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Botulinum Toxin and Cosmetic Fillers (Children) Bill 2019-21

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Summary

The purpose of the Botulinum Toxin and Cosmetic Fillers (Children) Bill 2019-21 is to prohibit specific cosmetic procedures being performed for purely aesthetic purposes on young people under the age of 18 years old in England.[1]

In cosmetic procedures, Botulinum toxin is used to reduce the appearance of wrinkles[2], whilst dermal fillers are used to fill out wrinkles and creases in the skin or increase the volume and definition of the lips and cheeks.[3]

Currently there are no statutory provisions restricting access to these procedures for children and young people. A 2017 report by the Nuffield Council on Bioethics on Cosmetic Procedures and Ethical Issues noted that there are statutory minimum age limits of 18 for other appearance-related procedures such as tattoos and sunbed use.[4]

The 2013 Keogh Review of the Regulation of Cosmetic Interventions called for "greater protection for vulnerable people", noting that young people and girls in particular, were becoming more concerned with their appearance.[5]

The Bill, a Private Members' Bill, is sponsored by Laura Trott MP. It was selected through the ballot procedure where Laura Trott came fourth. The Explanatory Notes state that this is a 'handout Bill' from the Department for Health and Social Care (DHSC).

The Bill was introduced into the House of Commons on 5 February 2020 and its Second Reading took place on 16 October 2020. On 25 November 2020, the Bill passed Committee Stage unamended. Report stage is due to take place on 12 March 2021.

1 Botulinum Toxin and Cosmetic Fillers (Children) Bill Explanatory Notes, pg.1
2 Botox injections, NHS, last reviewed 9 Jul 2019
3 Face and lip fillers (dermal fillers), NHS, last reviewed 16 Jul 2019
4 Cosmetic procedures: ethical issues, Nuffield Council on Bioethics, 22 Jun 2017
5 Review of the Regulation of Cosmetic Interventions, Department of Health, April 2013, pg.11

1. Background

A growing range of cosmetic procedures are now available to consumers. The Explanatory Notes state that since 2012:

> there has been a growing prevalence and normalisation of non-surgical cosmetic procedures, associated with the rise in social media and the increasing accessibility and affordability of providers on the high street as technologies and products in this field have advanced.[6]

The Bill seeks to restrict the access of people under the age of 18 to two non-surgical cosmetic procedures: botulinum toxin and dermal fillers.

The Explanatory Notes to the Bill states that its purpose is to prohibit specific cosmetic procedures being performed for purely aesthetic purposes on young people under the age of 18 in England.[7] The Bill also intends to safeguard children from the potential health risks of botulinum toxin and dermal fillers.[8] Under the arrangements set out in the Bill, under 18s will still be able to access these procedures from doctors, dentists, pharmacists and nurses where there is an assessed medical need.

The Explanatory Notes were put together by the Department for Health and Social Care. They state:

> 14. In line with convention on handout PMBs there has been no public consultation on the policy. Department officials have consulted with a range of industry stakeholders from both the medical, beauty and pharmaceutical sectors, and there is universal support for the principle of introducing an age restriction on these procedures. There is also support for limiting the range of practitioners that the approved procedure may then be delegated to (doctors, dentists, nurses and pharmacists) and limiting their administration to circumstances where there is an assessed medical need.[9]

The 2017 Conservative manifesto included a commitment to "ensure there is effective registration and regulation of those performing cosmetic interventions".[10]

6 Botulinum Toxin and Cosmetic Fillers (Children) Bill Explanatory Notes, pg. 2
7 Botulinum Toxin and Cosmetic Fillers (Children) Bill Explanatory Notes, pg. 2
8 Botulinum Toxin and Cosmetic Fillers (Children) Bill Explanatory Notes, pg. 2
9 Botulinum Toxin and Cosmetic Fillers (Children) Bill Explanatory Notes, pg. 3
10 Forward Together, our plan for a stronger Britain and a prosperous future, The Conservative and Unionist Party Manifesto, 2017

2. Reports on the safety and regulation of cosmetic procedures

All procedures, surgical or non-surgical, come with a risk of complication. The risks associated with surgical procedures are at least in part mitigated by regulation, restricting these to medical professionals who have undergone prescribed training.

There has been much discussion about the risks posed to patients undergoing non-surgical cosmetic procedures, commonly undertaken by individuals who aren't subject to professional regulation or minimum training requirements.

The cosmetic procedure industry has faced increasing pressure to adopt tighter regulation following a high-profile investigation into silicone breast implants[11] (see section 2.1), and numerous reports in the media of consumers who had experienced adverse effects following procedures.[12] [13]

Several reports examining the provision of the cosmetic procedures have highlighted concerns about industry regulation, calling on the government and regulators to improve the standard and oversight of care.

This section provides an overview of the key reports and reviews into the safety and regulation of cosmetic procedures, with a focus on non-surgical procedures.

2.1 PIP breast implants

In March 2010, the French regulator, the French Agency for the Safety of Health Products (AFSSAPS), discovered that manufacturer Poly Implant Prothèse (PIP), had been using a grade of silicone filler in its breast implants that was not of the standard previously approved for implant use.

The Medicines and Healthcare products Regulatory Agency (MHRA) regulates medicines, medical devices and blood components for transfusion in the UK. Following communication from AFSSAPS, the MHRA issued a medical device alert advising that the product was no longer suitable for implant, and directing the quarantine and return of the product to distributors.[14]

An expert group led by Sir Bruce Keogh reviewed the evidence of the potential risks to health of the PIP breast implants and published their

11 Poly Implant Prothèse (PIP) breast implants: final report, DHSC, 18 Jun 2012
12 Botched dermal fillers which disfigured woman's face left her blind in one eye, The Independent, 18 Jan 2020
13 Woman's Botox party warning after lip filler swelling, BBC News, 5 Dec 2018
14 All models and lot numbers of silicone gel filled breast implants - unapproved composition of silicone gel, MHRA, 17 Dec 2014

findings in a final 2012 report.[15] The review found that PIP implants did not show any evidence of significant risk to human health and made recommendations for the future care of affected women.

2.2 The Keogh Review

The PIP implant case raised considerable concern about the clinical safety and regulation of cosmetic surgery and other cosmetic interventions in general.

In light of these concerns, the then Secretary of State for Health, Andrew Lansley, asked Sir Bruce Keogh to reconstitute his expert group to "look at how the safety of patients considering cosmetic interventions can be better ensured in the future".[16]

The Review of the Regulation of Cosmetic Interventions was published in April 2013 and focussed on three main areas:

- high quality care with safe products and responsible providers;
- an informed public to ensure advice is accurate and the vulnerable are protected; and
- accessible redress in the case of things going wrong.[17]

The review highlighted concerns in a number of areas, such as the lack of protection for people undergoing non-surgical interventions, for example, dermal fillers not being classified as a regulated activity by the CQC.[18]

It also highlighted the lack of accredited training courses, and a lack of restrictions about who could establish a training course purporting to offer a qualification. The review made 40 recommendations to the government, including that all those performing cosmetic interventions be registered and that dermal fillers be classified as prescription only medicines. In February 2014, the government published its response to the Review's recommendations, saying that they "fully accept[ed] the principles of the Keogh Review and the overwhelming majority of its recommendations for protecting people who choose cosmetic procedures".[19]

The Review also called for "greater protection for vulnerable people", noting that young people and girls in particular, were becoming more concerned with their appearance.[20]

2.3 The Nuffield Council on Bioethics report

The Nuffield Council on Bioethics is an independent body that examine and reports on ethical issues in biology and medicine.

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15 Poly Implant Prothèse (PIP) breast implants: final report, DHSC, 18 Jun 2012
16 Breast implants, Hansard, col 183, 11 Jan 2012
17 Review of the Regulation of Cosmetic Interventions, DHSC, Apr 2013
18 Keogh pg 24
19 Government response to the review of the regulation of cosmetic interventions, Department of Health and Social Care, 13 Feb 2014
20 Review of the Regulation of Cosmetic Interventions, Department of Health, Apr 2013, pg.11

In 2017, the Council published its report, Cosmetic procedures: ethical issues, which examined the growth, promotion and use of invasive cosmetic procedures.[21] The report looked at ethical issues in cosmetic procedures with a particular focus on the role and responsibilities of health and scientific professionals and others in responding to demand for invasive, non-reconstructive procedures with the aim of "enhancing" or "normalising" appearance.

The report made a number of recommendations, focussed on controls over practitioners, premises and, products as well as limiting young people's access to cosmetic procedures, the role of social media in cosmetic procedures and advertising and marketing.

The report highlighted specific pressures faced by young people with regard to appearance:

> Adolescents may be particularly sensitive to pressures to conform to prevailing peer and social pressures, and are at a vulnerable stage of development with respect to their sense of their own identity. Their access to cosmetic procedures raises particular ethical concerns.[22]

In response to a PQ asking if the government would implement the Report's recommendations, the then Minister of State at the Department of Health Philip Dunne said that it would help to inform the government's thinking about effective registration and regulation of those performing cosmetic interventions.[23]

2.4 Health Education England reports

Health Education England (HEE) is a Non-Departmental Public Body that works to ensure that the healthcare workforce has the appropriate numbers, skills, values and behaviours, and is rightly placed to support the delivery of healthcare and health improvement to patients and the public in England.

The then Department of Health commissioned HEE to report on the qualification requirements for practitioners who perform hair restoration surgery and non-surgical cosmetic procedures.[24]

In 2015, HEE published its findings in two reports. Part One summarises HEE's recommended qualification requirements for practitioners delivering cosmetic procedures.[25] These were developed by a group of industry and professional experts led by HEE, with the support of an Advisory Group. The qualification requirements were developed to "support improvements in the quality and standards of patient/client care and patient/client safety and protection".[26] Part One reiterates similar concerns from other stakeholders about the

21 Cosmetic procedures: ethical issues, Nuffield Council on Bioethics, 22 Jun 2017
22 Cosmetic procedures: ethical issues, Nuffield Council on Bioethics, 22 Jun 2017, ch.2
23 PQ 8395, 12 September 2017
24 Non-surgical cosmetic procedures, HEE, accessed 8 Jul 2020
25 Part One: Qualification requirements for delivery of cosmetic procedures: Non-surgical cosmetic interventions and hair restoration surgery, HEE, Nov 2015
26 Part One: Qualification requirements for delivery of cosmetic procedures: Non-surgical cosmetic interventions and hair restoration surgery, HEE, Nov 2015

regulatory landscape, stating "There are currently no restrictions on who may perform cosmetic procedures, no qualification requirements and an absence of accredited training courses…". Recommendations for qualification requirements were made for the following treatments:

- Hair restoration surgery
- Botulinum toxins
- Dermal fillers
- Lasers, intense pulsed light and light emitting diode
- Chemical peels and skin rejuvenation

Part Two provides a detailed account of the qualification requirements for the delivery of non-surgical cosmetic interventions and hair restoration.[27] HEE made a number of recommendations concerning the qualification standards, including that they be adopted as best practice and accepted as the industry standard and around the accreditation of courses and providers.

[27] Part Two: Report on implementation of qualification requirements for cosmetic procedures: Non-surgical cosmetic interventions and hair restoration surgery, HEE, Nov 2015

3. Regulating cosmetic procedures

A growing range of cosmetic procedures is now available to consumers. These can broadly be categorised as surgical and non-surgical procedures. There is no "official" definition of either term, although further discussion about this characterisation is provided in a report; The Nuffield Council on Bioethics, Cosmetic procedures: ethical issues.[28]

Examples of surgical procedures include breast augmentation, facelifts, rhinoplasty ("nose jobs"), abdominoplasty ("tummy tucks") and liposuction.[29] Examples of non-surgical procedures include dermal fillers, botulinum toxin, hair restoration and transplant, chemical skin peels and teeth whitening.[30]

Regulation varies between surgical and non-surgical procedures.

Surgical procedures

The regulation of surgical procedures is provided via the regulation of doctors, surgeons and their training, and of premises.

The Royal College of Surgeons (RCS) is a professional membership organisation and registered charity which exists to advance patient care.[31] As part of its work, the RCS supervises the training of surgeons in approved posts and examines trainees to ensure the highest professional standards.[32] The RCS state that all surgeons must first qualify as a doctor.[33]

There aren't any statutory restrictions on doctors who have not undertaken surgical training, from carrying out surgical procedures, and a number of groups have raised concerns about the lack of formal training requirements for doctors carrying out cosmetic surgical procedures. This is discussed in detail within the 2017 report on cosmetic procedures by the Nuffield Council on Bioethics (see pgs. 59-62).[34]

The General Medical Council (GMC) maintains the register of doctors in the UK and stipulates the requirements for entry to the register.

The Care Quality Commission (CQC) is the independent regulator of health and adult social care in England. The CQC is responsible for regulating cosmetic surgical procedures as a regulated activity, including all pre- and post-operative care.[35] The CQC maintains the

28 Cosmetic procedures: ethical issues, Nuffield Council on Bioethics, 22 Jun 2017, see summary and conclusions and box 1.6, prg. 4.27
29 Cosmetic procedures: ethical issues, Nuffield Council on Bioethics, 22 Jun 2017, box 1.6
30 Cosmetic procedures: ethical issues, Nuffield Council on Bioethics, 22 Jun 2017, box 1.6
31 About the RCS, RCS, [accessed 14 Oct 2020]
32 About our mission, RCS, [accessed 14 Oct 2020]
33 Qualifications of a Surgeon, Royal College of Surgeons [accessed 14 Oct 2019]
34 Cosmetic procedures: ethical issues, Nuffield Council on Bioethics, 22 Jun 2017
35 Surgical procedures, CQC, [accessed 14 Oct 2020]

register of care providers, monitors, inspects and rates services, and takes action to protect people who use services.[36] Further information is available on the CQC website.

Non-surgical procedures

There are few statutory controls on who may carry out non-surgical cosmetic procedures. A 2013 Review of the Regulation of Cosmetic Interventions carried out by Sir Bruce Keogh reported at the time:

> We were surprised to discover that non-surgical interventions, which can have major and irreversible adverse impacts on health and wellbeing, are almost entirely unregulated.
>
> […]
>
> *In fact, a person having a non-surgical cosmetic intervention has no more protection and redress than someone buying a ballpoint pen or a toothbrush.*[37]

Similarly, the 2017 report on cosmetic procedures by the Nuffield Council on Bioethics discussed the lack of statutory limits on who is permitted to offer cosmetic procedures:

> **Who can provide cosmetic procedures?**
>
> 4.3 There are relatively few statutory limits on who is permitted to offer cosmetic procedures. It is an offence for a person to imply that they are a registered medical practitioner if they are not (for example by taking the title of physician, doctor of medicine, or licentiate in medicine and surgery, without the necessary qualifications and registration), but there is no legally defined set of activities constituting 'the practice of medicine' that may only be performed by a doctor. Concern has been expressed that there is therefore nothing to prevent a person without appropriate qualifications treating patients under the title of, for example, 'aesthetic surgeon'. In contrast, any procedures within the mouth are held to constitute the practice of dentistry and may only be carried out by registered dental professionals.[38]

3.1 Botulinum toxin

Botulinum toxin is classed as a prescription only medicine (POM)[39] and under the Human Medicines Regulations 2012 is prohibited from sale or supply except in accordance with a prescription given by an appropriate practitioner.[40]

Botulinum toxin is produced by the Clostridium botulinum bacteria.[41] The toxin works by disrupting the process of muscle contraction, resulting in a temporary muscle paralysis.[42] When used for cosmetic

36 Who we are, CQC, [accessed 14 Oct 2020]
37 Review of the Regulation of Cosmetic Interventions, Department of Health, April 2013, pg. 26
38 Cosmetic procedures: ethical issues, Nuffield Council on Bioethics, 22 Jun 2017, pg. 55
39 British National Formulary, September 2020
40 The Human Medicines Regulations 2012, subsection 214(1)
41 Botulinum toxin injections, British Association of Aesthetic Plastic Surgeons, [accessed 12 Oct 2020]
42 Botulinum toxin injections, British Association of Aesthetic Plastic Surgeons, [accessed 12 Oct 2020]

purposes, this can help to reduce the appearance of wrinkles for a short period of time; usually between 3 to 4 months.[43]

Botulinum toxin has a number of therapeutic uses, such as the treatment of spasticity and the management of bladder dysfunction.[44]

"Botox ®" is one particular brand of botulinum toxin but is often used to refer to botulinum toxin products in general.

An NHS webpage on Botox injections provides a detailed information about the use of Botox for cosmetic procedures, including information about associated risks.[45] The webpage states the risks of Botox injections are small if "done correctly by a suitably qualified practitioner". Some of the associated risks are headache and flu-like symptoms for the first 24 hours, bruising, swelling and redness at the injection site.

3.2 Dermal fillers

Dermal fillers are used to fill out wrinkles and creases in the skin and can also be used to increase the volume and definition of the lips and cheeks.[46] Most dermal fillers used in the UK contain a natural substance called hyaluronic acid, and their effects usually last between 6 and 18 months.[47]

An NHS webpage on dermal fillers provides a range of information about the procedure.[48] It also includes information about associated risks which can include infection, a lumpy appearance under the skin and the filler moving away from the intended treatment area.[49] The website states that the risks depend on whether the procedure was done properly and the type of filler used.[50]

There are few statutory controls over who may administer botulinum toxins and dermal fillers.

The Explanatory Notes to the Bill emphasise that "practitioners do not need to be medically qualified to perform the procedures and there are no mandatory competency or qualification frameworks related to their administration".[51] It adds that the situation is the same for children, as it is for adults, when it comes to accessing the procedures:

> Currently, children, in the same way as adults, may access botulinum toxin and cosmetic filler procedures on the commercial market without a medical or psychological assessment.[52]

The 2017 report on cosmetic procedures by the Nuffield Council on Bioethics summarised the regulation of both procedures:

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43 Botox injections, NHS, [accessed 13 Oct 2020]
44 British National Formulary, September 2020
45 Botox injections, NHS, [accessed 13 Oct 2020]
46 Face and lip fillers (dermal fillers), NHS, last reviewed 16 Jul 2019
47 Face and lip fillers (dermal fillers), NHS, last reviewed 16 Jul 2019
48 Face and lip fillers (dermal fillers), NHS, last reviewed 16 Jul 2019
49 Face and lip fillers (dermal fillers), NHS, last reviewed 16 Jul 2019
50 Face and lip fillers (dermal fillers), NHS, last reviewed 16 Jul 2019
51 Botulinum Toxin and Cosmetic Fillers (Children) Bill Explanatory Notes, pg.3
52 Botulinum Toxin and Cosmetic Fillers (Children) Bill Explanatory Notes, pg.2

> Prescription medicines such as botulinum toxin (botox) may only be prescribed by doctors, dentists, and other health professionals who have qualified to become independent prescribers.
>
> However, there are no specific statutory controls over who can administer botox, and its prescription-only status can be circumvented through direct purchase over the internet.
>
> Similarly, there are currently no legal restrictions with respect to the skills or qualifications required for practitioners offering procedures such as dermal fillers, cosmetic peels, micro-needling, and treatments using laser, intense pulsed light (IPL) and light-emitting diodes (for discretionary powers over the use of lasers, see paragraph 4.28). These and other non-surgical cosmetic procedures may therefore be offered by health professionals, such as doctors, dentists and nurses, by non-health professionals such as beauty therapists, and indeed by anyone else who wishes to do so.[53]

The same report gave further details on the regulation of dermal fillers:

> Dermal fillers are not currently defined as either medical devices or medicines, unless they are marketed for medical purposes, such as lipoatrophy in people with HIV, or are pre-mixed with other substances such as anaesthetic that do fall within medicines regulations. They also fall outside the 2001 EU General Product Safety Directive, as this excludes products used as part of a 'professional service'. Their contents are therefore potentially *less* regulated than other consumer products, and there is no restriction at all on who may purchase them, or provide them as treatment.[54]

Regulating dermal fillers as medical devices

In response to an April 2019 PQ, the then Parliamentary Under-secretary for the Department of Health and Social Care, Jackie Doyle-Price, stated that all dermal fillers, irrespective of their composition and intended use, would be regulated as medical devices from May 2020. She also responded to calls to restrict the availability of dermal fillers to prescription only:

> Currently, the Medicines and Healthcare products Regulatory Agency only regulates dermal fillers that are placed on the United Kingdom market as medical devices, as defined in the Medical Devices Regulations 2002. The majority of these products are intended to be used in reconstructive surgery, and thus they are considered to be medical devices, although some manufacturers also indicate their products for aesthetic use as well.
>
> Cosmetic dermal fillers placed on the market without any medical purpose being attributed to them by the manufacturer fall outside the scope of the Medical Devices Regulations, although in practice the majority of the products on the UK market are CE marked as medical devices.
>
> From May 2020 all dermal fillers, irrespective of their composition and intended use, will be regulated as medical

53 Cosmetic procedures: ethical issues, Nuffield Council on Bioethics, 22 Jun 2017, pg.56

54 Cosmetic procedures: ethical issues, Nuffield Council on Bioethics, 22 Jun 2017, pg.69

> devices under Annex XVI of the Medical Device Regulations (EU 2017/745). The Regulations will significantly strengthen the quality assurance and safety of dermal fillers and ensure a consistent legal status of these products on the UK market. This will lead to a stronger market surveillance of these products.
>
> Medical devices cannot be designated as 'prescription only', as this term only applies to medicinal products. The Government currently has no plans to introduce such a category for medical devices.
>
> The Government is committed to the safe and effective regulation of medical devices in the UK; we continue to strengthen safety while ensuring patients and the public have fast access to new, innovative devices.
>
> Through the 'no deal' statutory instrument, which will amend the Medical Devices Regulations 2002, the UK will have a regulatory system in place, which will mirror all the key elements contained in Medical Device Regulations (EU 2017/745) and which will be brought into force in line with the transitional timetable being followed by the European Union for the full application of this Regulation.[55]

EU Regulation on medical devices

Regulation (EU) 2017/745 of the European Parliament and of the Council aims to update the rules on placing on the EU market, making available and putting into service, medical devices for human use and their accessories.[56]

Article 12 of the Regulation stipulates that common specifications should be developed for certain groups of products without an intended medical purpose:

> Certain groups of products for which a manufacturer claims only an aesthetic or another non-medical purpose but which are similar to medical devices in terms of functioning and risks profile should be covered by this Regulation. In order for manufacturers to be able to demonstrate the conformity of such products, the Commission should adopt common specifications at least with regard to application of risk management and, where necessary, clinical evaluation regarding safety. Such common specifications should be developed specifically for a group of products without an intended medical purpose and should not be used for conformity assessment of the analogous devices with a medical purpose. Devices with both a medical and a non-medical intended purpose should fulfil both the requirements applicable to devices with, and to devices without, an intended medical purpose.[57]

Annex XVI of the Regulation provides a list of products without an intended medical purpose, including:

> Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by

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55 PQ 246486, 29 April 2020

56 Summary of Regulation (EU) 2017/745 on medical devices, EUR-Lex, last updated 6 Apr 2020

57 REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, 5 May 2017

> subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.[58]

Delay to the application of Regulation (EU) 2017/745

The Regulation came into force in 2017 and was due to apply in the EU fully from 26 May 2020. On 3 April 2020, the European Commission submitted a proposal to defer the application of certain provisions of Regulation (EU) 2017/745 by one year.[59] The proposal outlined concerns about the increased demand for medical devices in light of Covid-19, and the need to avoid potential market disruption.

The European Parliament and Council accepted the proposal to defer the Regulation's application to May 2021.[60]

An Explanatory Memorandum submitted by the Department for Health and Social Care explains that the Regulation would have taken direct effect in UK law under the European Communities Act 1972, as saved for the purposes of the Transition period by the European Union (Withdrawal) Act 2018, as the date for its full application fell during the Transition Period.[61] Its new application date of May 2021 falls outside of the Transition Period.

In its guidance on EU regulations medical devices, the government has said that it will provide guidance for plans after the end of the transition period:

> **Update on delay to full implementation**
>
> The European Parliament and Council have approved a proposal to delay the full implementation of the Medical Device Regulation 2017/745 (MDR) for one year to 26 May 2021. This means that the full applicability of the MDR will fall outside of the transition period agreed with the EU.
>
> We are taking steps to plan for after the end of the transition period. We will provide guidance on this in due course in light of Government decisions required on the future of UK regulation. All decisions on regulations will be taken with a view to prioritising patient safety and ensuring patient access for medical devices.
>
> In the meantime, the existing regulatory requirements should continue to be met.[62]

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58 REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC, 5 May 2017

59 Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain of its provisions, European Commission, 3 Apr 2020

60 REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions, Official Journal of the European Union, 24 Apr 2020

61 Explanatory Memorandum on the decision from the European Commission to the European Parliament and the Council, to amend Regulation (EU) 2017/745 on medical devices as regards the dates of application of certain provisions, DHSC, 1 Jun 2020

62 Medical devices: EU regulations for MDR and IVDR, Gov.uk, last updated 24 Apr 2020

3.3 Children and young people's access to non-surgical procedures

The 2017 report on cosmetic procedures by the Nuffield Council on Bioethics also discussed concerns around children and young people's access to procedures and ethical considerations about how access should be managed for these groups:

> **Access to procedures by children and young people**
>
> 2.18 Finally, the question arises as to who may access cosmetic procedures, and whether there could be any justification for limiting access in any way, Specific concerns arise in connection with access by children and young people. Adolescents are particularly susceptible to pressures to conform to prevailing peer and social pressures; and are at a vulnerable stage of development with respect to their sense of their own identity. Moreover, appearance dissatisfaction in adolescence has consistently been identified as a risk factor for a variety of practices used to manage appearance and that are associated with long-term consequences, including eating disorders, depression, and low self-esteem.
>
> 2.19 While the law increasingly recognises the ability of children and young people to make decisions for themselves (see paragraph 4.46), this recognition is accompanied until adulthood by an ongoing protective role both on the part of parents and on the part of the state. This protective role is signalled in other areas of law through the absolute prohibition on those under 18 having a tattoo, or using a sunbed other than under medical supervision (see paragraph 4.48). Parents are explicitly excluded from providing consent on behalf of their children for either of these activities, demonstrating a clear limitation by the state on the role of parents with respect to some of the means by which bodies may be modified and appearance changed. Moreover, in the health context, health professionals would be acting against their ethical codes, and indeed the law, if they provided procedures that they did not believe to be in a child's best interests. The permissibility of carrying out invasive cosmetic procedures on a child or young person, without expectation of therapeutic gain, raises serious ethical concerns.[63]

The Keogh Review also said that there was a need for greater protection for vulnerable people, stating that young people and girls in particular are becoming more concerned with their appearance.[64] The Review also noted the impact of social media and growth in celebrity culture on young people's view of cosmetic procedures as a commodity.[65]

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63 Cosmetic procedures: ethical issues, Nuffield Council on Bioethics, 22 Jun 2017, pgs. 32-33

64 Review of the Regulation of Cosmetic Interventions, Department of Health, April 2013, pg.11

65 Review of the Regulation of Cosmetic Interventions, Department of Health, April 2013, pg.12

Box 1: Consent to treatment for children and young people

The NHS has published information about children, young people and consent to treatment.[66] It should be noted, however, that cosmetic procedures are rarely performed on the NHS, and thus this information may not be wholly applicable to consent for cosmetic procedures. The NHS states that people aged 16 or over are entitled to consent to their own treatment. The NHS also states that young people (aged 16 or 17) are presumed to have sufficient capacity to decide on their own medical treatment, unless there's significant evidence to suggest otherwise.

The NHS also discusses "Gillick competence" by which children under the age of 16 can consent to their own treatment if they're believed to have enough intelligence, competence and understanding to fully appreciate what's involved in their treatment.

The General Medical Council (GMC) maintains the register of doctors in the UK. The GMC has issued guidance on making decisions and assessing the capacity to consent.[67] This advises that the GMC and the law permit doctors to undertake procedures that "do not offer immediate or obvious therapeutic benefits for children or young people, so long as they are in their best interests and performed with consent". It also advises that doctors should consider the social, psychological and emotional benefits of the child, young person and their parents, which may be relevant in the "surgical correction of physical characteristics that do not endanger the child's life or health".

The GMC has issued separate guidance for doctors who offer cosmetic interventions, which states that doctors must only provide interventions that are "in the best interests of the child or young person",[68] and also refers to additional GMC guidance for treating people aged 0-18 years.[69]

The Joint Council for Cosmetic Practitioners (JCCP) maintains a voluntary register of practitioners delivering aesthetic treatments. JCCP, jointly with the Cosmetic Practice Standards Authority, has issued guidance for practitioners who provide cosmetic interventions.[70] The guidance states that "it is not appropriate to provide non-surgical cosmetic interventions to children under 16 years unless there are specific, medical indications". It further states that practitioners may provide non-surgical treatment to young persons aged 16-17 years with their consent, if they are competent to give it, or with the consent of a parent or the Court.

3.4 Voluntary registers

Practitioners offering non-surgical cosmetic procedures are not under any statutory duty to join a register, however they may join a voluntary register if they choose too. A number of voluntary registers stipulate minimum training requirements and require members to adhere to a code of conduct. Below we provide an overview of some of such registers.

In 2016, the British College of Aesthetic Medicine and British Association of Cosmetic Nurses issued a press release announcing their joint working on establishing the Joint Council for Cosmetic Practitioners (JCCP) in response to recommendations made in the second HEE report.[71]

66 Children and young people, consent to treatment, NHS, last reviewed 29 Mar 2019
67 Making decisions, GMC, [accessed 14 Oct 2020]
68 Guidance for doctors who offer cosmetic interventions, GMC, 12 Apr 2016
69 0-18 years: guidance for all doctors, GMC, 2007
70 JCCP and CPSA Guidance for Practitioners Who Provide Cosmetic Interventions – Second Edition, JCCP, May 2020
71 Joint BACN/BCAM Press Release – Establishment of the Joint Council for Cosmetic Practitioners(JCCP), BACN & BCAM, [undated]

The JCCP describes itself as the recognised self-regulators of the non-surgical aesthetic industry in the UK.[72]

The JCCP Practitioner Register has been established to enable practitioners delivering the aesthetic treatments set out in the Cosmetic Practice Standards Authority (CPSA) Framework of Standards and Competences to be accredited.

The CPSA website describes CPSA as an expert group of specialists with patient and public representation that is committed to safeguarding people who undergo non-surgical cosmetic treatment and hair restoration surgery. CPSA has compiled guidance on key areas of non-surgical cosmetic interventions.[73]

The JCCP voluntary register of practitioners and approved education and training providers was established in early 2018.[74]

The JCCP's practitioner register is separated into two parts; Part A is for registered healthcare professionals and Part B is for all other "aesthetic practitioners" who are not regulated by healthcare regulator.

The JCCP has published a code of practice for its registrants, and also provides a webpage for the public on raising concerns and its fitness to practice procedures. Further information about the JCCP is available on the JCCP website.

Save Face is a national register of accredited practitioners who provide non-surgical cosmetic treatments such as botulinum toxin and dermal fillers. The Save Face register is accredited by the Professional Standards Authority. The Save Face website enables members of the public to search for a registered practitioner and offers a range of information and guidance to support people in choosing a safe practitioner.

72 About us- mission statement & values, Joint council for cosmetic procedures, JCCP, [accessed 13 Oct 2020]
73 About the CPSA, CPSA, [accessed 13 Oct 2020]
74 Press release joint council for cosmetic practitioners (JCCP) Jan 2018, British College of Aesthetic Medicine, [accessed 13 Oct 2020]

4. Parliamentary and other comment

In a January 2020 response to PQ 6799 , the government said that it "supports the principle of increased protections" for children and young people, and their access to some injectable cosmetic procedures:

> **Non-surgical Cosmetic Procedures: Children**
>
> **Asked by Ranil Jayawardena, Conservative**
>
> **Asked on 22 January 2020**
>
> To ask the Secretary of State for Health and Social Care, with reference to the Answer of 21 October 2019 to Question 757 on cosmetic fillers and Botox injections for children, what progress he is making on (a) the review of industry standards of practice; (b) ensuring that effective registration and regulation of companies performing cosmetic interventions and (c) assessing the health risks and psychological impact of access arrangements to injectable cosmetic procedures by children.
>
> **Answered by Nadine Dorries, then Parliamentary Under-Secretary for the Department of Health and Social Care**
>
> **Answered on 30 January 2020**
>
> The Government remains committed to improving the safety of cosmetic procedures through better training for practitioners, and clear information so that people can make informed decisions about their care.
>
> The Department continues to consult with stakeholders on industry standards of practise and the health risks posed by current access arrangements to non-surgical cosmetic procedures. On the basis of the evidence gathered to date, the Government supports the principle of increased protections for children and young people for some injectable cosmetic procedures. The Department is exploring the legal implications and potential impacts of an age restriction that would bring these procedures in line with other body modifications such as tattoos and sunbed use.[75]

In a January 2020 PQ, the government was asked what assessment it had made of the potential merits of introducing a code of conduct for companies offering cosmetic fillers and Botox injections in relation to the age verification of clients, among other things. The government said that it was "committed to achieving the right regulatory balance between supporting excellent business practice" and supporting consumers. The government also referred to the response provided to PQ 6799, as quoted above.

During a May 2019 debate on the regulation of the medical aesthetics industry, the then Parliamentary Under-Secretary for the DHSC Jackie Doyle-Price said that she was committed to bringing forward

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75 PQ 6799, 30 Jan 2020

legislation to prohibit under-18s from having certain types of cosmetic procedures.

There has been some press comment. For example, The Sun welcomed the Bill's introduction, commenting that it "marks a win" for its *Had our Fill* campaign which has called for:

- Fillers to be made illegal for under 18s
- A crackdown on social media sites advertising fillers
- A Government-backed central register for approved practitioners[76]

The Nuffield Council on Bioethics said that the Bill "indicates that this important issue is still very much on politicians' agendas".[77]

[76] OVER AND P-OUT Kids under 18 face ban on 'dangerous' lip fillers in win for Sun campaign, The Sun, 4 Feb 2020

[77] New Bill to restrict under 18s' access to Botox and fillers echoes Nuffield Council concerns, Nuffield Council on Bioethics, 5 Feb 2020

5. The Bill

Explanatory Notes to the Bill sets out that the Bill's main purpose is to prohibit specific cosmetic procedures being performed for purely aesthetic purposes on young people under the age of 18 years old in England.[78] It is hoped that this will safeguard children from the potential health risks of botulinum toxins and dermal fillers. Both procedures will still be available to under 18s, provided by doctors, dentists, pharmacists and nurses, where there is an assessed medical need.

Below, we provide an overview of the legal provisions set out by the Bill. The Bill[79] and the Explanatory Notes[80] may be accessed on the Parliament.uk website.

Clause 1

Clause 1(1) makes it an offence, in England, for a person to administer botulinum toxin or a filler for cosmetic purposes, by injection, to a person under the age of 18. The clause also defines a 'a filler' as any substance used for dermal or mucous membrane filling (whether or not designed to be so used) with the intention of changing the appearance of a person. It also sets out what would be considered a 'cosmetic use'. As such, the Bill enables the continued use of dermal fillers for treatment purposes, where there is an assessed medical need, in people under aged 18 years.

Subsection 4 provides a defence for a person charged with an offence under subsection (1) if:

- The defendant was a registered medical practitioner
- The defendant was a regulated health professional who was acting in accordance with the directions of the registered medical practitioner
- The defendant had taken reasonable steps to establish the person's age, or had reasonably believed that the person was aged 18 or over

A person who commits an offence under this clause is liable on summary conviction to an unlimited fine.

Clause 2

Clause 2 deals with the liability of business owners and creates an offence. Under Clause 2(1), a business owner would commit an offence if, in the course of their business, a person other than an "approved person" administers, in England, botulinum toxin or a subcutaneous, submucous or intradermal injection of a filler for a cosmetic purpose, to a person is under 18 years of age.

Under Clause 2(2), it would also be an offence for a person to make such arrangements by, or on behalf of, a business owner. The

78 Botulinum Toxin and Cosmetic Fillers (Children) Bill Explanatory Notes
79 Botulinum Toxin and Cosmetic Fillers (Children) Bill 2019-21
80 Botulinum Toxin and Cosmetic Fillers (Children) Bill Explanatory Notes

Explanatory Notes give the example of an employee of the business "making an appointment, or agreeing via digital or social media to undertake the procedure".

As with clause 1, the meaning of 'cosmetic use' is defined.

> Under Clause 2(3), a person who commits an offence relating to the administration or arranging for the administration of botulinum toxins or fillers as stipulated in subsection 1 is liable on summary conviction to an unlimited fine.

Clause 2(4) provides business owners charged with such an offence with a defence, if it is proved that they "took all reasonable precautions and exercised all due diligence to avoid committing it".

Clause 3

Clause 3 makes provision as to offences by bodies corporate. Clause 3(2) refers to directors, managers or secretaries of a body corporate or any person purporting to act in such capacity. Clause 3(3) also refers to "any other similar officer" of the body corporate.

Under these clauses, if an offence is proven to have been committed with the consent or knowledge of any such "officer", that person – as well as the body corporate – commits the offence and is liable to be proceeded against and punished accordingly. Under these clauses, if an offence is proven to have been committed under clause 2 with the consent or knowledge of any such "officer", that person – as well as the body corporate – commits the offence and is liable to be proceeded against and punished accordingly.

The Explanatory Notes give examples of how this may apply:

> For example, this could apply if a national aesthetic clinic chain neglected to implement training programmes for staff alerting them to the offence and the actions that could be taken to prevent the offence occurring. Or a hotel allows the hire of a function room or suite to a business without undertaking checks to establish the nature of the business activities that will be taking place.[81]

Clause 4

Clause 4 provides trading standards in local authorities (a local weights and measures authority in the Bill) with enforcement powers for clauses 2 and 3.[82]

Clause 4(2) refers to the Consumer Rights Act 2015. The Explanatory Notes further explain that the Bill does not create any new enforcement or investigatory powers, but rather that local authorities should use their existing powers under Schedule 5 of the Consumer Rights Act 2015.

Clause 4(3) amends the Consumer Rights Act 2015 to enable local authorities to enforce the provisions set out in the Bill, and as indicated by clause 6(2), this extends to England, Wales, Scotland and Northern Ireland.

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81 Botulinum Toxin and Cosmetic Fillers (Children) Bill Explanatory Notes, prg.31
82 Botulinum Toxin and Cosmetic Fillers (Children) Bill Explanatory Notes, prg.32

Clause 5

This clause enables amendments to be made to other secondary legislation as a consequence of this Bill.[83] As indicated by Clause 6(2), this provision extends to England, Wales, Scotland and Northern Ireland.

Clause 6

Clause 6 sets out that the Bill is applicable in England and Wales only, whilst Clauses 4(3) and Clause 5 extend to England, Wales, Scotland.

The Bill's Explanatory Notes stipulate that a money resolution is required for the Bill.

83 Botulinum Toxin and Cosmetic Fillers (Children) Bill Explanatory Notes, prg.35

6. Second Reading

Second Reading of the Bill took place on 16 October 2020. The Bill's Sponsor Laura Trott MP introduced the Bill and outlined why the Bill was needed, highlighting the dangers of possible adverse effects following the procedure and a lack of regulatory oversight for practitioners.[84]

There was widespread support for the Bill in the debate. They spoke of pressures on young people with respect to physical appearance and raised concerns about the effect of social media on young people. Members also raised concerns about the regulatory structure concerning cosmetic procedures, with particular concern about the lack of training prescribed for practitioners and suggestions of a practitioner register.

Many Members recounted being surprised to learn that there weren't already existing legislative restrictions on under 18s accessing botulinum toxin and dermal filler services, and that 18 was an appropriate age limit.

Members expressed support for the continued access to botulinum toxin and dermal fillers for under 18s undergoing medical treatment.

James Cartlidge (Cons), referring to the Bill's application in England, raised the possibility of people travelling across the border to access procedures.[85] The issue was also mentioned by other MPs during the debate.

Minister for Health, Edward Argar, attended the debate in place of Minister of State for mental health, suicide prevention and patient safety, Nadine Dorries. Mr Argar said that the government supported the Bill and hoped that it would receive the support of the whole House.[86] Mr Argar highlighted existing statutory age restrictions in place for tattooing, teeth whitening and sunbed use, and said it made "little sense" that there are no similar protections for invasive injectable cosmetic procedures. Mr Argar also said that the DHSC was exploring a range of options for increased oversight of practitioners, including a system of registration or licencing. Mr Argar said that the Bill's proposals would ensure that procedures for under 18s are placed within a clinical framework, which permit the procedures to continue under the directions of a doctor and to be administered within a regulated environment for medical purposes.

84 HC Deb, 16 October 2020, vol 682 c650
85 HC Deb, 16 October 2020, vol 682 c655
86 HC Deb, 16 October 2020, vol 682 c688

7. Public Bill Committee

The Bill was considered by a Public Bill Committee on 25 November 2020 and was reported to the House following a single sitting without amendment.[87]

Carolyn Harris (Lab) moved **amendments 1** (considered alongside **amendment 2**) which would have amended clause 1 in order to specify that a defence for medical practitioners to being charged with an offence under subsection 1 should only apply where the practitioner deemed the procedure to be medically necessary.[88]

Ms Harris set out concerns about the Bill's original wording:

> I am concerned that the Bill, as it is currently worded, would allow registered medical practitioners, as well as regulated health professionals under the direction of a registered medical practitioner, to carry out procedures on any person under the age of 18 without needing to provide medical evidence. I want to be absolutely clear: no practitioner should be exempted from this measure simply because of their qualification level.[89]

Kevan Jones (Lab) expressed concern at the regulation of medical practitioners and said that there was "clear evidence that medical practitioners are prescribing [botox] in a way that leads to queries over the medical supervision".[90] Further, he said:

> I accept that there are situations where the prescription of botox, even for under-18s, is medically needed, but that needs to be explicitly in the Bill—that would then provide protection. I accept that there is then going to be an argument about the courts having one description and the GMC another. The problem is, however, that the GMC is failing. We need the law to be very clear that medical practitioners need a medical reason for prescribing botox for under-18s. Without having the wording in the Bill, people might somehow argue that because they are a medical practitioner, they can prescribe it whatever. The idea being advanced through these amendments, arguing about the medical necessity, would make the Bill stronger.[91]

The Minister argued that any deficiencies the amendment sought to tackle should show up on post-implementation review.[92] The Bill's Sponsor, Laura Trott, said that she agreed with the sentiments behind the amendments but pointed to existing guidance for doctors and outlined complexities around defining the terminology used in the amendment:

> I completely agree with the sentiments behind the amendments. It is right that we should restrict these treatments for under-18s to only where it is absolutely medically necessary. The advice I have received is that that is covered in the Bill, inasmuch as UK doctors must be registered and hold a licence to practise with the GMC. The GMC publishes specific ethical guidance that says

87 PBC Deb, 25 November 2020
88 PBC Deb, 25 November 2020, c1
89 PBC Deb, 25 November 2020, c4
90 PBC Deb, 25 November 2020, c4
91 PBC Deb, 25 November 2020, c4
92 PBC Deb, 25 November 2020, c5

> that doctors performing cosmetic interventions can provide treatment to children only when it is deemed to be medically in the best interests of the patient.[93]
>
> I accept that, as the right hon. Member for North Durham said, in some cases at the moment this is not happening correctly when it comes to botox, but to create a new legal precedent around the wording "deemed medically necessary" would add a layer of complexity, given that it is generally for the GMC to decide what is in the best interests of the patient. As he also mentioned, it would also produce two different authorities—the GMC and the court—which would then opine on the same issue. That could cause confusion.

Ms Trott committed to working with the Members on strengthened wording which would be brought forward on Report.[94] Amendments 1 and 2 were subsequently withdrawn.

Judith Cummins (Lab) moved **amendment 3**. With respect to a defence for an offence committed under subsection 1, where the defendant is required to have taken reasonable steps to establish a person's age, the amendment proposed an additional requirement for the defendant to require and record proof of this information.[95]

Ms Cummins expressed concern that the wording of the Bill left the Bill open to interpretation:

> I am concerned that, as currently worded, the Bill leaves open to interpretation what reasonable steps a practitioner must make to establish the age of the person receiving the procedure. I want the Bill to make it clear that practitioners must request proof of age before any procedure is undertaken, verify the authenticity of that document and ensure that it is recorded, to ensure that there is no doubt about a client's age. We need clear and explicit guidelines to ensure that vulnerable young people do not fall through the net.[96]

Ms Trott said that whilst she agreed that it was necessary to ensure providers have proof of age before carrying out treatment, she considered that the amendment was "too narrow" in that the defendant was already required to establish the steps that they took to evidence proof of age.[97] Ms Trott said that it was already implicit that this could and should include recording information, but it should not be limited to that. Ms Trott put forward that the intent of the amendment would be more appropriately contained in guidance which she expected professional bodies to produce should the Bill become law. Amendment 3 was subsequently withdrawn.

As part of the stand part debate for Clause 1, Kevan Jones (Lab) raised more general concerns about the regulation of doctors with respect to safety concerns and cosmetic procedures.[98]

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93 PBC Deb, 25 November 2020, c6
94 PBC Deb, 25 November 2020, c6
95 PBC Deb, 25 November 2020, c6
96 PBC Deb, 25 November 2020, c7
97 PBC Deb, 25 November 2020, c7
98 PBC Deb, 25 November 2020, c10

Mr Jones moved **amendment 4** which introduced an offence to advertise or promote the administration of botulinum toxin and dermal fillers for a cosmetic purpose to a person under 18 years old.[99] Mr Jones said that it was a "probing amendment to get concerns on the record" and raised concern about the advertising of botox consultations on social media.

Mr Jones had also proposed that new clause 1 would make it necessary for the government to report on preventative measures:

> "(1) The Secretary of State must prepare a report on steps that are being, and will be, taken to seek to prevent offences being committed under this Act.
>
> (2) That report must include any steps to prevent the advertising or promotion of the cosmetic use of botulinum toxin and fillers on children.
>
> (3) The report must be laid before Parliament no later than the end of the period of six months beginning with the day on which this Act is passed."

Mr Jones said that the purpose of new clause 1 was to ensure oversight over the effectiveness of the Bill.

Responding to amendment 4 and new clause 1, Ms Trott outlined work being undertaken with respect to advertising:

> I note that there is a lot more work going on this area, which is welcome. In January, the Committee of Advertising Practice and the Medicines and Healthcare Products Regulatory Authority issued an enforcement notice to the beauty and cosmetics industry and have started to use monitoring tools to take down posts on social media, which is a welcome development, although obviously we need more.[100]

Ms Dorries and Ms Trott both acknowledged that his concerns were outside the scope of the Bill but committed to further work in this area. Amendment 4 was subsequently withdrawn.

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99 PBC Deb, 25 November 2020, c12
100 PBC Deb, 25 November 2020, c15

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