April 2013

ESR Statement on the Recast of the European Medical Devices Directives

The European Society of Radiology (ESR) is the European body representing the radiology profession with over 54,000 individual members and acts as the umbrella organisation of all national radiological societies in Europe as well as Europe's subspecialty organisations in the field of radiology. The Society's mission at all times is to serve the health care needs of the general public through the support of science, teaching and research and the quality of service in the field of radiology.

The ESR welcomes the European Commission's proposals for a new Regulation regarding the evaluation and approval of medical devices in Europe and applauds in particular the relevant provisions aiming to strengthen the safety for patients in Europe by improving the regulatory system.

Advances in medical imaging technology and related IT developments have had great benefit for Europe's patients, improving the accuracy and quality of diagnosis and care, increasing patient safety and reducing healthcare expenditure.
For professional organisations such as the ESR, the primary objective is to ensure the highest level of safety of medical devices to Europe's patients.

At the same time it is important that the medical devices legislation does not impede or slow down the pace of innovation and research and fosters smooth access to promising technologies to Europe's patients. The ESR considers it important to maintain Europe's leading role in biomedical imaging research in the global setting by fostering innovative research and by providing tools for rapid implementation into the clinic.

The ESR considers it important that new and emerging technologies are accounted for in the new regulatory environment in order to allow safe and timely implementation of such technologies to the benefit of Europe's patients.

Harmonisation should be another key element in the recast process of the current medical devices legal framework. Therefore, the European Society of Radiology welcomes any approaches to align legal requirements and harmonise their interpretation and implementation in the pre-and post-market phases. This should, however, not lead to increased administrative efforts and decelerated procedures for market access.

The ESR would like to make the following concrete suggestions to the current EC proposal for a Regulation on Medical Devices, largely in line with the claims of other professional organisations, such as the European Society of Cardiology.

Clinical validation of safety and efficacy

The ESR does not consider current certification procedures sufficient for high-risk (class III) devices. Clinical trials and proof of validity to demonstrate safety and efficacy are essential and should be required for high-risk devices. The ESR would like to underline that medical professionals play a key role in the clinical evaluation and validation of medical devices and should that their scientific expertise should be considered in any approval process of medical devices.

Radiologists and in particular the subspecialty of interventional radiologists, are among those medical professions using active implantable medical devices for their patients, such as stents.

Open access to medical device data for physicians, researchers and patients

The ESR is of the opinion that open access to the full information (application, evaluation, conclusions) would prove valuable to both physicians and patients and encourages the European institutions to reconsider the current proposal that foresees sharing a summary of the dossier only.

Independent expert advice

The rapid developments and increasing complexity of the medical devices sector require increase consultation of independent professional experts in the various fields involved. The ESR would, like other professional organisations, be willing to nominate independent experts for the medical imaging field.

Notified Bodies

ESR welcomes enhanced quality control of Notified Bodies as well as harmonisation efforts in terms of their quality standards as well as improved coordination of national competent authorities.