RESPONSE TO

DEPARTMENT OF HEALTH CONSULTATION:

REVIEW OF THE REGULATION OF COSMETIC INTERVENTIONS

OCTOBER 2012

Introduction

This response is submitted by Action against Medical Accidents (AvMA), which is the UK charity for patient safety and justice. AvMA's work includes providing a helpline and casework service for patients who have suffered injury as a result of health treatment, including cosmetic interventions of various kinds. AvMA also works closely with the legal profession, maintaining a relationship with lawyers who specialise in clinical negligence claims and medical experts who act as independent expert witnesses. AvMA is the foremost patients' charity working to improve patient safety in the UK and has a long called for better regulation of cosmetic treatments in the interests of patient safety.

This response has been produced by Edwina Rawson in close liaison with the chief executive of AvMA. Edwina Rawson is a partner specialising in medical negligence at Field Fisher Waterhouse LLP, and is seconded to work for AvMA in relation to cosmetic treatment issues.

AvMA feel it would be helpful to set out some key points before addressing the specific questions in the consultation.

A <u>A public health issue</u>

AvMA believes that there is a serious public health issue surrounding cosmetic procedures, whether surgical or non-surgical, in that patients do not appear to recognise the risks associated with them. Our experience is that patients do not exercise the same degree of caution when considering cosmetic procedures as they do when undergoing procedures that are clinically indicated. Cosmetic patients seem to believe that cosmetic procedures are somehow risk-free and consequently can be undertaken lightly. This has been fuelled, whether deliberately or otherwise, by the media, advertising, and the celebrity culture in which we find ourselves. We live in a society where many people are sufficiently concerned about their appearance to undergo procedures for which there is no clinical need, and according to Mintel this market is destined to continue to grow.

The lack of appreciation of risks is highly prevalent in relation to dermal fillers and Botox. The culture of 'Botox parties', where patients were encouraged to attend clinics for a glass of wine and chat whilst waiting to have their treatments may be fortunately historic, but the sense that these are not medical procedures and form part of a more usual beauty regime (akin to facials and manicures) remains to a large extent. There is little or no appreciation of the risks; little or no understanding that the person giving the procedure needs to be appropriately trained; and little or no consideration of the setting where the treatment is offered. Hence, beauticians and other non-medical practitioners have developed a place in the market of administering dermal fillers and Botox.

In addition, in the cosmetic surgery market generally, there is the potential for each patient to undergo many procedures, and often patients have more than one. This again differentiates it from the usual medical market.

AvMA suggests that a number of factors make the cosmetic surgery market unique: the lack of appreciation of risks; patients' concern about their appearance which may result in them seeking repeated procedures, and the fact that considerable money can be made by practitioners from cosmetic procedures. AvMA believes that the combination of these factors makes these patients particularly, and inherently vulnerable, and AvMA believes that patient safety is very much at risk.

AvMA submits that the Government must consider statutory regulation of the cosmetic treatment market in the context of this cultural modern-day phenomenon. Further, caution must be exercised in the degree to which patients can be expected to protect themselves by, for example, researching procedures and outcomes. In order to take the first step in researching these, the patient has to be aware that the procedure is, in the first place, of sufficient seriousness to warrant this. As mentioned

this is often lacking. Even where such steps have been taken, our experience is that the pressure to change may be such that the patients decide it is a risk worth taking. Accordingly, protection must be regulation-led, not patient-led.

B Self-regulation of injectables

AvMA is firmly of the view that any self-regulation scheme, including the 'Treatments You Can Trust' (TYCT) scheme introduced by the Independent Healthcare Advisory Services (IHAS) for injectables, does not provide adequate patient safety.

Whilst we appreciate the point that ‘something is better than nothing’, a key difficulty with the IHAS scheme is that it is trying to balance many competing interests, ranging from the commercial interests of providers of dermal fillers and Botox to patient safety. Further, as the scheme is only voluntary, many providers are outside it.

The IHAS aims to introduce a quality mark which patients will associate with various standards being met and with 'Treatments You Can Trust'. The intention, as we understand it, is that when patients decide to have injectables, they will seek treatment from a practitioner who has the TYCT mark, on the basis that the mark is indicative of safety and good standards. AvMA submits that this assumption is fundamentally flawed.

It is clear that the TYCT scheme is trying to create something akin to the Gas Safe Register (previously Corgi). It is likely that most people will seek out a Gas Safe engineer to do their gas work. However, as suggested, we believe that the assumption behind the TYCT scheme is fundamentally flawed because consumers *know* and *acknowledge* that gas is potentially dangerous and therefore they *need* the protection of a registered Safe Gas engineer. However, patients do *not* know and acknowledge that injectables are potentially 'dangerous' and accordingly that they need protection.

It is, of course, recognised that a solution to the above problem is to educate patients so that they come to understand that there are risks associated with these procedures such that they should only be done by a qualified person. But, it is likely to take many years to 'undo' the lack of appreciation of the risks, and this may not be even possible if there are contrary messages from the media and advertising.

There is also concern that the IHAS scheme lacks sufficient teeth in relation to checking and monitoring the applicants for registration, and monitoring the standards of the registrants after registration. For example, we understand that no site checks are done before registration, and 24-hours notice is given before any sites are checked once on the register.

AvMA also has concerns about the mark 'Treatments You Can Trust' as it feeds into the misunderstanding that dermal fillers and Botox are inherently safe, which they are not.

C Statutory Regulation of injectable treatments

AvMA submits that the provision of dermal fillers and Botox should expressly be brought within the remit of the Care Quality Commission (CQC). The principle should be that the provision of any form of treatment which has the potential to cause significant harm should be subject to registration with the CQC. This would have the benefit of applying statutory standards across the board and removing the voluntary element of self-regulation.

D Lack of redress

AvMA submits that there is a serious lack of meaningful redress in relation to some cosmetic procedures, which have resulted in a poor outcome.

If a patient has been injured as a result of negligently performed cosmetic surgery, then the patient should have a claim for compensation. However, litigation is not available to all patients who have had a poor outcome from injectables because in some cases the injury, whilst devastating for the patient, is relatively short-term (such as droopiness from Botox or lumpiness from non-permanent dermal fillers) and low value in terms of the amount of compensation that would be paid in the event of a successful claim. The same applies to negligently performed cosmetic surgery which results in a potential claim that would also only be of low value. In these cases, the overriding principle of proportionality in litigation, i.e. that the legal costs should be proportionate to the amount of compensation, cannot be satisfied and patients would find it difficult to find a solicitor to take on their case. This is unfortunate as there is ample anecdotal evidence that potential litigation can help raise standards of medical care.

In the absence of a realistic prospect for most patients injured by injectable treatments to be able to litigate to obtain compensation, consideration should be given to creating a special scheme, paid for by the industry itself or through compulsory insurance cover, to make it easier for injured patients to obtain compensation.

E Complaints procedures and Support for complainants

There is no equivalent in the private sector to the NHS Complaints Procedure. The NHS Complaints Procedure is well publicised and under it, patients have statutory rights. Ultimately, NHS complainants have recourse to the Ombudsman. Private sector complaints procedures are often not publicised and lack independence. Whilst the CQC provides that there has to be a complaints procedure in place, this only applies to those organisations that are required to register with the CQC. AvMA's experience is that often cosmetic procedure patients are reluctant because of embarrassment and are either not aware of or too intimidated or non-trusting of complaints procedures. Whilst in the NHS complainants are guaranteed access to a funded 'independent complaints advocacy service' no equivalent service is funded in this sector. Consequently many problems are brushed under the carpet and never come to light.

AvMA submits that it is important for patients falling into the categories above to have access to specialist, independent advice to help inform them of their rights and advise and assist with regard to complaints and other forms of redress. This would help empower patients and ensure problems with services come to the surface and enhance learning for patient safety. We recommend that an independent specialist advice service is funded to support patients in this sector. This could be funded through a levy on providers and/or with Department of Health support. We further recommend that independent sector complaints procedures are brought into line with the NHS procedure and include statutory rights for patients.

F Review of the Medicines Healthcare Products Regulatory Authority (MHRA)

AvMA believes that the way the MHRA has exercised its functions in relation to a number of products which it regulates, including the PIP breast implant issue, raises serious questions about its fitness for purpose. We recommend that a review of the MHRA is conducted and that in particular attention is paid to whether the MHRA is too close to and reliant on members of the industries it regulates.

Response to Consultation Questions

Regulation of medical devices and implants and other products

1 ***What are the risks and benefits presented by dermal fillers?***

The medical profession will be best placed to respond to this point. However, as AvMA is contacted by patients who are not satisfied with the outcome of dermal fillers we are able to provide comment based upon what patients tell us.

The benefits sought are changes in facial appearance including:

- Filling out of facial lines and creases often as a result of aging.
- Plumping out of the lips, either as a result of loss of volume due to the aging process or because the patient would like fuller lips.
- Less commonly (from our perspective) plumping out of cheeks to give the appearance of high cheek bones.

Accordingly, the benefits sought are physical in the form of an alteration to the face and psychological in that this gives a perceived improvement in the aesthetics of the face.

The problems we are contacted about include:

- Lumpiness and asymmetry
- Movement of the filler (we have only had this in relation to cheek injections)
- Poor aesthetic outcomes
- Tissue necrosis
- Infection

A high proportion of unsatisfied patients reported problems following the injection of permanent fillers, rather than semi-permanent ones. Some people contacting us have required surgery to remove the permanent fillers and have sometimes had permanent disfigurement. In cases involving the lips, this has on occasion resulted in functional problems and the need for long-term treatment.

Administration of dermal fillers

AvMA submits that dermal fillers should only be administered by doctors, dentists or nurses in a clinical setting, who have medical training in facial anatomy and competency in administering medical procedures. In addition, medical expertise is required in dealing with complications and side-effects. Further, we endorse the recommendation of the Expert Group on the Regulation of Cosmetic Surgery, January 2005 (recommendation 13), that permanent fillers should only be injected by a doctor.

Accordingly, it should not be permissible for beauticians or other non-medical practitioners to administer fillers.

2 ***What clinical evidence might be required to regulate dermal fillers (with no claimed medical purpose or benefit) under the existing medical devices regulations?***

AvMA's belief is that it will be difficult to collate any reliable clinical evidence about dermal fillers. First, there are no formal systems in place for reporting and collating the evidence and, secondly, patients are often reticent about sharing their experiences. Many patients feel that because the procedure was voluntary and cosmetic, they have somehow brought the unfavourable outcome upon themselves. It is the exception to the rule for a patient to want publicity about their experience.

AvMA submits that the vulnerability of patients for the reasons set out above, and the significant amount of anecdotal evidence about poor services and poor outcomes provide sufficient impetus for improving regulation.

AvMA are of the view that dermal fillers should be treated as prescription-only medicines, which would take them outside the medical devices regulations. See below. AvMA further submits that provision of dermal fillers should be subject to statutory regulation as with Botox and any form of treatment which has the potential to cause serious harm.

3 ***Are any further changes needed to the categories of devices and implants subject to regulation in addition to the likely changes set out above?***.

AvMA submits that the government should classify dermal fillers as a prescription-only medicine rather than devices.

As mentioned, AvMA submits that dermal fillers (and Botox) should only be administered by doctors, nurses and dentists. As a result, it is important for there to be safeguards in place to restrict the people to whom manufacturers can sell fillers, to minimise the risk of dermal fillers being purchased by non-doctors, nurses and dentists. Reclassifying dermal fillers as prescription-only medicines would mean that fillers are treated in the same way as Botox, and could only be purchased by doctors dentists and prescribing nurses.

Reclassifying dermal fillers as a prescription-only medicine would also increase patient safety by introducing a higher standard of product testing. As a device, fillers will only have to pass CE mark requirements. Drug testing takes longer and is more expensive, but is vital for patient safety. The cost would, ultimately, be passed to the patient. This approach would be similar to that in the USA where dermal fillers are treated as a drug controlled by the Food and Drug Administration.

4 ***Are there any other areas where additional strengthening of the regulatory system is required that will not be addressed in the forthcoming revision of the medical devices legislation?***

AvMA submits that the following should be considered in the review:

Lasers: The lack of protection afforded to patients undergoing intense light treatment needs to be reconsidered and statutory regulation re-introduced. See response to question 13.

Botox: The provision of Botox should also be considered. Botox is a prescription-only medicine so can only be prescribed by doctors, registered nurses, and dentists. But, there is no proper control over the *administration* of Botox. Botox can have serious side effects including muscle and facial droopiness and anaphylactic shock, the latter of which requires urgent medical attention. Presently, the provision of Botox is within the remit of the voluntary TYCT scheme.

AvMA submits that Botox should only be administered by doctors, nurses and dentists. It should be brought within the remit of the CQC.

5 ***Earl Howe's review of the actions of the MHRA and Department of Heath in relation to PIP silicone breast implants recommended that this review should 'examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery.***

Routine incident reporting and review of outcome data by individual surgeons and providers should be the norm.' How can health providers, professional bodies, regulators and patient groups promote the best possible understanding of the role of the incident reporting system and ensure that professionals in particular understand what they have a duty to report?

AvMA believes that the development of more appropriate procedures for complaints and redress and the empowerment of patients through more and better information and specialist independent advice would all contribute significantly to developing a culture of clinical governance and patient safety. See sections D and E above.

AvMA is concerned to see stronger clinical governance and clinical audit, and would like to comment particularly on improving the reporting of incidents.

There is, of course, a balance to be struck between protecting the medical profession from complaints that lack merit, and upholding valid complaints. AvMA are concerned that an alarmingly high number of patients who contact us report that they were treated dismissively by their surgeons when they expressed concerns about their treatment, sometimes even where a second surgical opinion has been obtained which raised concerns.

AvMA submits that it may be difficult to be prescriptive about precisely when to report an adverse outcome, but in most cases it should be obvious to a reasonable and prudent practitioner. There are likely to be similar obligations to the insurers to report incidences which may result in a pay out. Cosmetic surgery is unique in that the patient has a say in the outcome, unlike surgery which is clinically indicated, so consideration has to be given to whether the practitioner has performed what he/she was contracted to perform even if the practitioner thinks he/she got a satisfactory cosmetic outcome.

AvMA also suggests that medical insurers should be obliged to provide details of surgeons who have had successful claims made against them. A concern of the medical profession may be that sometimes a decision is made to pay compensation in a case for 'commercial' reasons, rather than because the case has merit. Whilst the medical profession's representatives may well weigh up the costs of continuing to defend a case with the costs of settling at an early stage, it is not our experience that settlements are reached in cases that the defendant thinks are without merit. Further, the patient's solicitor will have obtained an independent medical opinion which would have considered the medical records and documents, and made criticisms of the treatment provided. It would be unusual for a case to settle before such a report has been obtained.

AvMA submits that a body needs to be appointed to collate and analyse this information. We suggest this could be the GMC. Also, AvMA submits that there should be much more information available to patients about the performance and competence of surgeons. It is presently extremely difficult to ascertain any comparative data at all about a surgeon's performance and competence. Whilst the GMC may report the outcome if a doctor is found to have been unfit to practise, this does not go far enough and, in our experience, the GMC is not an organisation that is commonly known to patients. This lack of available information needs to be given serious consideration, especially if patients are expected to protect themselves by doing their own research (although see above on this point).

Regulation of practitioners

6 ***Is there evidence that the current requirements for doctors practising cosmetic surgery are insufficient? Should all cosmetic surgeons be required to have specialist training, ie be on the Specialist Register?***

All surgeons carrying out cosmetic surgery should be on the specialist register, and see below.

7 ***Currently 'cosmetic surgery' is not recognised as a specialty for which doctors can train and achieve a Certificate of Completion of Training (CCT) leading to inclusion on the Specialist Register. Is there evidence to suggest a need to introduce a new Specialty for 'Cosmetic Surgery' or are there alternatives, such as a different form of training, eg credentialing, that would demonstrate competence?***

AvMA is of the view that cosmetic surgery should be introduced as a recognised speciality requiring a Certificate of Completion of Training. It is unacceptable that any registered doctor can perform cosmetic procedures, irrespective of whether they have the competence to do so. Whilst AvMA accepts that the majority of doctors would not entertain practising in an area in which they were not competent, this can not be relied upon in this unique market which combines vulnerable patients and high profits. In addition, caution needs to be exercised in ensuring that doctors who have qualified abroad have the appropriate skills and experience before being accepted on the register.

AvMA also proposes that all cosmetic surgeons should be obliged to give to patients' details of their qualifications, registration, memberships and continuing education. The GMC should provide information on what the qualifications mean and what to look for.

AvMA welcomes the introduction of revalidation in December 2012. However, it will be important that the revalidation of doctors who are not affiliated to the NHS or other body receive equally strict checks, as there are some cosmetic surgeons who operate independently without association to the NHS or other body. We understand this is currently being considered by the GMC.

AvMA submits that there should be a cosmetic surgery register. Surgeons would have to be registered in this specialty in order to perform cosmetic surgery

8 ***Do people who deliver cosmetic interventions like fillers, Botox, laser treatments or chemical peels, have the appropriate skills to deliver them? How could their performance be monitored?***

AvMA submits that only doctors, nurses and dentists, have the appropriate skills to deliver such cosmetic interventions. Statutory regulation with the CQC would ensure some monitoring and enable action to be taken when required.

9 ***Earl Howe's review of the actions of the MHRA and Department of Health in relation to PIP silicone breast implants recommended that this review should 'examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery. Routine incident reporting and review of outcome data by individual surgeons and providers should be the norm.' How can medical revalidation be used to promote this?***

The medical profession may be best placed to deal with this, although the yellow card scheme under the MHRA may not be being used effectively and provides a possible means of improving the position.

10 ***Should practitioners be required to ensure that records of all cosmetic interventions are kept? This is generally done for implants but is it reasonable to do for other devices such as dermal fillers?***

Yes, they should be treated as medical records. Keeping records may also be required to obtain insurance.

<u>Regulation of organisations providing cosmetic interventions</u>

11 ***Is it right that private providers of cosmetic surgery meet the standards expected of the NHS?***

The same standards should apply in the NHS and private sector.

12 ***The CQC registration requirements place a duty on providers to protect their patients from unsafe treatment, but it is not clear how far this extends in the private sector to providing appropriate after care where a patient has suffered harm as an unexpected consequence of treatment. Do we need to impose a clearer legal requirement on registered organisations to provide after-care to their patients? If so, for how long after the original treatment?***

The duty to deal with after-care should be the responsibility of the surgery provider, and the surgery provider should bear the cost of dealing with unexpected consequences rather than the NHS. It is hoped that unexpected consequences would only be in the minority of cases and should not pose an unreasonable financial burden on the provider. However, there is concern that less scrupulous practitioners would withhold appropriate treatment in the interests of avoiding the cost. In such cases, there would be no option other than for the NHS to pick up the tab.

AvMA submits that it is not appropriate to put a time frame on the duty to give after-care. It would need to be for as long as there was a causal link between the original procedure and unexpected consequences. It is expected that in many cases, any unexpected consequence would materialise reasonably close in time to the procedure, so there would not be any hardship in leaving the timeframe indefinite.

13 Do you think the existing regulation of lasers and lights is proportionate to the risks they present with regard to cosmetic interventions?

AvMA has been contacted by patients injured by lasers, usually burns. Known possible adverse consequences are scarring, changes in pigmentation, and damage to the eyes.

AvMA finds it regrettable that lasers were deregulated in October 2010 in spite of representations from patients groups such as AvMA, medical experts, and representatives of the industry itself. It was particularly regrettable given that the Department of Health risk assessment itself acknowledged that this would lead to more patients being harmed, which is the case. There is currently no statutory regulation, unless the local authority under the Local Authorities Act 1991 requires a licence for this. Accordingly, the requirement for a licence is patchy resulting in different standards in different localities.

AvMA submits that the regulation of lasers should be re-introduced within the scope of the CQC. For the reasons explained above, AvMA does not believe that patient safety is protected adequately by TYCT type industry led voluntary schemes.

14 ***Should providers of surgical cosmetic interventions be required to audit their processes and ensure that all their practitioners take part in clinical audit?***

Yes. The revalidation being introduced by the GMC in December 2012 should assist. As mentioned above, an appropriate system needs to be in place for monitoring surgeons who are not part of the NHS or other body.

15 ***Should providers of non-surgical cosmetic interventions delivered in non-healthcare settings, for example beauticians administering dermal fillers or laser hair removal, be required to audit their processes and ensure that all their practitioners take part in clinical audit?***

AvMA submits that non-surgical interventions should not be provided by non-medical practitioners in non-healthcare settings.

16 ***Should providers be required to ensure that records are kept on the implants and devices they implant? If so, for how long?***

Yes. Many of the implants have a long shelf-life so for any meaningful analysis to be done in the future is likely to require the information should be held indefinitely.

Questions on insurance and indemnity requirements

17 ***Should providers be required to take out an adequate indemnity arrangement and/or to participate in a bond arrangement such as provided by ABTA in the travel industry? If so, for how long?***

There are a number of scenarios relating to insurance.

Individual liability: All individuals providing cosmetic procedures should have individual professional indemnity insurance to cover the cost of claims against them, and this should be at an appropriate level.

AvMA submits that appropriate insurance with an appropriate level of cover should be a pre-requisite for obtaining registration with CQC. Also, there should be an obligation on the practitioner to advise patients as to whether they have insurance in place and the limit of indemnity Unexpected outcomes: AvMA recognises that there could be a place in the market for a bond arrangement to cover the medical costs of dealing with unexpected outcomes of the procedure, which have arisen not as a result of fault. The cost would be borne by the practitioner, but ultimately passed to the patient.

PIP situation: AvMA recognises that there could be a place on the market for a bond arrangement to cover situations similar to the PIP disaster. This could involve charging more for the implants, with an amount going into an insurance fund. Again the cost would ultimately be passed to the patient. Patients should be protected if the business fails.

Abroad: AvMA is aware of considerable concern about the costs to the NHS of dealing with complications following cosmetic procedures which have been performed abroad. Whilst the NHS must always be able and willing to deal with urgent health needs, however they arise, patients should ensure that their overseas provider has appropriate indemnity arrangements and/or take out their own insurance to cover any further costs arising from a procedure abroad. The advantage is that appropriate cover would be in place to meet these costs privately, and take the work away from the NHS. There also needs to be better public information about the pitfalls of seeking treatment abroad and the need to check on what indemnity is cover is in place.

AvMA would welcome the opportunity to contribute to further more detailed consideration of this issue together with the Department and other stakeholders.

18 ***How could cosmetic surgery organisations make it easier for patients to access their health records?***

Patients already have entitlement to copies of their medical records under the Data Protection Act 1998. It should not be an issue, but in our experience it is often very slow for records to arrive and these are often incomplete. This service could be reviewed in the revalidation process.

19 ***What can be done to protect patients if their provider goes out of business?***

See response to question 17 above.

Questions on consent, information and advertising for cosmetic interventions

20 ***What more, if anything, is needed to ensure that people have the information and time they need to give informed consent? Is sufficient weight given to the psychological assessment of the individual?***

AvMA feels strongly that safeguards must be introduced in relation to consent. The combination of a patient who is willing to pay for cosmetic treatment for which there is no clinical indication and the opportunity for the doctor to profit necessarily results in the very real risk that possible side-effects and complications may be played-down.

Further, because there is no clinical indication for the procedure, AvMA submits that the duty in relation to providing information on risks should be different to other medical settings. In cases where there is a clinical indication for a procedure, the law recognises that the amount and nature of the information provided by the doctor depends heavily on the nature and severity of the condition, the complexity of the treatment, the risks associated with the procedure and the patient's own wishes.[1] However, in cosmetic procedures, where there is no clinical need for treatment, doctors should have a higher burden to advise on risks and this should include advising on all of them. [Would we include, say, death?]. Any discretion to be selective should be removed in this context.

Further, it is important that the information should be *presented* in a way which does not undermine the risks. The information should be given orally, and in print, and by a doctor (or for injectables, a nurse or dentist). It should not be acceptable for doctors to give only a brief explanation of the risks and to give the patient a print-out to read at their own leisure. A proper, oral explanation of the risks needs to be provided, possibly by reference to the print-out at the same time. Patients must be allowed time to ask questions.

Further, the information should be standardised across the UK, so that patients have the same information wherever they live. This should be relatively inexpensive, relatively easy to prepare, and should be provided with input from the relevant organisations, such as AvMA and from the medical profession.

Revalidation should check that this process is being carried out properly.

Whilst the medical profession will be best placed to comment upon the patients for whom surgery would be inappropriate, AvMA would expect this to include patients with a recent history of psychiatric illness, dysmorphobia and unrealistic expectations of outcome. It will require a doctor to make this assessment.

In summary, AvMA submits that:

- Patients are told of all the risks of the procedure;
- There should be standardised information across of UK about risks; and
- Consent for surgery should be dealt with by a doctor, to rule out inappropriate patients

21 ***Should providers be required to carry out a two-stage consent process (i.e. allowing a cooling off period between consultation and surgery)?***

[1] Sidaway v Board of Governors of the Royal Bethlehem Hospital and Maudsley Hospital [1985] AC 871; Birth v University College London Hospital NHS Foundation Trust [2008] EWCH 2237; Chester v Afshar [2004] UKHL 41 pt 2

There should always be at least a 14-day cooling-off period including for non-surgical procedures such as injectables.

22 ***Do you think the existing regulation of the advertising of cosmetic interventions is proportionate?***

AvMA does not believe that regulation of advertising by the Advertising Standards Authority is adequate in relation to cosmetic surgery, and its primary position is for a ban on advertising all cosmetic surgery advertising, including injectables. (If fillers are treated as prescription-only medicines, advertising will not be permitted in any event). This would follow the lead of France. Whilst it may be suggested that advertising is important for provider differentiation and patient information about procedures, AvMA does not find this compelling. It is clear from the nature and tone of the adverts that there is a single, recurrent message: the *promise* – the promise of beauty and enhanced looks. Consequently, the adverts are more akin to *enticements* rather than to improve awareness or educate. In a market where, as mentioned, patients are inherently vulnerable to pressure to change their appearance and where the providers can make considerable amounts of profits, patients need greater protection.

A downfall of the ASA is that it relies upon complaints being made. AvMA is aware of some occasions where the ASA has intervened, but by the time it has done so the advert has been published or had air-time and then benefits further from the publicity surrounding its ban (if we assume 'no publicity is bad publicity.').

Further, it is missing the point to rely on the public to trigger a withdrawal of a campaign. Whilst the public may react to the most unpalatable adverts, for the most part they are not likely to do so. As mentioned, as they are consciously or unconsciously not aware of the risks, they do not see the deception in the presentation of adverts which suggest a great outcome without risk.

AvMA submits that advertising of cosmetic procedures, including injectables, should be banned.

23 ***Is there evidence that advertising on cosmetic interventions needs to be regulated using a different system used for general products and services?***

N/A – see above

24 ***What is your view on the use of incentives to promote the sale of cosmetic interventions (such as time-limited price offers)?***

AvMA submits that incentives to promote the sale of cosmetic interventions should not be permissible.

A national implant registry

25 ***How could a national implant registry be set up and funded? Which treatments should it cover? Should participation be a statutory requirement for providers? Should patients have the right to opt out of having their information recorded?***

AvMA would strongly support the introduction of a National Implant Registry.

Specific sectors/forms of treatment

26 ***Are there any specific forms of treatment or sectors which you think should be subject to more (or less) regulation than at present? Examples include surgical body modification eg***

tongue splitting; body enhancement implants; cornea tattooing and jewel implants into the cornea.

See above response to question 4.

AvMA

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