



Review of the Regulation of Cosmetic Interventions

Call for Evidence

Review of the Regulation of Cosmetic Interventions

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Review of the Regulation of Cosmetic Interventions

Call for Evidence

Prepared by the Department of Health

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Introduction

The recent events surrounding Poly Implant Prothèse (PIP) silicone breast implants raised significant concerns about the safety and well-being of women who had received these products. The PIP Expert Group has assessed all of the available evidence and provided clear advice to ensure that those women affected are offered the appropriate careⁱ. Furthermore the review by Earl Howe has examined the response of the Department of Health and the Medicines and Healthcare products Regulatory Agency (MHRA) to the issue and made recommendationsⁱⁱ.

However, the PIP case has shone the spotlight on cosmetic surgery and other cosmetic interventions in general, including their clinical safety and regulation. It led to serious questions being asked about the regulation of cosmetic surgery and other high risk cosmetic treatments – for example, why the EU regulatory system had not detected the PIP fraud earlier; why it was difficult to reliably trace people who had received cosmetic implants; whether the private cosmetic sector is properly regulated; whether vulnerable people are put under excessive pressure to undergo cosmetic procedures and whether they are properly informed about the risks.

In light of these concerns, on 11 January 2012 the Secretary of State for Health announced in Parliament that Sir Bruce Keogh would convene a group of experts to look at how the safety of patients considering cosmetic interventions can be better ensured in future. The review is expected to cover surgical cosmetic interventions such as breast augmentation, and non-surgical cosmetic interventions such as injectable dermal fillers. It will consider a wide range of issues such as regulation and clinical governance, information and consent and outcomes-based registers. This review aims to provide recommendations to government on the appropriate arrangements required to ensure patients receive the protection they need when accessing cosmetic services and interventions.

This call for evidence enables all interested parties to feed in their views for Sir Bruce Keogh's Review Committee to consider.

Scope of the Review

Cosmetic interventions are described as: “operations or other procedures that revise or change the appearance, colour, texture, structure, or position of bodily features, which most would consider otherwise within the broad range of ‘normal’ for that person.”

The interventions to be considered for the purpose of this review could potentially include:

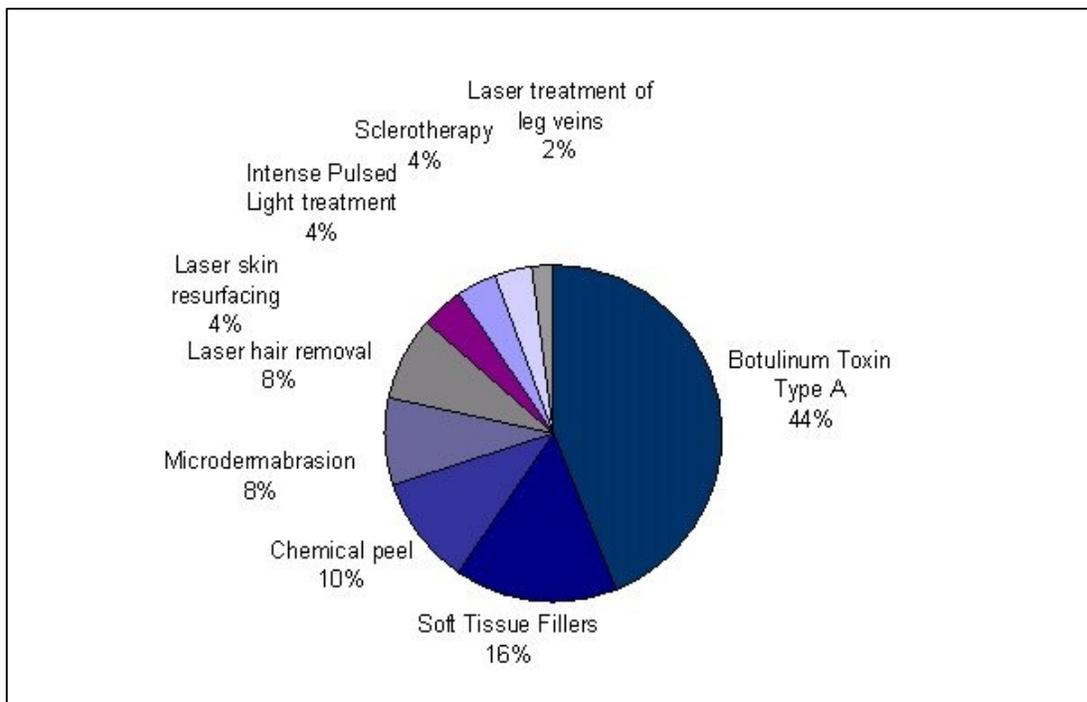
- a) the surgical insertion of a medical device or prosthesis, or other surgery intended to change the appearance of the body,
- b) injection with any product, whether medicinal or otherwise,
- c) any other form of intervention at the discretion of the review team,

where the intervention is not clinically indicated to safeguard or improve the physical and mental health of the recipient. The review does not cover surgery that is clinically indicated, such as reconstructive surgery for a breast cancer patient following a mastectomy.

1. Background

- 1.1. Cosmetic surgery interventions have increased substantially over the last decade. Data from the British Association of Aesthetic Plastic Surgeons (BAAPS) suggest that the number of cosmetic surgery procedures carried out by their members increased from 38,274 in 2010 to 43,069ⁱⁱⁱ in 2011 – an increase of 12.5%. As BAAPS represent about a third of UK cosmetic surgeons, the true number of operations could be around three times as many.
- 1.2. Cosmetic surgery represents only one part of the sector. Mintel estimate that over 90% of cosmetic interventions are non-surgical such as botulinum toxin injections (e.g. Botox®) and injectable dermal fillers and that these amount to 74% of market value of the sector^{iv}. The UK cosmetic interventions industry is sizable. It is estimated that the industry was worth £2.3bn in 2010^v and is forecast to continue to grow. The breakdown of non-surgical cosmetic interventions in figure 1 is based on US data due to a lack of available statistics in the UK.

Figure 1: Non-surgical procedures carried out in the US, % by type 2009



Source: American Society of Public Surgeons/Mintel^{vi}

Clinical risk of cosmetic interventions

- 1.3. The clinical risks associated with a procedure vary depending on the particular procedure. For example, any surgery (cosmetic or clinical) carries risk of complications. Advice from the Royal College of Anaesthetists is that the risk of anaesthetic mortality in healthy adults is of the order of 1 in 100,000^{vii} to 1 in 250,000^{viii}.
- 1.4. Other procedures such as botulinum toxin injections also carry risks – these are considered to be smaller but are more difficult to quantify. The license (marketing authorisation) for a botulinum toxin injection will list the side effects that the product may have.
- 1.5. Information on the safety of products falling outside medicines and medical device legislation is difficult to assess. For products classed as cosmetics, products are deemed to be safe if they comply with the safety levels laid down in legislation. The safety of products that are neither medical nor cosmetic is assessed under the general provisions of the General Product Safety Directive (2001/95/EC) but only where these products could reasonably be considered to be used directly by a consumer.

2. Examples of Cosmetic Interventions

- 2.1. The following are examples of cosmetic interventions (surgical and non-surgical) that illustrate the current regulatory framework around:
- the product
 - the practitioner
 - the organisation
 - patient consent, information and advertising
- 2.2. More information on different cosmetic procedures can be found on the Department of Health website^{ix}.

Breast Implants (a surgical intervention)

Purpose

- 2.3. To enlarge the breasts.

The treatment

- 2.4. Breast implants involve surgery and the treatment normally takes around one hour. The procedure usually involves a general anaesthetic, although some surgeons use a combination of local anaesthetic and sedation. The surgeon makes a small cut underneath the armpit, beneath the nipple, underneath the breast or in the abdomen before inserting the implant. The cuts are then stitched up. Most surgeons will require the patient to stay overnight at the hospital or clinic.

Risks

- pain
- bleeding and haematoma
- infection
- scarring +/- abnormal scarring
- altered nipple sensation

- interference with mammography
- asymmetry +/-Synmastia
- capsule and capsular contracture
- rupture
- seroma
- silicone bleed/ migration and granulomas

Product

- 2.5. The breast implant (a medical device) must carry a CE (Conformité Européenne) marking which is affixed by the manufacturer and its appropriateness checked by an EU notified body. The CE marking is authorised for use on a product that has been assessed as meeting the relevant essential requirements. Once CE marking has been awarded the product can be marketed in all EU countries without further controls. The manufacturer must have in place a relevant post-market surveillance programme to assess long-term safety and performance, the data from this feeding back into the risk assessment.
- 2.6. The great majority of breast implants are made from a silicone elastomer shell filled with either saline or silicone.

Practitioner

- 2.7. Breast augmentation can only be carried out by a qualified doctor. A doctor does not necessarily have to be a surgeon to carry out cosmetic surgery unsupervised outside of the NHS, nor be on the Specialist Register or if on the Specialist Register have a registered entry that refers to cosmetic practice or similar. The only legal requirement is that doctors should be fully registered. Ethical guidance from the GMC ("Good Medical Practice")^x makes clear that doctors are expected to practise only in the clinical fields in which they are competent, but at present this competence is self-assessed and exceptions will only be brought to the attention of the regulator (the General Medical Council or General Dental Council) if a complaint is made. This also applies to nurses and midwives.
- 2.8. However, the introduction of medical revalidation from December 2012 will see doctors' competence assessed by an annual appraisal for which they will need to provide evidence of satisfactory practice including feedback from patients and colleagues, evidence of continuing professional development, reviews of complaints and relevant information about clinical outcomes. More information on medical revalidation can be found below. Similarly, insurance cover and practising rights in a private hospital may be difficult to secure for doctors working outside their competence.

Organisation

- 2.9. Because breast augmentation is a surgical procedure and therefore a regulated activity, the hospital or provider for whom the doctor works will be regulated by the Care Quality Commission (CQC). The organisation will therefore need to meet the CQC registration requirements set out on page 48.

Consent, Information and Advertising

- 2.10. It is a legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation or providing personal care for a person^{xi}. As part of this, the patient must have access to appropriate information to give informed consent. The content of information resources is covered by general Consumer Protection and Advertising legislation stating that they must not be misleading.

Dermal fillers (a non-surgical intervention)

Purpose:

- 2.11. To plump up fine lines, wrinkles, some scarring, and augment the lips by restoring volume and definition.

The treatment

- 2.12. The practitioner injects the filler in a series of small injections and the area gently massaged. Some treatments require the application of a local anaesthetic cream, and others which are carried out by doctors or dentists may be performed using nerve block anaesthesia. The treatment time can vary between 30 minutes to an hour.
- 2.13. The area may be a little swollen and tender for 24 hours and during that time you should avoid coffee, alcohol, hot drinks and the sun.

Risks:

- a small risk of allergic reaction to the filler
- bruising of the treated area/ bleeding
- scarring
- asymmetry/poor cosmetic result
- recurrence of cold sores
- bacterial infection

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- fillers are a single use item, and part-used syringes should not be reused
- skin necrosis

Product

- 2.14. Dermal fillers are made from a variety of materials and the effects can be either temporary or permanent, depending on the type of filler. Dermal fillers may or may not be regulated as medical devices depending on whether they are claimed to have a medical purpose or not.

Dermal fillers classified as medical devices

- 2.15. Any fillers placed on the market as medical devices must meet the requirements of the Medical Devices Directive. Such materials must be CE-marked, which indicates that the manufacturer has verified that the product will not compromise the clinical condition or the safety of patient when used under the conditions and for the purposes intended, and that any risks are acceptable when weighed against the benefits anticipated from the clinical use intended by the manufacturer.

Dermal fillers not classified as medical devices

- 2.16. Dermal fillers placed on the market not as medical devices may fall within the scope of the General Product Safety Directive (2001/95/EC) but only if those products are sold to the consumer for self-use. It should be noted that products supplied as part of a professional service are not yet covered by the General Product Safety Regulations but the provision of such services may be covered by the Health and Safety at Work etc Act, 1974.
- 2.17. There are dermal fillers derived from collagen, some which come from a bovine source and some from porcine. Other fillers are synthetically produced in a laboratory and are derived from hyaluronic acid. Fillers derived from both collagen and hyaluronic acid are temporary biodegradable products which last 3-9 months depending on the product and the amount used. Fillers made using collagen will require a skin test whereas fillers made from hyaluronic acid will not.

Practitioner

- 2.18. Dermal fillers can be administered by non-healthcare professionals. This will be covered by the general provisions of the Health and Safety at Work etc Act.

Organisation

- 2.19. If the organisation falls outside of the scope of CQC registration (ie it does not provide any regulated healthcare services), it will still be covered by the Health and Safety at Work legislation.

Consent, Information and Advertising

- 2.20. It is a legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation or providing personal care for a person^{xii}. As part of this, the patient must have access to appropriate information to give informed consent. The content of information resources is covered by general Consumer Protection and Advertising legislation stating that they must not be misleading.

Botulinum toxin injection (a non-surgical intervention)

Purpose

- 2.21. Some botulinum toxin injections have been licensed for cosmetic use on glabellar lines (the vertical lines between the eyebrows), where the severity of the lines has an important psychological impact for the patient. Botulinum toxin is also sometimes used 'off-licence' on wrinkles around the eyes, and on the lower part of the face and neck, often in combination with dermal fillers.

The treatment

- 2.22. When a person smiles or frowns, this is a result of a nerve signal from their brain to their muscles causing the muscles to contract. Botulinum toxin is a purified protein that blocks this signal from brain to the nerve endings. This means that when a person laughs or frowns, the overlying skin becomes smoother and unwrinkled while the untreated facial muscles work normally, and facial expressions are unaffected.
- 2.23. The skin is first cleaned and then small amounts of botulinum toxin are injected into the area to be treated.

Risks/side effects

- drooping of the eyelid
- swelling of the face/eyelid
- mild inflammation of the cornea
- difficulty in completely closing the eye
- overflow of tears
- dry eyes and sensitivity to light

- dizziness
- blurred vision
- weakness of the facial muscles^{xiii}

Product

2.24. Botulinum toxin. Trade names include Botox®, Vistabel®, Xeomin, Bocouture, Azzalure, Dysport® and Neurobloc®. Botulinum toxin injections are a prescription-only medicine and will have been granted a Marketing Authorisation from the MHRA or another EU Regulatory Authority. The Summary of Product Characteristics (SPC) details the safety and efficacy of a medicine, and lists the known adverse reactions.

Practitioner

Prescribing

2.25. As a prescription-only medicine, a botulinum toxin injection needs to be prescribed by a healthcare professional who is registered as an independent prescriber. Their respective professional standards detail their prescribing responsibilities. Some brands of botulinum toxin – for example Xeomin, Dysport® and Neurobloc® - are not licensed for cosmetic use. Practitioners have a responsibility to explain that these medicines are not licensed for cosmetic use and ensure that the patient understands this. Some brands of botulinum toxin - Botox®, Vistabel®, Bocouture and Azzalure - have been licensed for cosmetic use on glabellar lines (the vertical lines between the eyebrows).

Administration

2.26. Botulinum toxin injection can be administered by a physician or other appropriate practitioner; or administered by anyone acting in accordance with the directions of an appropriate practitioner. On the latter point, the responsibility lies with the appropriate practitioner even if the product is administered by a third party. If the individual administering the product is a doctor, nurse, dentist or pharmacist, then they need to follow their appropriate professional standards. If the product is administered by an individual who is not a health professional, then the individual is not covered by professional standards. Some botulinum toxin injections state in their Summary of Product Characteristics (SPC) that they must be administered by a physician. The administration of these products by a non-physician would be using the product outside the terms of its licence, known as 'off-label' use.

Organisation

- 2.27. The subcutaneous injection of a substance or substances for the purpose of enhancing a person's appearance is explicitly exempt from regulation with CQC. If the organisation falls outside of the scope of CQC registration (ie it does not provide any regulated healthcare services), it will still be covered by the Health and Safety at Work legislation.

Consent Information and Advertising

- 2.28. It is a legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation or providing personal care for a person^{xiv}. As part of this, the patient must have access to appropriate information to give informed consent. The content of information resources is covered by general Consumer Protection and Advertising legislation stating that they must not be misleading.

Chemical Peel (a non-surgical intervention)

Purpose

- 2.29. To improve the appearance of the skin, correct the appearance of facial blemishes, and to reduce the effects of smoking and sun exposure. Peels can also be used for reducing uneven pigmentation, acne and acne scarring.

The treatment

- 2.30. A chemical peel is designed to accelerate the removal of old, dead skin cells at the surface of the skin to promote new cell growth, and can be used to treat a particular area (such as lines around the eyes or mouth), or all over the face, arms, hands and neck. Chemical peels can take anything from a few minutes to over thirty minutes, depending on the type of peel. There are three types of peel: superficial, medium, or deep.
- 2.31. Deep peels penetrate deeper into the lower part of the dermis. They are performed using phenol (a strong form of TCA) and may require a local anaesthetic and sedative. The peel is applied to the face, and the treatment feels as if the face is 'freezing'. The peel may be left on the face for up to 30 minutes or more, depending on the desired effect.
- 2.32. Post peel pain is treated with painkillers. There will be some peeling, redness and discomfort for a few days depending on the type of peel used. Most of the swelling should disappear within 14 days, although there may be some redness of the skin for some time after that – up to three months in some cases. A deep peel is a 'one-off' treatment with lasting effects, unlike superficial and medium peels.

Risks (becoming more common as the peel becomes deeper):

- infection
- skin colour changes
- scarring
- altered sensation and texture

Product

- 2.33. As chemical peels fall outside of the Cosmetic Products (Safety) Regulations 2008 (CPSD), they may fall within the scope of the General Product Safety Directive (2001/95/EC) but only if those products are sold to the consumer for self-use.
- 2.34. Deep peels are performed using phenol (a strong form of TCA) and may require a local anaesthetic and sedative.

Practitioner

- 2.35. As the product is not a medicine or medical device, it can be administered by non-healthcare professionals^{xv}. This will be covered by the general provisions of the Health and Safety at Work Act.
- 2.36. It is recommended that deep peels are carried out by a surgeon or dermatologist with relevant skills and experience in an establishment registered with the CQC^{xvi}.

Organisation

- 2.37. This is covered by the general provisions of the Health and Safety at Work Act.

Consent, Information and Advertising

- 2.38. It is a legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation or providing personal care for a person^{xvii}. As part of this, the patient must have access to appropriate information to give informed consent. The content of information resources is covered by general Consumer Protection and Advertising legislation stating that they must not be misleading.

Laser hair removal

Purpose

- 2.39. To remove facial and body hair.

The treatment

- 2.40. Hair follicles are heated using the laser beam. This damages the hair follicle, which reduces the hair growth and thickness over time. Each treatment may take between 15 minutes to over an hour. The patient's eyes should be protected with specially designed goggles during the treatment and there may be a certain amount of pain and skin irritation.
- 2.41. The number of treatments needed will depend on the area to be treated, the type of hair (ie colour and thickness) and the system which is used – different systems will work differently on different skin types and hair colours. In addition, the laser and IPL beam only works on hair follicles which are actively growing at the time of the treatment – and hair will continue to grow from follicles which are not active at the time of the treatment. This means that a course of treatments may be needed before the area is fully clear of hair. The duration of this course of treatments may be up to a year.
- 2.42. Intense Pulsed Light (IPL) systems can also be used for hair removal. Although these sources of light are different to laser beams in that laser beams are more concentrated, they work in the same way as a laser beam when removing hair.
- 2.43. The patient will need to avoid sun exposure / tanning before and after the treatment.
- 2.44. Long-term – but not permanent – hair removal can be achieved with lasers, IPL and LHE machines. Further courses of treatment may be needed if hormonal changes cause hair regrowth, or if hair follicles which were dormant at the time of the course of treatment become active and grow new hair.

Risks

- 2.45. Laser and Intense Pulse Light Source (IPLS) or Intense Pulsed Light (IPL) treatments may include the following risks:
- the treated area may become red and a raised rash may be present which should resolve over 24 hours. Occasionally patients have permanent skin reactions
 - patient/user skin abrasion, including burn

Product

- 2.46. A class 3b laser used for this type of non-surgical treatment would be CE-marked as a medical device since it can be used for surgical procedures. An IPL would not generally be CE-marked as a medical device, as they are usually used for non-surgical procedures.

Practitioner

- 2.47. Treatments using both laser and IPL can be administered by non-healthcare professionals, eg beauticians. This will also be covered by the general provisions of the Health and Safety at Work Act.

Organisation

- 2.48. There is no uniform regulatory or cosmetic clinic licensing scheme in England. The majority of London councils exercise some form of their licensing powers, requiring the provider to apply for a 'Special Treatments License'. In these cases providers must comply with a code of conduct, covering access to expert advice, staffing, maintaining a register, safety, qualifications and maintenance of equipment.
- 2.49. Organisations providing laser and IPL hair removal will also be covered by the general provisions of the Health and Safety at Work Act.

Consent, Information and Advertising

- 2.50. It is a legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation or providing personal care for a person^{xviii}. As part of this, the patient must have access to appropriate information to give informed consent. The content of information resources is covered by general Consumer Protection and Advertising legislation stating that they must not be misleading.

3. Summary of questions asked in this call for evidence

3.1. When addressing the questions posed in this call for evidence, it would be helpful if the following principles of Better Regulation^{xix} were considered:

- can satisfactory outcomes be achieved by alternative, self-regulatory, or non-regulatory approaches or is regulation necessary?
- does an analysis of the costs and benefits demonstrate that the regulatory approach is superior by a clear margin to alternative, self-regulatory or non-regulatory approaches?
- can the regulation and the enforcement framework be implemented in a fashion which is demonstrably proportionate, accountable, consistent, transparent and targeted?

3.2. It would also be helpful to have, where they exist:

- examples of problems that have occurred under the current system, or where weaknesses in the current system mean there may be a risk of problems occurring;
- information on the potential costs and benefits of different options for action.

Regulation of medical devices and implants and other products

1. What are the risks and benefits presented by dermal fillers?
2. What clinical evidence might be required to regulate dermal fillers (with no claimed medical purpose or benefit) under the existing medical devices regulations?
3. Are any further changes needed to the categories of devices and implants subject to regulation in addition to the likely changes set out above?
4. Are there any other areas where additional strengthening of the regulatory system is required that will not be addressed in the forthcoming revision of the medical devices legislation?
5. Earl Howe's review of the actions of the MHRA and Department of Health in relation to PIP silicone breast implants^{xx} recommended that this review should 'examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery. Routine incident reporting and review of outcome data by individual

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

Regulation of practitioners

6. Is there evidence that the current requirements for doctors practising cosmetic surgery are insufficient? Should all cosmetic surgeons be required to have specialist training, ie be on the Specialist Register?
7. Currently ‘cosmetic surgery’ is not recognised as a specialty for which doctors can train and achieve a Certificate of Completion of Training (CCT) leading to inclusion on the Specialist Register. Is there evidence to suggest a need to introduce a new Specialty for ‘Cosmetic Surgery’ or are there alternatives, such as a different form of training, eg credentialing, that would demonstrate competence?
8. Do people who deliver cosmetic interventions like fillers, Botox®, laser treatments or chemical peels, have the appropriate skills to deliver them? How could their performance be monitored?
9. Earl Howe’s review of the actions of the MHRA and Department of Health in relation to PIP silicone breast implants^{xxi} recommended that this review should ‘examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery. Routine incident reporting and review of outcome data by individual surgeons and providers should be the norm.’ How can medical revalidation be used to promote this?
10. Should practitioners be required to ensure that records of all cosmetic interventions are kept? This is generally done for implants but is it reasonable to do for other devices such as dermal fillers?

Regulation of organisations providing cosmetic interventions

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

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13. Do you think the existing regulation of lasers and lights is proportionate to the risks they present with regard to cosmetic interventions?
14. Should providers of surgical cosmetic interventions be required to audit their processes and ensure that all their practitioners take part in clinical audit?
15. Should providers of non-surgical cosmetic interventions delivered in non-healthcare settings, for example beauticians administering dermal fillers or laser hair removal, be required to audit their processes and ensure that all their practitioners take part in clinical audit?
16. Should providers be required to ensure that records are kept on the implants and devices they implant? If so, for how long?

Questions on insurance and indemnity requirements

17. Should providers be required to take out an adequate indemnity arrangement and/or to participate in a bond arrangement such as provided by ABTA in the travel industry? If so, for how long?
18. How could cosmetic surgery organisations make it easier for patients to access their health records?
19. What can be done to protect patients if their provider goes out of business?

Questions on consent, information and advertising for cosmetic interventions

20. What more, if anything, is needed to ensure that people have the information and time they need to give informed consent? Is sufficient weight given to the psychological assessment of the individual?
21. Should providers be required to carry out a two-stage consent process (i.e. allowing a 'cooling-off' period between consultation and surgery)?
22. Do you think the existing regulation of the advertising of cosmetic interventions is proportionate? 1
23. Is there evidence that advertising on cosmetic interventions needs to be regulated using a different system used for general products and services?
24. What is your view on the use of incentives to promote the sale of cosmetic interventions (such as time-limited price offers)?

A national implant registry

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

Specific sectors/forms of treatment

- 26 Are there any specific forms of treatment or sectors which you think should be subject to more (or less) regulation than at present? Examples include surgical body modification eg tongue splitting; body enhancement implants; cornea tattooing and jewel implants into the cornea.

4. The regulation of medicines, medical devices and other cosmetic products

4.1. Medicines are defined as:

- any substance used for the treatment or prevention of disease, or
- any substance that may be used or administered with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

4.2. Medical devices are all healthcare products, other than medicines, used for the diagnosis, prevention, monitoring and treatment of disease, injury or disability. Some examples of medical devices are hip implants, breast implants and heart pacemakers. The full definitions as set out in legislation follow.

4.3. 'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception

4.4. and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

4.5. 'Active medical device' means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

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- 4.6. 'Active implantable medical device' means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.
- 4.7. Medicines and medical devices bring widespread benefits for patients and the public, but no product is free of risk. Regulatory decisions therefore involve weighing risks of harm against the likelihood of benefits and determining whether the risks that exist are outweighed by the benefits that the medicine or device brings. The risks must be acceptable in relation to the potential benefits to patients and users.
- 4.8. Medicines and medical devices are regulated under separate regulatory systems. In summary, the main difference between how medicines and medical devices are regulated lies in how a product gets onto the market. All medicines are directly approved by the MHRA which issues a 'marketing authorisation', (formerly known as a product licence) or 'certificate registration' (granted to homeopathic or traditional herbal medicinal products).
- 4.9. Medical devices are approved by private sector organisations called 'notified bodies'. Their approval is needed before a CE marking can be put on the device, though the manufacturer of low risk devices simply registers in the Member State in which they (or, for non-EU manufacturers, their representative), is based. The MHRA audits the performance of UK notified bodies. Manufacturers can use any of the notified bodies who have been designated across Europe. More detail is given below.

The legal framework for medicines regulation

- 4.10. Medicines are regulated under European Community (EC) legislation Directive 2001/83/EC relating to medicinal products for human use, amended by Directives 2002/98/EC, 2003/63/EC, 2004/24/EC and 2004/27/EC.
- 4.11. In simple terms, a marketing authorisation or certificate of registration from the MHRA is required before any medicine can be placed on the market in the UK. If no suitable licensed medicine is available then an unlicensed product can be used but only in very limited circumstances. To begin the licensing process, companies and/or researchers must apply to the MHRA for permission to test drugs through clinical trials, if these trials are to be conducted in the UK. In order to receive permission to run a trial, they must first satisfy the MHRA that they have met strict safety criteria. All the test results from these trials on how well the medicine works and its side effects, plus details of what the medicine contains, how it works in the body, and who it is meant to treat, are then sent to the MHRA for detailed assessment.
- 4.12. Once the MHRA is satisfied that the medicine works as it should, and that it is acceptably safe, it is given a marketing authorisation. The company and any

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wholesalers must also be able to satisfy the MHRA that the manufacture, distribution, and supply of the medicine meet the required safety and quality standards. Companies which manufacture, import or wholesale medicines are required to hold a licence from the MHRA for that purpose.

- 4.13. The safety of a medicine continues to be monitored after it has been granted a license. The main way in which the MHRA monitors medicines' safety is to collect reports of possible or suspected side effects from patients and health professionals. These reports are made on 'Yellow Cards' which are available from multiple sources, including the MHRA website. Marketing Authorisation and Registration Holders also have a legal obligation to pass on reports that they receive about suspected side effects of their products that are defined as serious.
- 4.14. All reports of suspected adverse reactions are evaluated on a weekly basis to find possible new safety issues as well as other new information on the possible side effects of medicines. The MHRA also evaluate information on medicines' safety from other data sources from the United Kingdom and from around the world, including published literature, study reports and data or assessments from other medicines regulators. When necessary, we will take action to ensure that the medicine is used in a way that minimises risk and maximises benefits to the patient.

The legal framework for medical device regulation

- 4.15. Medical devices are regulated under the provisions of a number of EU Directives, covering different categories of medical device. The overarching legislative framework for medical devices is part of the EU's 'New Legislative Framework', which is concerned with facilitating operation of the single market in various areas of product legislation. The principles of this Framework are common across a number of sectors; they are used, for example, in relation to the safety of toys and personal protective equipment. The relevant EU Directives are translated into Medical Device Regulations in UK law.
- 4.16. Broadly, these regulations bring into UK law EU Directives that set out:
 - how device manufacturers must ensure that the devices they manufacture are safe and fit for purpose;
 - how products are certified prior to marketing;
 - who is able to undertake certification;
 - how marketed devices should be registered;
 - how incidents involving death or serious deterioration of health related to devices must be reported by manufacturers to the competent authority (in the UK, the Medicines and Healthcare products Regulatory Agency – MHRA);

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- what the competent authority must do with that information; and
 - how the competent authority can inspect, monitor, investigate and enforce compliance with the regulations.
- 4.17. Under the Medical Device Directives, devices are placed into four categories according to risk – classes I, IIa, IIb and III – where class I is the lowest and class III the highest risk. Examples of the types of device in each category are:
- Class I – a sticking plaster; a pair of spectacles
 - Class IIa – disposable contact lenses, syringes
 - Class IIb – dermal fillers, gastric bands, lasers
 - Class III – breast implants; hip joints.
- 4.18. A manufacturer of class I devices can self-certify conformity with the essential requirements, whereas all other devices will require assessment by an independent third-party organisation, known as a notified body, of which there are around 80 across Europe.

The role of the competent authority

- 4.19. Central to EU medical device regulation is the concept of the ‘competent authority’. In the UK, the Medicines and Healthcare products Regulatory Agency (MHRA) is the competent authority and has a number of responsibilities for the regulation of devices and promotion of medical device safety. In addition, if a manufacturer decides to conduct a clinical trial on their product to obtain data to support the CE marking process, they must seek the approval of the relevant competent authority before the trial can commence.
- 4.20. Competent authorities are responsible for authorising and regularly auditing the performance of notified bodies. A key role of the competent authority is to ensure that the notified bodies have the appropriate technical competence to be able to cover the product scope for which they have been designated. Routine monitoring of notified bodies by the MHRA involves two processes – office audits and witnessed assessments.
- 4.21. Office audits generally focus on specific client files, reviewing the complete process from receipt of application, assignment of assessors, reports and issue of certificates. For high-risk devices such as implants, the audit team will include technical and clinical experts to support the assessment. In witnessed assessments the focus is in ensuring that the assessor has the right level of competence and fully addresses all the issues found during their assessment. Any issues in either audit process are highlighted, with

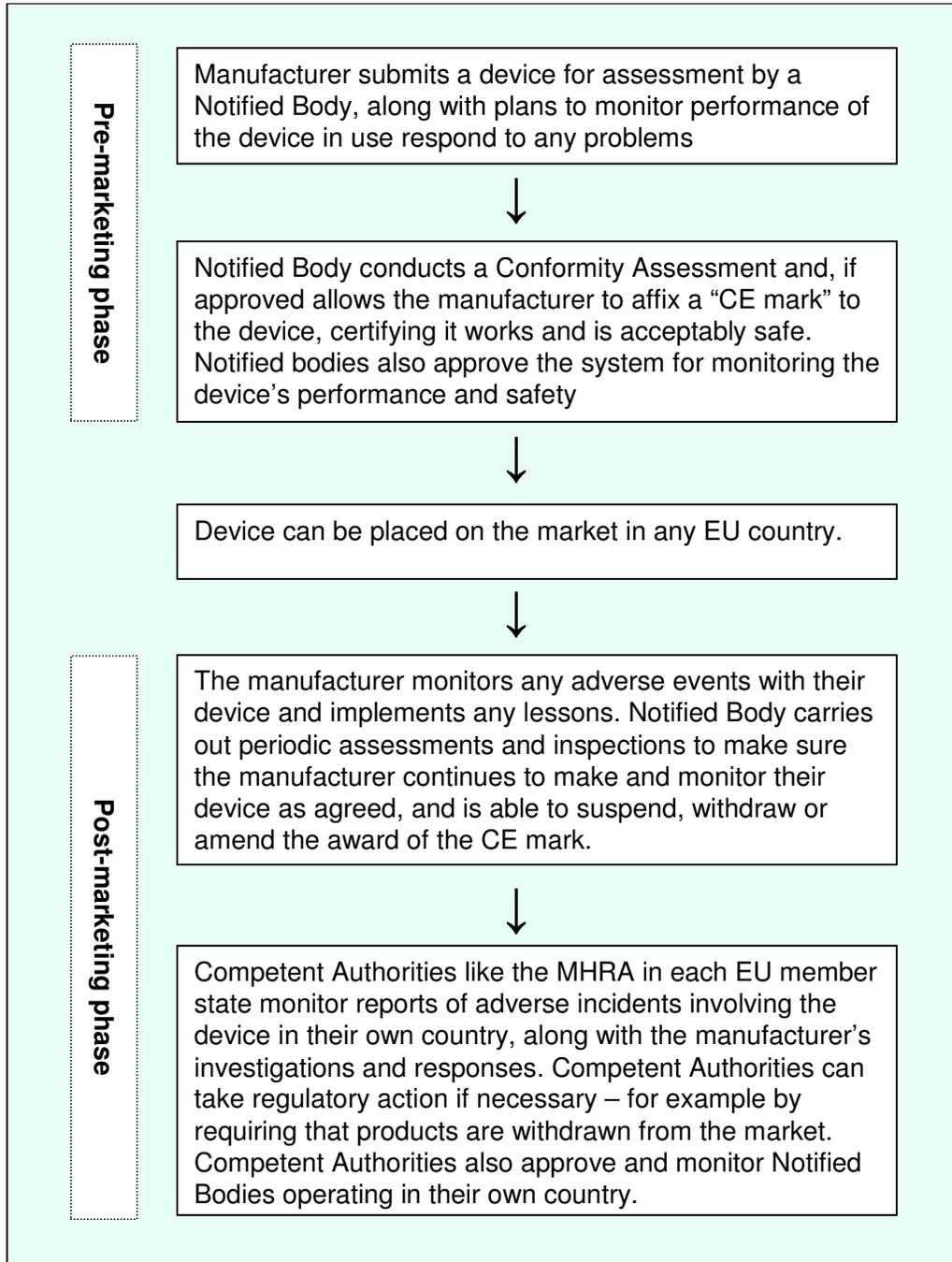
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the Notified body required to provide acceptable corrective action plans which are monitored by the MHRA.

- 4.22. In the event that a breach of medical device legislation is identified, the MHRA is able to take enforcement action proportionate to the breach. Manufacturers will normally be given the chance to put matters right themselves on a voluntary basis, but if they do not the MHRA has a range of enforcement powers under the Consumer Protection Act 1987, Medical Devices Regulations 2002 and the General Product Safety Regulations 2005. All of these measures could be exercised before prosecution is considered. Prosecution, which could carry a penalty of up to £5,000 per offence and/or six months imprisonment, would normally only be undertaken as a last resort where either a serious offence has been committed or all else has failed. .

Device regulation in practice

Figure 2: European medical device regulation – key stages in the process for class II and III devices



Pre-marketing

- 4.23. Higher risk medical devices such as breast implants are certified by notified bodies. There are over 80 of these independent organisations across Europe, including six in the UK. The role of notified bodies in relation to medical device regulation is to determine whether a particular medical device meets the relevant regulatory requirements and, whether, when used as intended, it works properly and is acceptably safe. This process is known as a conformity assessment.
- 4.24. If a device is assessed by the notified body as meeting the accepted standards of safety, the notified body issues a certificate of conformity which authorises use of a CE mark of conformity. This allows the manufacturer to apply the CE marking to their device and it can then be marketed in all EU countries without further controls.
- 4.25. A manufacturer can select any notified body across Europe, irrespective of location, to assess their product for CE marking, provided that their field of expertise covers the device being considered. Once assessed and approved for market, the device can be sold in all other EU countries without further assessment by the regulatory bodies in that country (ie the marketing of a device must be allowed in the UK if a notified body in another EU country has approved the device for CE marking).
- 4.26. For very low-risk devices, such as non-medicated bandages, CE marking can be applied without independent assessment by a notified body on the basis of a declaration of conformity by the manufacturer.
- 4.27. The manufacturer must develop a quality system to ensure that the production and the product continue to conform to regulatory requirements. The system must include arrangements to obtain, record and review experience of the device from the marketing phase, including reviews of risk analysis and plans for any corrective action that may be required. EU guidance stipulates that this should include reviewing data on long-term effects, in particular in relation to chronic toxicity. This system must also enable the manufacturer to fulfil their obligation to notify the competent authorities of incidents related to their devices immediately on learning of them.
- 4.28. The notified body must audit the quality system to determine that it meets the necessary requirements.

Post-marketing

Post-marketing surveillance by the manufacturer

- 4.29. Manufacturer must give and undertaking to maintain a systematic procedure to review experience gained from their devices after they are placed on the EU market, and to implement appropriate means to apply any necessary corrective action. This must include an obligation for the manufacturer to notify the competent authorities of:

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- 4.30. (a) any adverse incident which might lead to or might have led to the death of a patient or user or to a serious deterioration in their state of health. These should be reported to the competent authority where the incident occurs;
- 4.31. (b) any field safety corrective action (e.g. systematic recall) undertaken by the manufacturer to reduce the risk of adverse incidents with the device. These should be reported to every Member state with that product on their market.
- 4.32. In the UK these reports are sent to the MHRA.

Post-marketing surveillance by the notified body

- 4.33. The aim of post-market surveillance by the notified body is to ensure that the manufacturer carries out the approved quality system and is providing the notified body with the agreed information. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and produces an assessment report. It may also pay unannounced visits to the manufacturer and carry out or ask for tests in order to check the quality system is working properly.
- 4.34. If a notified body finds that a manufacturer has not been compliant, it can suspend or withdraw the certificate issued, or place restrictions on it. In cases where an intervention of the competent authority may become necessary, the notified body should inform its competent authority. The Member State shall then inform the other Member States and the Commission.

Medical Device User reporting and its link to vigilance

- 4.35. Health professionals and members of the public can submit adverse incident reports for medical devices online via the MHRA website, or by email and mail to a dedicated address. The vast majority (over 90%) of those who submit incident reports now do so via the website. It is difficult to assess the percentage of adverse events that occur and are then reported directly by healthcare professionals and members of the public. Earlier research has suggested a figure of 10% of reports is submitted^{xxii}. However, recent research into adverse incident reports for breast implants suggests that in some areas this may be higher, in the region of 15% - 18%. These latter estimates do not include device manufacturer reporting, which is central to the medical device vigilance and incident reporting system. In some instances the MHRA will already have been made aware of these adverse events via the reports received directly from the healthcare professional or member of the public.

Post market surveillance by the competent authority

- 4.36. MHRA passes all adverse incidents reported directly to them by healthcare professionals and members of the public to the relevant manufacturer for their

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assessment and investigation. This is a legal obligation under the Medical Device Directives.

- 4.37. MHRA ensures that any information brought to its knowledge regarding medical devices incidents, regardless of their source, are recorded and evaluated centrally. This includes assessing the manufacturer's subsequent investigation into the incident and any conclusions and/or planned corrective actions.
- 4.38. MHRA is obliged by the MDD to inform the Commission and the other Member States of any corrective actions that are contemplated or initiated; this is done via exchange of a confidential National Competent Authority report.
- 4.39. The manufacturer is normally responsible for the investigation of an incident, while the relevant national competent authority (normally the one in which the incident occurred) monitors progress. The national competent authority may then intervene, or initiate independent investigation if appropriate.
- 4.40. The manufacturer must inform the relevant competent authority of the results of its investigation, and consult the competent authority on any necessary action. This may include the manufacturer withdrawing a product if concerns warrant it. The competent authority may take further action it deems appropriate, consulting the manufacturer where possible.

MHRA enforcement powers

- 4.41. The MHRA has the power to prosecute when regulations have been breached. The courts can impose fines or prison sentences when the law has been broken. The MHRA can withdraw unauthorised / illegal products from the market.
- 4.42. Specific powers that the MHRA has via various pieces of legislation are:
 - **Compliance Notice** (Regulation 62(1)). In addition, Regulation 62(1) of the Medical Devices Regulations 2002 provides the power to issue notices for non-compliance with the Regulations (Compliance Notice). These powers are in the main, for technical breaches where a device is thought not to conform to an essential requirement, but where it does not compromise health or safety. The notice generally requires the person on whom it is served to ensure that the device conforms within the period stated in the notice.
 - **Restriction Notice.** Regulation 63(1) of the Medical Devices Regulations 2002 provides that where MHRA is of the opinion that it is necessary to restrict the availability of a particular medical device, or of devices of a particular class or description, in order to protect the health or safety of any individual or individuals of any class or description, they may serve on any person a Restriction Notice. This

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will include such directions restricting the availability of that device or those devices as appears to be necessary.

- **Offences against the Safety Regulations** (Consumer Protection Act, Section 12). These restrictions relate to the supplying, offering or agreeing to supply goods where the safety regulations prohibit a person from doing so.
- **Prohibition Notices** (Consumer Protection Act, Section 13). These prohibit the supply of any goods which are considered to be unsafe or are not in compliance with Regulations.
- **Notices to Warn** (Consumer Protection Act, Section 13). These require a manufacturer to issue at their own expense a warning about any relevant goods, which are considered unsafe.
- **Suspension Notices** (Consumer Protection Act, Section 14). These suspend the supply of any goods for a period of up to six months, where it is suspected that a safety provision has been contravened. Compensation may be payable if it is later established that there was no contravention.
- **Forfeiture Orders** (Consumer Protection Act, Section 16 and 17). Enforcement authorities may apply for an order for the forfeiture of goods where there has been a contravention of a safety provision.
- **Obtaining Information** (Consumer Protection Act, Section 18). MHRA, on behalf of the Secretary of State, has the power to serve a notice requiring a person to furnish information or to produce records for the purposes of deciding whether to serve, vary or revoke a prohibition notice or a notice to warn.
- **Test Purchases** (Consumer Protection Act, Section 28). This gives enforcement authorities the power to make test purchases for the purposes of ascertaining whether or not the Regulations have been breached.
- **Recall Notice** (General Product Safety Regulations). For consumer medical devices only under Regulation 15 of the GPSD Regulations 2005.

Products falling outside the scope of medicines and medical products legislation

4.43. Some products used in cosmetic interventions will fall outside the scope of the medicines and medical products legislation.

Cosmetics

4.44. Cosmetics are regulated by the Cosmetic Products (Safety) Regulations 2008, the UK transposition of the Cosmetics Directive. The Directive lays down rules on the

composition, labelling and packaging of cosmetic products. In 2009, the Directive was recast as a European Regulation (1223/2009) which has direct effect across the EU. Cosmetic products are defined in the EU Regulation as substances or mixtures of substances intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, etc.) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours. The Directive specifically mentions in Annex I that peeling products are not classed as cosmetic products.

- 4.45. For example, skin exfoliators containing salicylic acid (the active ingredient) up to a maximum of 2% fall within the Cosmetics Directive. A skin exfoliator with salicylic acid content greater than the maximum defined level in the Cosmetics Legislation would be an illegal cosmetic product. A chemical peel containing salicylic acid at a much higher level than 2% would not be classed as a cosmetic product and could not be marketed under the Consumer Protection legislation^{xxiii}. More information on the different types of chemical peels can be found on the DH website^{xxiv}.

Equipment

- 4.46. Some equipment or machinery used in cosmetic interventions, is regulated by the Supply of Machinery (Safety) Regulations 2008 (SMR08) which requires that new machinery used for cosmetic interventions, for example microdermabrasion equipment (used to remove the outermost layer of dead skin cells) is designed and constructed to be safe; is CE marked; is supplied with instructions in English and is accompanied by a Declaration of Conformity stating that it meets all relevant requirements.
- 4.47. Both the Health and Safety Executive (HSE) and local trading standards enforce the provisions of SMR08 depending on the field of use of the equipment (HSE leads where machinery is for use at work using its powers under the Health and Safety at Work Act, while Trading Standards lead where machinery is used by consumers in domestic situations, using their powers under the Consumer Protection Act).
- 4.48. For the second-hand supply of equipment or machinery for use at work used in cosmetic interventions, section 6(1) of the HSW Act places a general health and safety obligation on anyone in the supply chain. This obligation includes providing information and instructions on safe use. Enforcement of section 6 of the HSW Act is undertaken by HSE.
- 4.49. The Medical Devices Regulations 2002, as amended, regulate medical devices used for diagnostic or therapeutic purposes. Where a medical device is also a machine it is excluded from the scope of the SMR08 although it must still meet the relevant essential health and safety requirements. HSE does not have a role in respect of these Regulations, even for workplace equipment, and enforcement falls to the Medicines and Healthcare products Regulatory Agency.

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- 4.50. Products that fall outside medicines and medical products, and cosmetic regulations, may be covered by the general provisions of the General Product Safety Directive 2001/95/EC transposed in the UK as The General Product Safety Regulations 2005 (GPSR). The GPSR apply to products intended for consumers, or likely to be used by consumers even if not intended for them, that are supplied or made available commercially, including products made available for a consumer's own use during the provision of a service. The GPSR apply to products to which there are no other similar applicable provisions in Community law relating to the safety of the product. The scope is therefore extremely broad. They are enforced by the local trading standards officers although the Secretary of State for Business, Innovation and Skills, as well as any other Minister in charge of a Government department or any Government department is also an enforcement authority.
- 4.51. The GPSR apply to products intended for consumers, or likely to be used by consumers even if not intended for them, that are supplied or made available commercially, including products made available for a consumer's own use during the provision of a service. The GPSR apply to products to which there are no other similar applicable provisions in Community law relating to the safety of the product. The scope is therefore extremely broad. They are enforced by the local trading standards officers although the Secretary of State for Business, Innovation and Skills, as well as any other Minister in charge of a Government department or any Government department is also an enforcement authority.
- 4.52. The purpose of the GPSR is to ensure that consumer products placed on the market, or offered or agreed to be placed on the market, or supplied or offered or exposed or possessed for supply, must be safe (the general safety requirement - regulation 5). The onus of ensuring safety is on the producer or distributor who is therefore liable if the GPSR are breached (offences under regulation 20 of the GPSR).
- 4.53. A product is considered safe when under normal or reasonably foreseeable conditions of use it does not present any risk or presents only the acceptable minimum risks compatible with the product's use that is consistent with a high level of protection for the safety and health of persons.
- 4.54. This legislation would cover, for example, an injectable dermal filler (that works without exerting a pharmacological, immunological or metabolic action) that does not make a medical claim but only where it is supplied and marketed for self use to the consumer. It should be noted that products supplied as part of a professional service are not yet covered by the General Product Safety Regulations but the provision of such services may be covered by the Health and Safety at Work etc Act, 1974.

Revision of the legislation covering medical devices

- 4.55. As legislation in the UK covering medical devices is derived from EU directives, there is limited scope for the UK to unilaterally change the legislation or introduce additional

controls above and beyond those set out by the EU. However, the legislation is currently being reviewed at a European level, which provides the UK with an opportunity to seek to make changes to the legislation as it is negotiated by the EU Member States and European Parliament.

- 4.56. The European Commission have made clear that they are not anticipating a substantial restructuring of the regulatory framework, meaning that the current structure involving notified bodies undertaking pre-market assessment of devices and competent authorities largely involved in post-market vigilance will remain. There is good consensus, however, that the existing regulatory framework is in need of strengthening in a number of areas, and we expect to see provisions included in the draft legislation to address the following:
- a. the inconsistent performance of notified bodies;
 - b. insufficient clinical evidence relating to the safety and performance of a device before it is placed on the market;
 - c. the need for additional pre-market scrutiny for some high-risk devices;
 - d. imprecise and variable post-market surveillance by manufacturers;
 - e. the need for traceability of devices to improve vigilance and post-market surveillance; and
 - f. greater coordination and transparency so that we systematically use the breadth of information available to individual notified bodies and competent authorities across the EU to inform regulatory actions.
- 4.57. In addition, it is likely that a significant change to the scope of the Medical Device Directives will be proposed, with the legislation expanded to include certain implantable or invasive devices without a medical purpose, but that are similar to medical devices in terms of their risk profile and characteristics. The proposal will list such products in an annex as it has proved impossible in the past to agree a simple definition of a medical device without a medical purpose, sometimes termed a 'quasi-medical device'. The list currently includes:
- a. plano contact lenses^{xxv};
 - b. implants for modification or fixation of body parts^{xxvi};
 - c. facial or other dermal or mucous fillers;
 - d. equipment for liposuction; and
 - e. invasive laser equipment intended to be used on the human body.

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- 4.58. The purpose of this extension is to address an inconsistency in the current regulatory framework where, for example, corrective contact lenses are regulated as medical devices and cosmetic contact lenses are regulated under General Product Safety legislation, and products such as dermal fillers may or may not be regulated as medical devices depending on whether they are claimed to have a medical purpose or not.

Questions on the regulation of medical devices, implants and other products

- 1 What are the risks and benefits presented by dermal fillers?
- 2 What clinical evidence might be required to regulate dermal fillers (with no claimed medical purpose or benefit) under the existing medical devices regulations?
- 3 Are any further changes needed to the categories of devices and implants subject to regulation in addition to the likely changes set out above?
- 4 Are there any other areas where additional strengthening of the regulatory system is required that will not be addressed in the forthcoming revision of the medical devices legislation?
- 5 Earl Howe's review of the actions of the MHRA and Department of Health in relation to PIP silicone breast implants^{xxvii} recommended that this review should 'examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery. Routine incident reporting and review of outcome data by individual surgeons and providers should be the norm.' How can health providers, professional bodies, regulators and patient groups promote the best possible understanding of the role of the incident reporting system and ensure that professionals in particular understand what they have a duty to report?

In answering the above questions, it would be helpful if the principles of Better Regulation could be considered as set out in chapter 3.

5. Regulation of practitioners

Healthcare professionals

- 5.1. The majority of mainstream healthcare professionals in the UK are regulated. Health professionals are regulated by statute to ensure public protection. As a result, the nine health regulatory bodies in the UK (see annex A) have four main statutory duties:
- to establish standards of competence, ethics and conduct;
 - to establish standards for education, training and continuing professional development;
 - to keep a register of those who meet the standards; and,
 - to deal with registrants who fall short of those standards through the taking of ‘fitness to practise’ action.
- 5.2. Regulation works practically by protecting professional titles (and, in some instances, function) – thus restricting their use to professionals registered with the appropriate regulatory body. A major benefit of regulation is therefore the exclusive right to practise the profession. The fees that professionals pay to their regulatory body fund the cost of regulation.
- 5.3. The detail of the way that health and social care professionals are expected to act is set out in the codes of conduct (and any supplementary guidance) established by their regulatory bodies. The specific wording of requirements on health and social care professionals will vary from profession to profession, although core principles are broadly applicable to all professions. The principles and values on which good practice is based for medical practitioners, for example, are set out in ‘Good Medical Practice’^{xxviii}.
- 5.4. Where a healthcare professional fails to observe the standards set by their regulatory body, such as the General Medical Council (GMC) for doctors, the Nursing and Midwifery Council (NMC) for nurses, the General Dental Council (GDC) for dental professionals and the General Pharmaceutical Council (GPhC) for pharmacists, then action can be taken against them through the regulators’ fitness to practise procedures.
- 5.5. The remit of a health care profession’s regulatory body extends to all of a practitioner’s professional work and not just their work as an NHS or local government employee. Therefore, the same standards are applicable to those practising their profession in a private, or self-employed capacity whether whole time, less than full time or as part of a portfolio career.

The Medical Register

- 5.6. The law requires any doctor who treats patients to be registered with the GMC with a licence to practise. While doctors work in many different environments, only those who are registered with a licence to practise can, for example:
- work as a doctor in the NHS or in private practice
 - write prescriptions
 - sign death and cremation certificates.
- 5.7. Doctors who do not have a licence to practise are more likely to be working, for example, as lecturers in a medical school, as managers, or outside the UK. Organisations, such as the NHS and other healthcare providers, are required to ensure that the doctors they employ have a licence to practise if their work requires them to do so.
- 5.8. As well as a doctor ensuring they hold a licence to practise, they must ensure that their registration is appropriate for the type of post or practice that they will be undertaking.
- 5.9. The different types of registration for doctors are as follows:
- provisional - for trainees in the first Foundation year (F1);
 - full - for trainees that have successfully completed F1 (or equivalent overseas);
 - specialist registration - for doctors who have successfully completed postgrad training (or equivalent) and have obtained a CCT or CESR/CEGPR (see below).
- 5.10. Doctors, employers and members of the public can check the type of registration that a doctor has, whether they have a licence to practise, and the date from which it is effective, on the List of Registered Medical Practitioners, maintained by the GMC.

Basic medical qualifications

- 5.11. This refers to the period before full registration with the GMC. It comprises five years at medical school (usually - there are also some degree-entry four year courses) and the first year of the Foundation Programme. Provisional registration with the GMC comes after successful completion of the medical degree and full registration to practise medicine following successful completion of the first year of the Foundation Programme. However, trainees must also successfully complete the second Foundation year before they are eligible to enter specialty training.

General practitioners

- 5.12. General practitioners are doctors who have undertaken basic medical training and who go on to undertake a further period of vocational training of at least three years. General practitioners provide a wide range of health services, and often look after patients for a number of years.

Surgical qualifications

- 5.13. Surgeons are doctors who have undertaken basic medical training and who go on to specialise in surgery. They will spend two years training in basic surgery, and then five or six more years specialising in a particular type of surgery – for example, orthopaedic surgery or plastic surgery.

Specialist Surgical Qualifications

- 5.14. Surgeons from a number of surgical specialities perform cosmetic operations allied to their main specialty. A specialist surgical qualification shows that a surgeon is highly qualified and experienced in their chosen surgical specialty, but it may not indicate that they have received any special training in cosmetic surgery, or that they have experience in doing cosmetic surgery or in a particular cosmetic procedure. The UK recognised surgical specialties are:

- Cardiothoracic Surgery
- General Surgery
- Neurosurgery
- Oral and Maxillofacial Surgery (OMFS)
- Otolaryngology (ENT)
- Paediatric Surgery
- Plastic Surgery
- Trauma and Orthopaedic Surgery
- Ophthalmology
- Urology
- Vascular Surgery.

Specialist training

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- 5.15. Postgraduate medical training in the UK is delivered using regulator approved curricula and assessment systems for each specialty or sub-specialty. These set the standards against which trainee doctors' competency progression will be assessed. There is a clear career structure with explicit paths to follow. Specialty and GP training programmes are usually delivered by training schools overseen by local postgraduate deans. Most programmes are initially broad based and become specialty focused over time.
- 5.16. Specialty training programmes vary in length and are tailored to the requirements of the specialty. The medical Royal Colleges and Faculties have produced national curricula for each training programme to meet the standards required, and to be formally approved, by the General Medical Council (GMC). These curricula state the competencies doctors need to gain by following the programme, providing explicit standards and guidance for assessment including completion of the programme as a whole.
- 5.17. When a doctor has successfully completed their specialty training programme, they receive a Certificate of Completion of Training (CCT) which makes them eligible for entry to the GMC's Specialist Register or GP Register.

Specialist registration

- 5.18. The GMC maintains a Specialist Register. Since 1 January 1997 it has been a requirement that in order to take up a consultant post (other than a locum consultant appointment) in a medical or surgical specialty in the NHS^{xxix}, a doctor must be included on the Specialist Register. There is a separate general practice (GP) register.
- 5.19. Only those doctors who have trained and qualified in a surgical specialty, or who have been assessed as having equivalent qualifications, training and experience and are therefore on the Specialist Register through the award of a Certificate of Eligibility for Specialist Registration (CESR), can practise unsupervised as a surgeon in the NHS. Those on the Specialist Register need to satisfy the training, qualifications and continuous development set out by the professional body responsible for that specialty. It is not possible to be entered on the Specialist Register without also holding full registration.

Requirements for practitioners carrying out surgical cosmetic interventions

- 5.20. A doctor needs to hold full registration in order to practise medicine (unsupervised) in the UK. Doctors need to be on the Specialist Register in order to hold an NHS Consultant post and hence lead on surgery provided in the NHS^{xxx}. Someone who only has a basic medical qualification should not undertake unsupervised surgical procedures.

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- 5.21. A doctor does not necessarily have to be a surgeon to carry out cosmetic surgery unsupervised outside of the NHS, nor on the Specialist Register (see above) or if on the Specialist Register have a registered entry that refers to cosmetic practice or similar. The only legal requirement is that doctors should be fully registered. Ethical guidance from the GMC ("Good Medical Practice")^{xxx} makes clear that doctors are expected to practise only in the clinical fields in which they are competent, but at present this competence is self-assessed and exceptions will only be brought to the attention of the regulator (the General Medical Council or General Dental Council) if a complaint is made.
- 5.22. This also applies to nurses and midwives (see below). However, the introduction of medical revalidation from December 2012 will see doctors' competence assessed by an annual appraisal for which they will need to provide evidence of satisfactory practice including feedback from patients and colleagues, evidence of continuing professional development, reviews of complaints and relevant information about clinical outcomes. More information on medical revalidation can be found below. Similarly, insurance cover and practising rights in a private hospital may be difficult to secure for doctors working outside their competence.

Anaesthetic qualifications

- 5.23. Anaesthetists are doctors who have undertaken basic medical training and who go on to specialise in anaesthesia. They will spend seven years undertaking specialist training.

Doctors from overseas

- 5.24. Some doctors, surgeons and anaesthetists undertake training in their home country and then come to the UK to work. Their qualifications will not be the same as those listed above. However, all doctors from abroad must be registered by the GMC before they can practise in the UK, and surgeons who hold qualifications from recognised training establishments in the European Union will appear on the GMC's specialist register. Other doctors who have not undertaken the whole of their training in the UK will also appear on the specialist register if the General Medical Council assesses their qualifications, training and experience as equivalent and they have been awarded a Certificate of Eligibility for Specialist Registration (CESR) or a Certificate of Eligibility for the General Practice Register (CEGPR).

Medical Revalidation

- 5.25. The purpose of revalidation is to assure patients and the public, employers and other healthcare professionals that licensed doctors are up to date and fit to practise. When medical revalidation is brought in later this year (subject to final decisions by ministers) doctors will be subject to a periodic check on their competence in all the fields in which

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they practise, including any private practice. However, current plans for revalidation aim to assure patients and the public, employers and other healthcare professionals that licensed doctors are up to date and fit to practise.

- 5.26. Revalidation will build on existing processes, strengthening them to meet the needs of regulation and to ensure greater consistency. For the vast majority of doctors, the more systematic annual appraisal will provide the basis for reflective practice and improvement, an essential developmental process.
- 5.27. In the proposed model for revalidation the recommendation that a doctor should be revalidated, and effectively re-licensed, will depend on satisfactory completion of five annual appraisals, 360-degree (“multi-source”) feedback from patients and colleagues, evidence of continuing professional development, reviews of complaints and relevant information about clinical outcomes.
- 5.28. A doctor may not be able to obtain clinical negligence indemnity if the insurer is not satisfied with a doctor’s competence to carry out a certain procedure. Doctors will be legally obliged to have clinical indemnity from October 2013.

The Dental Register

- 5.29. The General Dental Council (GDC) regulates dental professionals in the United Kingdom. All dentists, dental nurses, dental technicians, clinical dental technicians, dental hygienists, dental therapists and orthodontic therapists must be registered with the GDC to carry out dental treatment, cosmetic or otherwise, in the UK.
- 5.30. The GDC keeps registers of dentists and dental care professionals. To join the registers, dental professionals need to meet the professional standards set by the GDC.

Dental qualifications

- 5.31. There are 13 dental specialties. Dentists can work in a particular branch of dentistry (such as restorative dentistry) but only those on the Specialist Lists can call themselves a ‘specialist’ in a particular area. There is no specialty for cosmetic dentistry. Further information on the role of the GDC is available at www.gdc-uk.org.
- 5.32. Most dentists undertake a five-year course of study leading to a degree. Dentist graduates can register with the GDC immediately after graduation and they must be registered with GDC before they are allowed to practise dentistry in the UK. They then need to undertake a one year post graduation/registration course of vocational training to obtain a performer number to work in the NHS. A dentist could work in the private sector without doing the one year period of post graduate training.

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- 5.33. Dentists are allowed to prescribe botulinum toxin (for example, Botox ®). Some dentists offer botulinum toxin and dermal filler treatments.
- 5.34. Dental qualifications include:
- BDS – Bachelor of Dental Surgery
 - BChD – Bachelor of Dental Surgery
 - LDS – Licence in Dental Surgery
 - ORE – Overseas Registration Examination.
- 5.35. Following first registration, dentists are required to undertake a minimum of 250 hours continuing professional development every five years based on the GDC’s mandatory CPD requirements. Registration is removed for non-compliance. The GDC provides advice and guidance in support of the requirements and has identified a number of topics that registrants are encouraged to undertake regularly. All dental professionals should carry out CPD that support the principles set out in the GDC’s Standards for Dental Professionals and that advances professional development as a dental professional.

Requirements for practitioners carrying out non-surgical cosmetic interventions

Nursing and Midwifery

- 5.36. The Nursing and Midwifery Council (NMC) is the statutory regulator of c.670,000 nurses and midwives in the UK.
- 5.37. The NMC is responsible for setting the standards for nurses and midwives to meet in their working lives. Nurses and midwives have a code of conduct that they must follow that states how they must work and behave. This is published by the NMC and is entitled “The code: standards of conduct, performance, and ethics for nurses and midwives”^{xxxii}. The code includes a professional requirement to recognise and work within the limits of their competence.
- 5.38. The NMC sets standards for education, to make sure nurses and midwives have the right skills and qualities when they start work. They also set standards for education throughout nurses’ and midwives’ careers, after they initially qualify. Nurses and midwives must continually train and take part in learning activities to show that their skills and knowledge are up to date^{xxxiii}.
- 5.39. The NMC keep (and publish^{xxxiv}) a register of all nurses and midwives in the UK. It is illegal to work as a nurse or midwife without being on the NMC register. In order to be

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on the register, nurses and midwives must pay a yearly fee and prove that they fulfil the NMC's requirements for keeping their skills and knowledge up to date.

- 5.40. If an allegation is made about a nurse or midwife that they do not meet the standards for skills, education and behaviour that the NMC set, or that there is a problem with their work, the NMC has powers to investigate. If, after investigation, such allegations are found proven then the NMC may take 'fitness to practise' action against a registrant in order to protect the public. For instance, they might apply conditions to the terms of someone's registration or strike them off the NMC register altogether, meaning that they can no longer practise.

Nursing qualifications

- 5.41. Nurses undertake at least three years of study and practical experience at degree or diploma level before they qualify, specialising in adult, children's, mental health or learning disability nursing. After qualification nurses can go to specialise further in a wide variety of nursing roles in the community, in hospitals and other organisations. Some nurses also choose to specialise in non-surgical cosmetic treatments.
- 5.42. The Nursing and Midwifery Council (NMC) register only records those qualifications for which the NMC sets standards, which may not necessarily include all non-surgical cosmetic procedures.
- 5.43. Nursing qualifications include:-
- RN – Registered Nurse
 - RGN – Registered General Nurse
 - BA (Hons)/BSc/Diploma in Nursing

Assurance of Voluntary Registers

- 5.44. In November 2012, the Council for Healthcare Regulatory Excellence (CHRE) - soon to be renamed the Professional Standards Authority for Health and Social Care - is expecting to launch a new accreditation scheme for voluntary registers. The CHRE will set standards for organisations that hold voluntary registers for people working in a variety of health and social care occupations.
- 5.45. Organisations will be able to apply to the CHRE for accreditation of their register. The CHRE will publish a list of accredited registers on its website and will allow them to use the CHRE 'quality mark' on their literature and their websites to help show that they are accredited. This means that employers, commissioners and members of the public will be able to choose to use people in health and social care who are on a register of an organisation that has been assessed by the CHRE and accredited.

Non-healthcare providers of cosmetic interventions

- 5.46. Some non-surgical cosmetic interventions, eg dermal fillers, can be carried out by non-healthcare professionals such as beauty therapists and hairdressers. There are no additional legislative requirements on people working in these professions above those that apply to the service sector.
- 5.47. The Health and Safety at Work Act (HSWA) 1974 is the main piece of health and safety legislation applicable to cosmetic interventions in 'non-health' locations. The issue of public safety is particularly relevant. Section 3(1) of the HSWA requires employers to ensure, so far as is reasonably practicable, that people other than their employees are not exposed to risks to their health and safety.
- 5.48. Beauty therapists and hairdressers may choose to belong to a relevant trade organisation.

Beauty qualifications

- 5.49. Beauty therapists train to carry out a variety of treatments, and they also study anatomy and physiology, health and safety in the workplace, first aid and salon management. Typically a therapist will train for between 1–3 years depending on the qualification they hope to gain. They will be assessed on their written and practical work, often by means of exams.
- 5.50. There are a number of qualifications in beauty therapy. The main qualifications are listed below:
- NVQ / SVQ Levels 1–4
 - BTEC National or Higher National (a BTEC certificate in laser treatment is available)
 - ONC / OND
 - HNC / HND in Beauty Therapy
 - ITEC Diploma or Certificate
 - VTCT Diploma or Certificate
 - CIBTAC Diploma.
- 5.51. These qualifications may not include training in all non-surgical cosmetic treatments.

Manufacturers' qualifications

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- 5.52. Manufacturers of products (like dermal fillers) and machinery (like lasers and intense-pulsed light machines) often offer courses to doctors, dentists, nurses and therapists who wish to buy and use their products, and some manufacturers give certificates to attendees who complete the course. Typically these courses are short, and may cover subjects like bringing in more clients as well as the safe use of the product or machine. As the training provided by manufacturers is not checked or accredited, it can often be difficult to make a judgement about the value of the course and the certificate.

Questions on the regulation of practitioners

6. Is there evidence that the current requirements for doctors practising cosmetic surgery are insufficient? Should all cosmetic surgeons be required to have specialist training, ie be on the Specialist Register?
7. Currently 'cosmetic surgery' is not recognised as a specialty for which doctors can train and achieve a Certificate of Completion of Training (CCT) leading to inclusion on the Specialist Register. Is there evidence to suggest a need to introduce a new Specialty for 'Cosmetic Surgery' or are there alternatives, such as a different form of training, eg credentialing, that would demonstrate competence?
8. Do people who deliver cosmetic interventions like fillers, Botox®, laser treatments or chemical peels, have the appropriate skills to deliver them? How could their performance be monitored?
9. Earl Howe's review of the actions of the MHRA and Department of Health in relation to PIP silicone breast implants^{xxxv} recommended that this review should 'examine ways of promoting a stronger culture of clinical governance, clinical audit and reporting in cosmetic surgery. Routine incident reporting and review of outcome data by individual surgeons and providers should be the norm.' How can medical revalidation be used to promote this?
10. Should practitioners be required to ensure that records of all cosmetic interventions are kept? This is generally done for implants but is it reasonable to do for other devices such as dermal fillers?

In answering the above questions, it would be helpful if the principles of Better Regulation could be considered as set out in chapter 3.

6. Regulation of organisations

- 6.1. The Care Quality Commission (CQC) is the independent regulator of health and adult social care providers in England and has a key responsibility in the overall assurance of essential levels of safety and quality of health and adult social care services. Under the Health and Social Care Act 2008 all providers of regulated activities, including NHS and independent providers, have to register with CQC and meet a set of essential requirements of safety and quality.
- 6.2. CQC forms part of the wider quality framework, having responsibility for:
- providing independent assurance and publishing information on the safety and quality of services;
 - registering providers of regulated activities (including NHS, adult social care and independent sector healthcare providers);
 - inspect most providers at least once a year to ensure they are meeting government standards (biannually for dental services);
 - using enforcement powers (where appropriate) to ensure service providers meet requirements or, where appropriate, to suspend or cancel registrations;
 - undertaking special reviews and investigations of particular services, looking across providers and commissioners of health and adult social care;
 - monitoring the use of the Mental Health Act; and
 - operating a proportionate regulatory system that avoids imposing unnecessary burdens on providers and on the regulator itself, and helping to manage the impact of regulation more generally on health and adult social care service providers and commissioners.
- 6.3. The regulated activities for which providers of cosmetic interventions have to register with CQC are:
- surgical procedures carried out by a healthcare professional for cosmetic procedures, where the procedure involves the use of instruments or equipment which are inserted into the body; and
 - diagnostic and screening procedures.

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- 6.4. The subcutaneous injection of a substance or substances for the purpose of enhancing a person's appearance, body piercing, tattooing, and removal of hair roots or small blemishes on the skin by the application of heat using an electric current, are explicitly exempt from regulation with the CQC.
- 6.5. All providers of regulated activities must be registered and continue to meet the registration requirements setting out essential levels of safety and quality. The registration requirements cover:
- **Respecting and involving people who use services**

People must be treated with respect, involved in discussions about their care and treatment and be able to influence how the service is run.
 - **Consent to care and treatment**

Before people are given any examination, care, treatment or support, they must be asked if they agree to it. This is known as consent.
 - **Care and welfare of people who use services**

People must be protected against the risks of receiving unsafe care or treatment.
 - **Meeting nutritional needs**

Food and hydration are provided as a component of the service, it must meet people's reasonable individual dietary needs.
 - **Cooperating with other providers**

People must get safe and coordinated care when they move between different services.
 - **Safeguarding people who use services from abuse**

People must be protected from abuse, including sexual abuse, physical or psychological ill-treatment, theft or neglect.
 - **Cleanliness and infection control**

People should be cared for in a clean environment and protected from the risk of infection.
 - **Management of medicines**

People must be given the medicines they need when they need them, and in a safe way.

- **Safety and suitability of premises**

The provider must ensure that the premises are safe, suitable, secure and adequately maintained

- **Safety, availability and suitability of equipment**

People should be safe from harm from unsafe or unsuitable equipment.

- **Requirements relating to workers**

People must be cared for by staff who are properly qualified and able to do their job.

- **Staffing**

There must be enough members of staff to keep people safe and meet their health and welfare needs.

- **Supporting workers**

Staff must be properly trained and supervised, and have the chance to develop and improve their skills.

- **Assessing and monitoring the quality of service provision**

The service must have quality checking systems to manage risks and assure the health, welfare and safety of people who receive care.

- **Complaints**

The provider must have an effective complaints procedure in place.

- **Records**

People's personal records, including medical records, must be accurate and kept safe and confidential.

Other Requirements:

- **Fees**

People who pay for a service should know how much they have to pay, when and how to pay it, and what they will get for the amount paid, eg does it include aftercare, and if so, what level of aftercare and for how long.

- **Notification of death of a person who uses services**

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Deaths of people who use services must be reported to CQC so that, if necessary, action can be taken.

- **Notification of other incidents**

Important events that affect people's health, welfare and safety must be reported to CQC so that, if necessary, action can be taken.

- 6.6. The scope of registration is proportionate to risk and based on the activity being carried out rather than the setting. This provides the same assurance of essential levels of safety and quality wherever people access services. The list of regulated activities reflects the risk of harm to the person using the service and what contribution regulation by CQC could make to the mitigation of those risks.
- 6.7. Failure to comply with the requirements is an offence, and under the 2008 Act, CQC has a wide range of enforcement powers that it can use if the provider is not compliant.

Clinical governance

- 6.8. In order to fulfil the registration requirements relating to the care and safety of patients, all healthcare providers are expected to operate appropriate systems of clinical governance. This term was first introduced in 1998 to describe the culture, structures and processes which healthcare organisations need to have in place in order to ensure patient safety and strive for continuous improvement in the quality of their services. In the present context, there are two particularly important elements of clinical governance:
 - proactive clinical risk management, that is the analysis of all the procedures carried out by the provider in order to identify potential risks to patient safety and reduce these to the lowest possible level;
 - a commitment to clinical audit, that is a systematic analysis of the outcomes of patient care in order to learn from mistakes and improve the quality of care for the future. A particularly important component is the analysis of patient safety incidents, that is incidents which led or could have led to actual patient harm.
- 6.9. Part of the role for CQC is to assure itself that all registered providers have the appropriate clinical governance systems for the clinical services they provide. Assessing this for very small providers, as are commonly found in the cosmetic surgery sector, may be a particular challenge.

Application to providers of cosmetic interventions

- 6.10. Any provider that carries out cosmetic surgery must be registered with the Care Quality Commission (CQC), as surgical procedures are a regulated activity. As a requirement of their registration with the CQC, the provider must have clinical governance systems

in place to ensure that their staff are sufficiently qualified and experienced to perform the cosmetic interventions that they offer. It is the responsibility of the provider as an employer to deal with any concerns, and to report doctors to the professional regulator if their concerns call into question their fitness to practice.

- 6.11. For providers who are individual practitioners working on their own or outside a formal clinical governance structure, the professional regulator is reliant on complaints direct from patients. The 2010 National Confidential Enquiry into Patient Outcome and Death (NCEPOD) report, On the face of it, examined the issue of clinical governance and most, but not all, sites indicated that they made the results of their clinical audits available to any external governing body^{xxxvi}.

Organisations providing cosmetic interventions falling outside of CQC's remit (those performing no regulated activities)

- 6.12. Organisations that fall outside CQC's remit need to abide by the provisions of the Health and Safety at Work legislation. This places a duty on employers to protect the safety of their employees and customers by requiring them to assess and prevent/control risks. Under this legislation, local authorities have general health and safety enforcement powers, which include the use of improvement and prohibition notices and ultimately prosecution if they judge that there is a risk to customers' health and safety.
- 6.13. Health and safety enforcement is split between the Health and Safety Executive (HSE) and Local Authorities (LAs). Treatments undertaken under the supervision of a registered medical practitioner, physiotherapist, osteopath, chiropractor or registered dentist fall to the HSE to enforce, as do those treatments administered from a domestic property (e.g. acupuncture). LAs enforce those treatments undertaken by non-registered medical practitioners and non-healthcare professionals e.g. beauticians.
- 6.14. In addition to these powers, tattooing, semi-permanent skin-colouring, cosmetic piercing (ear and body piercing), electrolysis and acupuncture are regulated through specific legislation by local authority registration and byelaws in the Local Government (Miscellaneous Provisions) Act 1982. Where an LA adopts the Local Government (Miscellaneous Provisions) Act 1982 they can require the registration of persons and premises carrying out these activities. There are also two other private Acts under which boroughs in London may regulate skin piercing.
- 6.15. Certain local authorities, including most London authorities, also regulate the non-surgical uses of class 3b and 4 laser and intense pulsed light (IPL), which require the provider to apply for a Special Treatments license. Providers must comply with a code of conduct, covering access to expert advice, staffing, maintaining a register, safety, qualifications and maintenance of equipment.

- 6.16. Class 3b and 4 lasers and Intense Pulsed Light (IPL) can be used in cosmetic interventions such as hair removal, tattoo removal, skin rejuvenation, removal of benign pigmented lesions and treatment of active acne. Laser liposuction and laser teeth whitening treatments are also available. There is no statutory regulation of cosmetic laser and ILS/IPL treatments in England.

Voluntary Registers

- 6.17. “Treatments You Can Trust” (TYCT) is a register of cosmetic injectable providers, managed by the Independent Healthcare Advisory Service (IHAS). Its website can guide consumers to treatment providers who have been checked and registered by TYCT. Providers who are included on the register are fully qualified, trained and insured and they will deliver treatments which comply with TYCT standards delivered in facilities which are clean, hygienic and comfortable. TYCT is now establishing a registration scheme for accredited providers of cosmetic laser and intense light source (ISL) or Intense Pulsed Light (IPL) treatments, with appropriate training.

Questions on the regulation of organisations providing cosmetic interventions

- 11 Is it right that private providers of cosmetic surgery meet the standards expected of the NHS?
- 12 The CQC registration requirements place a duty on providers to protect their patients from unsafe treatment, but it is not clear how far this extends in the private sector to providing appropriate after-care where a patient has suffered harm as an unexpected consequence of treatment. Do we need to impose a clearer legal requirement on registered organisations to provide after-care to their patients? If so, for how long after the original treatment?
13. Do you think the existing regulation of lasers and lights is proportionate to the risks they present with regard to cosmetic interventions?
14. Should providers of surgical cosmetic interventions be required to audit their processes and ensure that all their practitioners take part in clinical audit?
15. Should providers of non-surgical cosmetic interventions delivered in non-healthcare settings, for example beauticians administering dermal fillers or laser hair removal, be required to audit their processes and ensure that all their practitioners take part in clinical audit?
16. Should providers be required to ensure that records are kept on the implants and devices they implant? If so, for how long?

In answering the above questions, it would be helpful if the principles of Better Regulation could be considered as set out in chapter 3.

7. Indemnity and insurance requirements

- 7.1. Indemnity can be defined as an arrangement in which one party offers protection to another party against future loss or damage.
- 7.2. Insurance can be defined as a specific type of indemnity arrangement in which one party is contracted to provide financial protection to another party against future loss or damage.

What is indemnity insurance for?

- 7.3. Service provision is not always of the quality we would expect and in some cases poor quality services can result in harm. In cases where the harm can be shown in a legal context to be negligent, a person may have a right to bring legal proceedings to claim compensation from the provider for the losses arising as a result of the harm. Where legal liability can be established, it is the responsibility of the provider to pay the compensation in full, as well as the reasonable costs involved in bringing the claim.
- 7.4. Patient records are often requested and used in the making of a claim. Enabling people to access their own health and care records (beginning with their GP records, where they wish it by 2015) is a core commitment in the Government's information strategy for health and care in England^{xxxvii}. The NHS Constitution makes clear that "You have the right of access to your own health records. These will always be used to manage your treatment in your best interests." People may well have the same expectations of easy access to information held about them, and any cosmetic interventions they have had, in the private healthcare sector.
- 7.5. It is generally good practice for providers to purchase indemnity insurance or other arrangement that will help meet the costs of these claims. In terms of clinical care, this is generally called clinical negligence cover or medical malpractice cover. Providers will buy different levels of cover depending upon the level of risk associated with the service and the provider's own means to meet those risks should they materialise. Larger providers with a big cash reserve may decide not to buy indemnity because they have the resource to deal with claims as they are made. However, even if the indemnity is insufficient to meet the costs of a claim, the provider will still be responsible for ensuring the claimant receives the full compensation, i.e. they would have to pay any shortfall as a result of an insufficient indemnity policy.
- 7.6. The costs of buying indemnity will be factored into the price that a provider charges for its services. Making specific requirements for providers to have indemnity may increase

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the costs of delivering cosmetic interventions, which in turn may result in higher prices for the service user.

- 7.7. However, there will always be risks in buying any product or service from a provider that could go out of business. This is particularly important for cosmetic surgery, where harm may appear sometime after the surgery. In these circumstances, it may be more difficult to make a claim for compensation against the provider. However, if a provider was insured, this may provide additional protections that are not available under other types of indemnity. Requirements in the Third Parties (Rights against Insurers) Act 2010 may allow some claims to proceed against the insurer of a provider that goes out of business (or similar circumstances), so long as the insurance policy is still active and subject to the terms that are in place for the policy.

Existing and future requirements

Organisations

- 7.8. Where interventions are paid for by the NHS, providers are required under contract to hold adequate and appropriate indemnity arrangements in place. However, there are no general requirements on provider organisations to hold indemnity so people will need to be careful when considering a cosmetic intervention and consider the risks. It may be reasonable for a provider to be asked what indemnities are in place, and we would encourage people to do so for all products and services where there is a potential risk of harm.

Healthcare professionals

- 7.9. There is currently no consistency across the 9 statutory health professions' regulators with regard to legislation or guidance on the need to hold insurance and indemnity. The Government believes that it is unacceptable for individuals not to have access to recourse to compensation where they suffer harm through negligence on the part of a healthcare professional.
- 7.10. In June 2010, an Independent Review Group commissioned by Government to look at these issues concluded that requiring healthcare professionals to have insurance or indemnity cover in place as a condition of their registration was the most cost effective and efficient means of ensuring that individuals harmed due to the activities of healthcare professionals could seek redress.
- 7.11. Therefore, the Government intends to achieve greater consistency by amending existing legislation and introducing new legislation to provide a consistent framework within which the health regulators can make suitable rules and regulations on the subject. This will be implemented by October 2013, in line with the requirements of the EU Directive on Patients' Rights in Cross Border Healthcare which requires that

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“systems of professional liability insurance, or a guarantee or similar arrangement that is equivalent or essentially comparable as regards its purpose and which is appropriate to the nature and the extent of the risk, are in place for treatment provided [in Member States]”.

- 7.12. This is only with regards to prescribed healthcare professionals. There will therefore be potential gaps where cosmetic interventions are undertaken by people falling out of these groups (either non-healthcare professionals or non-prescribed health professionals).

Non-healthcare professionals

- 7.13. Some professional organisations for non-healthcare professionals may require indemnity cover as a condition of membership.

Questions on indemnity requirements

- 17 Should providers be required to take out an adequate indemnity arrangement and/or to participate in a bond arrangement such as provided by ABTA in the travel industry? If so, for how long?
- 18 How could cosmetic surgery organisations make it easier for patients to access the information they hold about the patient?
- 19 What can be done to protect patients if their provider goes out of business?

In answering the above questions, it would be helpful if the principles of Better Regulation could be considered as set out in chapter 3.

8. Consent, information and advertising

Consent and information

- 8.1. Consent is the principle that a person must give their permission before they receive any type of medical treatment. Consent is required from a patient regardless of the type of treatment being given, from a blood test to an organ donation. The principle of consent is an important part of medical ethics and the international human rights law.
- 8.2. For consent to be valid, it must be voluntary and informed, and the person consenting must have the capacity to make the decision. These terms are explained below.
 - **Voluntary:** the decision to consent or not consent to treatment must be made alone, and must not be due to pressure by medical staff, friends or family.
 - **Informed:** the person must be given full information about what the treatment involves, including the benefits and risks, whether there are reasonable alternative treatments, and what will happen if treatment does not go ahead. Healthcare professionals should not withhold information just because it may upset or unnerve the person (see below).
 - **Capacity:** the person must be capable of giving consent, which means they understand the information given to them and they can use it to make an informed decision.
- 8.3. Consent should be given to the healthcare professional directly responsible for the person's current treatment, such as the nurse arranging a blood test, the GP prescribing new medication, or the surgeon planning an operation.
- 8.4. It is important that anyone considering a surgical or non-surgical procedure considers their reasons for wanting the procedure, their expectations of the results the procedure may bring, as well as making sure that they have all the information they need to make a properly informed decision about whether to go ahead.
- 8.5. When a patient first approaches cosmetic surgery providers they may meet or speak to a 'patient adviser' who is not a doctor or nurse. The Department of Health believes that patients should receive advice about surgery only from doctors and nurses, as they have the qualifications and expertise to give high-quality advice. Currently it is up to patients to check whether their adviser is a doctor or nurse, and whether they are registered with the General Medical Council or Nursing and Midwifery Council.
- 8.6. If the patient decides to go ahead with a procedure they should be offered an appointment to talk to a surgeon. Being clear about their expectations of the procedure

will make sure that the surgeon can give the correct advice about whether the procedure will achieve the desired results.

8.7. The GMC and the Independent Healthcare Advisory Service have produced guidance on Good Medical Practice in Cosmetic Surgery^{xxxviii}. This guidance is non-statutory. It sets out best practice in cosmetic surgery, and makes the following recommendations for cosmetic surgeons regarding information and consent:

- “ensure that for any procedure recommended, the patient is appropriately informed about risks and contra-indications. Patients should be given verbal and written information at the consultation stage, including the general and procedure-specific risks, including the alternatives and the complications associated with cosmetic surgery procedures
- the reasons for the choice of a particular cosmetic surgery treatment must be discussed with the patient prior to procedure
- recommend procedures that will best meet the needs of the patient
- surgery provided or arranged must be based on sound clinical judgment of the patient’s needs and the likely effectiveness of the surgery
- obtain informed consent by ensuring the patient is fully involved in decisions about their care and be satisfied that the patient is fully informed about the surgery, in particular any associated risks, has understood what is proposed and consents to it
- give patients a “cooling off period” of at least two weeks between consultation and surgery, to allow the patient adequate time to reflect on their decision rather than rushing into surgery. Where the patient is adamant to proceed with surgery within the cooling off period, you must ensure that they have signed a disclaimer to this effect
- provide written information detailing post-surgical instructions and aftercare after the surgery has taken place.”

8.8. In addition to the above guidance, consideration could be given to specific requirements regarding psychological assessment of potential patients. It is important that protection is given to prospective patients with psychiatric disorders and/or significant psychological problems that would affect their ability to benefit from cosmetic surgery/procedures, or for whom procedures may cause a deterioration to their psychiatric/psychological state. Currently this assessment will usually be carried out by the surgeon or as part of the general assessment of a potential patient’s suitability for surgery. The 2010 enquiry by the National Clinical Confidential Enquiry into Patient Outcome and Death (NCEPOD), On the face of it, collected data from cosmetic surgery providers on their organisational structures surrounding the practice of cosmetic

surgery. Of the sites that returned data, only 35% carried out routine psychological evaluation prior to cosmetic surgery, and in only 4% of those sites were assessments routinely performed by a clinical psychologist. Despite it being a recommendation in the IHAS and GMC guidance mentioned above, nearly a third of the sites that returned a questionnaire to the NCEPOD survey did not carry out a two-stage (deferred) consent process^{xxxix}.

Advertising of cosmetic interventions

- 8.9. The rules on advertising of cosmetic interventions is covered by the rules on advertising goods and services, administered by the Advertising Standards Authority (ASA). The ASA is the independent UK body responsible for ensuring that advertising in all media is legal, decent, honest and truthful, for the benefit of consumers, business and society. It does this by administering the UK Advertising Codes.
- 8.10. The Advertising Codes are written and maintained by two industry bodies: the Committee of Advertising Practice (CAP) and the Broadcast Committee of Advertising Practice (BCAP). CAP writes and maintains the UK Code of Non-Broadcast Advertising, Sales Promotion and Direct Marketing ('the CAP Code') and BCAP writes and maintains the UK Code of Broadcast Advertising ('the BCAP Code'). The rules, developed in line with Government's better regulation principles, are designed to protect those whose circumstances put them in need of special protection, while retaining an environment in which responsible advertising can operate. The Advertising Codes sit within a legal framework which means that, where appropriate, they reflect the standards required in law, e.g. with reference to misleading and unfair advertising. However, they also contain rules that go beyond legal requirements, such as those relating to harm, offence and social responsibility.
- 8.11. Both Codes are administered by the ASA which, as well as adjudicating on complaints, also undertakes a significant programme of proactive monitoring and compliance work. The ASA system is not voluntary. Advertisers cannot 'opt out' of complying with the mandatory rules and when advertisers get it wrong they face both financial loss from having an ad campaign pulled, and damage to their reputation through the publication of an upheld ASA adjudication. In the rare event of an advertiser refusing to amend or withdraw their ad following an ASA adjudication, or in the event of a particularly serious breach, the system has a range of sanctions available to it to enforce its decisions, details of which can be found at www.asa.org.uk.
- 8.12. The ASA system is both self-regulatory (for non-broadcast advertising e.g. press, poster, cinema, online, video-on-demand (VOD) services and direct mail) and co-regulatory (for TV and radio advertising). On the rare occasions the ASA is unable to secure compliance with the rules on unfair, aggressive and misleading advertising in non-broadcast media it can refer advertisers to the Office of Fair Trading for further regulatory action. For broadcast advertising, the ASA operates under a co-regulatory

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partnership with Ofcom. The ASA has a contract with Ofcom which gives it day-to-day responsibility for maintaining standards and for acting on complaints about TV and radio ads. Broadcasters are obliged to comply with the BCAP Code under their broadcast licences. Non-compliant broadcast advertisers can be referred to Ofcom. Despite there being a dual system of co-regulation and self-regulation, in effect the rules are broadly similar and day to day enforcement and administration is the same. CAP operates a voluntary copy service for non-broadcast advertisers.

- 8.13. Advertising of cosmetic surgery is subject both to the general rules in the Advertising Codes which require that marketing communications do not mislead, harm, be capable of causing serious or widespread offence or be socially irresponsible, as well as specific rules that require, for example, that medical practitioners who wish to advertise their services must have relevant and recognized credentials, and that marketers should encourage consumers to take independent medical advice before committing themselves to a significant treatment.
- 8.14. Additionally, CAP has issued guidance to advertisers, based on previous ASA adjudications, on how the ASA is likely to interpret and apply the advertising rules in relation to cosmetic surgery. CAP advises, for example, that advertisers are likely to breach the rules if they exaggerate the achieved results of cosmetic surgery, trivialize surgery, or infer that treatments are safe, risk free or easy.

Questions on consent, information and advertising for cosmetic interventions

- 20 What more, if anything, is needed to ensure that people have the information and time they need to give informed consent? Is sufficient weight given to the psychological assessment of the individual?
- 21 Should providers be required to carry out a two-stage consent process (ie allowing a 'cooling-off period between consultation and surgery)?
- 22 Do you think the existing regulation of the advertising of cosmetic interventions is proportionate?
- 23 Is there evidence that advertising on cosmetic interventions needs to be regulated using a different system used for general products and services?
24. What is your view on the use of incentives to promote the sale of cosmetic interventions (such as time-limited price offers)?

In answering the above questions, it would be helpful if the principles of Better Regulation could be considered as set out in chapter 3.

9. National implant registry

- 9.1. The Secretary of State for Health has requested that the Review include consideration of an outcomes-based register of frequently implanted devices. Such a register could include medical devices such as breast implants used in cosmetic surgery as well as other implants used in clinical practice, such as heart valves and replacement joints. There is already considerable clinical support for such a comprehensive register, and it could build on the success of the National Joint Registry, and provide the United Kingdom with a valuable asset for further innovation and safety improvement.
- 9.2. The data collected as part of such an outcomes-based register of devices could include:
- date of operation
 - anonymised patient identifier
 - device used
 - surgeon
 - place of operation
 - clinical outcome
 - date of any revision procedure
 - reason for revision
- 9.3. Some different models of outcome databases are set out below.

Cardio-thoracic outcomes database

- 9.4. In 1977 the Society for Cardiothoracic Surgery (SCTS) began to collect data on outcomes following surgery. In 1996 the implementation of the SCTS database enabled a more sophisticated data collection and by 1999 the Society had undertaken and reported the results of a national audit of all cardiac surgery. Since 2005 clinical outcomes from the SCTS database have been published on the CQC website, allowing the public to see the clinical outcomes of cardiac surgeons benchmarked against national standards^{xi}.
- 9.5. The implementation of professionally-led national audit for cardiothoracic surgery has led to improvements in quality through the collection, analysis and publication of clinical outcomes data.

- 9.6. The SCTS publication, *Maintaining Patients' Trust: Modern Medical Professionalism 2011*, describes the costs of the cardiothoracic model as follows:
- 9.7. 'The majority of the costs associated with SCTS model are those for local data collection and are approximately £45,000 per hospital per year. The resource for essential clinical input into the process is currently met from within existing allocations in most hospitals... National data collection, collation and analysis costs around £290,000 per annum for England. The total costs for measuring the quality of clinical outcomes is £1,480,000 per annum in England, which is less than 1% of the total NHS spend on adult cardiac surgery. Routine collection of patient experience and multi-source feedback data incurs minimal incremental cost. There are large cost saving benefits associated with improving clinical quality, and analysis about improved length of stay in the United Kingdom compared to an international standard suggests savings of over £5,000,000 per annum to the NHS purely for isolated coronary artery surgery^{xii}'

Pacemaker registry

- 9.8. The National Pacemaker Database was established in 1977 and is now part of the wider Central Cardiac Audit Database. The database collects data on all types of heart pacemakers and provides an audit of the level and equity of provision of cardiac pacemakers, implantable defibrillators and cardiac resynchronisation therapy in the United Kingdom. Over 500,000 devices are recorded on the database.
- 9.9. The database is part of the Cardiac Rhythm Management Audit which aims to monitor the use of implantable devices and interventional procedures for management of cardiac rhythm disorders in UK hospitals. The Audit aims to:
- to improve the care of patients who undergo pacemaker, ICD and cardiac ablation procedures in the UK
 - to look at activity, trends and outcomes in pacing, ICD and cardiac ablation practice in UK hospitals
 - to provide assessment of treatments, evaluate associated risk factors and measure long term survival rates of patients who undergo pacemaker, ICD and cardiac ablation procedures in the UK
 - to continue to collect and develop the presentation of data from pacemaker, ICD and electrophysiology centres in the United Kingdom (list of all centres in the UK)
 - to explore the usage of new software technologies to undertake rapid linkage and analysis of data
 - to provide new analyses and outputs of the data as defined by the clinical group

- to receive process and present performance management of audit data.
- 9.10. The funding of this work, and that of the wider National Institute for Cardiovascular Outcomes Research comes largely from the Healthcare Quality Improvement Partnership (HQIP)^{xlii}, which is supported by the Department of Health), acting for the Department of Health and its National Clinical Audit Advisory Group^{xliii}. NICOR also receives funding from the British Heart Foundation, the George A Moore Foundation, the Association of British Healthcare Industries and the East Midlands Specialised Commissioning Group^{xliv} on behalf of the Specialised Commissioning Groups across England.

The National Joint Registry (NJR)

- 9.11. The National Joint Registry (NJR) of England and Wales was established in 2002 to improve patient care by collecting information on all hip, knee and ankle replacement operations and monitoring the performance of replacement hip, knee and ankle joints (implants). From April 2012, the NJR also collects data on shoulder and elbow replacements.
- 9.12. The recently revised goals of the NJRSC (draft yet to be formally agreed) are to:
- Monitor in 'real time' the outcomes achieved by brand of prosthesis, hospital & surgeon, and highlight where these fall below an expected performance in order to allow prompt investigation and support follow-up action
 - Inform key stakeholders (eg patients, clinicians, providers, regulators and suppliers) of the outcomes achieved in joint replacement surgery
 - Evidence variations in outcome achieved across surgical techniques in order to inform best practice
 - Enhance patient awareness of joint replacement outcomes to better inform patient choice
 - Support evidence based purchasing of joint replacement implants for healthcare providers to support cost effectiveness
 - Support post market surveillance of implants

Security and confidentiality

- 9.13. At the heart of the NJR is a database of all the joint replacement information that is collected by hospitals, including patients' personal information (subject to patient consent). To avoid sending paper records through the post and to ensure maximum data security, the NJR uses an electronic system for collecting the data and encryption for transferring the data to the database. Suppliers have to sign a data confidentiality

agreement to access data on the Supplier Feedback System. If the supplier needs to share NJR data for any reason (eg for the investigation of a product complaint) they need to seek written approval of the NJR (and the agreement of any other manufacturers involved).

Who can use the data?

- 9.14. Patients' personal data is treated as confidential at all times and cannot be used outside of the NJR. This data is only available to the patient that it relates to them and their surgeon. Procedures are in place to protect the information and to keep it confidential. Data collected via the NJR may be used for medical research but only if it has passed ethical review and if the outcomes are expected to provide significant benefits to the healthcare of patients. However, any data provided is anonymised so that it is not possible to identify individuals. In accordance with the Data Protection act (1998), patients can request a copy of the personal information that the NJR holds about them at any time.

Funding

- 9.15. The NJR obtains its funding from a levy that is placed on the sale of certain implants. Suppliers of joint implants collect levies from the purchasing NHS Trust or independent healthcare hospital for each applicable implant. The Healthcare Quality Improvement Partnership (HQIP) then collect the levies from the suppliers and manages this income in a restricted fund. Spending from this fund is in accordance with the strategic plan adopted by the NJR Steering Committee. The levy, set on an annual basis by the NJR Steering Committee, is £20.00 for the period 2010/2011.

Previous UK Breast Implant Registry (UKBIR)

- 9.16. The UK Breast Implant Registry (UKBIR) (formerly the National Breast Implant Registry) was set up at the Wessex Centre for Plastic and Maxillofacial Surgery at Odstock Hospital in Salisbury (now the Odstock Centre for Burns and Plastic Surgery, Salisbury District Hospital) in 1993. A pilot study to look at long term follow up of women registered with the Registry indicated that only a limited number of implanted women were willing to take part in follow up. This low level of participation meant that the results of any future studies would have been of limited value. Based on this conclusion the decision was made to close the registry at the end of March 2006.

Tracking of medical devices

- 9.17. One key aspect of improving post-market surveillance of medical implants is in improving their traceability. This could be done by developing existing plans for a Unique Device Identifier, involving manufacturers placing an exact code on each implant, which the NHS would accurately record within an existing dataset, for example in the Hospital Episode Statistics (HES) data about hospital admissions and outpatient

attendances which exists in England. This one code could therefore identify the implant a patient has and link with all relevant outcomes. The aim of this would be to move post-market surveillance of medical implants from relying largely on adverse incident reporting to a more sophisticated proactive analysis of the ongoing performance of an implant over its lifetime. Furthermore, it provides an opportunity to link together anonymised NHS clinical data to deliver research outputs that help to improve and safeguard public health.

- 9.18. The benefits of using outcomes to analyse the performance of devices have been demonstrated recently by the central role that the National Joint Registry of England and Wales (NJR) played in identifying problems with metal-on-metal hip replacements in 2010 (analysis of information from the NJR led to a worldwide voluntary recall of the device in question, and has subsequently brought about rapid changes in clinical practice in the UK)^{xiv}.
- 9.19. As part of the forthcoming revision of the EC Medical Device Directives, it is likely that the EC will mandate the central registration of all medical devices available for use in the EU, possibly using a system of Unique Device Identification (UDI). The Commission recognise that different Member States are currently addressing the issue of UDI and traceability individually, and so plan to issue a Recommendation before the end of 2012 that will set out the principles that a UDI system should follow.
- 9.20. The MHRA is currently examining how the current use of barcoding in the NHS^{xv} and likely proposals in the revision of the Medical Devices Directives to mandate a system of Unique Device Identification (UDI) across the EU could be used to facilitate better traceability of devices and linkage with outcomes. Such an approach would support manufacturers' responsibilities to undertake appropriate PMCF studies in a co-ordinated and cost-effective manner. We will examine the Commission proposals when they are published.

Question on a national implant registry

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

In answering the above questions, it would be helpful if the principles of Better Regulation could be considered as set out in chapter 3.

10. Specific sectors/forms of treatment

Question on specific sectors/forms of treatment

- 26 Are there any specific forms of treatment or sectors which you think should be subject to more (or less) regulation than at present? Examples include surgical body modification e.g. tongue splitting; body enhancement implants; cornea tattooing and jewel implants into the cornea.

In answering the above questions, it would be helpful if the principles of Better Regulation could be considered as set out in chapter 3.

Annex A

The health regulators and the professions regulated

Health professional regulator	Regulated health profession
General Chiropractic Council	Chiropractors
General Dental Council	Dentists Dental hygienists Dental therapists Clinical dental technicians Orthodontic therapists Dental nurses Dental technicians
General Medical Council	Doctors
General Optical Council	Dispensing opticians Optometrists
General Osteopathic Council	Osteopaths
General Pharmaceutical Council	Pharmacists Pharmacy technicians
Health Professions Council	Arts therapists Biomedical scientists Chiropodists Clinical scientists Dieticians Hearing aid dispensers Occupational therapists Operating department practitioners Orthoptists Orthotists Paramedics Physiotherapists Podiatrists Practitioner psychologists Prosthetists Radiographers Speech and language therapists
Nursing and Midwifery Council	Nurses Midwives
Pharmaceutical Society of Northern Ireland	Pharmacists

Glossary

Adverse device incident (for reporting purposes) - any malfunction or deterioration in the characteristics and/or performance of a medical device, as well as any inadequacy in the labelling or instructions for use which, directly or indirectly might lead to or have led to the death of a patient, or user or of other persons or to a serious deterioration in their state of health.' In this instance a 'serious deterioration' in the state of someone's health can include:

- a life-threatening illness
- permanent impairment of a body function or permanent damage to a body structure
- a condition necessitating medical or surgical intervention to prevent either of the first two criteria (this includes increase duration of surgery and conditions requiring hospitalisation or prolongation of existing hospitalisation)
- indirect harm as a consequence of an incorrect diagnostic result
- foetal distress, foetal death or any congenital abnormality or birth defect.

ASA – The Advertising Standards Agency is the UK's independent regulator of advertising across media, including TV, internet, sales promotions and direct marketing.

BAAPS – the British Association of Aesthetic Plastic Surgeons. Association "established for the advancement of education in, and the practice of, Aesthetic Plastic Surgery for public benefit".

BAPRAS – British Association of Plastic, Reconstructive and Aesthetic Surgeons. Professional association that "exists to promote the best evidence-based practice in plastic, reconstructive and aesthetic surgery in order to achieve the highest standard of patient care through professional support in education, research and the development of knowledge".

BMA – British Medical Association

Body Dysmorphic Disorder – Defined as a preoccupation that causes significant distress with one or more defect in one's appearance for which most people can hardly notice or do not believe to be important.

Breast augmentation/reduction – Breast augmentation involves surgically inserting an artificial implant to increase the size of the breast. Breast reduction involves removing excess tissue to reduce the size of the breasts.

Breast implant – a medical prosthesis used in post-mastectomy breast reconstruction or for breast augmentation.

Breast Implant Registry – a voluntary registry of breast implant usage in the UK which was operated from 1995 to 2005. It was shut down due to a high proportion of women not consenting to their details being recorded, meaning the information the registry contained was of inadequate quality for research purposes.

Central Alerting System (CAS) – a web-based system for issuing patient safety alerts, medical device alerts, public health notices and other safety critical guidance to the NHS. It enables alerts to be emailed to key contacts across the health care system and allows the onward cascading of this information to relevant health care workers. It also provides a web portal for accessing relevant information.

Competent Authority – national body responsible for the compliance with and enforcement of the EU Medical Devices Directive as it applies to medical devices, device manufacturers and notified bodies in their Member State. In the UK this is the MHRA.

Cosmetic intervention – operations or other procedures that revise or change the appearance, colour, texture, structure, or position of bodily features, which most would consider otherwise within the broad range of ‘normal’ for that person.

CQC – Quality Care Commission is the regulatory body for all health and social care services in England.

CPSD – Cosmetic Products (Safety) Regulations 2008

GMC – General Medical Council is the regulatory body for doctors in the UK.

GPSR – the General Product Safety Regulations 2005

IHAS – Independent Healthcare Advisory Services is a representative organisation for the independent healthcare sector.

MDA – Medical Devices Agency – the predecessor to the MHRA with responsibility for medical device safety and regulation.

MDA – Medical Devices Alert – notice issued by MHRA with important safety information related to a medical device sent to key contacts across the healthcare system using the Central Alerting System with instructions for further cascading to relevant health care workers, as well as being posted on the MHRA website.

Medical Device – defined in European law as “any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings.

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MDEG – Medical Device Expert Group. Established by the EU Commission, MDEG is composed of delegates from member state competent authorities, industry and other stakeholder representatives in the area of medical devices and is the forum in which the implementation of the Medical Devices Directive is discussed. In closed session, MDEG consists of member state competent authorities only and is a forum to discuss all issues relating to the implementation of the medical device directives. MDEG is responsible for publishing guidance documents which reflect the consensus position of its members on interpretation of the Medical Devices Directive.

Medical Device Liaison Officers - members of staff designated in all NHS trusts and primary care trusts in England who are responsible for encouraging effective and comprehensive adverse incident reporting and action on medical device safety publications through encouragement and training of healthcare and support staff and medical device users.

Medical Devices Directives – European Union legislation which, when translated into national law in EU member states, provides the legal framework for regulation of medical devices in Europe.

MHRA – the Medicines and Healthcare products Regulatory Agency, the UK competent authority responsible for regulation of medicines, medical devices, blood and blood components. MHRA is an Executive Agency of the Department of Health.

Notified Body – third-party private sector organisations designated by their national competent authority and commissioned by manufacturers to determine whether a particular medical device meets the relevant regulatory requirements and, whether, when used as intended, it works properly and is acceptably safe (the process known as conformity assessment).

Post-market surveillance – a systematic procedure to review experience gained from their devices after they are placed on the EU market, and to implement appropriate means to apply any necessary corrective action. This undertaking must include an obligation for the manufacturer to notify the competent authorities of:

- (a) any adverse incident which might lead to or might have led to the death of a patient or user or to a serious deterioration in their state of health;
- (b) any field safety corrective action (e.g. systematic recall) undertaken by the manufacturer to reduce the risk of adverse incidents with the device.

SMR08 – Supply of Machinery (Safety) Regulations 2008

TYCT – Treatments You Can Trust – A provider register run by IHAS. Registered Providers are fully qualified, trained and insured and will deliver treatments which comply with a minimum of standards and are delivered in facilities which are clean, hygienic and comfortable.

End Notes

ⁱ <http://www.dh.gov.uk/health/2012/06/pip-report/>

ⁱⁱ <http://www.dh.gov.uk/health/2012/05/pip-review/>

ⁱⁱⁱ <http://www.baaps.org.uk/about-us/audit/1105-britons-tighten-belts-in-more-ways-than-one>

^{iv} *Cosmetic Surgery, Market Intelligence*, Mintel, 2010 p 29

^v *Ibid.* p 27

^{vi} *Ibid.* p 32

^{vii} Royal College of Anaesthetists risk information leaflet October 2009: <http://www.rcoa.ac.uk/patients-and-relatives/risks>

^{viii} S Fasting, abstract cited from http://www.hopkinsguides.com/hopkins/ub/citation/20224619/%5BRisk_in_anaesthesia%5D

^{ix} *Cosmetic surgery information for patients*, Department of Health, 2006, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4125519

^x http://www.gmc-uk.org/ihas_code_of_practice_good_medical_practice_in_cosmetic_surgery_2.pdf 33720281.pdf

^{xi} *Reference guide to consent for examination or treatment (second edition)*, Department of Health, 2009, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643

^{xii} *Ibid.*

^{xiii} <http://www.mhra.gov.uk/home/groups/par/documents/websiteresources/con108643.pdf>

^{xiv} *Reference guide to consent for examination or treatment (second edition)*, Department of Health, 2009, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643

^{xv} Chemical peels for the purposes of improving the appearance of skin would not be considered a medical device. However, chemical peels may be considered a medical device if the manufacturer makes specific medical claims, eg the treatment of acne. However the claim that they may be used on acneic skin is not considered sufficient to indicate a medical purpose.

^{xvi} *Cosmetic surgery information for patients*, Department of Health, 2006, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4125519

^{xvii} *Reference guide to consent for examination or treatment (second edition)*, Department of Health, 2009, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643

^{xviii} *Reference guide to consent for examination or treatment (second edition)*, Department of Health, 2009, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_103643

^{xix} <http://www.bis.gov.uk/bre>

^{xx} <http://www.dh.gov.uk/health/2012/05/pip-review/>

^{xxi} <http://www.dh.gov.uk/health/2012/05/pip-review/>

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- xxii *An Organisation with a Memory*, Department of Health, 2000: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4065083
- xxiii <http://www.bis.gov.uk/policies/consumer-issues/product-safety/cosmetic-products-safety-regulations-2008-as-amended>
- xxiv http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4138410.pdf p 49-51
- xxv This refers to non-corrective contact lenses, such as those changing the appearance of the iris
- xxvi Examples being calf, buttock or pectoral implants.
- xxvii <http://www.dh.gov.uk/health/2012/05/pip-review/>
- xxviii http://www.gmc-uk.org/guidance/good_medical_practice.asp
- xxix Excluding Foundation Trusts in England.
- xxx Ibid.
- xxxi http://www.gmc-uk.org/ihas_code_of_practice_good_medical_practice_in_cosmetic_surgery_2.pdf 33720281.pdf
- xxxii This is accessible from the NMC's website at: <http://www.nmc-uk.org/Documents/Standards/The-code-A4-20100406.pdf>
- xxxiii Details of the NMC's education standards are accessible from their website at: <http://www.nmc-uk.org/Educators/Standards-for-education/>
- xxxiv The NMC's register is accessible at: <http://www.nmc-uk.org/Search-the-register/>
- xxxv <http://www.dh.gov.uk/health/2012/05/pip-review/>
- xxxvi <http://www.ncepod.org.uk/2010cs.htm>
- xxxvii *The Power of Information*, Department of Health, May 2012 <http://informationstrategy.dh.gov.uk>
- xxxviii http://www.gmc-uk.org/ihas_code_of_practice_good_medical_practice_in_cosmetic_surgery_2.pdf 33720281.pdf
- xxxix *On the face of it*, NCEPOD, 2010, <http://www.ncepod.org.uk/2010cs.htm>
- xl Bridgewater B, Cooper G, Livesey S & Kinsman R on behalf of the Society for Cardiothoracic Surgery in Great Britain & Ireland. *Maintaining Patients' Trust: Modern Medical Professionalism* 2011. ISBN 1-903968-29-1. Publisher Dendrite Clinical Systems Ltd, Henley-on-Thames.
- xli Ibid.
- xlii <http://hqip.org.uk>
- xliii <http://www.dh.gov.uk/ab/NCAAG/index.htm>
- xliv <http://www.emscg.nhs.uk/>
- xlv http://www.njrcentre.org.uk/njrcentre/MetalonMetalHipImplants/tabid/237/Default.aspx#DePuy_ASR_Device
- xlvi <http://www.dh.gov.uk/health/2012/01/it-systems-coding/>