SASCI Draft Submission on Medical Device Regulations (due 22 October 2011)

1. Who SASCI is and what its members do

South African Society of Cardiovascular Intervention (SASCI) represent the scientific, educational, socioeconomic, ethical and professional interest of cardiovascular interventionalists in South Africa, with a membership of over 90 cardiologist, we are the only national organisation exclusively representing practising interventional cardiologists.

SASCI is dedicated to maintaining the highest standards of practice for our specialists and the highest quality of care for those patients who require our care. As a result, we seek to serve as a reference resource of knowledge for members, patients and funders in matters related to our discipline.

The introduction of new technology is a constant in modern medicine. While authorities in the U.S.A. and European Union, such as the Food and Drug Administration (FDA) and Conformite Europeenne (CE) provide regulatory clearance on safety and effectiveness, practising medical practitioners may require scientific evidence on net health outcomes before offering new procedures to their patients.

SASCI as an official Special Interest Group of the South African Heart Association subscribe to the European Society of Cardiology (ESC) guidelines. The ESC guidelines are regularly updated to include the latest appropriate Evidence Based Medicine but local guidance (comment) is needed from time to time.

The main types of products used by SASCI members include, but are not limited to: Disposable devices for access to the vascular system; diagnostic and guiding catheters; stents, balloons and guidewires; heart valves; contrast media pumps; FFR, IVUS and other diagnostic machines and radiographic equipment (C-arms etc.). The majority of devices and equipment used by SASCI members is imported, mainly by local subsidiaries of multi-national companies.

2. General comments on the draft regulations

SASCI supports the envisaged regulation of medical devices as necessary and in the interest of patient safety and the quality and efficacy of such devices.

SASCI notes that some concepts are introduced into the draft regulations, such as the categorization of medical devices, which are globally not known. In the interest of efficiency and patient access to technologies, and competition in technology, SASCI urges that South Africa do not reinvent wheel, and adopt systems that align

with the GHTF system. It is also highly recommended that South Africa do not re-evaluate medical devices registered in recognized authorities.

SASCI also recognize that the Medicines Control Council will be responsible for the implementation of the regulations. It recommends that committees be established that relate to the functions required for medical devices and that staffing includes persons knowledgeable about medical device regulation. The expertise at the Department of Health's Radiation Control could be leveraged in this regard.

The draft regulations, once finalized, should be guided by the principle of ensuring the continued availability of medical devices that are safe and of a good quality.

3. Comments on regulations that affect users and health establishments

Draft regulation 19 provides as follows:

19. (1) The head of any health establishment must ensure that persons who are employed at such health establishment and who use medical devices are appropriately trained and competence to operate, use or otherwise deal with such medical devices.

(2) The head of a health establishment shall ensure that any patient using a medical device at that health establishment is appropriately informed to use such medical device.

SASCI agrees with the fact that users of medical devices should be **appropriately trained and competent** to use such devices. However, it is not likely that the head of a health establishment would be able to evaluate if a medical device user is appropriately trained and experienced, due to the wide range of devices, and differences even in particular models or upgrades of the same device.

SASCI therefore proposes that the manufacturers/importers, as is customary currently, take responsibility to ensure that the users of their devices are sufficiently trained and experienced, such training being subject to vetting by professional societies such as SASCI. Manufacturers/importers should be obliged to issue certificates to verify that the level of competency alluded to in draft regulation 19 would be achieved:

(3) The manufacturer/importer of the medical device has to ensure that sufficient systems are in place to ensure that certified training programmes and support are available to the users of their devices, and the users of devices should be subject to peer review.

Draft regulation 20 governs the duties of health facility heads:

The head of a health establishment shall ensure that-

(a) medical devices are used safely;

(b) adverse events are reported as required;

(c) medical devices are maintained according to the manufacturer's instructions;

(d) a procedure for reporting complaints relating to the use of medical devices is in place;

(e) a record is kept of-

(i) medical devices service and repairs history;

(ii) staff training records; and

(iii) adverse event reports.

The above would require of hospital managers to have quite sophisticated mechanisms in place to implement and monitor these duties. As far as adverse events are concerned, SASCI's members recommend that the legal duty rests, as is customary currently, with the manufacturer/importer, who then has to take appropriate action. Reporting to the regulatory authority is not required in all instances, neither is recall required in all instances (refer draft regulation 17).

SASCI recommends that draft regulations 16, 17 and 20 be amended to align with the following GHTF documents:

- Medical Devices: **Post Market Surveillance**: National Competent Authority Report Exchange Criteria and Report Form (SG2 - N79R11: 2009)
- Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices (SG2-N54R8: 2006)
- Medical Devices Post Market Surveillance: Content of Field Safety Notices (SG2-N57R8: 2006)
- Guidance on How to Handle Information Concerning Vigilance Reporting Related to Medical Devices (SG2-N8R4)
- Review of Current Requirements on Post Market Surveillance (SG2/N47R4: 2005)

A further consideration relates to the Consumer Protection Act's provisions on **product failure** and the liability that may flow from that for all in the supply chain. SASCI recommends that there is a clear Memorandum of Understanding on device failure or safety complaints, to ensure that appropriately placed bodies adjudicate complaints on product failure or unsafe device.

As far as maintenance is concerned, SASCI members often experience the issue of health facilities not having sufficient budget to ensure that equipment are

maintained as it should be. Maintenance should be defined as inclusive of spare parts, technical servicing, replacement, etc. This also means that the document recently released on the **management of health facilities** should include specific criteria for hospital managers relating to medical devices.