EUROPEAN COMMITTEE FOR STANDARDIZATION

"Learning to Reach 'Consensus' in European CEN

Introduction

Medical care is not provided to the same level across the 28 members states of the E.U. and, as a result, few 'European Standards' of medical care have been developed.

Patients believe that standards of medical care are universal throughout the E.U. but that is far from the case. Brexit is unlikely to remove the need to negotiate with the E.U. on medical regulatory matters. Indeed, it may make the skills required for such negotiations even more important because medical products, devices and services will continue to be developed and used throughout geographical Europe, including the United Kingdom.

There is no agreed (European) specialty of "Cosmetic Surgery" – and even less regulation for "Aesthetic Medicine", and even less again for "Beauty Therapy". As the European Commission started in their answer to Question E-001136/2011;

"Whilst Plastic Surgery is one out of the 52 specialties listed in Annex V, 5.1.3 of Directive 2005/36/EC and thus benefits from automatic recognition, cosmetic surgery is not listed in that Annex."

The Impact of Standards produced by the European Committee for Standardisation (CEN)

European Standards sit below the level of European and national legislation but they are "ignored at the peril" of governments. Most CEN standards are to do with products, not services. Where products are concerned, the Medical Devices [product] Directive (MDD) is met by means of a new product meeting the relevant, harmonised European Standard (EN); and it is then by a process known as "presumption of conformity" that the MDD is deemed to have been met. On that basis, the product is granted the CE mark. With services, (i.e. who can do which treatments, in what sort of premises etc.) the same principles are followed. A standard sets a basic framework for the delivery of the service throughout the CEN corresponding nations (currently 34 nations- see below) and, as such, gives an indication of the level of service, which patients can expect to be provided in any signatory state.

(The CEN website states: "CEN's National Members are the National Standardisation Bodies (NSBs) of the 28 European Union countries, the Former Yugoslav Republic of Macedonia, Serbia and Turkey plus three countries of the European Free Trade Association (Iceland, Norway and Switzerland).")

The CEN standard in Cosmetic Surgery and Non-Surgical, Medical treatments (EN 16372/EN16844)

In 2010, as a result of the concerns about poor standards delivering cosmetic surgical and non-surgical, medical services throughout Europe (yet before the PIP Breast Implant scandal) the Austrian Plastic Surgery Society sponsored the setting up a CEN standard in Cosmetic Surgery and Non-Surgical, Medical treatments via the Austrian Standards Institute. The proposal was to set out a basic set of standards, including every element of the patient care from advertising, consent and record keeping through to what equipment should be in a treatment room, which patients could expect to receive throughout the CEN corresponding countries. The proposal was met with universal approval and easily reached the required six positive votes from National Standards Institutions supporting the proposal to allow the work stream to be taken up. Standards do not come for free and the Austrian Plastic Surgery Society underwrote the cost of the standard (€9000).

The National Standards Institutions of each corresponding country were then invited to set up a national panel of experts representing all interested parties. The British Standards Institution set up a 'Mirror Group' representing all interested parties in the field. Mr Mike Regan, a laser safety expert, who had intimate knowledge of how the European Standards system worked, accepted the chair of the group. The group included a lay representative and a senior manager from the BSI. No one receives payment for working on a standard and individuals are responsible for their own expenses for attending national and international meetings. It became rapidly clear how important it was to have an independent chair, experienced in the workings of the CEN Standards system.

Consensus

The whole premise of a European Standard is reaching 'Consensus', which the BSI defines as;

"General agreement, characterised by the absence of sustained opposition to substantial issues by any important part of the concerned interests and by a process that involves seeking to take-into-account the views of all parties concerned and to reconcile any conflicting arguments. **NB Consensus need not imply unanimity**."

In practice, consensus means that everyone must negotiate. 'Shouting loudly', 'dirty negotiating', 'shroud waving' and 'protectionism', all standard medical negotiating tactics fail immediately in this negotiating environment. Every voice is 'actively' heard but unjustifiable positions are immediately rejected. Sustained objections are examined in great detail and compromise sought. Chairing such a group requires a particular skill set, including a calm but firm approach and the ability to encourage individuals to examine entrenched positions in the light of often impassioned arguments of others. ***"No!"*** without an evidence base is not a negotiating stance that works.

A Personal statement from Mr Mike Regan BSI CH403 Chair

"As Chair to the BSI CH403 Mirror Committee, I would say that there were three main factors in the committee's successful work of agreeing and publishing the two Standards that were assigned to us for development:

- first and foremost a great team of experts: aesthetic doctors, nurses, plastic surgeons, and others willing to put in significant amounts of time and effort over several years directed towards the ultimate goal of developing Standards that will improve patient safety;

- a well-developed administrative and organisational system of support from BSI (the British Standards Institution), and - at the pan European level - from CEN (the European Committee on Standardisation);
- the emphasis both within BSI and in CEN on working by way of ***consensus***.

The final agreement at European level of Standards such as these is by means of weighted voting by all Member States. Nevertheless, the emphasis on *developing* the Standards as far as possible by means of consensus laid the ground for the eventual positive overall vote."

Mike Regan
Chair, BSI CH403
Aesthetic surgery & non-surgical medical services

Preparatory work

A draft document of the work stream is produced and circulated to the National Standards Institutions, who, in turn, circulate it to all registered, interested parties, who are invited to send a delegation to the national mirror group. The draft is examined line by line by all Mirror Group members, including lay representatives. Individual comments are sent to the BSI secretariat who amalgamates them into one document setting out the agreed position of the mirror group. That document is then, in turn, sent to the host Standards Institution who, in turn, produces the document to be discussed at the plenary sessions. This process can be arduous, especially when the translation into English of other nations' comments can lose their intended meaning.

Plenary Sessions

Plenary sessions are organised by the host Standards Institution, in this case Austria, who supplying the Chair (Dr K Gruhn PhD). All CEN standards are produced in English and then translated into the languages of corresponding nations.

A lead delegate attends with a team of 2 colleagues, all chosen by the Mirror Group. Prior to departure, the Mirror Group examines the agenda items line by line and agrees the position it will take on each item. The Mirror Group sets clear boundaries for the negotiating position, which it feels the delegation can adopt on each item. If the position the other nations reach in the plenary session is beyond the limits set for the delegation there is no room to move from the pre-agreed position and the delegation must abstain if they cannot negotiate the other nations back to an acceptable position, previously agreed by the mirror group. If multiple nations object to a statement, it can be agreed that it be deleted after a vote of the delegations in the room. The BSI mirror group were very fortunate in having an extended core team of delegates who immediately worked very well together bringing complementary skills to the negotiating table

The BSI delegates, it has to be said, have an advantage in the Plenary Sessions, which are all held in English. As a result, the BSI delegation often had the role of editing other delegations' comments and wishes into an appropriate, agreed form of English. It must be very tiring for non-native English Speakers to translate from English to home language, think of the required response then translate it back into English and the English delegates need good interpersonal skills so that translating other non-native English speakers' words does not result in them feeing of less importance, less valued or sidelined.

Voting in the plenary session is by weighted voting, which means the larger European nations have significant power in the discussions and if one or two vote against any aspect of the work stream or the entire document, it may fail. Considerable inter-personal negotiating skills are required by the chair of the plenary sessions and the national delegate teams to keep things on track.

On one occasion, intransigence led to the chair of the plenary session explaining to the group that, if consensus was not reached on one fundamental matter, the Standard would fail there and then, and we would all be going home having wasted months of work, time and expense. The session was temporarily suspended and, on resuming, the 'log jam' had cleared.

A very significant difficulty encountered was trying to combine Surgical and Non-Surgical Medical Treatments in one standard. The interested parties for the two areas came from very different constituencies and it was agreed that they should be split into 2 work streams. Both were delivered successfully. The Surgical Standard was delivered first, in 2014, and the Medical, Non-Surgical Standard in 2018. All CEN standards are organic and are revised after a defined time period to ensure they remain current and fit for purpose.

Conclusion

CH403 was one of the first CEN Medical Service standards. The lessons learned and skills gained by those who attended the Mirror Group as well as those who attended Plenary Sessions as delegates are those that will help any medical manager or leader in negotiations at every level, especially when it comes to negotiating medical issues with the EU post-Brexit.

N Mercer
Mr M Regan
Ms S Taber

NB "In mid-2017 the European Commission published the New Medical Devices Regulations, MDR. This means that from 2020 onwards the CE marking process for aesthetic products will incorporate a new "common specifications" approach, that will be applied in conjunction with the existing "harmonised standards" methodology."