

RESPONSE TO THE EXPERT GROUP REPORT ON THE REGULATION OF COSMETIC SURGERY: ACTION PLAN

SUMMARY

The Expert Group Report on the Regulation of Cosmetic Surgery provides a set of sensible recommendations which form a firm platform for further action.

In broad terms we will –

- Develop patient education and information materials as soon as possible, in partnership with other organisations where appropriate, with **information relating to current arrangements for cosmetic surgery available by summer 2005**, and updated information as changes to regulatory arrangements come on stream.
- review by **summer 2005** the need and scope for additional regulation of aesthetic fillers and in particular any that contain human tissue. The Medicines and Healthcare products Regulatory Agency will work with interested parties, including DTI, and will take into account the likely emergence this year of proposals from the European Commission for the regulation of tissue engineered products.
- Work with the Healthcare Commission and other stakeholders to develop plans for **bringing additional cosmetic procedures within the remit of the Healthcare Commission by the end of 2005/06**. Other changes to the regulations and associated standards currently in force will be made to the same timeframe.
- Ask the relevant professional bodies and competent authority to develop appropriate specialist training programmes as a matter of urgency for surgeons undertaking cosmetic procedures.
- Recommendations relating to professional matters, particularly the General Medical Council, will be dealt with through our wider work on system reform currently in development.

It is important that these recommendations are not treated in isolation but benefit from being taken into the wider programmes of healthcare reform in development or already underway. So, for example, a number of the recommendations relate to our wider programme of work, prompted in part by the Fifth Report of the Shipman Inquiry, to consider what system reforms are necessary to professional regulation and complaints systems. Similarly, recommendations relating to dentistry will be taken forward through the wider

reform programme already underway in dental services. Where appropriate we will respond directly – for example in relation to provision of information for potential cosmetic surgery clients.

In all cases it will be essential for us to work closely in partnership with professional groups, providers of cosmetic surgery services, the Healthcare Commission, patient representatives and other stakeholders to secure prompt implementation.

RESPONSES TO INDIVIDUAL RECOMMENDATIONS

Professional training, development and accountability

Recommendation 1

That cosmetic surgeons working in private practice and undertaking cosmetic surgery, with exemption from being on the Specialist Register by virtue of working in the sector prior to April 2002, ensure that their independent professional appraisal and validation process includes a strong demonstrable component of peer review of their clinical procedures case work. This would be in addition to the requirements on them under National Minimum Standard A4.2.

Response: Agreed. This will be developed as part of the wider programme of work on system reform for professional regulation.

Recommendation 2

That all cosmetic surgeons and nurses provide to potential and actual patients details of their qualifications, registration, membership of professional organisations, and other medical training and education. The Certificate of Completion of Specialist Training (or equivalent) is the minimum qualification for surgical practice for surgeons who are not exempt under standard A4.2 of the Care Standards Act.

Response: Agreed. Target for implementation: **summer 2005**. We will follow this through by:

- Agreeing with the relevant professional groups the format and content of information that should be provided;
- Considering whether this requirement should be built into the standards against which the Healthcare Commission inspects cosmetic surgery providers;
- Ensuring potential patients are made aware of this requirement through patient information.

Recommendation 3

That training programmes for cosmetic surgery are evolved by each of the Specialist Advisory Committees (SAC) of the relevant medical and surgical specialities.

Response: Agreed. Target for implementation: as soon as the necessary changes can be agreed by the relevant professional bodies and competent training authority.

Recommendation 4

That the Healthcare Commission look at whether the standards relating to practising privileges for surgeons are adequate for contemporary clinical practice in cosmetic surgery.

Response: Agreed. Target for implementation: **end of 2005/06.**

Recommendation 5

That all persons who advise patients about cosmetic surgery should be doctors or nurses.

Response: Agreed in principle. We will address this by asking the relevant professional organisations to provide evidence-based advice about the skills and competencies required to advise patients. After due consideration this will be implemented through standards against which the Healthcare Commission will inspect providers, and patient information. Target for implementation: **end of 2005/06.**

Non-surgical cosmetic procedures

Recommendation 6

That steps are taken to ensure that the law pertaining to the injection of botulinum toxins is more consistently adhered to; that is that the botulinum toxins are prescribed by a doctor, and administered by a doctor (or a nurse under direction of a doctor) for a specific patient.

Response: Agreed. We will address this in two ways:

- Working with the relevant professional bodies to remind doctors and nurses of their obligations and ensure these are reflected in their training criteria; **(Target date: as soon as possible)**
- Through the patient education workstream, ensuring that prospective patients are aware of the circumstances under which botulinum toxins should be administered, and what to do if these requirements are not met. **Target date for publication: summer 2005**

Recommendation 7

That the facilities where botulinum toxins are injected be licensed with the Healthcare Commission and therefore subject to its regulations.

Response: Agreed, subject to regulatory impact assessment and resourcing. Target for implementation: **end of 2005/06.**

Recommendation 8

That dental practices undertaking private cosmetic dentistry¹, and other non-dental aesthetic procedures be brought within the remit of the Healthcare Commission.

Response: Agreed in principle. We will work with the Healthcare Commission and other stakeholders to develop detailed proposals for the registration of these facilities, with a view to implementation in 2006 (subject to regulatory impact assessment, legislation and the need for the implementation timeframe to be co-ordinated with the wider reform programme in dentistry).

Recommendations 9 and 10

Rec 9: That current legislation and regulation governing the use of lasers – that every facility defined in the legislation should be registered with the Healthcare Commission – are more consistently enforced. That laser procedures are overseen by a doctor and conducted by appropriately trained and qualified practitioners.

Rec 10: That the recommendation in the Healthcare Commission's report to carry out a risk based review of the approach to regulation of the provision of laser services is implemented.

Response: Agreed. Target for implementation: If changes to regulation are recommended following the review, these should be in place by **end of 2005/06**.

Recommendations 11 and 12

Recommendation 11

That the classification of aesthetic fillers, whether they are medical devices or not, be reviewed to ensure that the regulations applying to filler products are clear and easily understood by patients and the public and bring all filler products within a consistent regulatory framework. Classification of fillers should include whether the fillers are permanent, semi-permanent or temporary.

Recommendation 12

That an investigation into the risks of transmission of blood-borne viruses and vCJD in filler products containing human tissue be conducted. If a risk is identified patient safety must be protected through licensing and regulation of products.

Response: There is no evidence that there has been any transmission of blood-borne viruses or vCJD from aesthetic fillers but we do believe there may be a risk. We are working with the relevant expert groups as a matter of urgency to determine the risk and what might be done to eliminate it.

¹ Cosmetic dentistry is defined as treatment that is not clinically necessary to secure oral health.

There are prospects that in the first half of 2005 the European Commission may bring forward proposals for legislation to regulate tissue engineered products. Potentially such proposals could cover at least some aesthetic fillers containing human tissues. Negotiation and implementation of legislation in Europe relating to a new regulatory category of products realistically could take several years. The MHRA will co-ordinate work, involving others as necessary, to recommend what may be the best regulatory approach to aesthetic fillers containing human tissue. Depending on the publication of the Commission's proposals, the MHRA would aim **by summer 2005 to make provisional recommendations.**

Recommendation 13

That temporary aesthetic fillers are only injected by a doctor or nurse, and that permanent and semi-permanent fillers are only injected by a doctor.

Response: We Agreed in principle. We will address this by asking the relevant professional organisations to provide evidence-based advice about the skills and competencies required to advise patients. After due consideration this will be implemented through standards against which the Healthcare Commission will inspect providers, and patient information. Target for implementation: **end of 2005/06.**

Recommendation 14

That the facilities where aesthetic fillers are injected be licensed with the Healthcare Commission and therefore subject to its regulations.

Response: Agreed in principle. This links to recommendation 11, as further work is needed to define and classify aesthetic fillers. We will work with the Healthcare Commission and other stakeholders to develop regulatory impact assessments and detailed proposals for the registration of these facilities. Target for implementation: **end of 2005/06**

Public Education

Recommendation 15

That the information referred to in Recommendation 2 be published by the responsible practitioner and made openly available for patients and the public. This should be monitored by the Healthcare Commission, where practitioners fall within its regulatory framework.

Response: Agreed. This will require amendments to the standards under which providers of cosmetic surgery are inspected. As with other changes to the standards, we expect them to be made by **end of 2005/06.**

Recommendation 16

That the Department of Health ensures that accredited, detailed advice and educational materials are available for patients and the public setting out what

standards, registration and qualifications to expect and what questions to ask when considering cosmetic surgery.

Response: Agreed. We will work with stakeholders to develop appropriate information as soon as possible in **summer 2005**. Further tranches of information will be made available as other changes proposed as a result of this report come into effect.

Recommendation 17

That all organisations providing cosmetic surgery and procedures publish information for patients on treatments available, details of how to complain, their rights as a consumer and of other organisations which can provide help and advice. The monitoring of this should be included within the Healthcare Commission's regulatory framework for all registered organisations.

Response: Agreed. This is covered now in the national minimum standards against which the Healthcare Commission inspects cosmetic surgery providers. We will review with the Healthcare Commission whether this needs tightening up and amend the standards as necessary.

Recommendation 18

That all advertising for cosmetic surgery and publications by providers of cosmetic surgery include the provider's registration number with the Healthcare Commission.

Response: Agreed. The Healthcare Commission already has a policy in place that registered providers can use its logo and their registration number in advertisements, and will consider making an explicit recommendation to providers that this should be included. We are also working with the Committee of Advertising Practice to explore whether such a requirement could be included in advertising codes of practice.

Recommendations 19 and 20

Recommendation 19

That the General Medical Council improves the recording and classification of data about complaints so that comparisons can be made between different medical specialties and procedures.

Recommendation 20

That the GMC make information about specialty registration and qualifications held by doctors more clearly available to the public on its website.

Response: Agreed. Both these recommendations will be taken forward as part of our wider plans for system reform in professional regulation and complaints.