Department of Health

Government Response to the Review of the Regulation of Cosmetic Interventions

Cm 8776

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Presented to Parliament
by the Secretary of State for Health
by Command of Her Majesty

February 2014

Cm 8776

£6.25

You can download this publication from https://www.gov.uk/dh

ISBN: 9780101877626

Printed in the UK for The Stationery Office Limited on behalf of the Controller of Her Majesty's Stationery Office

02/14 33921 2612862

Printed on paper containing 75% recycled fibre content minimum.

Foreword by Dr Dan Poulter MP, Parliamentary Under-Secretary of State for Health

The Government welcomes the independent report *Review of the Regulation of Cosmetic Interventions*[1] and would like to thank Professor Sir Bruce Keogh, the chairman, and the other members of the Review Committee. We agree with the overwhelming majority of the Review's findings and recommendations.

Few people would fail to have been shocked by the scandal resulting from faulty Poly Implant Prothèse (PIP) breast implants. Most people would have been outraged, as was I, to hear stories of women who were left in fear for their own health after discovering that their breast implants were leaking or that they contained substances that should not have been put in their bodies.

The PIP scandal shone the spotlight on some of the murky practices of a cosmetic interventions industry that is rapidly expanding, having gone from being worth £720m in 2005 to £2.3bn in 2010, and is estimated to rise to £3.6bn by 2015. Cosmetic interventions have gone from being a niche market to a popular norm that is routinely available on many high streets.

This is why the Government commissioned a review of cosmetic interventions, including their clinical safety and regulation.

There are examples of high quality surgical and non-surgical cosmetic interventions provided by trained staff to high standards of care and satisfaction. It is these high standards that should be universal, so that patients, who expect and deserve the highest quality, can be sure to know that they are always getting it. Where there is room for improvement – and this report indicates that there is room for considerable improvement – those providing cosmetic interventions, who are not making the grade must raise their game or face the consequences.

A key focus for the review was to investigate the many and growing number of non-surgical procedures that have become popular in recent years, such as dermal fillers, botulinum toxin and laser hair removal. These account for 9 out of 10 cosmetic interventions and are worth 75 per cent of the market in total.

No longer the preserve of the wealthy few, these procedures are offered in buy-one-get-one-free and group deals, and as competition prizes. Botulinum toxin (commonly known as Botox) is licensed for specific medical conditions. It is not a cosmetic and its inappropriate use can carry risks. Nevertheless, Botox treatments are so easy to come by that they can be done in your lunch break. Cosmetic procedures have permeated popular culture to the extent that characters in TV soaps and reality shows are frequently extolling their virtues in our living rooms.

It is here that patients – who actually think of themselves as consumers – often lack the proper information to make a fully informed choice about cosmetic interventions. At its worst, this is an industry that is exploiting people's insecurities, driven only by profits

1 https://www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions

and with no regard to the physical and mental wellbeing of patients.

So it is hard to believe that, while these procedures can change the way you look temporarily and sometimes permanently, to date there has been virtually no regulation of the industry and no controls over who can perform these treatments or where they are carried out, despite the fact that they can so easily go wrong. Dermal fillers, for example, can lead to bruising and swelling. They can cause gangrene if they block blood vessels. They can even cause permanent damage to your eyesight if used by the untrained.

Anyone having cosmetic surgery should have the right to know their chosen clinic is appropriately regulated, that they are being treated by a qualified person and if things go wrong that they have protection. Their decision to go for the treatment in the first place should be their own and not one influenced by aggressive marketing.

The Government's body confidence campaign[2] is an example of how we are working to support increased resilience to low body image and more informed and confident decision-making; cosmetic advertising should not undermine this.

This paper outlines a range of measures already underway on which we are working with healthcare regulators and patient safety organisations to improve the quality of training and care provided by the industry to practitioners and patients. This is the beginning of a process in which we shall ensure proportionate and appropriate improvements in the industry to better protect the consumers and patients of tomorrow.

2 https://www.gov.uk/government/publications/body-confidence-campaign-progress-report-2013

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HIGH QUALITY CARE AND AN INFORMED AND EMPOWERED PUBLIC

The Government takes careful note of the findings of the Review Committee and agrees with the overwhelming majority of the Review's recommendations. Many of these are about tightening controls already in place, or putting in new systems of control. We want to achieve a proportionate response, underlining what's good in the industry and giving it the nudge it needs to correct its failings and inadequacies. The outcome should be to reassure the public that, through action, the industry can provide patients the high quality of care they are being asked to pay for and so repair the reputation that bad practice has damaged. Many actions to improve care and oversight of practitioners, products and companies in the cosmetic industry are already underway, and we shall also be examining appropriate legislative options where they are necessary.

The Response is structured around four thematic approaches to implementing the main findings of the Review.

The first is around surgical interventions undertaken by highly regulated healthcare professionals. The Parliamentary Under-Secretary of State for Health and Department of Health officials have already begun working with the professional bodies to improve how this is done, setting standards of training, guidance and, in particular, improving the ethical framework for cosmetic practitioners. A particular focus of this work is improving how consent is obtained for cosmetic surgery and to ensure that it is brought into line with good practice in the NHS.

The second theme is around non-surgical interventions, including those which are undertaken by unregulated non-healthcare practitioners. Here the Department of Health will look to strengthen standards through training and qualifications and how far supervision from regulated professionals can support self-regulation of the sector. We agree with the Review's conclusions that people need to be able to identify and choose practitioners with appropriate qualifications, to be able to ascertain in advance skills and experience in practitioners performing a given procedure and that there must be accountability. Again the Department of Health has initiated work around the approach to gaining the consent of those undergoing interventions and we are looking at options particularly in improving supervision of unregulated practitioners by regulated healthcare professionals. This will be underpinned by standard setting by professional bodies, such as the Royal College of Surgeons and the General Medical Council.

The third theme is around safe products and safe use of products. The PIP scandal exposed the lack of co-ordinated record keeping which would have helped to identify those patients who had these implants. The national joint registry gives good data

on implanted hip and knee joints and the Department of Health supports the principle of a breast implant registry, that will not only help us keep a trace of implants being used, but also monitor their performance and safety. We will help establish this with a pilot project. This will be further supported by changes being made to EU legislation on product safety and post-market surveillance of devices. Safe use of products was another concern, particularly the injection of dermal fillers. We've already outlined the intention to improve standards of training and qualification of cosmetic practices and there is a clear need to look at how products are being used in practice and how they can be further controlled, including the need for regulation.

Finally, we want to focus on those undergoing such interventions, to ensure they have access to independent and evidence-based information to help inform their decisions and make better choices when consenting to cosmetic interventions. Redress is a key theme here and we are looking at this in more detail.

These recommendations are being actively discussed with the administrations in Scotland, Northern Ireland and Wales, in view of devolved elements, with an aim of reaching four country support for all aspects of the response to the recommendations.

1. Surgical Interventions

Recommendation 1

The Royal College of Surgeons (RCS) should establish a Cosmetic Surgery Inter-specialty Committee. This should consist of representatives from all the relevant specialty associations and professional associations and societies, including plastic surgery, ENT surgery, maxillofacial surgery, ophthalmology, breast surgery and gynaecology. Its task should be to:

a. **Set standards for the training and practice of cosmetic surgery.**
b. **Make arrangements for the formal certification of all surgeons regarded as competent to undertake cosmetic procedures, taking account of training and experience.**
c. **Establish and oversee a clinical audit database for cosmetic surgery, working with the Healthcare Quality Improvement Partnership (HQIP).**
d. **Work with the Parliamentary and Health Service Ombudsman (PHSO) on dispute resolution (see recommendations regarding accessible resolution and redress).**
e. **Meet the General Medical Council (GMC), Care Quality Commission (CQC), and the Medicines and Healthcare products Regulatory Agency (MHRA) regularly and, when appropriate, with provider representatives, to discuss current issues and share information and intelligence on the quality of care being provided.**
f. **Develop a specific code of ethical practice for cosmetic surgery, in collaboration with the GMC, to include guidance on advertising, insurance requirements and the psychological assessment for patients.**

Recommendation 2

The RCS Inter-specialty Committee should work with the CQC and the new Chief Inspector of Hospitals to ensure that providers follow the standards developed. In the meantime, the Review Committee recommend that only doctors on a GMC Specialist Register should perform cosmetic surgery, and that those doctors

should work within the scope of their Specialty specific training.

Recommendation 3

The RCS Inter-specialty Committee should be responsible for developing clear, credible outcome measures for cosmetic surgery that are published at individual surgeon and provider level on the NHS Choices website.

Recommendation 25

Evidence-based standardised patient information should be developed by the RCS Inter-specialty Committee on Cosmetic Surgery. This should be done with input from patient organisations. This information should be available on NHS Choices and the Parliamentary Health Service Ombudsman (PHSO) website.

Recommendation 26

Patient Decision Aids (PDAs) should be developed for cosmetic procedures and these should be piloted by the RCS Inter-specialty Committee on Cosmetic Surgery.

Recommendation 27

The RCS Inter-specialty Committee on Cosmetic Surgery should develop and describe a multi-stage consent process for operations. This consent process should be undertaken by the operating surgeon and its use should be mandated as part of the Code of Practice.

The Government agrees with the need for the development of standards for the training and practice of cosmetic surgery, providing confidence to the patient that the individual is fit to practise. We also support the recommendation that only doctors on the GMC Specialist Register[3] should perform cosmetic surgery, and that those doctors should work within the scope of their Specialty specific training.

We are pleased that the RCS supports the concept of establishing a Cosmetic Surgery Inter-specialty Committee (CSIC) under the auspices of the College and agrees with the overarching principles in the related recommendations above for the CSIC to set clinical standards for the training and practice of cosmetic surgery. The CSIC has been established and work is underway.

The clinical standards developed will, in due course, be submitted to the GMC for approval as part of a new framework for regulated credentials that the GMC is developing. Credentialing is a system which will enable doctors to demonstrate competences in a particular field of practice and have those competences publicly recognised by the regulator. This system has obvious value in fields of practice such as cosmetic surgery where regulation is limited. It will bring standards for cosmetic surgery within the existing statutory regime, ensure they have universal recognition and are within the structures regulating fitness to practise for all doctors.

The CQC welcomes the Report and will work closely with the RCS and the GMC on these recommendations. In due course they will make sure judgements they make about quality and safety of services take account of whether cosmetic providers reflect good practice promoted by appropriate professional bodies such as the RCS standards.

Valid consent is the key to improving patient care and should be at the heart of a code of ethical practice for cosmetic surgery. Any code would need to fit within the framework

3 http://www.gmc-uk.org/doctors/register/information_on_the_specialist_register.asp

of values and principles that apply to all UK based doctors in the GMC guidance *Good Medical Practice*[4]. Since this code would need to be enforceable, it should be underpinned by existing statutory regulation. The GMC has agreed to lead on this aspect of work, working with the CSIC, and hopes to see completion before the end of 2014.

The Government recognises the importance of and supports the requirement in recommendation 27 for a multi-stage consent process for operations. We believe that the consent process can be undertaken by an operating surgeon rather than the lead operating surgeon (thus conforming to practice in the NHS), but we agree with the principle that the responsibility of obtaining consent should never be delegated to support staff. The GMC guidance *Good Medical Practice* emphasises the importance of giving patients sufficient time to reflect, before and after making a decision, especially if the information is complex or if what is proposed involves significant risks. This requirement can be interpreted as requiring a 'cooling off period', and has been described by others as a two-stage process. Patient Decision Aids (Recommendation 26) play a role here. In due course, CQC will ensure that guidance that they publish about meeting national standards signposts where appropriate to GMC guidance. Judgements that CQC make about the quality and safety of services will take into account whether care and treatment being provided, including consent arrangements, reflects guidance issued by appropriate professional and expert bodies, such as the RCS. CQC can use the fact that RCS guidance has not been followed as evidence of a breach of the registration requirement relating to consent to care and treatment and take appropriate enforcement action against the registered provider in question if within the independent sector or recommend that enforcement action be taken by either Monitor or the NHS Trust Development Authority.

The CQC notes the recommendation regarding the new Chief Inspector of Hospitals. They will make sure that independent healthcare providers are included in new plans to inspect hospitals.

Recommendation 9

The CQC should work with professional organisations to produce inspection guidelines for cosmetic surgery providers.

Full participation in all clinical audit and data collection programmes that have been recommended by the RCS Inter-specialty Committee should be part of CQC registration requirements and full participation by surgeons should be an essential component of their annual appraisal and revalidation. The CQC should use this data and clinical audit findings to analyse outcomes and assess risk, and this data should be used to guide inspection teams.

Risk-based and unannounced CQC inspections should be performed.

The inspection teams should have appropriate expertise and experience in this sector.

CQC are currently reviewing their internal information about cosmetic surgery that is available to support their inspectors. The review will include input and advice from the RCS and other professional organisations.

CQC will work closely with the CSIC so that they establish appropriate data collection requirements sets for the sector. Further work will be necessary to establish full details of the clinical audit and data collection programmes.

CQC currently carries out unannounced inspections and will continue to do so. CQC will also continue to inspect at any time if they

4 http://www.gmc-uk.org/guidance/good_medical_practice.asp

have concerns, or when they do not hold enough information about a service.

CQC is in the process of revising their current inspection methodology. It is anticipated that in future all hospital inspections will include input from specialist advisors. This recommendation therefore fits with the new CQC inspection methodology and the move towards CQC inspectors specialising in the sector that they inspect, including the cosmetic surgery sector.

Recommendation 10

Data on performance should be made publicly available at surgeon and provider level.

The Government agrees that outcome data on providers should enable regulators, professional organisations and the public to judge performance. The CSIC will develop relevant data sets to enable audit and benchmarking of performance in cosmetic surgical procedures.

Recommendation 11

Providers should be required to notify the public on their websites of any CQC inspection concerns or notices.

Regulation 7 and Schedule 2 of the *Care Quality Commission (Registration) Regulations 2009*[5] set out a timeline and circumstances in which CQC must publish details of any enforcement action taken against a registered provider. Although we would strongly encourage providers to publish inspection concerns or notices on their own websites, we believe that the publication of these notices by CQC, in line with their regulations, provides the necessary transparency to enable the public to make informed decisions about the quality of a cosmetic surgery provider. The Government will refresh its patient information to point those thinking of cosmetic interventions to the CQC website before deciding to undergo a treatment.

Recommendation 12

All providers must keep full patient records, including clear operative records and precise details of any implant or device used. Providers should also be able to access data of implant cohorts readily and this should be available to regulatory authorities. Details of the surgery and implant used must be sent to the patient and to the patient's GP.

We think this is a vital aspect of improving cosmetic interventions. The *Health and Social Care Act 2008 (Regulated Activities) Regulations 2010*[6] currently require providers to keep full patient records and to work in co-operation with other providers, such as GPs sharing information to ensure that appropriate care planning and support takes place to protect the health, welfare and safety of service users.

CQC will take account of this when publishing guidance about meeting national standards and when making judgments about the quality and safety of services providing cosmetic surgery.

Recommendation 13

Independent healthcare providers should only allow practising privileges to those cosmetic surgeons who can demonstrate that they have achieved and are able to maintain competence in the procedures which they offer.

We agree with this recommendation which is the current practice. CQC will work closely with the CSIC to ensure that standards developed in relation to the specialist registration and training for surgeons are

5 http://www.legislation.gov.uk/uksi/2009/3112/made

6 http://www.legislation.gov.uk/ukdsi/2010/9780111491942/contents

taken account of in guidance that CQC publish about meeting national standards.

CQC will also ensure that their internal mechanisms for supporting inspectors include information about cosmetic surgery and practising privileges. CQC and GMC will share information if there are concerns about a surgeon.

2. Non-surgical interventions

Recommendation 4

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.

Recommendation 5

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 agrees with the aims of these recommendations to improve and standardise training and supervision of practitioners of non-surgical interventions. It considers that certain non-surgical cosmetic interventions should, to an appropriate extent, involve clinical professionals. Two types of training are being considered, the practice and the supervision of that practice. We will work with the professional regulators to ensure their codes of practice reflect the responsibilities of regulated professionals to both practice and supervise. We are looking at options, including legislation to underpin this, for example through controls on cosmetic interventions, and are not considering any relaxation of the role of clinical professionals. This would bring a greater degree of properly trained professionalism to the industry, where regulated professionals will only wish to supervise properly trained practitioners.

Recommendation 6

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.

Recommendation 14

Those training to be non-surgical practitioners should have a clear understanding of the requirement to operate from a 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.

The Government accepts the principle of these recommendations. HEE will work with regulators, Royal Colleges and other stakeholders to conduct a review of the training and skills needed for non-surgical cosmetic procedures and the qualifications required to be responsible prescribers. This work will be completed by the end of April 2014. As part of the review, HEE may make recommendations on who might be the suitable bodies to accredit qualifications for providers of non-surgical interventions.

Recommendation 28

For non-surgical procedures, a record of consent must be held by the provider.

We agree that this is good practice and that appropriate training should ensure record

keeping is done responsibly. The CQC does not regulate non-surgical cosmetic interventions. We will work with professional and regulatory bodies to ensure that codes of practice are strengthened for responsible professionals.

The GMC's guidance in *Good medical practice* and on *Consent: patients and doctors making decisions together*[7] already require this. The GMC will ensure that the issue is fully covered in the ethical framework for cosmetic surgery. We are working with the other regulators, notably the General Dental Council and the Nursing and Midwifery Council, with a view to supporting them to adapt their frameworks in a similar fashion.

Recommendation 7

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.

Recommendation 8

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.**

We do not believe that a new regulated profession is the only way of improving patient safety by practitioners of non-surgical cosmetic interventions. Many practitioners of non-surgical cosmetic interventions – nurses, dentists and doctors – are already on professional registers. In addition, the GMC's current work to develop credentialing for doctors may enable areas of credentialed competence to be demonstrated. The Government believes clinical involvement in certain non-surgical cosmetic interventions is key in improving standards amongst practitioners who are not members of a regulated profession. In particular, inspired by models of prescription, the treatment should only be carried out by appropriate healthcare professionals or persons who are nominated on the basis of their possession of relevant training and skills for the procedure in question. Legislative options are being explored. In due course, we will be working with the professional regulators with a view to their guidance and standards reflecting this.

3. Ensuring safe products

Recommendation 15

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 device.

The MHRA, an executive agency of the Department of Health, is responsible for the regulation of medicines and medical devices. The regulatory framework for medical devices is largely set at a European level. The UK, like any other EU Member State, must comply with requirements set out in EU legislation.

Proposals to revise the medical devices directives were published by the European Commission in September 2012[8] and are currently under negotiation in the EU through the ordinary legislative procedure. These

7 http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp

8 http://ec.europa.eu/health/medical-devices/documents/revision/

proposals include a change to existing legislation that will mean that certain invasive or implantable devices without a medical purpose will fall within the scope of the new legislation governing medical devices. This is achieved through listing the devices covered in an annex; the Commission's proposal includes:

- implants for modification or fixation of body parts;
- facial or other dermal or mucous membrane fillers;
- equipment for liposuction;
- invasive laser equipment intended to be used on the human body; and
- intense pulsed light equipment.

Whilst the proposals for new legislation are in negotiation and subject to change, early indications are that this particular aspect of the new legislation has support from both the Council of Member States – where the UK has been a strong proponent – and the European Parliament and so is likely to remain in the final legislation. The UK will continue to pursue this during negotiations.

We support the principle that dermal fillers and other non-surgical cosmetic products should be prescription only, or otherwise that there should be control over who may administer them. We are also currently working with the MHRA and at a European level to progress greater product control of fillers and other products.

Recommendation 16

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.

The GPSD is currently under revision as part of the Product Safety and Market Surveillance package of proposals that was adopted on 13 February 2013[9]. The package contains a proposal for an EU regulation on Consumer Product Safety. This proposal extends the previous scope of the GPSD to include those non-food products "which are provided to consumers in the course of a service provision, whether or not the product is operated by the consumer himself." As drafted, the precise scope of the provision is unclear which could lead to uncertainty as to exactly what products are affected and therefore potentially to unintended consequences. The Government is pressing the European Commission for clarity on this point. However, as drafted, we envisage that the provision will bring products used in cosmetic interventions into the scope of the proposal.

Recommendation 17

All European Notified Bodies should be regularly and rigorously assessed and audited, to ensure they all work to the same high international standards; and reports of these assessments should be made public.

The Government agrees with this recommendation. The current regulatory system in the EU can only be as strong as the weakest player and the current requirements on and auditing of notified bodies is inconsistent across the EU.

This is a key area that is being addressed in the revision of the medical devices directives. In negotiations, the UK Government has and will continue to press for more transparency in all aspects of the legislation and will critically examine whether enough is in place specifically in relation to notified bodies.

The Government has worked with the European Commission and other Member States to improve the quality of notified

9 http://ec.europa.eu/consumers/safety/psmsp/

bodies in advance of the new legislation coming into force. As a result, the Commission has published implementing legislation[10] which moved the voluntary programme of joint audits of notified bodies onto a mandatory, statutory footing. Under the new legislation, notified bodies are subject to audits by 'joint assessment teams' comprising of assessors from more than one EU country and the European Commission. Additionally, designation of notified bodies will be limited to a period of five years. This is a significant move to improve the quality of regulators across the EU. The new requirements will be underpinned by greater transparency of notified bodies and their work.

The MHRA was central to the pilot of voluntary audits which took place this year ahead of the Commission's implementing legislation and has been a key contributor to the task force set up to progress these audits. A full programme of joint audits was put in place for the whole of 2013 and the first joint audit took place in the UK during January 2013.

Recommendation 18

There needs to be unannounced inspections of manufacturers of class III and IIb medical devices to ensure production is compliant with the regulations. Reports of such inspections should be made public where possible.

The Government considers that risk based audits are generally the most appropriate of inspections, but unannounced inspections can be an important aspect of the regulatory framework and reduce the risk of fraudulent activities by manufacturers. This is being addressed in the revision of the medical devices EU directives.

However, actions are already being taken to increasing the number of unannounced inspections by notified bodies in advance of the new legislation coming into force. Details of how notified bodies should be conducting audits, with a particular focus on unannounced audits, were set out in the Recommendation published by the Commission in September 2013[11]. Under the Recommendation, unannounced visits should occur at least once every three years, should be no less than one day in length and should be executed by at least two auditors. Additionally, notified bodies can carry out unannounced audits on the manufacturers, on critical subcontractors or on crucial suppliers.

The MHRA will work with UK notified bodies to ensure that the recommendation is appropriately implemented in the UK.

Recommendation 19

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.

Recommendation 20

A system should be developed by the MHRA to link the Unique Device Identifier for all implants to the patient's electronic record, enabling routine collection through Hospital Episode Statistic (HES) data. This information would enable assessment of implant performance, and the tracking and tracing of patients in case of a safety alert. The use of HES in the private sector hospitals which implant devices into people should be a CQC registration requirement.

10 http://ec.europa.eu/dgs/health_consumer/docs/recommendation_ip-13-854_en.pdf

11 http://ec.europa.eu/dgs/health_consumer/docs/regulation_ip-13-854_en.pdf

The new proposed EU regulation on medical devices includes an EU-wide register of medical devices and an intention to bring certain invasive and implantable products without a medical purpose within the scope of the regulation. Therefore, a comprehensive register of cosmetic devices available on the EU market will be in place, as well as information about safety concerns with these devices. The Government will ensure that the new database is implemented as efficiently and effectively as possible.

The incorporation of Unique Device Identifiers (UDIs) into the patient electronic records of all patients receiving implants in England has a number of potential benefits for patient safety and the provision of care. Such a system would:

- facilitate better identification of patients in the event of a safety alert or recall;
- improve post-market surveillance of implants, making it easier to identify long term problems with implants;
- improve incident reporting to/safety monitoring by the MHRA;
- reduce medical errors; and
- improve purchasing policy and stock management by hospitals.

The new legislation on medical devices includes proposals to require UDIs on all medical devices sold in Europe. Whilst relatively little detail has been set out in the proposed legislation, tertiary EU legislation (similar to secondary legislation in the UK) will set out further details about how the UDI requirements will apply to different classes of devices, the organisations that will issue the UDIs, obligations on manufacturers, suppliers and healthcare institutions to maintain UDI traceability records, implementation timescales, etc.

NHS England and Trusts will encourage surgeons and nurses to adopt good practice in recording and reporting use of devices to implement registries and roll-out of UDI. This will provide a model for the private sector to follow.

The CQC is exploring the development of private hospital episode data (PHES) and is considering incentives and levers to encourage independent health care providers to submit such information.

Recommendation 21

Until such a system is developed, a National Breast and Cosmetic Implant Registry should be established and operational within 12 months. All cosmetic surgery providers need to keep a minimum data set that should be defined by the RCS Inter-specialty Group. This should include details of the implant, the surgeon, the hospital and appropriate outcomes, and these data need to be held in electronic format until the registry is operational. These data should be easily accessible in the case of a product recall.

The PIP scandal demonstrated the difficulties with identifying complete cohorts of patients who had received a specific implant. The work on the UDI explained above will go some way to improving the ability to identify patients with specific implants. It will take time to make progress on this at a national level and in the meantime the Government has set up a pilot project for a breast implant registry, which will give us information to go forward with a permanent registry while taking into account issues of patient confidentiality. The focus of this would be to collect data on the safety and integrity of devices, including longer term use and associated complications. This offers an important research opportunity as well as a means of integrating into the forthcoming UDI.

Recommendation 22

The Director of Patient Safety for NHS England should develop a framework to encourage and support the reporting of suspected device failures to the MHRA.

NHS England fully accepts this recommendation and the Director of Patient Safety will develop such a framework.

Recommendation 23

Formal relationships need to be developed between the MHRA, and professional organisations such as the Academy of Medical Royal Colleges and the Specialist Associations whose members implant medical and cosmetic devices and deal with the consequences of failure.

The Government agrees with this recommendation. As a result of recommendations in the *Review of the actions of the Medicines and Healthcare products Regulatory Agency (MHRA) and the Department of Health*,[12] the MHRA now has presence on the safety committees of the RCS, Association of Anaesthetists and the College of Radiologists. The MHRA will attend other key professional safety committees, where they exist, and support other Royal Colleges and societies to create them, if they do not exist.

In addition, in order to increase clinical engagement with adverse incident reporting the MHRA has initiated a new programme to work with professional and representative bodies to create and promote device specific reporting webpages for key procedures involving implantable devices.

The MHRA is also reviewing the functioning of its own Committee for the Safety of Devices to look at whether its existing clinical engagement and advice arrangements can be improved and modified to take further advantage of the best clinical expertise available and improve information exchange with the clinical community.

Recommendation 24

Assessment of systems for reporting adverse events should be part of CQC's registration and assessment of providers. Adverse incident reporting should be a standard component of professional appraisals and revalidation.

We accept this recommendation. It is already the case that providers registered with CQC are required to notify them about certain adverse incidents, for example, including any injury resulting in changes to the structure of a service user's body and the service user experiencing prolonged pain or prolonged psychological harm. A review of "significant events" is already one of the six types of supporting information all licenced doctors have to bring to their appraisal for discussion and reflection as part of revalidation.

As well as adverse incident reporting to CQC, there is a requirement to report adverse incidents relating to medical devices to the MHRA. The MHRA saw an unprecedented rise in adverse incident reporting levels in calendar year 2012 (25%). Increased reporting by manufacturers and, encouragingly, from the private sector primarily drove this increase. There was also increased reporting by members of the public. The MHRA is working in partnership with NHS England to improve medical device governance at trust board level within the NHS and support this with an enhanced Medical Device Liaison Officer role. This partnership will also seek to improve and link the National Reporting and Learning System (NRLS) and the MHRA medical device reporting routes to increase quality and quantity of reporting to both

12 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/152327/dh_134043.pdf.pdf

the MHRA and the NRLS. This work will encourage and provide a framework for an open and fair reporting culture and improved local medical device governance designed to establish best practice for compliance with the relevant CQC registration requirements. This will also involve the MHRA developing new types of aggregated device information to feedback to trusts.

Both the MHRA and GMC have made significant progress towards developing a strong reporting culture. Working alongside the Cosmetic Review Committee, the GMC in partnership with the MHRA made improvements to the *Good practice in prescribing and managing medicines and devices*[13]*.* The guidance includes reference to the need to report medical device adverse incidents to the MHRA. The MHRA are in discussions with the Nursing and Midwifery Council, General Dental Council and Health and Care Professions Council to achieve similar outcomes.

4. Responsible information, resolution and redress

Recommendation 29

The RCS Interspecialty Committee should develop a code of ethical practice developed for all practitioners of cosmetic interventions, and this should include standards to ensure that any advertising is conducted in a socially responsible manner.

Recommendation 30

CAP should extend its guidance note on cosmetic surgery advertising to cover non-surgical cosmetic procedures, and the sponsoring of TV and other programmes.

Recommendation 31

The Review Committee considers that the following advertising practices are socially irresponsible and should be prohibited by the professional registers' codes of practice:

- **Time-limited deals**
- **Financial inducements**
- **Package deals, such as 'buy one get one free' or reduced prices for two people such as mother and daughter deals, or refer a friend**
- **Offering cosmetic procedures as competition prizes.**

We agree with the Review Committee's view that advertising and marketing practices should not trivialise the seriousness of cosmetic procedures.

We agree that socially responsible advertising needs to be included within ethical practices for all providers and practitioners of cosmetic interventions and we believe that the GMC should lead on developing a code for this.

In response to recommendation 30, the Committee of Advertising Practice and the Broadcast Committee of Advertising Practice have published new, expanded guidance on the marketing of cosmetic interventions. The new Help Note[14] is designed to reach a wider audience and to provide guidance which covers the marketing of both surgical and non-surgical procedures. It also specifically addresses a number of issues of concern highlighted in the Review such as responsible advertising claims, the use of 'before' and 'after' photographs and sales promotions.

13 http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp

14 http://www.cap.org.uk/~/media/Files/CAP/Help%20notes%20new/CosmeticSurgeryMarketingHelpNote.ashx

Recommendation 32

Providers and practitioners should provide continuity of care. Patients should be offered appropriate follow-up and after-care, rather than stand-alone procedures.

We agree with this recommendation, which is good clinical practice for responsible professionals. Providers that are currently registered with CQC are required to provide continuity of care. We are working to ensure that this recommendation is taken forward as part of training and accreditation requirements, and appraisal and revalidation.

Recommendation 33

All organisations providing cosmetic surgery should have a doctor on the Board as Medical Director who is professionally accountable for all work carried out by the provider organisation and for its procedures, practices and wider activity.

The Government supports the view that cosmetic surgery organisations need to take corporate responsibility for the clinical practice for which they are responsible and that individual practitioners need to take professional accountability for their own practice. Under current regulations each provider must have a Responsible Officer, a senior doctor who must demonstrate that they have systems in place to ensure that all doctors engaged in cosmetic surgery are providing high standards of care. The Responsible Officer, who will often also be the Medical Director, also has statutory responsibilities for ensuring that all doctors employed by or contracting with the organisation are competent and fit to undertake the duties they are being given.

In June 2013, CQC launched its own consultation, *A new start: Consultation on changes to the way CQC regulates, inspects and monitors care*[15]. This included developing new fundamental standards as part of the requirement for registration with CQC. This would set in law a clear baseline below which care must never fall and will allow CQC to take tough action against a provider that does not meet these standards, including prosecuting individual directors where it can be established that they had neglected their duty to ensure that the basic standards of care are provided.

In July 2013, the Department of Health published a consultation document, *Strengthening corporate accountability in health and social care*[16]. This proposed a new requirement that all Directors of providers registered with CQC must meet a new fitness test. In the *Mid Staffordshire NHS Foundation Trust public inquiry: government response*[17], we announced we will establish a new stronger fit and proper persons test for board level appointments, which will mean that the CQC are able to bar Directors who are unfit from individual posts at the point of registration. This will apply to providers from the public, private and voluntary sectors. Where a Director is considered by CQC to be unfit it could either refuse registration, in the case of a new provider, or require the removal of the Director on inspection, or following notification of a new appointment. Further details will be set out in the response to the consultation on corporate accountability which will be published shortly. We plan to publish the draft regulations for consultation at the same time.

15 http://www.cqc.org.uk/public/sharing-your-experience/consultations/consultation-changes-way-we-inspect-regulate-and-monito

16 https://www.gov.uk/government/consultations/improving-corporate-accountability-in-health-and-social-care

17 http://francisresponse.dh.gov.uk/

Recommendation 34

The remit of the Parliamentary and Health Service Ombudsman (PHSO) should be extended to cover the whole private healthcare sector, including cosmetic procedures and ophthalmology. Providers should offer advice on their complaints procedures to their patients, and where appropriate this advice should be available on their websites.

Recommendation 35

Complaints against providers that are investigated and upheld by the Ombudsman should be publicly available.

The private sector has voluntary redress mechanisms in place, although the coverage of these is more patchy in the non-surgical sector of cosmetic interventions. The Government agrees with the principle that a single, independent point of redress for all privately funded healthcare complaints would increase consumer confidence and improve accessibility. We have begun to explore the role of the Health Service Ombudsman in delivering this, and will undertake further work to ensure the right solution is put in place for providing a more transparent and accessible redress system across the private healthcare sector.

Recommendation 36

All individuals performing cosmetic procedures must possess adequate professional indemnity cover that is commensurate with the type of the operations being performed.

Recommendation 39

The insurance status of all practitioners should be displayed on the practitioner register.

Recommendation 40

In order to ensure that all patients are adequately protected, overseas surgeons operating in this country should have the same level of professional indemnity as UK-based surgeons.

The Government agrees that individuals performing cosmetic procedures should possess adequate professional indemnity cover. In the case of doctors, currently their professional code of practice places a professional duty on them to have adequate insurance or indemnity cover. A failure to have such arrangements in place can potentially lead to fitness to practise proceedings.

The Government intends to lay an order under s.60 of the *Health Act 1999*,[18] which will mean that a regulated health care professional (e.g. doctor, nurse etc.), who is practising other than on a temporary and occasional basis, must have appropriate insurance and/or indemnity cover. A regulatory body can require information on insurance and/or indemnity cover as a condition of registration of the health care professional (and in the case of doctors - obtaining a licence to practise). It will be a decision for the relevant health care regulator as to whether the insurance status of practitioners will be displayed on the relevant professional register. Failure to comply with either the obligation set out in the primary legislation, or with professional rules or regulations made under that legislation can result in fitness to practise proceedings.

These provisions will mean that all surgeons affected by the new legislation, including overseas surgeons practising as such in the UK, should have appropriate cover and both home and cross border patients should be covered. Where the surgeon is from another EU Member State and provides services

18 http://www.legislation.gov.uk/ukpga/1999/8/contents

on a temporary and occasional basis in the UK, then by virtue of the Directive on *Mutual Recognition of Professional Qualifications, EU Directive 2005/36/EC*,[19] they are exempt from requirements relating to, amongst other things, "registration with a professional organisation or body" which a host Member State places on professionals established in its Member State. However, Member States are required to seek a written declaration from the applicant, in advance of the provision of services, to include details of any insurance cover.

The Government is committed to ensuring that patients in the UK are not put at risk by doctors that do not have the necessary knowledge of English. This is why in September 2013, we published the consultation *Language controls for doctors: proposed changes to the Medical Act 1983*[20] to give the GMC additional powers to ensure that, where concerns around the language capability of a doctor arise following registration, it can introduce proportionate language checks as part of the licensing process. The proposals will also enable the GMC to bring fitness to practise proceedings on the grounds of deficient language ability. Following this consultation the Government has laid a draft s.60 Order in Parliament *The Medical Act 1983 (Amendment) (Knowledge of English) Order 2014*[21] seeking to bring these proposals into effect.

Recommendation 37

Device manufacturer risk pools should be established. The Department of Health should work with the EU and industry to help support this. This risk pool would meet the costs of complications or corrective surgery in the event of wholesale problems with a device.

Recommendation 38

Patients' rights should be protected even when a provider goes out of business. Providers of cosmetic surgery must either enter a risk pool or have appropriate insurance/financial arrangements to provide treatment following certain complications. The NHS should be able to recoup costs for management of certain complications following cosmetic procedures if the provider has been found to have failed the patient following surgery. A similar arrangement already exists following motor vehicle accidents.

The Government agrees with the principle that patients should have recourse to financial compensation if they have been harmed by a practitioner, provider or product and insurance and indemnity arrangements provide for this. For cover where providers have gone out of business, some professional bodies have begun developing such products with the insurance industry and we will discuss the possibility of extending products as widely as possible across the cosmetics sector.

We are sympathetic to the principle of empowering the NHS to recoup costs for management of certain complications following cosmetic procedures. This raises a number of complex issues which will need further consideration before we would be in a position to consider whether to legislate to accomplish this.

19 http://ec.europa.eu/internal_market/qualifications/policy_developments/legislation/index_en.htm

20 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/237302/language_controls_doctors_consultation.pdf

21 http://www.legislation.gov.uk/ukdsi/2014/9780111108932

CONCLUSION

This Review lays bare the problems associated with cosmetic interventions and the Government is determined to act to help the sector make improvements to patient care. Work on a number of recommendations is already underway, such as strengthening the involvement of clinical professionals in non-surgical interventions, improving training for providers of Botox or dermal fillers and improving standards for cosmetic surgery. Some of the measures in the paper indicate a need for legislation; we are looking at where this might be needed and at the most appropriate legislative options. There are good practitioners and providers working in the cosmetics industry already, but we are clear that this needs to become the norm.

We accept the review findings that:

- the responsibility of prescribing professionals should be emphasised by professional regulators in their codes and action taken if practice does not conform to expectations;
- those administering and supervising cosmetic interventions should be appropriately trained and accountable. Non-healthcare practitioners administering cosmetic interventions should be properly trained and, where appropriate, work under the supervision of a regulated professional;
- the products used in cosmetic interventions should be more closely controlled and monitored;
- to begin with, breast implants, but eventually all implanted devices including dermal fillers, should be monitored; and
- those who choose to undergo a cosmetic intervention should have access to all the relevant information in order to give informed consent and have recourse to adequate redress in the event of something going wrong.

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ISBN 978-0-10-187762-6