Medical Xpress

ESC Policy Conference makes recommendations for new EU medical device legislation

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The European Society of Cardiology (ESC) is calling for a single, co-ordinated European system to oversee the evaluation and approval of medical devices. The call is being made in a paper published online in the *European Heart Journal* reporting on a conference held by the ESC in January 2011 looking to increase the input of medical experts in developing medical device policy.

"The ESC believes that the approval of devices used in medicine shares similarities in terms of ethical responsibilities as the approval of new drugs," said Professor Michel Komajda, the President of the ESC, who was one of the authors of the paper. As the European Union is currently engaging in the revision of the current regulation system of medical devices, he added, it was felt an "opportune time" for the cardiology community to share their expertise and views from the clinical and academic perspective. The current system for testing and approving devices in Europe was established more than 20 years ago, and concerns have been raised that it should adapt to technological advances and changing patterns of medical practice.

The policy conference highlighted the system that currently operates in Europe where the manufacturers of medical devices must satisfy the relevant "essential requirements" of safety and performance but do not need to establish that their device has an impact on clinical outcomes, even if it is a completely new technology. Instead, unlike the

manufacturers of pharmaceutical agents , the manufacturers of medical devices are allowed to use surrogate or functional endpoints in studies.

"Standards of testing of medical devices are less rigorous in Europe than the US, where they have to undertake trials to show that the device has an impact on clinical outcomes, with the reality that European patients are currently exposed to an unfair proportion of the risks associated with developing new devices," said Professor Alan Fraser, who chaired the ESC Policy conference.

Taking the example of balloon angioplasty to illustrate the level of testing required, he said that manufacturers in Europe would only need to establish that the diameter of the artery is greater following the procedure or that a new balloon is equivalent to other balloons already on the market, and not that there had been any impact on clinical outcomes, such as mortality.

In Europe there are estimated to be around 200,000 different types of medical devices, produced by more than 11,000 companies, which employ more than half a million people and have combined annual sales of more than € 72 billion.

The ESC Policy Conference - which was held at European Heart House January 27-28 2011 - was attended by around 50 delegates including experts from the five sub speciality organizations of the ESC, the American College of Cardiology, American Heart Association, the World Heart Federation, experts from the European Commission and the US Food & Drug Administration, and invited representatives from the device trade associations Eucomed and COCIR.

The delegates at the Policy conference called for:

- A single co-ordinated European system to oversee the evaluation and approval of medical devices. This was felt to be the most efficient way of achieving integration and harmonization of processes between the competent authorities so that they apply uniform and higher standards. It could be organized as a medical devices division of the European Medicines Agency(EMA) or an entirely new body.

- The Notified Bodies (NBs) should be reorganized as an integrated structure, with regulatory authorities directing applications for assessment of devices to appropriate specialist NBs. The NBs could become the technical division of a new European medical devices agency or could remain decentralized while operating within an integrated system. Furthermore, the meaning of the CE mark should be reviewed since it is often interpreted as meaning that clinical effectiveness has been established.

- Product standards should be developed for each category of medical device in class II and III (medium and high risk), with medical experts recommending specific standards for their clinical performance and effectiveness including requirements for follow-up studies.

- Adequate transparency, with the content of dossiers prepared by companies when submitting their devices for approval being disclosed to physicians so that they can know the technical performances of the devices.

- There was recognised to be a need to introduce comprehensive registries of devices and their outcomes, with every physician having a responsibility to report complications of devices.

The EHJ paper highlighted the complexities of the current system of European medical device regulation which is the responsibility of the 27 member States of the European Union (EU), each of which has its own national "competent authority". Unlike the EMA, established in 1995, where companies can submit a single application for authorisation by the European Commission (EC) and marketing throughout Europe, there is no single, common European agency for assessing devices, and the main role of the EC is purely advisory.

Devices are assigned to four groups according to their perceived risk before they are approved – low-risk cardiovascular devices in Class I (such as stethoscopes), IIa (which includes devices for monitoring blood pressure and diagnostic equipment), IIb (which includes diagnostic radiology equipment such as X-ray machines) and Class III (which includes implantable devices such as coronary stents , prosthetic heart valves and defibrillators). Any manufacturer wishing to obtain approval to market a new device in classes IIa, IIb or III must undergo a conformity assessment procedure by one of the 74 Notified Bodies (NBs) in Europe dealing with medical devices, many of which are independent commercial organizations. Once the NB has reviewed the technical dossier submitted by the manufacturer and completed its evaluation of the application, it then issues a certificate that permits the manufacturer to affix a CE mark and to market the device throughout the EU. For devices in Class III, the manufacturer must conduct some human clinical investigations, but it is not compulsory that these are randomised clinical trials.

"This process has given rise to suspicions that companies may go "forum shopping" to select the NB that will conduct the least burdensome or the fastest review," write the authors of the paper, adding that no systematic audit of NBs has ever been published.

The paper also cites a number of well publicised failures of

cardiovascular devices that may relate to limited evaluation prior to approval. Publication of the consensus document in the EHJ coincides with a series of articles looking at the regulation of medical devices in the *British Medical Journal* and also a TV Programme in the UK, Dispatches: The Truth About Going Under the Knife on Monday 16 May at 8pm on Channel 4.

More information: Fraser AG, Daubert JC, Van de Werf F, et al. Clinical evaluation of cardiovascular devices – principles, problems, and proposals for European regulatory reform. Report of a policy conference of the European Society of Cardiology. European Heart Journal. Doi 10.1093/eurheartj/ehr171

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