Feature Article

Keogh: Have We Really Moved On From The 2005 Recommendations?

Some eight years ago now, back in 2005, we brought you a feature article entitled '**Chief Medical Officer Announces Shake Up of Regulation of Private Cosmetic Surgery - What does it all mean?**' which highlighted the submissions to Sir Liam Donaldson, then Chief Medical Offer (CMO) of two reports published by the Healthcare Commission (predecessor to the Care Quality Commission as industry regulator) and a Department of Health based Expert Group looking at the current systems in place for the regulation of the cosmetic surgery industry in England and whether they were sufficient to ensure patient safety.

The Healthcare Commission's '*Provision of Cosmetic Surgery in England*' and the Expert Group's '*Regulation of Cosmetic Surgery*' were both published on the same day, 28th January 2005.

The Expert Group report highlighted that, while there is no firm evidence of harm to patients under the then, current arrangements for regulation of cosmetic surgery, this was a growing area with more people wanting to have procedures and new and different procedures being developed all the time, which they believed demanded a more robust regulatory structure.

The primary findings of the Healthcare Commission report were concerned with the need to scrutinise the then, currently unregulated cosmetic procedures such as Botox®, chemical peels and injectable fillers, with strong recommendations for further reviews into cosmetic and aesthetic procedures currently available in the marketplace as well as emerging treatments, in order to ensure the safety and quality of services provided in England.

After analysing these two reports, the CMO produced an action plan on the recommendations for the industry.

Fast forward to 2013 and the report entitled the '*Review of the Regulation of Cosmetic Interventions (in England)*' has just been published at the end of April by a committee of mixed professionals headed up by NHS Medical Director, Professor Sir Bruce Keogh, spawned as a reaction to the scandal surrounding the fraudulent PIP breast implants.

So, it sounds rather familiar doesn't it? We've been here before. Take a long, hard look at ourselves, see what's wrong and recommend some improvements, all in the name of patient safety of course. But, has anything really changed? Is the current system even any better than the last time it was reviewed, almost a decade ago? Or, are the same old recommendations being put forward for regulators and legislators to simply ignore again, potentially at the detriment of patient safety? Let's review what came before and what Keogh brings 'new' to the table.

Past Reports in a Nutshell

Healthcare Commission's Provision of Cosmetic Surgery in England

This report detailed the findings of the Healthcare Commission (HC)'s investigation into private cosmetic surgery provision in England. In general the report recommended further review of current and emerging cosmetic and aesthetic procedures in order to ensure the safety and quality of cosmetic services in England as the HC admitted that '*while there are numerous estimates of the number of establishments that provide unregulated cosmetic and aesthetic procedures, the actual number is unknown*'.

For this report a total of 211 of their own inspection reports from 2002 to 2004 were reviewed by them. These reported on 156 separate establishments, with 55 being inspected twice. This was not an exhaustive list of cosmetic surgery providers, and did not include newly registered providers or laser specific establishments. Of the inspection reports, 184 came from acute hospitals, 11 from cosmetic surgery only establishments and 16 from small establishments.

The Healthcare Commission's recommendations within their report were broadly that:

- specialised training in cosmetic surgery within specialist training (for the specialist register) should be established and made mandatory.
- a separate category of cosmetic only establishments be defined within HC registration and recommended that the standards relating to cosmetic surgery should be reviewed to provide standards more tailored to the specialty.

The Healthcare Commission also endorsed a recommendation previously submitted to government from a Health Committee report which noted that emerging techniques and technologies that pose any risk to patient safety should be evaluated and regulated.

The Expert Group's Regulation of Cosmetic Surgery

This report was designed to establish whether the then, current system for regulation of cosmetic surgery via the National Minimum Standards was sufficient to ensure patient safety and to make recommendations based on the group's findings. Their final 20 recommendations fell into three broad themes; recommendations about clinical training, qualifications and accountability, recommendations about cosmetic procedures, and finally, recommendations about public information and education. The Expert Group committee included representatives from the Department of Health, the Healthcare Commission, the Cosmetic Inter-Specialty Committee, large clinic chains, as well as Doctor and Nurse members.

With regard to the regulation of invasive cosmetic surgery they found no reason to consider the current inspection regime conducted by the Healthcare Commission to be inadequate, and welcomed their efforts to seek augmented regulatory powers of enforcement action against non compliant establishments without the need for court intervention. However, they did highlight concerns with current training and qualification requirements for clinicians.

The Expert Group also looked at non-surgical treatments and expressed concern at the off-licence use and advertising of botulinum toxins. They also scrutinised the regulation of aesthetic fillers, noting that the subcutaneous injection of such fillers is not regulated and that their classification as medical devices is unclear, all of which it found unsatisfactory. It called for better regulation and licensing of fillers. Remember, this is in 2005!

CMO's Action Plan

In response to the findings from the above two reports, the Chief Medical Offer was able to announce a broad range of improvement plans to the regulation of the private cosmetic surgery industry to be enacted (it said) during 2005 and beyond. Broadly these involved:

- developing patient education and information materials,
- reviewing the need and scope for additional regulation of aesthetic fillers,
- working 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.
- asking the relevant professional bodies and competent authority to develop appropriate specialist training programmes as a matter of urgency for surgeons undertaking cosmetic procedures.

Each of the 20 recommendations from the Expert Group report was provided with a response from the CMO and course of action. Some of the more 'interesting' ones, in light of the recent Keogh report, are highlighted below:

Recommendation 7
That the **facilities where botulinum toxins are injected be licensed with the Healthcare Commission** and therefore subject to its regulations.

CMO Response: Agreed, subject to regulatory impact assessment and resourcing.

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 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.**

CMO 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.

Recommendation 14
That the **facilities where aesthetic fillers are injected be licensed with the Healthcare Commission** and therefore subject to its regulations.

CMO 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.

As we know, the Department of Health went away and thought about all of this...for 18 whole months and finally came back in April 2007 and stated that the Government had considered statutory regulation of cosmetic injectable treatments, which would include dermal fillers and botulinum toxins. The Department of Health had worked closely with the cosmetic surgery industry to determine the form of regulation that would provide the best approach for both treatment providers and their patients, and the winner was...a self-regulatory scheme drawn up by the Independent Healthcare Advisory Services (IHAS) which we now know to be called the **Treatments You Can Trust** (TYCT) Register.

So fast forward to 2013...

Keogh – What Are The New Recommendations For The Industry?

The long awaited report, headed up by Professor Sir Bruce Keogh, commission in January 2012 and commenced in August of the same year investigating the *Regulation of Cosmetic Interventions in England*, has finally been published and calls for a complete reclassification of dermal filler products amongst other recommendations (40 in total) for the private cosmetic sector. Now where have I heard that before?

The Keogh committee also want to ensure that all practitioners are properly qualified for all the procedures that they offer, from cosmetic surgeons offering breast augmentations to those offering cosmetic injectable treatments. All of which would be overseen by an ombudsman to aid those who have received poor treatment.

Commissioned by the Government following the PIP breast implant scandal, the review has looked at the products used for surgical and non-surgical procedures, the people who administer them, the way they are advertised and the advice and support patients and consumers are given. The report sets out how it would like to see the aesthetic and cosmetic sector better regulated, practitioners better trained and the public having proper redress should things go wrong.

The cynic in me can't help but look back over my shoulder to the past and shake my head, we've been here once before, the sense of déjà vu is palpable, yet here we are again!

On first dissecting the industry, Sir Keogh admitted to being surprised that non-surgical interventions, which can have major and irreversible impacts on health if something goes wrong, are almost entirely unregulated, a fact also clearly highlighted at the time in the 2005 reports. Obviously since then the cosmetic use of lasers for hair removal has also been deregulated and is no longer covered by the CQC registration and inspection criteria (which took over from the Healthcare Commission in April 20009) as of October 2010, so the industry is even more unregulated as a whole than in 2005.

Of particular concern to the Keogh committee was the arena of dermal fillers where they noted that anyone can set themselves up as a practitioner, with no requirement for knowledge, training or previous experience and, in the absence of accredited training courses, anyone can set up a training course purporting to offer a (self-accredited) qualification. The casual use of products by unqualified individuals and reports of people buying injectable products over the Internet and self-administering alarmed the Keogh panel. Add to that the lack of sufficient checks in regard to the quality of the filler products themselves, currently poorly regulated under medical device regulations, which was likened to those imposed on a bottle of floor cleaner, meaning that the Review committee believes that dermal fillers are a crisis waiting to happen; but for how much longer?

They also noted that data on rates of reported adverse reactions caused by dermal fillers and other non-surgical cosmetic interventions are poor because there are no formal reporting mechanisms in place for many of these products.

Sir Keogh raised the issue that previous attempts at self-regulation in the non-surgical side of the industry have failed, which he put down to them being largely voluntary codes which have meant that only the best in the industry commit themselves to better practice, whilst the unscrupulous and unsafe carry on as before. The report states that despite efforts from IHAS, Treatments You Can Trust has attained limited support from the sector, with concerns that, as a trade body, IHAS is not the appropriate organisation to run an independent register. It also points out that from a consumer perspective awareness of the register is low. It concludes that the failure of the sector to self-regulate may also partly reflect public attitudes which assume that there is already legislation. An observation which we would all be hard pressed to disagree with.

For this reason, one of the key recommendations of the report is to make dermal fillers prescription only medical devices to tackle both concerns head on. The committee are determined that the production of dermal fillers should fall under the same controls as other implants as this will ensure that only those fillers that have passed vigorous appraisals of safety will be available, and only those with 'appropriate skill' will be able to administer them.

The Review report notes that people undergoing non-surgical treatments should be able to be confident that their practitioner has the required skill and expertise to undertake the procedure successfully and safely.

They argue that the question is not '*who should perform treatments*' but '*what should adequate training and accreditation involve*'? Noting that once the requirements for training are identified and understood, it should be possible to identify, for each professional group, which parts of the curriculum have been covered with prior training and which are consequently required to complete training. This will mean that different professional groups (e.g. medics like Doctors and Nurses versus non-medics like Beauty Therapists) will enter the training scheme at different points. Such a scheme could provide broad access, and may be able to provide professional training for those with no prior experience. The aim should be that, every practitioner, no matter what their starting point should attain the necessary skills and expertise to perform these varied procedures safely and to a high standard.

The training and accreditation process should ensure that practitioners are able to identify and manage complications of treatment and the curriculum and training requirements should be regularly reviewed to ensure that all practitioners are adequately trained in emerging procedures; this will involve regular retraining for those who wish to perform the latest treatments.

The committee believes that anyone prescribing fillers, or performing other potentially harmful non-surgical cosmetic procedures, should be accountable to a professional regulator.

The Review committee thus recommends that:

- **All non-surgical procedures must be performed under the responsibility of a clinical professional who has gained the accredited qualification to prescribe, administer and supervise aesthetic procedures.**
- **Non-healthcare practitioners who have achieved the required accredited qualification may perform these procedures under the supervision of an appropriate qualified clinical professional.**
- The Government's mandate for Health Education England (HEE) should include **the development of appropriate accredited qualifications for providers of non-surgical interventions and it should determine accreditation requirements for the various professional groups.** This work should be completed in 2013.
- **All practitioners must be registered centrally.** The register should be independent of particular professional groups or commercial bodies, and should be funded through registration fees.
- Entry to the register should be subject to:
    - achievement of accredited qualification
    - premises meeting certain requirements
    - adherence to a code of practice that covers handling complaints and redress,
    - insurance requirements, responsible advertising practice and consent practices
    - continued demonstration of competence through an annual appraisal.

Following on from this the Review committee found that the current regulation of non-surgical providers is insufficient to adequately protect public health and safety.

Therefore they recommend that:

- Those training to be non-surgical practitioners should have a clear understanding of the requirement to operate from safe premises, and the responsibilities involved. The training curriculum should include topics such as infection control, treatment room safety and adverse incident reporting. The code of conduct for those on the register should include an obligation to abide by certain clearly defined **minimum standards for premises**.

In relation to the products themselves, the Review report states that dermal fillers that do not claim to have a medical purpose (i.e. they are purely for cosmetic use) are exempt from EU medical device regulations and CE marking requirements before being able to be sold, thus products falling outside the medical devices regulations are only covered by the general provisions of the EU General Product Safety Directive. This maintains only a very general responsibility on distributors to place on the market (or supply) products that are safe in normal or reasonably foreseeable use. Furthermore, when a product such as a dermal filler is used as part of a 'professional service' it is currently exempt from the EU General Product Safety Directive. This means that in effect some dermal fillers used in cosmetic interventions in the UK are exempt from any product safety regulations! While this does not necessarily mean that the products are unsafe, it does mean that consumers and patients are reliant on manufacturers' and providers' own assessment of the safety of the product.

The Review report highlights that proposed revisions to the EU Medical Devices Directive are currently being discussed and may result in all dermal fillers and other implants for cosmetic use being classified as medical devices and therefore subject to the safety checks required for CE marking, but even if these changes are agreed, they are unlikely to be implemented before 2018, which Keogh believes leaves the public unprotected for too long. Manufacturers are currently not required to notify the MHRA that they are bringing medical devices or cosmetic implants to market in the UK and it is difficult therefore to get data on product use. According to the report, as a rough estimate, there are between 140 and 190 dermal filler products available in the UK (including CE marked and non-CE marked products), and there are no restrictions on who can purchase these products.

It therefore recommends that:

- The scope of the EU Medical Devices Directive should be extended to cover all cosmetic implants, including all dermal fillers. **UK legislation should be introduced to make fillers a prescription only medical devices.**
- The EU General Product Safety Directive (GPSD) should be revised so that products used as part of a professional service are no longer exempt from product safety legislation.
- Manufacturers should inform the MHRA when bringing a new product to the UK market and the MHRA should publish a list of the cosmetic devices available in the UK.

The **67 page report** of course goes into much more detail about the various aspects of the cosmetic intervention market within England and its findings and recommendations. The Review Committee believes that the Government needs to establish a regulatory framework that encompasses the whole cosmetic sector, rather than the 'piecemeal' set up that it currently sees. This would employ a 'clear, consistent and proportionate approach that is able to adapt to new developments'. The panel therefore hope that their recommendations, taken together, form a new legislative framework, demanded consistently by stakeholders and contributors to the evidence process that is proportionate to the potential risks of cosmetic interventions. The full report highlights three key areas in which changes are needed within the whole industry:

1. **high quality care** with safe products, skilled practitioners and responsible providers;
2. an **informed and empowered public** to ensure people get accurate advice and that the vulnerable are protected;
3. and, **accessible redress and resolution** in case things go wrong.

The key recommendations across the board are thus laid out as follows:

High Quality Care

- The scope of the EU Medical Devices Directive should be extended to include all cosmetic implants including dermal fillers, UK legislation should be introduced to enact the changes sooner. **Legislation should be introduced to classify fillers as a prescription-only medical device.**
- The Royal College of Surgeons (RCS) should establish an Interspecialty Committee on Cosmetic Surgery, made up of representatives of all the relevant specialty and professional associations. The purpose of this group is to **set standards for cosmetic surgery practice and training, and make arrangements for formal certification of all surgeons regarded as competent to undertake cosmetic procedures**, taking account of training and experience. While this is developed, only doctors on a GMC Specialist Register should perform cosmetic surgery, and those doctors should work within the scope of their specific training.
- **All those performing cosmetic interventions must be registered.**

- The Health Education England's (HEE's) mandate should include the **development of appropriate accredited qualifications for providers of non-surgical interventions** and it should determine accreditation requirements for the various professional groups. This work should be completed in 2013.
- Surgical providers should provide both the person undergoing a procedure and their GP with proper records.
- A **breast implant registry** should be established within the next 12 months and extended to other cosmetic devices as soon as possible, to provide better monitoring of patient outcomes and device safety.

An Informed and Empowered Public

- The RCS Interspecialty Committee on Cosmetic Surgery should develop and describe a **multi-stage consent process for operations**. Consent must be taken by the surgeon performing the operation to ensure that the patient and practitioner have a shared understanding of the desired outcome and the limitations, implications and risks of the procedure.
- **Evidence-based standardised patient information** should be developed by the RCS Interspecialty Committee on Cosmetic Surgery, with input from patient organisations.
- **For non-surgical procedures a record of consent must be held by the provider.**
- Existing advertising recommendations and restrictions should be updated and better enforced.
- The **use of financial inducements and time-limited deals to promote cosmetic interventions should be prohibited** to avoid inappropriate influencing of vulnerable consumers.

Accessible Resolution and Redress

- The remit of the **Parliamentary and Health Service Ombudsman** (PHSO) should be extended to cover the whole private healthcare sector. This will de facto include cosmetic procedures of all kinds.
- **All individuals performing cosmetic procedures must possess adequate professional indemnity cover** that is commensurate with the type of operations being performed.
- **For surgeons working in this country, but who are insured abroad, indemnity insurance must be commensurate with similar UK policies.**
- The Review Committee supports the future development of insurance products such as risk pool arrangements, to cover product failure and certain complications of surgery.

Sir Bruce is keen to put the minds of practitioner's at rest by clarifying; "*these recommendations are not about increasing bureaucracy but about putting everyone's safety and wellbeing first.*"

He went on to say; "*We would like to see everyone who chooses to have any cosmetic procedure better protected. We would like to see people who carry out procedures trained to a high standard. We would like the public to feel confident they are going to be well looked after and, if things go wrong, that they will be supported. And ultimately, if someone needs to step in on the side of patients, we think there should be an ombudsman to do that. We very much hope that our report will lead to a safer environment for patients and this industry in the future.*"

Industry Reaction

Thus far the report and its contents have been welcomed by key organisations and professionals within the aesthetic industry. Many of the leading organisations representing medical professionals such as plastic surgeons, doctors, nurses and beauty therapists have been vocal in their responses and drive to work closely with Government to put better practices and regulation in place. Product manufacturers, particularly the larger suppliers of dermal filler brands have welcomed the news also, but with some caution as to the most appropriate way forward.

Here we detail some of the responses:

Commenting on the report, **Consulting Room™ Advisor, Consultant Plastic Surgeon and BAAPS President Rajiv Grover** said; "*We are thoroughly relieved that the Review has come to the same conclusions as we have over the years, specifically the urgent need for dermal fillers to require a prescription for use. This measure will kill three birds with one stone: regulating which ones come onto the market, who can inject them and automatically banning their advertising.*"
Sally Taber, Director of the Independent Healthcare Advisory Services and responsible for managing **www.TreatmentsYouCanTrust.org.uk** welcomed the Keogh Review and said; "*The successful implementation of the recommendations on non-surgical procedures to ensure patient safety relies on two things. First, to end bad practice, the new qualification for cosmetic injectables must be underpinned by medical knowledge to ensure these medical treatments are administered safely. Second, it is important that these recommendations are executed swiftly to stop patients falling through the net. IHAS will be happy to utilise its existing framework and established industry guidelines to work constructively with the Government to expedite the process.*"

Tim Goodacre, BAPRAS Chair of Professional Standards and a member of the Review's Working Group on Training and Education in Cosmetic Surgery, said;"*...This is a strong series of recommendations and we are pleased that many of our priorities have been included. We hope they achieve Parliamentary approval and support quickly so that the detailed implementation work can begin and patients can be sure of high quality care and controlled outcomes at all times.*"

Dr. Samantha Gammell, President of the British College of Aesthetic Medicine (BCAM) said: "*BCAM is both pleased and relieved that the Review has put forward recommendations which are both sensible and proportionate in relation to cosmetic treatments. BCAM has long advocated the regulation of the use of dermal fillers in view of the potentially very serious complications which can arise from their use and we are delighted at the proposal that these products should become prescription only medicines. We also welcome the committee's recommendations regarding requirements for verifiable training in the field of aesthetic medicine which is the central focus of the College.*

We are thrilled that the Review has taken on board the views we expressed in our evidence to them late last year and that so many of our suggestions have been adopted by Professor Keogh and his team in the final report. It is vital for the sake of the profession that cosmetic surgery and aesthetic medicine is appropriately regulated and is performed only by those who are qualified, skilled and able to deal with the rare but potentially serious complications."

The **British Association of Cosmetic Nurses (BACN)** issued a collective response by saying; "*If practitioners are to be licensed - who will license and how would it work? If there is to be accredited education - how will this be designed? what will the entry levels be? who will deliver and where will it be delivered? how will experienced practitioners demonstrate required standards? We strongly object to anyone other than nurses, doctors and dentists qualifying to undertake these procedures.*

If Premises are to be licensed - who will undertake this? what lessons have we learned? We support initiation of the HEE, PHSO, CQC and MHRA in engagement and consultation with clinical experts in pushing forward the recommendations towards credible and workable legislation. The group of experts in this case MUST include clinicians with direct and significant experience in the practices examined. Nurses experienced in aesthetics must be included and the BACN fully commit to engaging in this necessary process.

The BACN supports the development of a mandatory national register of non-surgical licensed clinicians with practitioners demonstrating competency in the relevant non surgical speciality, subject to audit, assessment, appraisals and revalidation.

The report appears to suggest that those who are not medical may become qualified to practice under supervision. With patient safety foremost, there is absolutely no imperative for this to be the case, and "under supervision " is open to interpretation.

We agree that the scope of EU Medical Devices Directive should be extended to include dermal fillers. These devices should only be supplied to and administered by nurses, doctors and dentists who are educated, licensed, regulated and accountable. Prescription only medicines may be administered by ANYONE once prescribed.

We are engaging with other stakeholders - BCAM, BAD and manufacturers - to come together at the earliest opportunity to influence the future landscape. We will be lobbying the media and government."

Habia announced that they would be holding a consultation event on 1st May amongst key beauty industry stakeholders to consider the recommendations of the Keogh Review, in order to formulate a united industry response. As yet no outcomes of the meeting have been published. **Rob Young, Habia MD** said; *'It is important we act now. As the Industry Authority, Habia intends to bring together a wide range of representatives of the beauty sector so that government can be presented with a united response before any decisions on legislation are made, and to ensure that beauty therapists are fairly and adequately represented. It is important that we do not allow the vested interests of other sectors and stakeholders to take precedence before the beauty industry has spoken*.'

Carolyne Cross, Chair of BABTAC & CIBTAC said; "*Whilst not all the changes are consistent with our own recommendations for cosmetic interventions, we are quietly confident that the outcome will work to benefit both the consumers and the industry practitioners. It is our belief that any changes should work to improve consumer safety and awareness, without creating a market monopoly and driving up prices.*

In terms of the impact on the beauty industry, we believe that there will be some significant changes in terms of regulations and qualifications, and as an organisation we have been driving for improved standards of training and regulation of our own industry providers. For therapists, it is likely that they will have to undertake additional training to become compliant, and whilst this has a cost implication for each salon, the outcome – better protected clients -

will be worth the additional expenditure. We hope that these changes will serve to support and develop already reputable businesses, whilst undermining the status of 'rogue traders' who practice without due care and attention."

Allergan (manufacturers of botulinum toxin brand Botox® and the Juvederm® range of dermal fillers) responded by saying; "*Allergan is in favour of regulatory changes to classify all cosmetic implants including dermal fillers as medical devices and supports many of the other proposals such as calls to strengthen the existing European Medical Device Directive, plans to establish accredited training standards for health care professionals administering cosmetic implants, as well as steps to improve consultation and record keeping of patient treatments.*

The report calls for a proposal to re-classify dermal fillers as prescription-only medical devices. This will require further thought to ensure the necessary legislation would bring about positive change in ensuring optimal patient outcomes. Specifically, any legislation change of this type will require significant time and could also mean that medical aesthetic nurses, who are generally already highly skilled and experienced, will need to re-train in order to obtain a prescribing licence."

Merz Aesthetics (manufacturers of botulinum toxin brands Xeomin® and Bocouture® and dermal filler brands Radiesse® and Belotero®) responded by saying; "*Merz Aesthetics warmly welcomes the move toward increased patient safety and care and believes that patients deserve a high level of quality and safety from our products and the medical aesthetic industry as a whole. As a pharmaceutical company with over a century's heritage Merz has always followed the most stringent approach with our full portfolio, regardless of whether they are a medical device or a prescription medicine. Merz are fully behind the move to reinforce the general public's perception of the UK medical aesthetics industry as professional, caring and above all, safe.*"

The full content of responses, as well as additional statements and views from clinic chains and long serving members of the industry are available on our **blog**.

Conclusion

So there you have it, a look back at what was revealed in 2005 and a resignation to the fact that not an awful lot has changed in 8 years now that the sector has been reviewed yet again!

Some argue that some of the recommendations are a little vague, empty of detail or open to massive interpretation. Concepts of being 'under supervision' and 'appropriate accreditations' are still very much up in the air and a source for much debate over coffee at recent events that I have attended.

Similarly the blurring between the 'them and us' of cosmetic surgery (plastic surgeons) and non-surgical medical aesthetics (doctors and nurses) has not been fully addressed when taking into account that many cosmetic doctors now carry out what some may call 'cosmetic surgery lite' procedures such as liposuction techniques (VASER®, BodyTite™ etc.) under local anaesthesia.

With talk in the Keogh report, as mentioned in the 2005 reports of doctors who perform 'cosmetic surgery' – something which has still yet to have any formal definition as a medical specialty – being recommended to be on the GMC Specialist Register (with exceptions for those practicing since before April 2002), a notion which is based on the GMC **Good Medical Practice in Cosmetic Surgery** document from May 2006, confusion reigns as to what the recommendations really mean for many cosmetic doctors now.

When discussed in 2005 it was pointed out that there are many difficulties for cosmetic surgeons currently in private practice to be able to even enrol on the GMC Specialist Register, in order to do so, it was noted that they would need to give up their private practice, find a job in the NHS and work for half a dozen years in order to gain the necessary experience to be placed on the Specialist Register in the specialty of plastic surgery (as cosmetic surgery isn't defined).

Of course there are those who argue that this is how it should be, a GMC Specialist Register listing is a prerequisite for BAAPS membership for example. But, the exemption for those practicing cosmetic surgery prior to 2002 puts them at an unfair advantage over more recently practicing private cosmetic surgeons if this recommendation is relied upon, as they may have limited specialist training or be working outside of their competences with little supervision.

Until cosmetic surgery is defined properly, it's going to be difficult to know where those cosmetic doctors who have chosen to train in and offer more invasive medical aesthetic treatment solutions which don't require a surgical scalpel in the same way as a face lift or breast augmentation do that are performed by main stream plastics/cosmetic surgeons, actually stand in the regulatory landscape.

So now begins another waiting game, with much lobbying by the industry and various stakeholder representatives, whilst we wait to see if the present Government, or the next one with elections due again inside of two years, will

implement any of these recommendations, look more closely at the issues that they raise or simply stick them on the back burner in times of austerity and red tape reform. It's likely that we may even see delays due to the ongoing drafting of the European CEN Standard for *Aesthetic Surgery and Aesthetic Non-Surgical Medical Services* which may be relied upon as a source of standards for any future regulatory requirements drawn up. With a time table which means we won't see that finalised until 2014, I don't think anyone should be attempting to hold their breath!

With many of the recommendations and issues raised being a mirror of some of the concerns highlighted in 2005, it is a little disheartening for many to see that the same problems and inadequacies persist close to a decade later, with the cries for more and better regulation just as vociferous as before.

Lorna Jackson

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She has become an industry commentator on a number of different areas related to the aesthetic industry, collating and evaluating statistics and writing feature articles, blogs, newsletters and reports for The Consulting Room™ and various consumer and trade publications, including *Aesthetic Medicine*, *Cosmetic News* and *Aesthetic Dentistry Today.*
