

November 2013

ESR Statement on the Recast of the European Medical Devices Directives

The European Society of Radiology (ESR) is an apolitical, non-profit organisation, dedicated to promoting and coordinating the scientific, philanthropic, intellectual and professional activities of radiology in all European countries. The Society's mission at all times is to serve the healthcare 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 is the European body representing the radiology profession with more than 58,000 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.

Recalling its position statement of April 2013 on the European Commission's proposal for a new medical devices regulation, the ESR reaffirms its opinion on the necessity of improving the regulatory system for medical devices in Europe to ensure an appropriate framework for an innovative market and to strengthen the safety for patients.

In light of the progress in the parliamentary process, the ESR would like to comment on a number of key elements the European Parliament (EP) has developed.

The ESR supports the creation of **special notified bodies** with heightened quality requirements to reinforce the assessment of class III devices. This is considered an improvement over the current system, and will ensure proper assessment and oversight mechanisms for those products with the greatest potential risk for patients. In this respect, we also deem the audit process to be carried out by the European Medicines Agency (EMA) a reasonable procedure to ensure that only those bodies with adequate resources and expertise may approve high-risk devices.

The ESR also approves of the measures to improve the quality of **notified bodies**, and considers it important to make sure that each device is authorised by the right notified body.

The fact that the European Parliament has not approved the introduction of a completely centralised **pre-market authorisation** procedure is also welcomed by the ESR, as there are considerable concerns regarding a centralised role for the EMA. The significant resources and expertise required to assess medical devices would have to be built up from scratch and it has not been demonstrated that such a system would significantly improve safety while potentially causing delays in patients' access to innovative technologies.

The ESR welcomes that the EP has made some progress in **defining the roles of relevant bodies**, and reiterates its call for a clear delineation of the responsibilities of all the bodies and organisations involved. This pertains in particular to the Medical Device Advisory Committee (MDAC) and the participation of stakeholders, but also includes the Assessment Committee for Medical Devices (ACMD) and the Medical Device Coordination Group (MDCG).

Recognising the urgent **need to improve patient safety** in Europe, the ESR calls on the EU institutions to work towards introducing an improved regulatory system as soon as feasible, but cautions all decision makers to put quality first and refrain from introducing changes of this magnitude without proper discussion, assessment and consultation.