



21 January 2013

## The revision of European Legislation on Medical Devices

### Response from the Institute of Biomedical Science

The Institute of Biomedical Science (IBMS) is the professional body for biomedical scientists working in the United Kingdom. It represents approximately 20,000 members employed mainly in the NHS, blood, and health protection agency services in the UK, private laboratories, research, industry and higher education. The majority of its members are regulated by statute by the Health Professions Council under the protected title of Biomedical Scientist. We welcome the opportunity to respond to this consultation and would wish to make the following comments.

Overall these proposals are very comprehensive and cover most of the important aspects of the proposed changes to European Legislation on medical devices in relation to biomedical science. The Institute is in broad agreement with the position taken by MHRA and would make the following points:

In respect to questions 4, 8, 24, we agree with the proposed wording and have no further improvements or clarifications.

In respect of question 29 we are highly supportive of the MHRA proposed position and feel this is necessary and timely. We would welcome clarification or views on what organisation would monitor the data provided.

In respect of question 63, we agree with the MHRA position but would wish to emphasise that there would need to be funding for this work.

In respect of question 65 we again agree with the MHRA position and feel that in this instance confidentiality should be kept to a minimum.

In conclusion, the Institute is pleased to take this opportunity to continue to participate in the MHRA consultation process.

This concludes the comments from the Institute of Biomedical Science.