placed on the market or made available. Such software falls automatically into the same class as that device and is subject to the requirements of the relevant Medical Device Directive, as amended.
- It is intended to create or modify medical information, where such alterations are made to facilitate the perceptual and/or interpretative tasks performed by the healthcare.
- It is used for the benefit of individual patients.
- It is intended to be used for any of the medical purposes listed in Article 1(2)a but it is specifically intended to be used together with a medical device to enable that device to be used in accordance with its intended use, then the software is considered as an accessory to a medical device. As such, it shall be treated as a medical device in its own right.
- It is noted that only the intended purpose, as described by the manufacturer, is relevant for the qualification purposes and that the risk related to a malfunction of standalone software used within healthcare is, in itself, not a criterion for its qualification as a medical device.

Software qualifies as an In-vitro diagnostic (IVDs) medical device when:

- it is intended to be used for the purpose of providing information derived from the in vitro examination of a specimen derived from the human body.
- the software allows for an 'expert function' which provides information within the scope of the IVD definition. An expert function is defined as a software function that is able to analyse existing information to generate new specific information according to the intended use of the software.
- the information provided by the software is based on data obtained from IVD medical devices only, or from both IVD medical devices and general medical devices for the purpose of providing information for diagnosis, relating to a physiological or pathological state, or; congenital abnormality, or; determine the safety and compatibility with potential recipients, or; monitor therapeutic measures then it may be considered as an IVD medical device or an accessory.
On the 23rd October, the HPRA held an information day on medical devices for stakeholders. The number of attendees on the day was in excess of 250 people comprising representatives from industry, healthcare professionals, research organisations, the European Commission and other state agencies and government departments involved in the medical devices sector.

The conference was opened by HPRA Chief Executive, Mr Pat O’Mahony, who stressed the importance of adopting a ‘can do’ attitude for patient safety and expressed the need for regulators to work together to improve the system through consistency, cooperation, continual assessment and oversight with clear criteria and increased transparency in the regulation of medical devices.

The importance of adopting and implementing an improved regulatory system for devices that has patient safety to the fore while promoting innovation was also the key message from guest speakers from the European Parliament (Mairead McGuinness MEP, Vice President of the European Parliament), the European Commission (Erik Hansson, Deputy Head of Medical Devices Unit (B2), DG Sanco), the UK competent authority, the MHRA (John Wilkinson) and from the European industry association, Eucomed (John Brennan). The theme of the morning session focussed on the ongoing work of the EU Commission and Competent Authorities to strengthen and build the existing European regulatory system for devices, through implementation of the EU Commission’s Joint Plan for Immediate Actions (Dalli plan). This plan, which was implemented in 2012 as a result of the crisis with PIP breast implants defines actions for competent authorities and for the Commission: to improve the performance and oversight of notified bodies for medical devices; to reinforce market surveillance of medical devices; to improve coordination and cooperation between European authorities and to enhance communication and transparency on medical devices. The HPRA has placed critical emphasis and focus on effective implementation of the joint plan. The EU Commission has reported on the implementation of the joint plan to date.7

References:

7 SWD(2014) 195 final ‘COMMISSION STAFF WORKING DOCUMENT Implementation of the Joint Plan for Immediate Actions under the existing Medical Devices legislation.’ Available at ec.europa.eu/health/medical-devices
In addition the audience were updated on progress of the new revised legislation which is currently being discussed at the European Council. The new legislation seeks to further enhance and develop the regulatory system with a view to adopting a more robust, transparent and enabling regulatory framework. The HPRA identified that achieving an effective and clear regulatory text was essential to protect public health and that it has devoted all possible resources to achieve this as soon as possible.

Another important aspect to the morning session were the overviews of the legislation and standards on the practical implications associated with putting devices into service in our hospitals and healthcare institutions. Colleagues from the Health Service Executive (HSE) made presentations on quality and patient safety in the management of the national decontamination unit (Caroline Conneely) and on the application of standards and a unified approach to equipment management within the HSE (Ronnie McDermott).

The conference also included a session on emerging initiatives on research, innovation and regulation of health products, with an overview of the HPRA’s lifecycle approach to market surveillance of medical devices; an insight into innovation of medical devices and health products in Ireland at the Health Innovation Hub in UCC, Cork (Colman Casey) and initiatives undertaken by HPRA to encourage research, innovation and effective regulatory practice with the establishment of the new ‘Regulatory Science Ireland’ initiative.

The afternoon comprised of parallel information sessions one targeted at healthcare professionals and clinical users and the other targeted at the industry and trade. The sessions provided information for the specific stakeholders on: the HPRA vigilance process and reporting issues to the HPRA; medical device market surveillance activities conducted by the HPRA; information on communication mechanisms used by HPRA to engage with our stakeholders; the implications of the new legislation and the likely responsibilities therein for the different stakeholder groups.

Feedback received from participants following the event was very positive and presentations are available to download at https://www.etouches.com/ehome/84694. If you have any questions on the topics raised in the presentations please send your queries to: devices@hpra.ie and we will do our best to answer them.
Proposals for new regulation on medical devices and *in vitro* diagnostic medical devices – state of play

The Working Party on Pharmaceuticals and Medical Devices at the European Council (‘the Working Party’) has made significant progress during the Italian Presidency of the European Council towards finalising the proposals for a Regulation on medical devices and *in vitro* diagnostic medical devices. The Italian Presidency organised ten meetings of the working party as well as facilitating a number of expert ‘technical’ meetings. The working party has concentrated on discussing various compromise proposals and the Presidency presented their progress report to the Council of Ministers responsible for employment, social affairs, health and consumer policy, EPSCO, on the 1st December. The progress report highlighted a number of key topics where further discussions are needed. Central to these is the European Commission’s proposed ‘scrutiny mechanism’ for certain high risk devices. A number of proposals have been tabled on this specific topic and it is hoped that a compromise can be reached on this critical issue early in the incoming Latvian Presidency. It is recognised that the outcome of the discussions on the scrutiny mechanism impact the remaining chapters of the proposed regulation. Some of the other topics highlighted included: aesthetic devices and the proposal to include them within the scope of the medical devices regulation; reprocessing of single-use devices; clinical investigations and clinical requirements; mechanisms for surveillance and designation of Notified Bodies; post market surveillance by manufacturers and the area of governance and coordination.

The HPRA will continue to support the Department of Health, who head the national delegation, at the Working Party discussions to promote development and agreement on these two proposals and we are optimistic that a general approach agreement of the European Council will be achievable during the Latvian Presidency.

In the last edition of the HPRA newsletter in August 2014 where we provided an overview of our new information notice communication, we have provided practical examples below of other types of communications issued by the HPRA in relation to medical devices. These overviews are intended to raise awareness of the different types of communications issued and for the latest information and updates to these notices please refer to our website.

We would very much welcome any feedback on the communications issued by HPRA in relation to medical devices, in particular with respect to the relevance of the topics covered, the readability, the presentation and the circulation and communication of the notices. Please send any feedback to devices@hpра.ie.
Safety advice on self-test products – new HPRA information brochure

The Health Products Regulatory Authority (HPRA) has published *Medical Devices - Self-Test Products*, an information leaflet to assist patients and members of the public who use self-tests for a medical purpose. The HPRA has developed this information guide in response to the increasing availability of self-test products which are available for a variety of health conditions. The HPRA has observed a number of concerning trends and issues identified by HPRA assessment of reported adverse incidents relating to their use. Such products can be used to diagnose a variety of conditions or to monitor a particular treatment, and they include pregnancy tests and test kits for measuring blood sugar. The HPRA leaflet includes advice for people who are thinking about buying a self test product and highlights the potential risks associated with self-testing.

The leaflet is intended to clearly outline the key information to consider when self-testing:

- If you have any concerns about your health or a test result consult a healthcare professional;
- No self test is 100% reliable;
- Certain factors may interfere with test results including the use of medicines or dietary supplements;
- People should always purchase products from a reliable source;
- Self-test products should always display a CE mark along with a four digit number. This indicates that the test meets the essential requirements for safety and effectiveness under EU law.

As competent authority for the regulation of medical devices in Ireland, the HPRA urges patients and members of the public to report suspected incidents of test failure and any other unexpected issue associated with the use of self-tests to their healthcare provider or the manufacturer of the device and to the HPRA. Reports can be submitted to the HPRA using the online user report form available at [www.hpра.ie](http://www.hpра.ie).

The Self-Test Products leaflet is available to download from the HPRA website. Printed copies can be ordered from [leaflets@hpра.ie](mailto:leaflets@hpra.ie).
In order to raise awareness of some of the common problems identified with the use of ambulatory insulin infusion pumps, the HPRA published **SN2014(42) Insulin Infusion Pumps** in November 2014.

In recent years, with the increased use of insulin infusion pumps, the HPRA has received a number of reports of adverse incidents associated with the use of these devices. Some of the common issues reported to the HPRA include the following:

- **Leaks**, where it has been reported that insulin leaked from the connection between the pump and the insulin reservoir.
- **Screen/display issues**, where it has been reported that the device screen was unresponsive. Reports have also been received of screen discolouration and dimming.
- **Keypad issues** where reports have been received of damaged or peeling keypads, difficulty in pressing buttons, buttons sticking and unresponsive keypads.
- **Incidents** where the device failed to alert users to battery or insulin delivery issues.
- **Device powers down without warning**.

These incidents can potentially result in either a delay in delivery of insulin or incorrect delivery of insulin. Screen/display issues also make it difficult for users to determine if they have actually delivered their insulin dose. In some cases, users have required medical attention or have been hospitalised due to symptoms of hyperglycaemia or hypoglycaemia.

In response to these issues, the HPRA has followed up with the relevant device manufacturer and, in some cases, with the notified body issuing the certificate for the device to ensure that an appropriate corrective action is taken when necessary. This has included discussion and cooperation on insulin pump issues with the EU Commission and with colleagues from other European competent authorities. In a number of cases the device manufacturers have initiated field safety corrective actions to address these issues.

As the Competent Authority for medical devices, the HPRA’s role is to monitor the manufacturer’s investigation of these incidents and ensure that appropriate action is taken to ensure that any safety concerns are addressed. The HPRA encourages patients and healthcare professionals to continue to report such adverse incidents.

The HPRA advises that health care professionals/patients:

- Ensure you follow the manufacturer’s instructions as laid out in the device user manual / instructions for use.
- Ensure that you have received appropriate training in the use of these devices.
- Ensure that you are aware of the need to examine the device regularly for signs of wear or damage and make note of any error codes and alarms.
- Ensure that you have a back-up insulin delivery method available.
- Report any issues with these devices both to the manufacturer and to the HPRA.

- Forward this Safety Notice to all those within your organisation that need to be aware of this information.

In addition, readers should also note the Health Products Regulatory Authority (HPRA)’s recently published **safety notice SN2014(33) in relation to Magnetic Resonance Imaging (MRI) safety**. The notice is targeted at health care professionals to raise awareness of safety hazards for patients, visitors and hospital staff when in an MRI environment. The notice has been developed in response to trends and reported issues internationally and from feedback at national level relating to their use. The safety notice can be downloaded from the HPRA website [www.hpra.ie](http://www.hpra.ie).
Medical Device Expert Group (MDEG) - Vigilance

A meeting of the MD Expert Group on Vigilance was held in Brussels on 30th and 31st October 2014. It was the first meeting with a new Chairperson of the group from the European Commission. The area of device specific vigilance guidance was discussed in some detail. The group agreed that the cardiac ablation systems guidance would be presented to the MDEG Plenary meeting for final endorsement. A new simplified format for such guidance documents was proposed and received positive feedback from all stakeholders. Several topics were proposed for future device specific guidance, including one on coronary stents and one on artificial heart valves. There will be further discussion at the next meeting to identify which topics will be developed further for future device specific guidance documents.

The MHRA provided a further update on their national initiative regarding the publication of investigation outcomes on their website. They are involved in ongoing discussions with the various stakeholders.

An update was provided to Member States on the ongoing work of the taskforce that was convened to examine the area of coordination; it is envisaged that a further update will be provided to the wider group at the next meeting.

Colleagues from Sweden presented a study that they had conducted in the area of infusion devices. The study included the results of a questionnaire to healthcare professionals.

IVD Technical Group (IVDTG)

A meeting of the IVD Technical Group (IVDTG) was held on 15th October. During the meeting, further progress was made in relation to the proposed amendments to the Common Technical Specifications (CTS) for HIV Nucleic Acid Testing (NAT) assays. Other topics discussed included parallel importing, genetic tests for research use only and clinical evidence requirements. In addition, a proposal for a Notified Body Operations Group (NBOG) coding system for demonstrating competence of the Notified Body involved in the conformity assessment procedure for IVDs was presented. The work priorities of the group were also reviewed and a proposal to develop CTS for Chagas and Syphilis was presented. The potential need for CTS for HCV core antigen (Ag) assays was also raised in order to introduce requirements for both HCV core Ag and HCV Ag/Ab tests in a similar manner to HIV p24 antigen and HIV Ag/Ab combination tests. The terms of reference for the group were also discussed.

Competent Authorities for Medical Devices Rome,

The 35th Meeting of the Competent Authorities for Medical Devices was held in Rome in October 2014.

The Italian Presidency and the European Commission delivered updates on the status of legislative negotiations at the Council Working Party. The Presidency also provided an overview of its organisational structure and operations within the Italian Ministry of Health, which is the Competent Authority for medical devices in Italy.

The newly formed CAMD Executive group updated the CAMD plenary on the progress of their work so far in identifying key priorities/work items for the CAMD to focus on. These include a review of the existing European working group structures and operations, communications, market surveillance and clinical data. In addition, the Central Management Committee (CMC) was disbanded by the CAMD. Existing/ongoing work items of the CMC will be passed to the CAMD Executive for consideration.

Members discussed common issues impacting the Compliance and Enforcement working group (COEN), the working group on Clinical Investigation and Evaluation (CIE) and the Notified Bodies Operations Group (NBOG). HPRA delivered a
The results of this consultation and the feedback report are expected to be circulated in December 2014.

- Developments on in vitro diagnostic medical devices were discussed in the area of synthetic biology and its applications in biosensor development.
- The area of 3D printing was discussed in terms of qualification and classification of software applications and the development of custom made medical devices.

**COEN working group**

The Compliance and Enforcement Group (COEN) meeting was held in Brussels in October 2014. Updates were provided by the attending Member States on various issues of mutual interest to the group. During the meeting there were discussions around various market surveillance activities, projects and the development of different guidance documents. In particular the COEN is exploring opportunities to conduct joint projects/activities on market surveillance involving a number of European countries. This involves both identifying suitable projects and establishing mechanisms to enable effective cooperation. The next COEN meeting is scheduled for January 2015.

**International Medical Device Regulators Forum (IMDRF)**

The IMDRF Management Committee met in Washington in September 2014. The HPRA are part of the European delegation on this Management Committee. In addition the HPRA are acting as the NCAR secretariat for the IMDRF and are members of IMDRF working groups on Regulated Product Submissions, NCAR exchange and the Medical Device Single Audit Program.

This sixth meeting of the Management Committee included regulator members from Australia, Brazil, Canada, China, the European Union, Japan, the Russian Federation, and the United States of America. The Management Committee discussed ongoing work in relation to the Medical Device Single Audit Program (MDSAP), National Competent Authority Report (NCAR) exchange programme, developing a list of Recognized Standards in each global region, finalising a pilot for Regulated Product Submission (RPS) for medical devices and developing guidance on Software as a Medical Device (SaMD). In addition a number of proposed new work items were considered relating to Medical Device Patient Registries on the development of common terminology and code related to adverse events of medical devices and on the harmonization of Good Clinical Practices. Outcome statements and further information on the IMDRF Management Committee meeting can be found at [www.imdrf.org](http://www.imdrf.org).

**Medical Device Expert Group**

The Medical Device Expert Group met on the 17th November. The meeting delegates were updated about the recent organisational structures under the new European Commission which has resulted in the transfer of responsibilities for medical devices from DG Sanco to DG Internal Market, Industry, Entrepreneurships and SMEs under the responsibility of Commissioner Elzbieta Bienkowska.

The key focus of the meeting was an update on the progress of the joint assessment programme for notified bodies and in particular implementation of this programme on a mandatory basis since the start of 2014. The plenary was also updated on discussions on the revision of the legislation at the EU Council. Updates were also provided on: ongoing national measures being taken in Member States; the developments relating to harmonisation of standards from CEN and CENELEC; the ongoing work of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) relating to bisphenol A, nanomaterials and DEHP; and on the work and outputs from the European medical device working groups.