Review Article

A Compendium of Tattoo Piercing and Removal Laws in the US, Europe and India

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ABSTRACT

Tattoos have been used by humans for millennia to distinguish one individual from another. Multiple-colored tattoos injected into the dermis are intended to last the wearer's entire life. It is prohibited to manufacture tattoo ink and pigment without the proper authorization. Although tattooing is seen as aesthetically pleasing in a few of nations, there are no universally accepted guidelines for the practise. Nonetheless, because tattooing is overseen by state and local governments, the rules governing tattooing differ significantly between jurisdictions. Surveillance data indicate that the chemical purity of tattoo inks is still far from satisfactory. Distributors and manufacturers lack knowledge of many criteria and analytical methodologies, as well as their application. There are no standardised procedures in place for analysing tattoo and permanent makeup inks. Adapted methods created for other items are utilised to monitor the market. This paper investigates the present legislation regarding piercing tattoos, tattoo inks, and tattoo removal in the United States, Europe, and India.

Keywords: Tattoo, Permanent make up, Regulation of tattoo, Tattoo regulatory framework.

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INTRODUCTION

As far back as 3000 BCE, there have been tattooed human remains recovered. Tattoos are now widely accepted as a kind of body art and are popular among a wide range of demographics, with younger individuals and women showing a disproportionate preference for getting inked. A rising number of people are opting for laser or chemical tattoo removal to get this look. An effort to quantify the prevalence of the occurrence has been made by the Joint Research Center, with a focus on the number and characteristics of current tattoo/PMU (permanent make up) recipients, as well as the incidence of adverse health effects. As a result of long-term exposure to the chemicals injected, as well as their decomposition products, tattoos are applied by injecting coloured inks into the dermis. Using semi-permanent tattoos to mimic make-up is known as PMU. In the following material, the term "tattoo" will refer to both tattoos and PMU for the sake of brevity and clarity. Tattoo/PMU inks require standardised testing procedures that have yet to be created. In order to keep an eye on the market, test procedures adapted from those used for other items are employed.[1]

It's important to know what to expect while getting a tattoo if you want to avoid unpleasant side effects. Regulating tattooing is essential to its safety. Microorganisms often degrade tattooing ink that has been exposed to the manufacturing or tattooing processes. Since tattooing has become increasingly popular in Western countries, a number of new laws have been introduced. Because of the lack of constraints, many quality control requirements are being flouted by manufacturers and distributors, with disastrous results.

U.S. regulation and legislation

One in five persons has a tattoo. According to the US Food and Drug Administration, tattooing has been related to a number of adverse health effects (FDAs). Despite its extensive use, the production of tattoo ink is still subject to government oversight. Tattoo ink manufacture is controlled by federal and national governments through the FDA. Since each state has its own set of rules and regulations, this results in a variety of options. The question of whether or not limitations are excessively restrictive is determined by the jurisdiction in which they are implemented. Both the tattooing method and the regulatory environment provide challenges for the tattoo artist. Toxic contamination can occur during tattooing and from tattooing equipment. Tattoo ink, unlike other cosmetics, is not subject to the same kind of quality control that other cosmetics. A blood-borne pathogen can cause an infection if aseptic techniques are not employed throughout the tattooing procedure.[2]

Tattoo ink production falls within the purview of the FDA. There were fewer restrictions when compared to

food colouring. Food colouring is regulated by the FDA to the letter. Although tattoo ink can be sold on the open market, cosmetics must first be approved by the FDA. In spite of being classified as a cosmetic, there is no necessity for pre-market approval. In order for the FDA to investigate and take action, an adverse event must be reported. After the post-warning phase, product recalls and customer warnings will be far easier to implement. The outbreak of the *Mycobacterium Chelonae* skin infection in New York City in 2011 spurred the FDA to take action.

As a result, the FDA established a disease control and prevention branch tasked with investigating and documenting any adverse responses to tattoo inks that may occur. Health and safety, on the other hand, is a division that is both reactive and proactive in nature. Preventing tattoo ink contamination during manufacture is a challenge for the US Food and Drug Administration (FDA).[3]

Manual for the control of infections and procedures

Occupational Safety and Health Administration (OSHA), another government agency, is responsible for and supervises disease management in the US. Handling hazardous chemicals necessitates the administration of immunizations against hepatitis B, hand washing, and the proper disposal of sharps. Only employees who have been exposed to hepatitis B at work, such as through a needle stick injury, are required to receive the vaccine. However, there are exceptions in some organizations. Many tattoo parlours may be exempt from these regulations due to the fact that many of them employ independent contractors. Local governments are responsible for enacting legislation of this type, although they are not obligated to do so.[4]

Tattoo removal rules and procedures

A large number of rules and regulations are required. USA's most typical restrictions on removal of tattoos:

• Use an FDA-approved tattoo removal gadget to get rid of the ink.

• The medical director is a doctor employed by the practise.

• Laser operators must undergo safety training and certification, as well as a minimum of 16 hours of hands-on practise.[5]

Europe's regulation framework

Thanks to the cooperation of various EU countries, a European Union standard for tattoo ink manufacture has been established. There was a problem implementing tattoo laws because they were originally popular in the West. Strict guidelines are followed by only a small number of European countries. As recently as 1966, it was illegal in Denmark to acquire a tattoo on your head, wrists, or neck. Getting a tattoo when you're under 18 is now forbidden owing to the "Tattooing of Minors Act," passed in 1969. To prevent hepatitis B, the first infection control rules were put in place at tattoo parlours as far back as 1980. In order to safeguard the health of their citizens, other European countries have enacted laws governing minimum ages and levels of cleanliness. Manufacturing and distribution have contributed to an unwieldy mixture of chemicals entering the bloodstream and lymphatic system. They bear some responsibility for this mess. Tattoos are considered cosmetic products under ordinary product safety standards because their primary function is to enhance one's appearance. The European Commission has established ReSAP to evaluate the safety of tattoos and permanent cosmetics in light of their growing popularity in the European Union (2008).[6]

An earlier list of prohibited chemicals in tattoo inks was published (2003). These lists include carcinogenic aromatic amines as well as toxic colours and solvents. The EU Cosmetics and Dangerous Substances Directives are also mentioned in the resolution. As a result, tattoo inks can no longer include carcinogenic, mutagenic, or regeneratively hazardous chemicals. The lack of preservatives and sterility until use are also needed by tattoo ink chemical specifications, as are sterilisation and single-use packaging.

There are thirteen elements in total that were included in ResAP (2008), which took the place of ResAP (2003). At these levels, toxic metals such as cadmium, nickel, and lead can be present (2 ppm). The 5 ppb benzo [a] pyrene limit is applied to all PAHs, with no indication of which PAHs are being examined. Uniform criterion application is complicated by the unavailability of analytical methods for various elements and PAHs. Tattoo inks, according to ResAP (2008), need to be as pure as food colouring.[7,8]

It has been added to the "negative list," and phenylenediamine is on it. It wasn't because of a lack of sterility that preservatives were allowed to be used, but rather because of a change in the law. When the ResAP programme was launched in 2008, only 16 of the 18 member countries participated (2003). The United States has enacted legislation in the Netherlands, France, Spain, and Switzerland based on these standards.

The Netherlands passed a ResAP-based statute in 2003. (2003). In 2007, laws were adopted for their execution, including age limitations and prohibitions on tattooing in specified areas of the body. During the year 2013, a total of 701 samples of various colours of red, yellow, orange, and green tattoo inks were randomly examined, with 30% of all samples surpassing the aromatic amine limit and 12% exceeding the element limit, respectively. In 2004, France passed a law ensuring the safety of tattoos. ResAP enacted new chemical safety rules in 2013. Azo dyes and aromatic compounds, which have been linked to cancer, should not be used in tattoo inks. Professional tattoo artists and medical professionals in France have been required to report any negative or dangerous side effects since 2008 under the country's tattoo goods monitoring programme.

These new laws were part of Switzerland's national ordinance on goods for human contact that went into force this year. Nickel and antimony have no limit

amounts, unlike ResAP, which does (2008). In Switzerland, there are regular surveillance programmIt was determined that 39 (65 percent) out of 60 tattoo ink and permanent make-up samples examined in 2013 were unpleasant and 33 were banned from use. Aromatic amines, PAHs, and N-nitrosamines were identified as potential culprits. Preservatives were also used in a novel way. Tattoo inks in Spain are protected by the country's national cosmetics code. The Spanish Agency for Medicines and Health Products now requires that tattoo inks be certified by the distributor based on toxicological and quality data. The registry is where you may get this information. Each province in Spain has its own regulations on topics like sanitary requirements, tattoo studio registration, and qualifications for tattooists.[9,10]

Manual for the control of infections and procedures

When it comes to the prevention and management of infection, these generally acknowledged principles should be known and used by everyone in the patient care (National Institute for Health and Care Excellence 2012). Hand hygiene and skin care as well as the right use of personal protective equipment should be taught to tattooists (PPE). Blood and bodily fluid exposure must be controlled, as well as the proper disposal of sharps, as well as cleaning and disinfection of the surroundings and any necessary application of local anaesthetic.[11]

Regulations for tattoo removal

The EU doesn't have the guidelines. However, Tattoos and related treatments can now only use safe products due to the enactment of General Product Safety Directive (GPSD).

Regulators in India

Tattoos were becoming increasingly fashionable among Indian teenagers. There has been a remarkable rise in the number of people getting tattoos in the last few years. To prevent tattoo-related health issues, Indian tattooing rules are less stringent than those in the United States and Europe. It was not as closely monitored by CDSCO as other cosmetics, but the organisation nevertheless regarded tattoos as a cosmetic.[12,13]

Infection control and procedures manual

In order to ensure a successful tattoo, it is important to use proper gloves and carefully clean the needle. In addition, India lacked standard operating procedures and infection control practises, unlike Europe and the United States. Tattoo removal in India is unregulated, according to the CDSCO.[14,15]

DISCUSSION

In comparison to other countries, Europe now follows a diverse set of norms. There are no European regulations on the ink generated by the manufacturer. However, in several European countries, tattoo ink is subject to quality and toxicological checks. To comply with European classification requirements, the preservatives and content utilised in this product must be kept to an acceptable level. An emergency at the federal level can be handled immediately by the Food and Drug Administration (FDA). By recalling the ink from DIY tattoo kits, the Food and Drug Administration (FDA) prevented an outbreak of pandemic proportions in the United States. Consumers must report cases of abuse in order for the aforementioned organisation to take action, and early reporting is the only way to safeguard consumers and others. With minimal standards and a vast number of Americans getting tattoos each year, getting a tattoo is usually regarded safe, with only a few known incidents of complications.

In the same way that Europe and the United States have, India should create a similar tattoo ink manufacturing and adverse event tracking system. Because more and more Indians are considering getting tattoos, yet many aren't aware of the consequences of doing so. In order to ensure that the product's preservation limit is maintained and that the subject is free of microbiological contamination and protected from a wide range of skin disorders, a stronger rule is necessary.

CONCLUSION

Although tattoo laws were first enacted by the Council of Europe in 2003, only a few EU countries have followed suit since then. Tattoo inks and their ingredients are banned from use in several countries due to insufficient data on their biokinetics and toxicity and deficient analytical processes. Most countries do not have this rule and that is true. According to current tattooing trends and accompanying health dangers, this is a future that can no longer be imagined. The current scientific gaps must be filled, and information must be restricted, through international cooperation between regulators and scientists. Only then can all countries implement similar protective legislation for their people.

REFERENCES

1. I.M. Haugh a, S.L. Laumann, Anne E. Laumann. Regulation of Tattoo Ink Production and the Tattoo Business in the US. Curr Probl Dermatol. Basel, Karger, 2015;48:248–252.
2. Tattooing and Body Piercing | State Laws, Statutes and Regulations. National conference of State legislatures. [cited on 02/04/2022]Available URL: https://www.ncsl.org/research/health/tattooing-and-body-piercing.aspx
3. Body Art: State Regulations. CDC. [cited on 03/04/2022] Available URL: https://www.cdc.gov/niosh/topics/body_art/stateregs.html
4. Serup J, Kluger N, Bäumler W. Tattooed skin and health. Karger; 2015 Jan 1.
5. Tattoo and body art Safety. OSHAcademy. [cited on: 07/04/2022] Available URL; https://www.oshatrain.org/courses/studyguides/607studyguide.pdf
6. Advice and safe practice for permanent tattooing. Gloucester city council. [cited on 10/04/2022]. Available URL;

https://www.gloucester.gov.uk/media/2320/adviceandsafepracticeforpermanenttattooing.pdf

7. Peter Laux, Andreas Luch. The European Landscape of National Regulations of Tattoo Inks and Businesses. Curr Probl Dermatol. Basel, Karger, 2015;48:196–200.
8. Ian gray. Tattooing and body piercing. Public Health England. [cited on: 14/04/2022]; Available at: https://www.emcouncils.gov.uk/write/Tattooing_and_Body_Piercing_Ian_Gray.pdf
9. Noah N. Tattooing and piercing – the need for guidelines in EU. [cited on 24/04/2022] Available at; https://www.eurosurveillance.org/content/10.2807/esm.11.01.00589-en
10. Worp J, Boonstra A, Coutinho RA, Van den Hoek JA. Tattooing, permanent makeup and piercing in Amsterdam; guidelines, legislation and monitoring. Eurosurveillance. 2006 Jan 1;11(1):5-6.
11. Tattooing and body piercing guidance, Public Health England. [cited on: 14/04/2022]; Available at; https://www.cieh.org/media/2004/tattooing-and-body-piercing-guidance-toolkit-july-2013.pdf
12. artlawindia.com. India Ink. – Body Art and the Indian laws [Updated 2020 May 20; cited][cited on: 28/04/2022] Available from: https://www.artlawindia.com/post/india-ink-body-art-and-the-indian-laws
13. Kanav Rawat. India: Tattoos: A Legal Perspective. Clasis Law. [cited on: 03/05/2022] Available URL; https://www.mondaq.com/india/copyright/1100528/tattoos-a-legal-perspective-
14. Shatz BA, Weinstock LB, Swanson PE, Thyssen EP. Long-term safety of India ink tattoos in the colon. Gastrointestinal endoscopy. 1997 Feb 1;45(2):153-6.
15. Tattoos: Understand risks and precautions. Mayo clinic. [cited on: 10/05/2022]. Available URL: https://www.mayoclinic.org/healthy-lifestyle/adult-health/in-depth/tattoos-and-piercings/art-20045067

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