Mr Maurice Buckley
National Standards Authority of Ireland
1 Swift Square
Northwood
Santry
Dublin 8

8th November, 2012

CC: Minister for Health, Dr James Reilly

Dear Mr Buckley,

RE: CEN Project Committee - Aesthetic Surgery Services (prEN 16372:2011)

It is with great concern that I am writing to you today in regards to CEN's proposal to standardise Aesthetic surgery services in Europe. As a member of CEN, we ask that you do not support this initiative, nor continue with its progression.

In 2010 the European Committee for Standardisation (CEN) resolved to address the standardisation of services in the field of aesthetic surgery. It was argued that by establishing specific quality requirements patient safety is fostered. In fact, standardisation in the field of health services as embodied by the CEN standard prEN 16372:2011 - once legally binding - does not comply with European and national law and may compromise patient safety.

Although the CEN standards are voluntary, Member States` competencies are violated when standards become legally binding via referrals in national legislation which is ultimately the intention of the CEN:

> "*In addition, many standards are developed to support European legislation. 'Reference to standards' within a legislative text is viewed as a more effective means of ensuring that products meet the essential health and safety requirements of legislation than the writing of detailed laws. This allows both processes to support each other, without causing a slowdown.*[1]*"*

The CEN standard prEN 16372:2011 infringes the responsibilities of the Member States to organise and deliver health services and medical care as guaranteed by TFEU Article 168 paragraph 7: "*The responsibilities of the Member States include the management of health services and medical care and the allocation of the resources assigned to them*." The CEN standard prEN 16372:2011 harmonises technical qualifications and specialist training regulations, professional duties and ethical requirements as well as treatment procedures and quality assurance mechanisms at the European level. Thus, provisions on professional practice are harmonised which are part of the management of health services assigned to the Member States.

Should the CEN standard prEN 16372:2011 be adopted into national law, the risk is that regulatory provisions for healthcare services are created outside the expertise of the

[1] "Making European Standards",
http://www.cencenelec.eu/news/publications/Publications/MakingEuropeanStandards.pdf

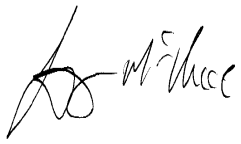
profession and that parallel structures are established at Member States level leading to legal uncertainty, ambiguities, conflicting legal regimes, a lack of supervision and consequently to a loss of quality. The distinct character of healthcare services is acknowledged in national laws as conferred to Member States by each constitution.

At national level it is recognised that it is in the direct public interest to guarantee that quality and practice of the medical profession to be regulated by designated competent authorities who can enforce that the technical qualifications, ethical requirements, professional duties, treatment procedures and quality assurance requirements ensuring the duty of care are defined and implemented with the necessary expertise. There is no piece of European legislation justifying a replacement by a CEN standard. The directive 2006/123/EC does not serve as justification for standardisation since healthcare services are exempted from the scope of the directive.

Therefore, the CEN standard prEN 16372:2011 will risk undermining and diluting the existing high medical and supervisory benchmarks already in place.

We kindly ask you to take up these concerns and refrain from pursuing the project, and to clarify the position of the NSAI on this particular issue. Should you wish to meet to discuss our position, please do not hesitate to contact us.

Kind regards,



Mr George McNeice
Chief Executive Officer
Irish Medical Organisation