RCS
ADVANCING SURGICAL STANDARDS

Briefing for EU Sub-Committee F on EU healthcare proposals

Introduction

This briefing sets out the views of the Royal College of Surgeons on key European directives ahead of the EU Sub-Committee F's evidence session with Earl Howe on EU healthcare proposals on Wednesday 21 November. We cover background, our views, and suggested questions for the Committee on:

- The medical devices directive
- Directive on the Recognition of Professional Qualifications
- The European Working Time Directive

The Royal College of Surgeons of England is committed to enabling surgeons to achieve and maintain the highest standards of surgical practice and patient care.

Proposed regulation on medical devices directive

Background

In September the European Commission published its proposed Regulation on medical devices, intended to replace two previous directives (one regarding medical devices, and the other regarding active implantable medical devices) which it accepts have become outdated.

The College position

Medical implants and devices more widely have brought significant benefits to patients, and therefore continual innovation in this field must be encouraged and facilitated. This should not, however, happen at the expense of patient safety.

We believe future regulation on medical devices needs to address three key points:

a) Transparency

We agree with the recent House of Commons Science and Technology Committee report on medical implants that transparency and access to information need to be addressed in the revision of medical device regulation. Manufacturers and regulators should publish rigorous clinical data to give the health service and patients evidence to help influence their decision-making about which implants to use.

In order to address the issue of transparency, we recommend establishing a central information service which can provide details of the notified bodies in each EU Member State. We also believe that there should be a centrally available database of approved implants and devices with key information on their manufacturer, approving notified body, evidence base, post-market surveillance and safety corrective actions where applicable.

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Although our recommendations require initial investment we believe that it will in the longer term prove cost effective as a tool that can benefit every area of regulation from speeding up approval decisions, to earlier indication of implant safety issues, and driving up regulation standards through increased potential for public scrutiny.

b) Role of the surgeons / clinicians

Ensuring the safety and performance of medical implants must involve a joint approach by regulators, industry, clinicians, patients and other stakeholders. There is a need to clarify the roles and responsibilities of each stakeholder, to ensure that the system is effective.

The clinician's role is vital and should be acknowledged as such – particularly in the monitoring of implant performance once on the market. It is important to define and mandate at European level how surgeons and other health professionals report performance and safety concerns regarding an implant.

Additionally, there is great potential for surgeons to fulfil a mandatory implant monitoring duty through audit and procedure registries. There is evidence to suggest that where audits and registries are well established, it is possible to identify problems with specific implants and devices as well as assess clinical outcomes and surgical performance more broadly.

c) Maintaining consistently high regulatory standards across Europe

Implants and devices once approved can be used throughout the EU, regardless of which Member State has conferred this approval. We are concerned about the risks to patient safety and high quality care due to the current potential for variability in the standards and expertise of national Competent Authorities and the Notified Bodies to which they delegate responsibility for approving medical devices.

The College believes that only the Notified Bodies who have the highest expertise and use the highest standards should be able to approve devices. We call for greater Member State collaboration and coordination in order to develop more stringent harmonised standards and criteria for notified bodies – in consultation with all Member States and stakeholders within them. This would enable national competent authorities to consistently assess performance of their notified bodies and hold them to account in a more transparent manner.

The College would also support the principle of decreasing the number of notified bodies undertaking regulatory duties in the EU – particularly for medical implants which are in the class three (highest risk) device category. Fewer notified bodies would decrease the likelihood of variation and make pan-EU quality assurance and accountability more feasible.

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Suggested questions for the Minister

We encourage members of the Committee to ask:

- Does the Government agree that the variability in standards for medical devices across Europe is creating risks for patient safety?
- What is the Government doing to mitigate concerns that sub-standard implants could be in use that have been passed by the current regulatory system?
- How is the Government working with the Medicine and Healthcare Products Regulatory Agency to bring forward plans to tighten regulation?

Directive on the Recognition of Professional Qualifications

Background

This directive aims to minimise barriers to the mobility of professionals within the UK, by making it easier for professionals qualified in one Member State to practice their profession in another.

In December 2011, the European Commission published a draft Directive, proposing a number of revisions to the original. These revisions addressed some of the concerns that the mobility of health professionals must not come at the expense of patient safety and protection. However, the College has a number of outstanding concerns, which we have outlined below.

College position

a) **The Professional Card** - We support the current proposals for a 'Professional Card' which would contain validated information about an individual's qualifications and professional status with the appropriate regulator. We are concerned about the quality assurance of the information on the Card and firmly believe that Competent Authorities in the host Member State should at all times retain the right to verify an individual's identity and qualifications pre-registration, whether they are using the Card or not. This is imperative if we wish to maintain the standards and integrity of the register. This principle should extend across all categories for automatically recognised professions.

   Further, on the grounds of public protection, the College does not believe doctors or dentists should be placed on such a register without the explicit satisfaction of the Competent Authority (regulator) in the host Member State. 'Tacit authorisation' is insufficient.

b) **Partial access to a profession** – We were disappointed to note that the recent revisions did not propose an explicit derogation for health professionals regarding 'partial access'. An individual unable to meet the required standards in the maximum allowable adaptation period (as currently defined), should not be granted access to the health professions to any extent, especially with the possibility of accessing patients and other vulnerable groups.

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c) **Notification of disciplinary sanctions –** We support the proposal for compulsory notification through the Internal Market Information (IMI) system which allows competent authorities to securely access information on a health professional if they are no longer able to practice due to disciplinary sanction. Additionally, we would recommend that notifications are issued for other sanctions which lead to a restriction of practice, e.g. temporary suspension or supervision order.

d) **Language requirements** – we are concerned that the wording of the new proposals does not sufficiently clarify where and how language checks of health professionals are permissible. We call for wording which retains the right of both the Competent Authority (ie the General Medical Council in the UK) and the Employer to check language and communication skills without the necessary precondition of serious doubt, whilst stipulating that these checks must be proportionate and complementary. For example, a professional should not have to undergo the same language check twice.

e) **A phased approach to modernisation**: **towards competencies -** It must be made clear that the move towards acknowledging and incorporating competencies as a useful qualification indicator should not equal standardisation. Member States must retain the right to develop and evolve their own competency requirements, as determined by the health systems and needs of their country. It should be emphasised that employers are responsible for ensuring the doctors and dentists are only employed in roles that are within their competence.

f) **Continuing Professional Development –** We believe the inclusion of CPD – a term used to refer to ongoing training and development of professionals – is an opportunity to raise standards, by requiring that CPD is mandatory in all member states.

In the context of both competencies and CPD, we remain concerned that the Directive omits the issue of recent practice. This means a doctor with a qualification gained decades ago can be included on the medical register, even if s/he has not practised medicine for several years.

Suggested questions for the Minister
We encourage members of the Committee to ask the Minister:

- What action is the Government taking to ensure that the relevant Competent Authority retains the right to verify an individual's identity and qualifications?
- Does the Government agree that it wishes the UK to retain the right to develop its own competencies and not standardise across Europe?

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The European Working Time Directive

Background

The basic provision of this Directive (to limit a working week to 48 hours) was extended to all doctors in training in 2009.

Two rulings by the European Courts of Justice (referred to as SiMAP and Jaeger) have also reduced doctors' flexibility around when they take breaks, and dictated that all time within a hospital should count as 'working time', even if a doctor is 'on call' and sleeping.

The College position

The College is concerned that the implementation of EWTD has:

- Impaired continuity of care for patients, as the move away from on-call rotas means surgeons may be unable to see a patient through to the end of their treatment and have to 'handover' instead.
- Seen an increase in spending on locums, to fill up gaps in rotas created by a short working-time allowance.
- Led to staff being stretched too thinly, particularly over nights and weekends.
- Reduced time available for training.

In August 2010, a survey of RCS members found that 80% of consultants felt that patient care had deteriorated as a result of EWTD.

The College wants to see the application of the Working Time Directive limited in the UK. Whilst we appreciate the Government's commitment to seek an EU-level agreement to amend the Directive, we are concerned about the slow pace of change.

We recognise the difficult of seeking agreement at a European level, so we have urged the Government to look towards improving flexibility in doctors' working hours. We would like to see the Jaeger and SiMap judgements lifted and a renegotiation of the 'New Deal' contract, which imposes financial penalties on the NHS for doctors who work longer hours.

Suggested questions for the Minister
We encourage members of the Committee to ask the Minister:

- What is the Government doing to limit the impact of EWTD on the NHS?
- What progress does the Minister expect to have made by 2015?

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