ANSES Opinion
Request No 2019-SA-0124
Related Request No 2012-SA-0036

The Director General

Maisons-Alfort, 10 June 2021

OPINION
of the French Agency for Food, Environmental and Occupational Health & Safety

on the "Risks associated with intense pulsed light (IPL) hair removal devices"

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It also contributes to the protection of the health and welfare of animals, the protection of plant health and the evaluation of the nutritional characteristics of food.
It provides the competent authorities with all necessary information concerning these risks as well as the requisite expertise and scientific and technical support for drafting legislative and statutory provisions and implementing risk management strategies (Article L.1313-1 of the French Public Health Code).
Its opinions are published on its website. This opinion is a translation of the original French version. In the event of any discrepancy or ambiguity the French language text dated 10 June 2021 shall prevail.

On 8 July 2019, ANSES received a formal request from the Directorate General for Health (DGS) and the Directorate General for Competition Policy, Consumer Affairs and Fraud Control (DGCCRF) to conduct an expert appraisal on the following issue: "Intense pulsed light hair removal: follow-up to the ANSES Opinion of December 2016 and expected additional information".

1. BACKGROUND AND PURPOSE OF THE REQUEST

1.1. Background

Demand for aesthetic procedures is growing sharply. Due to gaps in the regulations governing the conditions for the placing on the market of devices used for aesthetic procedures, and in light of the wide variability in the training levels of the operators who use such devices, regulating how these devices are used and made available has become a major topic of concern for the French public authorities. In the specific case of hair removal devices using intense pulsed light (IPL), there is also the fact that a number of French operators perform procedures outside of the regulatory framework defined by a Ministerial Order from 1962.

Furthermore, this Ministerial Order, now clearly obsolete due to changes in practices and techniques, was subject to a decision of the Council of State[1] that amounted to its repeal.

Unfortunately, this context has negatively affected various aspects that contribute to risk knowledge and control, such as the recognition of certain training programmes and the collection of vigilance data related to the use of IPL hair removal devices.

In 2016, as requested by the French Ministries of Health, Consumer Affairs and the Environment, ANSES issued an expert appraisal report and an opinion on the "Assessment of the health risks of the use of devices for aesthetic procedures implementing physical agents".

This initial expert appraisal work resulted in conclusions and recommendations concerning:

- the adverse effects described when using these devices, and the related contraindications;
- the conditions for the placing on the market of these devices, and their life-cycle management;
- the training of operators;
- and the implementation of an effective medical device vigilance scheme for these products.

The characteristics and operating principles of devices specifically intended for hair removal with intense pulsed light were covered in *ad hoc* chapters of this first report. IPL devices, which emit polychromatic, non-coherent light, constitute one of the two main classes of hair removal devices that use light energy; the other is that of laser devices, which emit monochromatic, coherent light.

IPL devices work by emitting energy in the form of light flashes over a wavelength range of 570 to 800 nm; this energy is mainly absorbed by two pigments contained in hair: eumelanin, which is responsible for dark brown or black skin, and pheomelanin, which produces fair or freckled skin. The energy deposited in the hair system raises the temperature of the hairs and hair bulbs, potentially leading to their destruction. To limit adverse effects in surrounding tissue relating to this use of heat, IPL devices should be designed and adjusted to emit energy in the intended range of wavelengths and should only be used when the colour contrast between the skin and hair is sufficient, so that most of the light energy is delivered to the hair structures in the skin tissue.

Various ranges of devices are currently available on the market: devices intended for therapeutic and aesthetic use by professionals, devices intended for exclusively aesthetic use by professionals, and home devices for aesthetic use by private individuals. However, the placing on the market, use and life-cycle management of these various ranges of devices are not covered by a suitable regulatory framework.

The use of IPL hair removal devices by non-medical professionals requires that the public authorities make changes to the regulations, in order to provide a framework guaranteeing the safety of consumers (see Opinion of the Council of State of 8 November 2019). Moreover, the entry into force of Regulation (EU) 2017/745 on medical devices, postponed to 26 May 2021, will ensure that devices intended for non-medical purposes, such as intense pulsed light hair removal devices, are subject to requirements similar to those applying to medical devices, once amendments to achieve this have been made to the French Public Health Code.

[1] https://www.legifrance.gouv.fr/ceta/id/CETATEXT000039357588/.

The DGS and DGCCRF therefore asked ANSES, via a request of 8 July 2019, to conduct an expert appraisal on intense pulsed light hair removal, as follow-up to the opinion published by ANSES in December 2016 ("IPL" Request No. 2019-SA-0124).

1.2. Purpose of the request

The purpose of the request was as follows:

"1. Technical characteristics of devices based on the risk and according to the type of user

ANSES's opinion is being requested as a priority with regard to the technical characteristics of devices that should be imposed or restricted depending on the user […].

2. Maintenance of devices

[…] On this point, your Agency should make recommendations in terms of conditions of use or essential maintenance issues for IPL devices, as regards both the manufacturer and the operator, in light of the identified risks.

3. Training

[…] This formal request is therefore seeking proposals concerning the content of training through the identification, based on your assessment of the risks associated with intense pulsed light hair removal, of risks that can be prevented through the acquisition of knowledge and skills in line with the various user profiles.

4. Contraindications and reporting procedures

To supplement the information given in your report of December 2016, you are expected to update, if appropriate, the list of contraindications for the use of these IPL devices, based on the updated literature data.

It would also be useful for recommendations to be issued concerning adverse events that should be reported and also concerning how these should be assessed by a national expert assessment agency".

In view of its sphere of competence and the experience acquired from its expert appraisal of aesthetic devices published in 2016, ANSES has updated its expert appraisal work to respond to this new request, in order to provide the available scientific data concerning the health risks associated with the professional and home use of hair removal devices implementing the intense pulsed light (IPL) technique. Other applications of IPL devices are not addressed here. The work undertaken therefore included the following:

- updating of the technical characterisation of the operating principles of IPL devices;
- updating of the data from the scientific literature concerning the adverse effects described in relation to the use of IPL devices;
- updating, based on available knowledge, of the recommendations previously issued in ANSES's opinion published in 2016 in terms of "performance obligations" for the maintenance of devices (long-term stability of the emission spectrum, etc.);
- updating of ANSES's recommendations issued in 2016 concerning training principles aimed at ensuring the safe use of IPL devices;
- an up-to-date review of the contraindications for IPL hair removal set out in the scientific literature.

Concerning the reporting of adverse events, in its opinion of 2016, ANSES recommended "subjecting adverse effects, incidents and accidents occurring during the use of aesthetic devices to mandatory reporting". This applied to all adverse effects observed.

Regulation (EU) 2017/745 on medical devices, which is supposed to enter into force in May 2021, states that aesthetic devices will be subject to requirements comparable to those applying to medical devices, especially in terms of medical device vigilance. The monitoring of the market for medical devices and the assessment of reports of adverse effects are tasks already entrusted to the French Health Products Safety Agency (ANSM).

2. ORGANISATION AND METHOD OF THE EXPERT APPRAISAL

2.1. Organisation of the expert appraisal

The expert appraisal was carried out in compliance with French standard NF X 50-110 "Quality in Expert Appraisal Activities – General Requirements of Competence for Expert Appraisals" (May 2003) with the aim of respecting the following points: competence, independence and transparency.

The expert appraisal falls within the sphere of competence of the Expert Committee (CES) on "Assessment of the risks related to physical agents, new technologies and development areas". ANSES entrusted the expert appraisal to the Working Group (WG) on “Intense pulsed light hair removal devices” (IPL Working Group). The methodological and scientific aspects of the work were regularly presented to the CES between 17 October 2019 and 15 April 2021. The report produced by the Working Group takes account of the observations and additional information provided by the CES members.

The expert appraisal work was mainly based on a review and critical analysis of the data published in peer-reviewed (scientific publications) and non-peer-reviewed (other articles, reports, etc.) journals.

The Working Group also collected supplementary information and data it considered useful for the expert appraisal from manufacturers of IPL hair removal devices and from associations of professional users of these devices. Given the health context related to COVID-19, all exchanges with these professionals took place in writing, via questionnaires.

ANSES analysed the interests declared by the experts prior to their appointment and throughout the work, in order to avoid potential conflicts of interest with regard to the matters dealt with as part of the expert appraisal. The experts’ declarations of interests are made public via the following website: https://dpi.sante.gouv.fr/.

This work was adopted by the CES on "Physical agents and new technologies" during its meeting on 15 April 2021.

2.2. Expert appraisal method

To answer the questions raised, the IPL Working Group initially reviewed the regulations and standards in force; it then prepared a review of knowledge concerning the epidermis, hair growth, and the operation of IPL hair removal devices. Next, the Working Group identified and described the main adverse effects expected with the use of these devices, due to their operating principle, in order to compare them with the effects reported and described by various sources of information.

In light of the identified risk factors, the Working Group then endeavoured to describe the three critical points that influence the safety of use of IPL devices and therefore the risk of occurrence of adverse effects:

- the essential functions of these devices, which need to be maintained to ensure their durability;
- the training of operators;
- the characteristics of the treated individuals and the contraindications for the use of these devices.

The Working Group's conclusions and recommendations provide a framework for limiting adverse effects related to the use of IPL hair removal devices.

All of the points set out in this opinion are described in further detail in the expert appraisal report on “Risks associated with intense pulsed light (IPL) hair removal devices”.

3. ANALYSIS AND CONCLUSIONS OF THE CES AND WG

The findings, conclusions and recommendations summarised here are based on the expert appraisal report on “Risks associated with intense pulsed light (IPL) hair removal devices” of February 2021, produced by the IPL Working Group. This report can be consulted to learn more about the foundations and concepts providing the basis for the expert appraisal results described below.

3.1. Adverse effects associated with the use of IPL hair removal devices

The Working Group carried out a systematic analysis of the available scientific literature in order to identify the described adverse effects. Based on a keyword search in the Scopus and PubMed search engines for the period running from 1 January 2005 to 28 May 2020, 100 publications were found. After eliminating duplicates, relevant articles were selected based on their titles and abstracts. In the end, 43 articles were selected following an evaluation of their methodological quality: they included 28 clinical studies, nine reports and case series, and six reviews.

The Working Group determined three levels of severity of adverse effects:

- minor: transient effect not requiring treatment;
- moderate: effect lasting from a few days to a few weeks and potentially requiring local or systemic treatment;
- serious: lesion with no aesthetic resolution, causing sequelae or a disability requiring long-term treatment, or delayed diagnosis of potentially malignant skin lesions.

For each adverse effect, the Working Group estimated the severity level based on the best factual data that were at its disposal at the time of the expert appraisal (those from the studies selected as part of the systematic analysis, despite their questionable robustness).

The effects listed in the expert appraisal report were considered in two types of situations depending on the conditions of use of IPL hair removal devices: compliant or not compliant with the manufacturers’ and authorities’ recommendations. The Working Group chose this approach based on its observation that some of the most serious effects identified were related to devices being used in a way that did not comply with the manufacturers’ recommendations.

Furthermore, the Working Group noted a high level of variability in the occurrence of adverse effects between the different studies identified or selected for analysis. A number of hypotheses may explain this. The articles identified during the expert appraisal had the merit of providing data on the tolerability and user safety of IPL hair removal devices, enabling

comparisons to be made between the various studies. However, the publications analysed by the Working Group were of poor methodological quality overall, quite likely because there is no regulatory framework for IPL hair removal devices, whose technical characteristics are seldom described. Moreover, most of these studies involved small populations of subjects, causing the analysed parameters to be associated with major uncertainties. Lastly, the power settings used for the devices in the studies were not specified for each individual, limiting their interpretation.

For certain effects, in the identified and selected studies, the reported incidence rates ranged from 0% to 100% of the included individuals. When the effects in question were difficult to separate from the very operating principle of IPL hair removal devices, e.g. for pain and oedema, it is highly likely that differences or ambiguities in the procedures described in the different study protocols led certain effects to be notified as tolerability issues in some cases but not in others; some authors may have considered that adverse effects expected on account of the technique were “normal” and did not need to be reported.

3.1.1. In conditions of use compliant with the recommendations

The operating principle of an IPL hair removal device is based on the deposition of energy in the hairs and hair bulbs, to destroy them via a thermal effect (photothermolysis), by targeting the large amount of melanin in the hair follicles, while minimising as far as possible the energy deposited in the surrounding tissue (directly or by conduction) to avoid damaging (i.e. burning) it.

The removal of hair by photothermolysis is therefore dependent on several conditions:

- the hair sheath must absorb more light energy than its environment (importance of the choice of filter, selection of the range of wavelengths);
- the light must penetrate to the depth of the hair follicles (requires large wavelengths and a high fluence and large spot size);
- the pulse duration must be shorter than the thermal relaxation time (TRT[2]) of the targets (hair follicles).

The main, immediate danger with this technique is an excessive thermal effect damaging the skin tissue. It is responsible for most of the adverse effects observed and their level of clinical severity, described below. These effects therefore depend on the energy that is deposited and absorbed in the surrounding tissue, which is essentially related to the concentration of epidermal melanin.

3.1.1.1. Minor effects

The minor effects of immediate onset include:

- **Subjective effects**, i.e. without any visible skin lesions, evaluated based on their intensity:
  - **Transient pain**: this effect was reported in widely varying proportions, ranging from 0% to 100% of individuals after an IPL hair removal procedure, in the 16 identified and selected clinical studies investigating this effect, with visual analogue scale (VAS) ratings of 0/10 to 6/10.

    The Working Group considers that it is difficult to separate such a transient effect from IPL hair removal, due to its operating principle, which involves a thermal effect.

[2] The TRT is the time required for the inside of the target chromophore to lose 50% of its heat.

- **Transient burning sensation**: this effect was reported in widely varying proportions, ranging from 0% to 100% of individuals after an IPL hair removal procedure, in the six identified and selected clinical studies investigating this effect.

  The Working Group considers that it is difficult to separate such a transient effect from IPL hair removal, due to its operating principle. Moreover, burning sensations and pain are symptoms that overlap.

- **Effects with objective clinical signs** resulting from skin inflammation due to a thermal effect:
  - **Transient erythema**: this effect was reported or observed in widely varying proportions, ranging from 0% to 100% of individuals after an IPL hair removal procedure, in the 21 identified and selected clinical studies investigating this effect. Two literature reviews also reported erythema as a side effect of IPL hair removal.

    The Working Group considers that it is difficult to separate such a transient effect from IPL hair removal, due to its operating principle, which involves a thermal effect.
  - **Perifollicular oedema**: this effect, occurring a few minutes after an IPL hair removal procedure, was reported in widely varying proportions ranging from 0% to 100% of individuals, in the 16 identified and selected clinical studies investigating this effect.

    Two literature reviews also reported oedema as an adverse effect of IPL hair removal.

    The Working Group considers that it is difficult to separate such a transient effect from IPL hair removal due to its operating principle, which involves a thermal effect.
  - **Desquamation**: this effect was reported in 14% of individuals after an IPL hair removal procedure, exclusively on the day of the procedure, according to the sole clinical study investigating this effect that was identified and selected as part of the expert appraisal.
  - **Purpura**: this effect was reported in 27% of individuals after an IPL hair removal procedure, according to the sole clinical study investigating this effect that was identified and selected as part of the expert appraisal.
  - **Minor burn**: burns, whose degree of severity was unspecified, were described as an adverse effect of IPL hair removal according to a review of the literature.

    A clinical study from 2012 specifically investigated clinical signs of burns, among other things, but did not find any. However, the Working Group was surprised by the pain reported in this study, which may have been a sign of underlying burns.

    Not having found any reports of moderate or serious burns in the two aforementioned studies, the Working Group chose to classify burns as minor effects. It considers that although such a minor effect may be imperceptible, it cannot be separated from the technique used (IPL hair removal), at least in tissue close to the hair bulbs, due to the very principle of the technique.
  - **Increased perspiration**: this effect was reported in 4% of individuals after an IPL hair removal procedure, in the sole identified and selected clinical study that investigated this effect.

3.1.1.2. Moderate effects

The moderate effects identified included the appearance or formation of:

- **Bullae[3] and vesicles**: this effect was reported in 4% to 20% of individuals after an IPL hair removal procedure, in the 10 identified and selected clinical studies that investigated this effect.
- **Scabs**: this effect was reported in 0% to 21% of individuals after an IPL hair removal procedure, in the 10 identified and selected clinical studies that investigated this effect.

[3] Medical term for blisters.

- **Fox-Fordyce disease (benign skin disease)**: a case report described a case of persistent Fox-Fordyce disease in the underarm area following IPL hair removal.
- **Paradoxical hair regrowth in exposed areas**: this effect was reported in 5% to 10% of individuals after an IPL hair removal procedure, in the two identified and selected clinical studies that investigated this effect.

  This is due to hair follicle stimulation with aggravation of pre-existing hair growth or the appearance of new hairs around the treated area. It has not been widely studied in the context of laser or intense pulsed light (IPL) hair removal. Certain facilitating factors were mentioned by the authors:
  - hormonal profile with hyperandrogenism, women under the age of 25, men under the age of 45;
  - higher-risk distributions: for women, the maxillary area, the area under the chin, and the cheeks; for men, the entire dorsal region, the cheekbones, and the upper limbs, especially if hair growth is not yet stabilised;
  - phototypes III, IV, and V[4];
  - the presence of downy hair on the treated area.

  The mechanisms responsible for this regrowth are poorly understood and several hypotheses have been put forward: activation of quiescent hair follicles through the deposition of energy not sufficient to destroy them, in particular around the treated area; synchronisation of hair cycles after the first IPL sessions, inducing a new anagen phase[5]; release, through the action of heat, of pro-inflammatory factors stimulating follicles in the anagen phase.
- **Leukotrichia (hair depigmentation)**: this effect was reported in 7% of individuals after an IPL hair removal procedure, in the sole identified and selected clinical study that investigated this effect.

  A literature review also reported leukotrichia as a side effect of IPL hair removal.

3.1.1.3. Serious effects

- **Chronic neuropathic pain**: reported for one individual on the roof of the mouth and in the nasal area, in a case report.
- **Unspecified skin pigmentation disorders or skin dyschromia** (reversible after several months of follow-up): this effect was reported in 0% to 20% of individuals after an IPL hair removal procedure, in the 10 identified and selected clinical studies that investigated this effect.

  One review mentioned pigmentation disorders (dyschromia) but did not give any details about the type or duration.
  - **Hyperpigmentation**: a literature review reported skin hyperpigmentation as a side effect of IPL hair removal, although no information was given as to its reversibility:
    - reversible after several months of follow-up. This effect was reported in 0% to 60% of individuals after an IPL hair removal procedure, in the 16 identified and selected clinical studies that investigated this effect;
    - persistent. This effect was reported in 10% of individuals after an IPL hair removal procedure, according to the sole identified and selected

[4] Phototypes I to VI classify skin colour from lightest to darkest.
[5] The longest phase in the hair cycle (two to five years). The large majority of the hairs on the head are in the anagen phase.

clinical study that investigated this effect, showing persistent hyperpigmentation more than 330 days after the procedure in individuals with phototype IV.

- **Hypopigmentation**: this effect was reported in 0% to 20% of individuals after an IPL hair removal procedure, in the identified and selected clinical studies that investigated this effect (three references).

- **Scars**: this effect was investigated in eight identified and selected clinical studies but was not observed in any of them.

  Scars were nonetheless described as a possible side effect of IPL hair removal, according to a review of the literature.

3.1.2. In conditions of use not compliant with the recommendations

3.1.2.1. Serious effects reported in the literature

- **Delayed diagnosis of skin lesions** leading to loss of chance in terms of disease progression and the risk of recurrence.

  Given the mode of action of IPL, changes in the pigmentation of naevi following IPL hair removal cannot be ruled out, which can pose difficulties for the diagnosis of cancer lesions[6] and therefore result in loss of chance for melanoma patients.

  Such situations, observed after IPL hair removal, were reported in two studies. They have also been reported after laser hair removal, which is based on the same photothermolysis principle.

  However, the Working Group did not have the information required to evaluate the likelihood of these diagnostic delays.

- **Changes in the appearance of benign melanocytic naevi** were reported in four publications, with dyschromia potentially suggesting malignant melanoma, without any malignant transformation but with a need for surveillance.

- **Eye damage (affecting the cornea, iris or retina)**: the danger results from the IPL light beam accidentally being directed towards the eye. These effects could potentially occur in a treated individual or operator if an accident happened during the procedure. They were reported in individuals after an IPL hair removal procedure in three case reports. Three ocular structures developed thermal lesions: the cornea, iris and retina.

  Although the Working Group did not have the necessary information to assess the incidence of these effects, these lesions are very serious and can cause partial loss of vision.

3.1.2.2. Potential effects that are expected due to the operating principle of IPL devices but have not been reported in the literature

■ **Effects of ultraviolet radiation**

It has been proven that repeated, prolonged exposure to UV rays (UVA, UVB and UVC rays, 220 nm ≤ λ ≤ 400 nm) increases the risk of skin cancer due to damage caused to DNA and to DNA repair mechanisms. The lamps used in IPL hair removal devices are capable of emitting UV light. However, IPL hair removal devices are not supposed to emit UV radiation, because

[6] It is recognised that most melanomas arise *de novo* (upon appearance of the mass or abnormal skin region). The risk factors for melanoma include an increase in the number of "dysplastic naevi" and increased exposure to the sun and ultraviolet radiation. However, it is not always easy to diagnose early-stage melanoma without a dermoscopic examination with clearly defined criteria.

they have specific cutoff filters that block wavelengths shorter than 400 nm. If these filters become damaged, UV emission is possible.

There is therefore a potential risk of damage being caused to keratinocytes, with the development of basal and squamous cell carcinomas, and also to melanocytes, with the development of melanoma. However, such UV-related lesions could only occur if the cutoff filter integrated into the IPL hair removal device were severely defective.

Since these are delayed-onset lesions and since cumulative exposure to “natural” UV rays occurs throughout a lifetime, the causal relationship between exposure via an IPL source and the development of a cancer lesion is very difficult to establish. Only long-term epidemiological studies, including exposure to IPL as a specific variable, would enable the causality between this risk factor and the use of this technique to be confirmed or refuted.

- **Long-term effects of repeated thermal exposure**

The Working Group did not find any publications dealing with cancer induced by the thermal effect associated with IPL treatments. However, due to the relative absence of hindsight as to the use of IPL hair removal devices, the short monitoring periods observed in the analysed studies, and the small populations of individuals included, no reliable information about such events (which can only be observed after five to 15 years) could be collected. Studies investigating the causal link between repeated exposure to heat and cancer phenomena in humans still need to be conducted before any conclusion can be drawn in this regard.

3.2. Adverse effects related to the technical characteristics of the devices, the individuals being treated, and the conditions of use

The efficacy and tolerability of IPL devices are related to the energy deposited both in the hairs (it has to be sufficient to destroy them) and in the adjacent tissue exposed to the device’s emissions. For the adjacent tissue, the objective is to minimise the amount of energy deposited in order to reduce the occurrence of adverse effects (tolerability). And yet the amount of energy deposited during a treatment depends, of course, on the device's settings but also on parameters related to the treated individual that have varying degrees of measurability:

- skin colour in the treated area at the time of the hair removal session (which should take into account not only the phototype but also the level of tanning in the area and therefore the level of melanin, which is the target chromophore with hair removal);
- hair colour, thickness and density;
- the individual response to thermal exposure;
- any use or application of photosensitising products;
- cumulative exposure of the skin to light-emitting devices, etc.

Therefore, it is not possible to determine, in “absolute” terms, based on a limited number of parameters related to the device, the conditions of use of these devices that would meet the hair removal objective while controlling the related adverse effects. For the Working Group, a simple energy fluence threshold, for example, does not seem suitable for guaranteeing the absence of adverse effects.

The Working Group considered conducting a comparative analysis of the roles of the various mechanisms leading to the photothermolysis of hair, in order to provide evidence to support individual parameter values for each individual and demonstrate their impact on potential adverse effects. However, the work necessary to develop a model capable of integrating these

parameters is part of a study and research approach that did not fall within the scope of the expert appraisal entrusted to the IPL Working Group.

3.3. Conclusions and recommendations to better control the risks associated with IPL hair removal

The user safety of devices used for IPL hair removal is closely linked to the energy absorbed by the epidermis, hair follicles and adjacent tissue; this depends on the emission characteristics of the devices and also the characteristics of the treated individuals. The Working Group identified some key factors that should be taken into account to understand the levels of exposure associated with these devices:

- Factors related to the device:
  - design operating conditions of the device;
  - stability of the device's operating characteristics, related to its design and maintenance;
  - correct use of the device, related to the training and skills of operators, the information provided to users of home devices, and compliance with good practices.
- Factors related to the individual:
  - characteristics of the individual at the time of hair removal: phototype, skin colour, hair colour, and individual response;
  - potential contraindications: pre-existing diseases, photosensitising treatment, etc.

As a result, the CES identified some critical points and is issuing recommendations with the aim of limiting the incidence and severity of adverse effects related to IPL hair removal.

3.3.1. Conditions for the placing on the market of devices

Considering the risks associated with the use of IPL hair removal devices, the CES recommends making their placing on the market conditional upon compliance with requirements similar to those that apply to medical devices using equivalent technologies. This recommendation is intended to be in line with the planned entry into force of the new European regulation on medical devices on 26 May 2021. This will involve the following:

- the preparation of a dossier to demonstrate compliance with the requirements of the European regulation, either evaluated by a notified body or self-evaluated; this dossier should be made available to the competent authorities before any placing on the market of a device:
  - a detailed description of the device’s operating principle;
  - the detailed technical characteristics of the device (spectral region, energy range, pulse width and shape, surface area of application, etc.);
  - the maintenance procedure for the device intended to ensure the long-term stability of its emission characteristics during its operation;
  - the minimum knowledge required by a user of the device to limit the risk of adverse effects;
  - a list of the various regulations and standards with which the device must comply;
  - a list of the device’s safety features;
  - contraindications for its use;
  - the device’s user manual.

- a detailed list of the clinical efficacy and safety studies that must be undertaken prior to placing on the market, in keeping with the regulations in force and the related guidelines (in terms of the number of individuals, monitoring period, etc.), including concerning the control of the device's settings by a system that automatically measures skin pigmentation;
- mandatory medical device vigilance managed by the public authorities.

The Working Group recommends that any device placed on the French market have, at the very least:

- an automatic system for measuring skin pigmentation, enabling the device's settings to be controlled;
- a detector of skin contact preventing any light beam from accidentally being fired in the absence of this contact, especially towards the eyes. The ability to neutralise or trick these contact detectors should be limited, as set out in the IEC 60335-2-113 standard on household and similar electrical appliances;
- a feedback sensor controlling the intensity of the emitted light;
- a reliable and durable filter preventing the device from emitting any UV light.

3.3.2. Necessary work to bring into line the standards on IPL and laser treatments

The Working Group questions the different ways in which the current standards address medical devices (NF EN 60601-2-57 standard) and home appliances (NF EN 60335-2-113 standard). A laser or IPL source classified in the highest risk group (Class 4 for lasers and Risk Group 3 for IPL), if it is integrated into a non-medical hair removal device equipped with a system of application to the skin preventing any radiation leakage outside of the targeted area of skin (the area in contact with the device), can be used by anyone with no upper limit on the emission level.

However, a Class 3B or 4 laser source or the equivalent for IPL, if it is integrated into a device that has a similar function but is considered a medical device, can only be used by medical personnel.

The CES recommends aligning the standards on IPL and lasers intended for hair removal, whether they apply to medical electrical devices or to electrical household appliances.

3.3.3. Contraindications

The Working Group identified some contraindications for IPL hair removal, based on the report published by ANSES on the safety of aesthetic devices (2016) and also based on the medical literature:

- occurrence of any skin abnormality (surface, texture or colour) or skin disease including:
  - history of skin cancer;
  - photosensitive dermatitis (lupus, for example);
  - autoimmune diseases;
  - history or high risk of keloid scars[7];

[7] Keloid scars are raised.

- psoriasis[8];
- vitiligo;
- herpes or a history of herpes on the area to be treated;
- multiple naevi or a dysplastic naevus[9];

- use of photosensitising or anticoagulant medication;
- application of any product (cosmetics, including self-tanners, topical medications, essential oils, "natural" products, etc.) to the area to be treated;
- age of under 15 years;
- unsuitable phototype or hair type: phototype 0 (albino people), depigmented hair, phototypes V and VI, downy hair, etc.;
- exposure to natural or artificial UV rays before or after hair removal (risk of pigmentation disorders). In the case of prior exposure, the IPL hair removal treatment should not be carried out until the individual has regained their baseline tan. Following hair removal, skin should not be exposed to UV light until any skin damage caused by the IPL has healed;
- eyebrow removal (because of the risk to the eyes);
- pregnancy, breastfeeding or hormonal treatments likely to modify hair growth[10];
- presence of a tattoo on the area to be treated;
- uncooperative[11] or uninformed customer.

3.3.4. Essential parameters that must be controlled to limit the occurrence of adverse effects with IPL hair removal

The Working Group identified various parameters that it considers need to be controlled to limit the adverse effects of IPL hair removal:

- verification that there are no contraindications prior to any IPL hair removal treatment;
- determination of skin and hair colour;
- good understanding of the operating principle and method of the IPL device;
- sensitivity test on a small part of the area to be treated, followed by a waiting period of at least 30 minutes before complete hair removal, to check that there are no excessive immediate adverse effects, as these can vary between individuals.

3.3.5. Precautions to be taken before any use of an IPL hair removal device

For IPL hair removal devices used by professionals, the WG and CES recommend that:

- the operator use a standardised questionnaire to interview the customer to verify the absence of any potential contraindications (recent sun exposure, use or application of photosensitising products, etc.);

[8] Psoriasis, on the contrary, is improved by UV rays (it is treated in UV booths), but it is associated with a different phenomenon called Koebner's phenomenon where any skin irritation – mechanical, for example, or after a laser session – can cause a psoriasis flare-up on the irritated area; this is not serious but it is unpleasant for the treated individual, so it is a relative contraindication.
[9] A risk factor for melanoma with the recommendation to avoid sun exposure to reduce its risk of occurrence.
[10] If there is any doubt, this should be verified with the prescribing physician.
[11] Customer refusing to comply with safety rules (wearing protective glasses, prior examination, etc.).

- the operator carry out a methodical evaluation of the skin on the area to be treated before any hair removal procedure;
- the operator ask the customer to consult a dermatologist, to rule out any contraindications:
    - before any hair removal series if they notice the slightest colour abnormality, a dark spot, an unusual texture, or a large number of naevi;
    - in case of changes to a medical treatment or use of a photosensitising product.
- the operator give their customer a brief report with their observations ("no suspicious abnormalities to report" or "skin abnormality requiring a dermatological examination"). This report should specify that it does not constitute a dermatological examination report or a certificate.

For home IPL hair removal devices, the Working Group recommends:

- a systematic consultation with a dermatologist before any series of hair removal procedures, in order to verify that there are no contraindications. This recommendation should be systematically included in the user manuals of these devices;
- providing users with a simple, reliable method for determining skin and hair colour.

In both cases, if an abnormality is observed, the dermatologist will be responsible for determining whether the individual's condition is compatible with IPL hair removal.

3.3.6. Device configuration in line with skin and hair colour

At the time of IPL hair removal, since skin colour on the treated area(s) is a key parameter for adjusting the device's settings and limiting the adverse effects of IPL hair removal devices, the CES recommends making it mandatory to implement a certified protocol for determining skin and hair colour on the area to be treated before every hair removal session. This protocol could be based on a certified method described in detail or on a certified device, whether integrated into the IPL hair removal device or separate. It should enable changes in skin colour over time on each treated area to be taken into account.

3.3.7. Maintenance and life-cycle management of devices

In light of the different technological choices made by manufacturers of IPL hair removal devices and the ever-changing technological landscape, the Working Group is proposing performance obligations intended to ensure the long-term stability of the operating characteristics of these devices, in order to limit or prevent the occurrence of the adverse effects they are likely to cause. To that end, all manufacturers should prove the effectiveness of the maintenance processes associated with the various devices placed on the market.

The following critical technical characteristics can potentially be responsible for adverse effects:

- the nature of the emission spectrum of the lamps, which depends on the energy delivered at each wavelength and the reliability of its settings;
- the temporal shape of the emitted light pulses.

The following systems are essential for ensuring safety and maintaining performance:

- optical filters, which maintain emissions within a selected, controlled spectral range of wavelengths;

- contact safety devices, preventing any flashes from being emitted by the device if the handpiece is not correctly placed on the area to be treated.

When present on devices:

- automatic skin colour detection systems enabling the device's light emission settings to be configured properly;
- a system for cooling the applicator in contact with the skin.

The CES recommends:

- introducing a requirement for the periodic verification of professional IPL hair removal devices, whose frequency should be set by the device's manufacturer, to guarantee that there are no dangerous deviations from the emission settings. These checks should be carried out by a certified body according to the frequency specified by the manufacturer, at the expense of the device's operator. The certified body should issue a compliance certificate, which should be made available to the authorities, with a sticker affixed to the device. A list of the settings to be monitored should be provided by the manufacturer;
- concerning home devices, integrating a maintenance indicator into the device to notify the need for maintenance (e.g. change of lamp), or disabling the device after a certain number of shots, with possible reactivation of the device by the manufacturer conditional on maintenance. This should be implemented in keeping with the French Anti-Waste, Circular Economy Act;
- the recommendations concerning the life-cycle management of devices issued in 2016 in ANSES's "Aesthetic device" opinion remain valid. In addition, the manufacturer should take care to remind users of their obligation to recycle waste from end-of-life electric and electronic equipment, specifying the collection process for electronic waste, in order to prevent any potentially dangerous reuse.

3.3.8. User training and information

The Working Group identified the training of professional operators-users of IPL hair removal devices and the provision of information to users of home devices as key points in order to prevent and limit the occurrence of adverse effects.

3.3.8.1. Common core of training for professionals

The Working Group noted wide variability in the training levels of the different professionals who use IPL devices to perform hair removal procedures: dermatologists, aesthetic physicians, operators acting under the responsibility of physicians, and beauticians.

The CES recommends that all professionals who perform hair removal procedures with IPL devices have a minimum skills base relating to the following themes:

- basic knowledge of the skin and its appendages, to be able to identify situations where a prior dermatological diagnosis is necessary;
- basic knowledge of intense pulsed light technology, enabling them to understand how IPL devices work and become proficient in their use, in order to ensure the safety of both treated individuals and operators;
- basic knowledge on how to maintain the devices.

To that end, **the CES recommends** adopting a training framework, with a minimum number of hours specifically dedicated to the use of IPL devices, including at least all of the content

mentioned in the previous paragraph. This may correspond to several training units. Part of it – 30 to 50% for example – should take the form of practical work with the use of IPL devices in particular.

Both initial and ongoing training seem appropriate for the training of IPL device operators. The training should be validated and recognised at national level[12], to be able to control methods for verifying knowledge and skills, recognise the level of certification obtained, and carry out training over a short period of time. The training frameworks adopted could be based on existing training schemes while ensuring that any diploma course is compatible with the National Directory of Vocational Qualifications (RNCP).

3.3.8.2. Provision of information to customers of IPL hair removal professionals

In view of the potential adverse effects associated with the use of IPL hair removal devices and the comfort that the technique can provide, the Working Group considers that the choice of having one's hair removed with an IPL device, despite the potential risks, is a personal decision and a matter of individual discretion. This implies that the treated individual has been correctly informed of the potential risks involved, to be able make an informed decision.

Therefore, **the CES recommends** systematising and regulating the content of the information given to customers of IPL hair removal professionals concerning the adverse effects that these procedures can cause. Professionals should set aside time where they inform their customers to this end, with the systematic provision and signing of a document on the principle of "informed consent".

3.3.8.3. Provision of information to users of home devices

In the event that the marketing of home IPL hair removal devices continues to be almost entirely unregulated, and if no specific training of their users is required[13], the Working Group considers that the level of user information is a critical point to limit errors in the use of these devices.

The CES recommends informing users of these devices by means of a clear, simple, short and objective manual, written in French in a way that is attractive and can easily be understood, concerning:

- the principle of use of the device in the form of diagrams, showing in particular the settings and the steps for their sequential configuration;
- the recommended conditions of use (using simple symbols);
- the possible adverse effects with their description, their level of severity and the frequency at which they have been reported according to the available scientific data;
- the precautions to be taken before any use (prior dermatological consultation, verification of the lack of contraindications, etc.);
- if the device's settings are not controlled by an automatic system for measuring skin pigmentation (whose reliability is demonstrated by the manufacturer), at least a colour chart for setting skin colour, with explanations;
- what should be done if an adverse effect is observed, including in terms of reporting to the competent authorities (see 3.3.10).

[12] Based on national frameworks.
[13] As with the measures taken to regulate the use of leisure drones.

The public authorities could publish a list of IPL hair removal devices identified as not complying with the safety recommendations in France; it could keep this list up to date for consumers, in particular for online purchases.

3.3.9. Determination of IPL hair removal treatment parameters

The Working Group notes that it is difficult to issue recommendations for the emission parameters of an IPL hair removal device that can guarantee the absence of adverse effects. To do so, the complex interactions between light energy and the epidermis would need to be taken into account. The appropriate parameter for determining the optimum configuration of an IPL hair removal device is not the energy emitted but rather the energy deposited in the target tissue (the hair system) and the adjacent tissue (essentially the rest of the epidermis). To determine this deposited energy, it would be necessary to incorporate, on a case-by-case basis, multiple parameters including those related to the device (fluence, wavelengths, etc.) and those related to the individual (skin and hair colour, contraindications, treated area, etc.).

3.3.10. Medical device vigilance or observatory for adverse effects related to hair removal devices, in particular IPL devices

The CES renews the recommendation, issued by ANSES in 2016, concerning the creation of an observatory for adverse effects related to hair removal devices, in particular IPL devices. Professional and domestic users of IPL hair removal devices should be informed of this creation.

The CES recommends that the "Adverse Health Event Reporting Portal",[14] managed by the French Ministry of Health, include the possibility of reporting adverse effects related to the use of IPL hair removal devices, to make it easier for the observatory to take them into account.

3.3.11. Recommendations concerning obligations of means

When carrying out its work, the Working Group identified some obligations of means that it considers essential to minimise certain health risks associated with the use of IPL hair removal devices:

- **the wearing of protective glasses**, for operators and users of devices intended for professionals or private individuals, and of protective eye shields for people treated by professionals, seems essential to limit the risk of potential accidental flashing towards the eyes, which may be rare but has serious effects. This recommendation is valid both for treated individuals and for operators of devices, and for both professional and home devices; **furthermore, it should be mandatory to include a pair of protective glasses with any home IPL device** (two pairs of glasses for a professional device);
- **not treating areas close to the eyes** (eyelashes and eyebrows);
- **not exposing the same area** to the IPL beam more than once during the same session;
- **complying with good shaving practices** prior to any IPL hair removal, to limit phenomena of burning hair and their consequences (fumes and burns);
- **washing the area to be treated** with ordinary soap[15] and water prior to any hair removal, to remove as much as possible all substances likely to modify interactions between light radiation and the skin (absorption, diffraction, reflection, etc.);

[14] https://signalement.social-sante.gouv.fr/psig_ihm_utilisateurs/index.html#/choixProduitPecPA.
[15] Containing fat and lye (or potash).

- **leaving at least one month between IPL hair removal sessions**, to avoid accumulating skin damage caused by the repeated deposition of light energy. Given the duration of the hair cycle, there are no benefits to increasing the frequency of IPL hair removal treatments on the same area;
- **prohibiting the use of anaesthesia during an IPL session**, to avoid masking pain, which can potentially be a warning sign of a more serious lesion (burn, etc.). This prohibition should be stated in the user manuals of IPL hair removal devices.

4. AGENCY CONCLUSIONS AND RECOMMENDATIONS

The practice of hair removal using IPL devices is no longer new. However, due to the wide variety of devices and technologies currently available on the market, whether intended for professionals offering hair removal services or for private individuals for use at home, special attention should be paid to the risks related to this practice. Presently, the widely differing information based on which users assess the quality and reliability of these devices and the risks associated with their use is provided exclusively by the manufacturers and distributors that place them on the market.

ANSES endorses the conclusions and recommendations of the Expert Committee on “Physical agents and new technologies”.

4.1. Frequency and types of observed or potential effects

ANSES's assessment of the risks associated with the use of IPL hair removal devices showed that the quality of most of the available clinical studies involving these devices is not sufficient to enable the risks to be quantified. Nevertheless, these analysed studies showed that various types of adverse effects are observed after IPL hair removal treatments.

Certain adverse effects that are classified as minor (transient and not requiring treatment), whether subjective (pain and burning sensations) or involving objective clinical symptoms (transient erythema and perifollicular oedema), appear inseparable from the principle of action of IPL hair removal devices.

In conditions of use compliant with the manufacturers’ recommendations, the expert appraisal identified some other less systematic adverse effects, including minor (desquamation and increased perspiration), moderate (bullae and vesicles, scabs, Fox-Fordyce disease (benign skin disease), paradoxical hair regrowth in exposed areas and leukotrichia) and serious effects (chronic neuropathic pain, skin pigmentation disorders or dyschromia, and scars). The observation of these effects is largely consistent with the thermal effects on which IPL hair removal is based and with burns, although these have not been reported in the literature.

In conditions of use not compliant with the manufacturers’ recommendations, this list also includes serious effects that can cause loss of function (eye damage: cornea, iris or retina) or interfere with the detection of life-threatening diseases (delayed diagnosis of skin lesions leading to loss of chance in cases of malignant melanoma).

Moreover, if the device’s optical filter becomes defective (breakage, loss of effectiveness, etc.), this can expose the person to ultraviolet radiation whose hazard characteristics

(carcinogenicity) are well established[16] (IARC, 2012); therefore, any such defects need to be prevented through appropriate maintenance depending on the technology used.

Lastly, since no relevant work or publications were identified, no conclusion could be drawn concerning other potential long-term effects related to exposure to IPL hair removal devices, namely those related to repeated thermal exposure.

While the available data are not sufficient to precisely quantify the level of risk for each adverse effect described[17], the information from the analysed clinical studies shows a high likelihood of minor and moderate adverse effects, whereas the most serious potential adverse effects seem less likely or even rare enough that they have not been observed.

More generally, the Agency stresses that the available clinical studies are not very robust, compared with those dealing with other devices involving human exposure, and advises the companies placing IPL hair removal devices on the market to significantly improve them with a view to better identifying key risk control parameters for various exposure configurations.

Furthermore, ANSES's expert appraisal showed that the effects induced – whether intended or unwanted – depend on the energy actually deposited in human body tissue. In practice, IPL devices expose both the target tissue for hair removal (hair bulbs and their stem cells) and the surrounding tissue, which should be protected as far as possible from overheating. To determine the energy deposited in these various tissues, it is necessary to take into account the device's characteristics and settings (fluence, wavelengths, etc.) combined with the individual's characteristics (skin and hair colour, contraindications, treated area, individual sensitivity, etc.). These parameters can vary independently of each other. Therefore, the potential effects of exposure can only be anticipated on a case-by-case basis, based on available values or estimates for each parameter, taking into account established knowledge and related uncertainties. ANSES therefore considers that it is not appropriate to define acceptable ranges of target values for the technical characteristics of a device that alone would guarantee its safety for all. Establishing a safe maximum energy level could sacrifice the effectiveness of this hair removal process and therefore the usefulness of exposure.

4.2. Regulation recommendations

In view of the various parameters that need to be considered to determine the energy deposited in tissue, the manufacturer-initiated development of a research-driven numerical model, to be experimentally validated and combined with further clinical studies, could lead to a decision-making tool for operators.

[16] IARC, 2012, Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 100D

[17] Missing data for determining excess risks related to IPL hair removal as part of a quantitative risk assessment, carried out effect by effect:
(a) absence of data on exposed population groups and on exposure levels in the general public;
(b) major uncertainties associated with the results of the available clinical studies due to methodological issues:
- few studies focusing on tolerability;
- vague descriptions of exposure parameters and exposed individuals in the clinical studies;
- methods of collecting tolerability data not described or inadequately described;
- post-exposure monitoring periods for individuals too short to evaluate certain effects;

(c) inability to determine relationships between the frequency of adverse effects and the exposure dose according to the available studies.

As a result, ANSES underlines the need to take measures to limit the occurrence of adverse effects associated with IPL hair removal devices. It therefore highlights the experts' recommendations in terms of:

- conditions for the placing on the market of devices;
- alignment of the standards applicable to IPL and laser treatments;
- contraindications;
- parameters to be controlled to limit adverse effects;
- precautions to be taken before any use of an IPL hair removal device;
- adjustment of settings based on skin and hair colour;
- maintenance and life-cycle management of devices;
- training of professionals and information for users;
- medical device vigilance;
- implementation of obligations of means: wear protective glasses, avoid treating areas near the eyes, shave and wash the area to be treated beforehand, prohibit the use of anaesthesia during an IPL session, avoid exposing the same area to the IPL beam more than once during the same session, and leave an interval of time between sessions.

The new Regulation (EU) 2017/745 on medical devices, which entered into force on 26 May 2021, may provide a legal basis for some of these recommendations, in particular concerning conditions for placing on the market as well as medical device vigilance.

4.3. Consumer devices

Going beyond the recommendations on regulating the use of devices by professionals performing aesthetic procedures, one of the points of consideration highlighted by this expert appraisal is the direct selling of IPL hair removal devices to the general public. IPL technology is indeed potentially dangerous, as stressed by this expert appraisal, and the use of these devices in conditions not compliant with the manufacturers' recommendations can potentially cause serious adverse effects. The means chosen by manufacturers to ensure their safe home use should therefore be in line with the users' level of prior knowledge.

In the absence of specific regulations for the placing on the market of IPL hair removal devices for private individuals, these devices are considered as goods whose free movement in the European market is guaranteed. Moreover, the distribution of these devices, whether from inside or outside the European market, is facilitated by online sales.

The development of IPL technology, whose operation and principles of interaction with the skin can be unknown or poorly understood, calls for a stronger framework for the placing on the market of these devices.

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