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Guidance

# Botulinum toxin and cosmetic fillers for under 18s: guidance for enforcement officers

Information for local authorities, the police and others involved in enforcing the Botulinum Toxin and Cosmetic Fillers (Children) Act 2021.

From:

Department of Health and Social Care

# **Applies to England**

### Documents



# Botulinum toxin and cosmetic fillers for under 18s: guidance for enforcement officers

HTML

## Details

This non-statutory guidance is for local authorities, the police and others who will be involved in enforcing the <u>Botulinum Toxin and Cosmetic Fillers (Children) Act 2021</u>.

The legislation came into force on 1 October 2021.

This guidance sets out:

• the background to the new age restriction on botulinum toxin and cosmetic filler treatments and details of the legislation

- information about the substances and how they are used in cosmetic treatments
- guidance on the offences and defences provided in the Act, with example scenarios of how they may be applied during enforcement activities
- a summary of enforcement powers and how enforcement bodies could work together to enforce the provisions in the Act

This guidance should be read alongside the Act.

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Guidance

# Botulinum toxin and cosmetic fillers for under 18s: guidance for enforcement officers

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Applies to: England

# Summary

### Key message

From 1 October 2021 it is a criminal offence to administer botulinum toxin (commonly known as 'Botox'®), or a filler by way of injection for a cosmetic purpose to a person under 18 in England, even if they have the permission of someone over 18.

It is also an offence to make arrangements or book an appointment to provide these treatments to anyone under the age of 18 in England.

There is separate:

- guidance for businesses
- guidance for under 18s and their parents and guardians

## Introduction

The purpose of this non-statutory guidance is to support local authorities and the police in successfully implementing the <u>Botulinum Toxin and Cosmetic Fillers</u> (<u>Children</u>) Act 2021 (the Act). The legislation came into force on 1 October 2021.

The main purpose of the Act is to prohibit the administering of botulinum toxin, or a filler by way of injection for a cosmetic purpose, to a person under 18 in England. It will also be an offence to make arrangements to undertake, or arrange for another person to undertake, these procedures on a person under 18 in England.

These procedures carry risks to physical health, including infection, blindness, and in rare cases death, and there are psychological implications associated with changing physical appearance. Young people are particularly vulnerable as they are developing physically and mentally, and there are ethical implications around the extent to which they can give informed consent to procedures.

The procedures will still be available to people under 18 but only in cases where the treatment has been approved by a doctor. Their administration may then only be carried out by an 'approved person' (doctor, dentist, pharmacist, nurse). Doctors should, as per their usual practice, follow guidance and standards issued by their regulator, the General Medical Council, when considering the use of either product type.

The police and weights and measures authorities (usually Trading Standards) have powers to enforce the legislation. However, this guidance will also be relevant to environmental health officers.

This guidance has been developed by the Department of Health and Social Care. It should be read alongside the Act.

### **Background to the legislation**

The Act received Royal Assent on 29 April 2021 and came into force on 1 October 2021.

The legislation was introduced into Parliament as a Private Member's Bill sponsored by Laura Trott, the Member of Parliament for Sevenoaks.

The Act aims to safeguard children from the potential health risks of botulinum toxin and cosmetic fillers. There are also ethical considerations about the extent to which people under 18 have the emotional and mental maturity to give informed consent to these invasive procedures when accessing them on the commercial market without a medical or psychological assessment.

The age restriction has been set at 18 years. This has been selected as it aligns with age restrictions in England on other comparable body modifications which carry health risks, such as tattooing, sunbed use and teeth whitening.

The prohibition aims to reinforce existing good practice within the cosmetics industry.

## The legislation

Under the Act, it is an offence for a person to administer, in England, to a person under 18 a:

- botulinum toxin
- subcutaneous, submucous or intradermal injection of a filler<sup>[footnote 1]</sup> for a cosmetic purpose

It is also an offence to make arrangements to undertake, or arrange for another person to undertake, these procedures to a person under 18 in England.

The exception to this is if the person administering the injections can show that they either:

- were a registered medical practitioner (doctor)
- were a registered health professional (nurse, dentist or pharmacist) acting in accordance with the directions of a registered doctor [footnote 2]
- had taken reasonable steps to establish the person's age, and reasonably believed that they were aged 18 or over

The Act also provides a defence for a business owner to prove that they took all reasonable precautions and exercised all due diligence to avoid committing an offence.

Consent is not a defence – the fact that a person under the age of 18 may have given their consent, or that a parent or guardian may have consented on their behalf, does not matter.

The police and local weights and measures authorities have powers to undertake enforcement action in relation to the provisions, including bringing forward prosecutions, investigating complaints and taking other steps. These steps may involve communicating with, and educating, practitioners or undertaking 'test purchasing' inspections to assess compliance. In undertaking enforcement action, a local authority may consult with the police as it considers appropriate.

## Procedures covered by the Act

### **Botulinum toxins**

Botulinum toxin is a naturally occurring substance produced by bacteria. When injected, it relaxes the surrounding muscle and temporarily freezes it. This can have the effect of smoothing out lines and wrinkles in the skin caused by facial expressions. It can also be used to treat several medical conditions.

Botulinum toxin is a prescription-only medicine, regulated by the Medicines and Healthcare Regulatory Agency (MHRA). The prescriber may delegate administration of the injections to another person who is not required to be a regulated healthcare

professional. The prescriber retains responsibility for ensuring that the secondary practitioner provides the treatment safely.

There are several trade names used for cosmetic treatments made with botulinum toxin, the most common of which is 'Botox'®. However, there are three brands which are licensed in the UK for cosmetic purposes. They are Azzalure®, Bocouture® and Botox®. There are other brands of botulinum toxin – including Dysport® and Xeomin® - but these are licensed for non-cosmetic purposes.

See <u>further information about botulinum toxin injections</u> on the NHS website.

### **Cosmetic fillers**

Cosmetic fillers, commonly known as 'dermal fillers', are injectable implants that are presented in the form of a viscous gel and commonly involve substances such as hyaluronic acid being injected beneath the surface of the skin to add volume and fullness. However, any substance inserted into or through the skin with a view to changing appearance, even if not commonly understood to be a 'dermal filler', would be covered by the Act.

Filler products can be used for medical treatment or for aesthetic purposes. Currently, a dermal filer may be regulated either as a general product, a medicine or a medical device, depending on its composition and intended use. Fillers classified as general products are not subject to licensing or manufacturing controls, and do not need a prescription to be obtained.

The Act only captures the substances being used or arrangements being made for their use when they are for a cosmetic purpose, enabling the products' continued use on under 18s for medical purposes. The definition set out in the Act captures all and any substances that are inserted into the body with the intention of producing a filling effect to change appearance.

In the UK, there are over 100 brands on the market, including Juvederm<sup>™</sup>, Restylane<sup>™</sup>, Belotero<sup>™</sup>, Teosyal<sup>™</sup> and Emervel<sup>™</sup>.

See <u>further information about cosmetic fillers</u> on the NHS website.

### The Yellow Card Scheme

If a patient or practitioner is concerned about the safety of a medicine or device following its administration, this can be reported to the MHRA which will investigate and take action to minimise risk and to protect public health.

Any concerns over the safety or performance of a dermal filler used for a medical purpose should also be reported to the MHRA.

Reporting side effects provides valuable information about the safety of the product used.

If there is any reason to suspect that the botulinum toxin is not a UK-licensed medicine, please report to MHRA through the <u>Yellow Card Scheme website</u> or by email to <u>fakemeds@mhra.gov.uk</u>.

Alternatively, officers and members of the public can report a suspected counterfeit product by contacting the MHRA's 24-hour counterfeit hotline telephone number on 020 3080 6701.

### Offences

The new law applies to everybody in England, not just businesses, including:

- providers of clinical healthcare services and regulated healthcare professionals working in these services
- commercial providers of cosmetic procedures for example, beauty therapists, mobile aesthetic practitioners, regulated healthcare professionals
- individuals performing the procedures on an informal basis

The new law makes it an offence for anyone to arrange or carry out these cosmetic procedures on under 18s in England.

It does not matter if the person under 18 does not live in England, or is just visiting. They will not be able to have anyone perform either procedure on them whilst they are in England.

### Offence of administering the substances to a child

The Act makes it an offence for a person to administer, in England, botulinum toxin or a cosmetic filler to another person where that person is under the age of 18. The police have powers for enforcing the offence.

#### Scenario 1

A 17-year-old (A) has previously paid for botulinum toxin injections to smooth their complexion from a registered nurse prescriber (B). After 1 October 2021, A approaches nurse B and asks for a top up treatment of botulinum toxin, which nurse B carries out.

An offence has been committed. This is because all the following are true:

- nurse B injected botulinum toxin into A
- nurse B took no steps to verify the age of A before carrying out the treatment
- although a registered nurse is one of the professions approved to administer botulinum toxin to under 18s under the provisions of the Act, nurse B is not acting under the directions of a doctor

#### Scenario 2

A 16-year-old (C) visits their local beauty salon and asks for a filler treatment in their lips to enlarge them. A beauty therapist (D) injects C with a filler product to increase volume. C's parents report the incident to the local authority.

Beauty therapist D has committed an offence because all the following are true:

- beauty therapist D injected a substance into C's lips
- beauty therapist D selected the substance and carried out the injection into C's lips with the intention of increasing their volume to change C's appearance
- beauty therapist D took no steps to verify the age of C before carrying out the treatment

#### Scenario 3

A 16-year-old (E) and their parent (F) attend a beauty clinic together and both of them ask for dermal fillers to be injected into their lips. Beauty therapist G asks E how old they are and establishes that E is 16 years old.

Parent F states that they are happy for their child to have the treatment and signs a form giving their consent for the treatment to be performed. E also signs a form to confirm that they wish to go ahead with the treatment.

Beauty therapist G injects both E and parent F with a filler product to enlarge their lips.

Even though parent F has given their consent for the treatment to be performed on their child, and E has also consented to it, an offence has been committed in respect of the treatment provided to E.

This is because it is an offence for anyone, other than an approved person acting under the directions of a doctor, to administer a cosmetic filler treatment to a person under 18 in England, even if the person themselves or a parent or guardian over the age of 18 years old has given their consent for it to be carried out.

#### Offence by persons carrying on a business or by bodies corporate

From 1 October a person who carries on a business must ensure they have a rigid system in place to help them confirm proof of age.

A person who carries on a business (a 'business owner') commits an offence if a person, other than a doctor, or a regulated health professional acting in accordance with the directions of a doctor, administers botulinum toxin or a filler by way of injection for a cosmetic purpose to a person under the age of 18 years old, in England.

A business owner commits an offence if they, or someone acting on their behalf (which may include a business owner's employees, a self-employed person contracted to work for the business owner, a member of staff from an agency or a person gaining unpaid work experience with the business), makes arrangements for botulinum toxin or a filler to be administered by injection for a cosmetic purpose to a person under the age of 18 years old, in England. This would cover, for example making an appointment, or agreeing via digital or social media to undertake the procedure.

By making it an offence for arrangements to be made to administer one of the products covered by the legislation to a person aged under 18, prosecutions are able to be brought even where the person aged under 18 did not go on to have the procedure administered because, for example, the person changed their mind or an enforcement agency intervened.

#### Scenario 4

A 15-year-old (H) messages a beauty therapist (J) who is advertising their services on social media and asks if they will give them dermal filler injections in their lips. Beauty therapist J arranges an appointment for H to visit their salon where they will perform the treatment.

H sends an electronic money transfer for the treatment fee to beauty therapist J to secure the appointment. H messages beauty therapist J later that evening cancelling the appointment, stating that their parents have forbidden them from having the treatment. Beauty therapist J refunds the treatment cost to H.

H's parents complain to the local authority that the beauty therapist was willing to perform the treatment on their child.

An offence has been committed because both the following are true:

- beauty therapist J had agreed to inject a cosmetic filler substance into H
- beauty therapist J failed to take any steps to check or establish H's age before making the appointment

It does not matter that the treatment fee was refunded or that the procedure was not carried out.

#### Scenario 5

A 16-year-old (K) phones an aesthetic clinic and asks to make an appointment for a nose filler treatment, which is advertised by the clinic as being a method of changing the shape of the nose through the insertion of dermal fillers.

The receptionist (L) books an appointment for K to have the treatment with a registered nurse (M) who is employed by N, the owner of the clinic. Receptionist L fails to establish K's age, or whether they have had the treatment approved by a doctor.

K attends the clinic for their appointment and enters a consultation room with nurse M. Nurse M asks K how old they are and declines to provide the treatment after establishing that K is under 18 years old and has not had the treatment approved by

a doctor. Nurse M reports the clinic to the local authority for failing to verify the age of its customers.

Receptionist L informs the local authority enforcement officer that they were not aware of the restrictions on making arrangements for cosmetic filler treatments to be performed on under 18s. Business owner N has not alerted staff to the new law and no training or guidance has been provided.

An offence has been committed by business owner N who has a duty to ensure that no arrangements are made on their behalf for dermal filler treatments to be provided to under 18s, except when approved by a doctor.

If an offence under the Act is committed by a body corporate with the consent or connivance of, or is attributable to the neglect of, an officer of a body corporate, then that officer as well as the body corporate is guilty of the offence.

These actions may have been undertaken, or neglected by, any person from the executive or management team members of the body corporate, or a person who proclaimed or implied they were acting in such a role.

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 if 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.

If a person carrying on a business or body corporate fails to comply with these requirements they commit a criminal offence punishable on summary conviction by an unlimited fine.

Both the police and local weights and measures authorities have powers to enforce the offence.

#### Scenario 6

A cosmetics business is owned by company O. Director P of company O says that staff should allow anyone to have procedure who is willing to pay.

Customer Q, aged 17, receives botulinum toxin injections by a member of staff at business R owned by company O. The incident is reported to the local authority by customer Q's parents.

The practitioner who undertook the procedure at business R has committed an offence under the Act.

Director P's approach had contributed to the offence and therefore P had also committed an offence.

### Defences

Consent is not a defence. It does not matter if the person under 18, or their parents or guardians, give their permission for the procedures to take place.

### Offence of administering the substances to a child

The Act provides for 2 defences that can be raised in respect of this offence

#### Defence 1

If the person administering the injections could show that they were an 'approved person', specifically:

- a registered medical practitioner (doctor)
- a registered health professional (nurse, dentist or pharmacist) acting in accordance with the directions of a registered doctor<sup>[footnote 3]</sup>

Botulinum toxin and filler products have legitimate clinical uses and this defence is intended to allow for the continued use of these substances in medical treatments on persons under 18 years old by an 'approved person'.

Enforcing officers should note this is a 2-stage defence, and that registered dentists, nurses and pharmacists may only administer the substances when they are acting under the directions of a doctor.

Doctors should, as per their usual practice, follow guidance and standards issued by their regulator, the General Medical Council, when considering the use of either product types.

Enforcement officers, as with any agency or member of the public, may escalate concerns about a health professional's fitness to practise to the appropriate regulator, [footnote 4] who will conduct an investigation.

A person assessed for one of the named procedures approved by a doctor can seek a referral either through NHS services (where appropriate and available) or make a private arrangement with a health professional from one of the listed categories, ensuring an appropriately trained and qualified practitioner may conduct the procedure.

#### Defence 2

The Act offers a defence if the person administering the injections had both:

- taken reasonable steps to establish the person's age
- reasonably believed that they were aged 18 or over

### Offence by persons carrying on a business or by bodies corporate

A business owner commits an offence if a person other than an 'approved person' (see defence 1, above) administers botulinum toxin or cosmetic filler to a person under 18 years old, in England.

If a business owner can demonstrate that they took all reasonable precautions and exercised all due diligence, then the business owner has a defence to the offence.

So, for example, the business owner may show that the business has a strict policy requiring proof of a person's age before allowing any appointments to be booked for the injection of one of the substances covered in the legislation, and that the policy was properly implemented but was circumvented by a high quality fake 'proof of age' document which would fool a reasonable person.

Guidance on the application of the new law has been developed for businesses and this includes examples of what businesses could put in place to demonstrate that they are complying with the law, as set out below:

- age verification checks: verify the age of potential customers by asking to see an identity card that bears the Proof of Age Standards Scheme (PASS) hologram
- staff training: have written procedures for staff for dealing with people who may be under 18, train staff in these procedures, keep records of this training and make sure the training is regularly updated
- introduce a dual-checking process: as it is now an offence to 'make arrangements' for one of the treatments to be provided to a person under 18, you should require customers to demonstrate proof of age prior to booking an appointment (whether face-to-face, over the phone or online), then verify the age of that customer again on the appointment date before carrying out the procedure
- for online bookings consider putting into place age-verification procedures using systems that are compliant with <u>PAS 1296:2018</u>, a code of practice for online age verification service providers
- use of till prompts: use prompts that appear on the till to remind staff to carry out age verification checks
- signage and CCTV: ensure you have adequate signs to inform consumers of the minimum legal age for a botulinum toxin or cosmetic fillers procedure
- keep and maintain a refusals register: this means keeping a record (date, time, incident, description of potential buyer) where sales of age-restricted procedures have been refused – this helps to demonstrate that you actively refuse sales and have an effective system in place

### Enforcement

The police have powers to enforce all the provisions in the Act.

Local weights and measures authorities can also enforce the Act in England through powers under the <u>Consumer Rights Act 2015 (Schedule 5)</u>.

Local authorities may need to authorise officers to carry out duties to secure compliance with the Act. This includes bringing forward prosecutions, investigating complaints and taking other steps. These steps may involve communicating with, and educating, practitioners, or undertaking 'test purchasing' inspections to assess compliance. Existing officers who are experienced in carrying out enforcement duties in relation to businesses, including some of those covered by the Act, such as Trading Standards Officers and Environmental Health Officers, could carry out this work as part of their other inspection activities.

Local authorities have the power to give a wide range of functions to other local authorities and may work together to consider how best to enforce this legislation within their areas. Local authorities could also consider incorporating the provisions in the Act within any existing joint working and information sharing arrangements with other enforcement bodies in their area, to co-ordinate inspection activities and any necessary enforcement activity.

# **Further information**

The following documents provide further guidance:

- the <u>investigatory powers of consumer law enforcers</u> under the Consumer Rights Act 2015 (Schedule 5)
- the government's code of practice for age restricted sales enforcement
- guidance for local authorities on the conduct of test purchasing

# Summary of offences under the Act

### Offence of administering certain substances to a child

#### Offence

(1) It is an offence for a person to administer, in England, to another person ('A'):

(a) botulinum toxin, or

(b) a subcutaneous, submucous or intradermal injection of a filler for a cosmetic purpose,

where A is under the age of 18.

(2) A 'filler' is any substance used for dermal or mucous membrane filling (whether or not designed to be so used).

(3) For the purposes of subsection (1)(b), an injection of a filler is, in particular, to be taken to be for a cosmetic purpose if:

(a) the filler is generally used for such a purpose, or

(b) the likely effect of the injection is to alter the appearance of the person injected

#### Defence

(4) It is a defence for a person charged with an offence under subsection (1) to show that at the time of the alleged offence:

(a) the defendant was a registered medical practitioner,

(b) the defendant was a regulated health professional who, in administering the botulinum toxin or the filler (as the case may be), was acting in accordance with the directions of a registered medical practitioner, or

(c) the defendant:

(i) had taken reasonable steps to establish A's age, and

(ii) reasonably believed that A was aged 18 or over

(5) A person is taken to have shown a matter mentioned in subsection (4) if:

(a) sufficient evidence of the matter is adduced to raise an issue with respect to it, and

(b) the contrary is not proved beyond reasonable doubt

(6) A person who commits an offence under subsection (1) is liable on summary conviction to a fine.

(7) In this section 'regulated health professional' means:

(a) a registered nurse

(b) a registered dentist within the meaning of the Dentists Act 1984 (see section 53 of that Act)

(c) a registered pharmacist within the meaning of the Pharmacy Order 2010 (S.I. 2010/231) (see article 3 of that Order)

(d) a registered person within the meaning of the Pharmacy (Northern Ireland) Order 1976 (S.I. 1976/1213 (N.I. 22)) (see Article 2 of that Order)

#### Penalty

Unlimited fine.

#### Offence by persons carrying on a business

#### Offence

(1) A person (a 'business owner') commits an offence if in the course of the business owner's business:

(a) a person other than an approved person administers, in England, to another person ('A'):

(i) botulinum toxin, or

(ii) a subcutaneous, submucous or intradermal injection of a filler for a cosmetic purpose, where A is under the age of 18

(b) arrangements are made, in England, by or on behalf of the business owner, for a person other than an approved person to administer, in England, to another person ('A'):

(i) botulinum toxin, or

(ii) a subcutaneous, submucous or intradermal injection of a filler for a cosmetic purpose, where A is under the age of 18

(2) For the purposes of subsection (1), an injection of a filler is, in particular, to be taken to be for a cosmetic purpose if:

(a) the filler injected, or arranged to be injected, is generally used for such a purpose, or

(b) the likely effect of the injection is, or would be, to alter the appearance of the person injected

#### Defence

4) It is a defence for a business owner charged with an offence under subsection (1) to prove that the business owner took all reasonable precautions and exercised all due diligence to avoid committing it.

(5) In this section:

• 'approved person' means:

(a) a registered medical practitioner

(b) a regulated health professional who, in administering the botulinum toxin or the filler (as the case may be), is or would be acting in accordance with the directions of a registered medical practitioner

- 'filler' has the same meaning as in section 1
- 'regulated health professional' has the same meaning as in section 1.

Penalty

Unlimited fine.

### Offences by bodies corporate

#### Offence

(1) This section applies where an offence under section 2 is committed by a body corporate.

(2) If the offence is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of:

(a) any director, manager or secretary of the body corporate, or

(b) any person who was purporting to act in any such capacity, that director, manager, secretary or person purporting to act as such (as well as the body corporate) commits the offence and is liable to be proceeded against and punished accordingly

(3) The reference in subsection (2) to the director, manager or secretary of the body corporate includes a reference to any other similar officer of the body corporate.

Defence

N/A

#### Penalty

Unlimited fine.

- 1. The definition set out in the Act captures all and any substances that are inserted into the body with the intention of producing a filling effect to change appearance.
- 2. This enables the procedure to be both approved and delivered by a single practitioner where appropriate.
- 3. This enables the procedure to be both approved and delivered by a single practitioner where appropriate.
- 4. A doctor register with the <u>General Medical Council</u>, a nurse registered with the <u>Nursing and Midwifery Council</u>, a dentist registered with the <u>General Dental</u> <u>Council</u> or a pharmacist registered with the <u>General Pharmaceutical</u> <u>Council</u>. ⊇