Central Consumer Protection Authority

Room No. 545, Krishi Bhawan, New Delhi - 110001

Case No: CCPA-2/71/2023-CCPA

In the matter of: Case against Kaya Limited regarding misleading advertisement

CORAM:

Shri Rohit Kumar Singh, Chief Commissioner

Shri. Anupam Mishra, Commissioner

Appearance on behalf of Kaya Limited:

Mr. Deepak Chawala and Mr. Aruj Dhingra

Date: 18.03.2024

ORDER

1. The Central Consumer Protection Authority (CCPA) received a complaint from Mr. Ajay Gupta, r/o 502, Mahavir Apartment, King Kothi Road, Hyderabad, (hereinafter referred as "complainant") against Kaya Limited (hereinafter referred as "opposite party") with regard to their misleading advertisement of weight loss/ fat loss/ slimming etc. by a machine called COOL-SCULPTING.

2. The opposite party in its alleged misleading advertisements has made the following claims:

a) *"Kaya's Non-surgical Fat Reduction"*

b) *"Kaya brings you easy inch loss with cool sculpting."*

c) The picture in the alleged misleading advertisements depicts major fat loss results all over the body from the CoolSculpting machine which appears to be misleading.

3. As per the show cause notice dated 5th September 2023 issued by CCPA, the opposite party was provided an opportunity to submit its response within 15 days to substantiate the claims and picturization made by them in their advertisement.

4. In response to the Notice, opposite party submitted its reply dated 05th October 2023 in which it denied each and every averment made in the complaint by Mr. Ajay Gupta. The following annexures were attached with the reply:

a) Copy of FDA certificate issued for the machinery/equipment used in the CoolSculpting procedure;
b) Kaya's CoolSculpting Consent Form.

5. The opposite party in its response inter alia submitted the following:

a) All the advertisements floated by Kaya Ltd. are in complete consonance with the representations made by Allergan Aesthetics (Parent Company - Zeltic Aesthetics Inc.), which is the Company involved in manufacturing and/ or supply of the machinery/ technology used in the process of the COOL-SCULPTING process. The description of the procedure, as reflected on the website of Allergan Aesthetics is reproduced below:

"The unique CoolSculpting® fat-freezing technology is a nonsurgical, scientifically proven way to reduce pockets of fat in trouble spots such as the abdomen, flanks, or under the chin in as little as one session."

b) The promotional advertisement made on the website and social media handles of Kaya Ltd., with respect to the COOL-SCULPTING procedure also states that the said procedure aids in the reduction of fat and does not, in any manner, indicate any possibility or false promise towards weight loss.

c) Kaya Ltd. has never committed or assured any of their clients that the procedure is for weight loss. On the contrary, it is always made known to the clients that the said procedure is for fat loss and the results may vary from one person to another.

d) The machinery/ equipment used for the COOL-SCULPTING procedure is approved by the U.S. Food and Drug Administration (FDA) authority and Allergen Aesthetics Parent Company - Zeltic Aesthetics Inc.) has procured all necessary licenses.

e) A copy of the FDA certificate issued to Zeltic Aesthetics Inc. is attached as Annexure- A.

f) The consent form containing certain terms and conditions regarding the COOL-SCULPTING procedure is attached in the reply as Annexure-B.

g) Kaya Ltd. has been successfully adopting the COOL-SCULPTING procedure for numerous customers who have achieved their desired results.

6. As per sub-section (1) of Section 19 of the Act, "*The Central Authority may, after receiving any information or complaint or directions from the Central Government or of its own motion, conduct or cause to be conducted a preliminary inquiry as to whether there exists a prima facie case of violation of consumer rights or any unfair trade practice or any false or misleading advertisement, by any person, which is prejudicial to the public interest or to the interests of consumers and if it is satisfied that there exists a prima facie case, it shall cause investigation to be made by the Director General or by the District Collector*"

Given the above, CCPA observed that a prima facie case is made out against the opposite party and referred the case for investigation through an order dated 10th November 2023 to Director General (Investigation) CCPA.

7. Vide letter dated 10.11.2023 the opposite party was provided an opportunity of hearing through video conferencing on 14.11.2023 to further substantiate their claims in the above-stated matter.

8. During the hearing, appearing on behalf of the opposite party, Mr Aruj Dhingra made the following submissions:-

i. The company provides the service of non-surgical fat reduction by virtue of a COOL-SCULPTING procedure which gives easy inch loss to the consumer subject to certain Terms & Conditions (T&C).
ii. The advertisement made by the company is in line with the statements made by the manufacturer Zeltic Aesthetics Inc. and the approval of US-FDA.
iii. The COOL-SCULPTING procedure works on the whole body where there are excessive fat cells by giving an inch loss.

9. Going by the submissions made by the opposite party CCPA vide mail dated 16.11.2023 asked the opposite party to furnish documents with respect to the following:

a) *"As per the FDA (US) approved "indication for use" the CoolSculpting system is used for cold-assisted lipolysis (breakdown of fat) of the submental area, thigh, abdomen, and flank in individuals with a body mass index (BMI) of 30 or less."*

In view of the above submissions made, the company is required to provide a scientific study that proves it works on the reduction of fat from the whole body.

b) As per the Note on page 5 of the CoolSculpting Consent Form submitted by the company along with its reply: "*In the U.S., the CoolSculpting procedure for non-invasive fat reduction is FDA-cleared for the flank (love handle), abdomen, and thigh. In Taiwan, non-invasive fat reduction is cleared only for the flank and abdomen."*

The company is required to provide Clinical trials of the Indian demographic showing the desired results on whole of the body. As mentioned above also provide the US-FDA clearance for usage of CoolSculpting machine on the specific parts of the body in India.

10. The opposite party by the e-mail dated 18.11.2023 has furnished its written submissions along with the following documents:

i. A copy of the Licence No. : IMP/MD/2022/000601 issued by Central Drugs Standard Control Organisation (CDSCO) for import of the machinery.
ii. FDA approval certificate.

11. On examination of the documents stated in para 10 above, CCPA found that:

a) All the scientific studies submitted are related to the US FDA clearance of cyrolipolysis for specific fat areas. The same is reiterated from the articles:

"FDA cleared a cryolipolytic device (CoolSculpting®; ZELTIQ Aesthetics, Inc., Pleasanton, CA, USA) for reduction of flank and abdominal fat. In April

2014, the FDA also cleared this system for the treatment of subcutaneous fat in the thighs"

"*such procedure is cryolipolysis, which has received FDA clearance for treatment of the focal fat deposits in the flanks (2010, K080521), abdomen (2012, K120023), and thighs (2014, K133212)"*

b) Further, Review of a publication by the Oxford University Press titled as "*The Safety and Efficacy of Cryolipolysis: A Systematic Review of Available Literature*" (https://academic.oup.com/asj/article/35/7/830/2589179), clearly mentions the side effects of the cryolipolysis procedure, that is "*Twelve patients (0.82%) reported complications with the most common being diminished sensation lasting greater than 4 weeks.*"

c) Further Form MD 15 of the Central Drugs Standard Control Organization (CDSCO) is a license to import given to the authorised agent M/s ALLERGAN HEALTHCARE INDIA PRIVATE LTD, SHRI ARHIANT COMP.,BLDG. NO. H-1, GALA NO. 10, THANE-BHIWANDI ROAD, DIST. THANE, BHIWANDI, TAL BHIWANDI-15 , Thane, Maharashtra (India) - 421302 Telephone No.: 919300622503 FAX: 08040707007 to import medical device(s) of the overseas manufacturer M/s ZELTIQ Aesthetics Inc, and to be responsible for the business activities of the manufacturer in India in all respects.

d) The Indication for Use, in the USA_FDA document clearly states that:

"*The CoolSculpting System is a skin cooling or heating device. The device is indicated for cold-assisted lipolysis (breakdown of fat) of the upper arm, bra fat, back fat, banana roll, submental area, thigh, abdomen, and flank, or "love handles" in individuals with a Body Mass Index (BMI) of 30 or less. The device is intended to affect the appearance of visible fat bulges in the upper arm, bra fat, back fat, banana roll, submental area, thigh, abdomen and flank. When used for cold-assisted lipolysis of the submental area, the device can also affect the appearance of lax tissue in the submental area.*

Cooling with the device may also be used to minimize pain and thermal injury during laser and dermatological treatments and act as a local anesthetic for procedures that induce minor local discomfort.

The CoolSculpting System is also indicated for use to provide localized thermal therapy (hot or cold) to minimize pain post-trauma and post-surgery, and for temporary relief of minor aches, pains, and muscle spasms. The optional massage function can also be used for the temporary relief of minor muscle aches, pain, and spasm and for temporary improvement in local circulation and temporary reduction in the appearance of cellulite.

The ZELTIQ Pretreatment Skin Wipe and Gel/Gelpad facilitate thermal contact of the device with a patient's skin by mitigating minor variances in device-to-skin contact."

Therefore from the above the Cool Sculpting procedure can only be used on the upper arm, bra fat, back fat, banana roll, submental area, thigh, abdomen, and flank, or "love handles" part of the human body not on the whole body as claimed by the opposite party and only in individuals with Body Mass Index (BMI) of 30 or less.

12. The investigation report from the Director General (Investigation) CCPA was received on 18th December 2023, which stated the following:

"*To enquire into the matter as per the directions of CCPA vide letter dated 10 Nov 2023, the matter was forwarded for investigation to BIS, Mumbai Branch office-I. Please see the Investigation report enclosed at C - On perusal of the Investigation report submitted by BIS, MUBO-I it is observed that the firm has not provided the feedback received from the customers which could be an scientific evidence in studying the effectiveness of treatment on Indian demography. The firm is using the tagline "easy inch loss" in the advertisement which is not covered under the USFDA certificate as per the investigation report. As the firm could not provide evidence on the above-mentioned two points, it is proposed that we may send the report to DoCA, CCPA for necessary action.*"

13. The opposite party on 6th February 2024 submitted the following clarification with respect to the DG investigation official visit on 08.12.2023:

i. The non-production of the feedback received from customers who availed the Cool Sculpting service sought by the said Official during his visit was due to the said information was not readily available at the opposite party headquarters. But the same could be arranged within 3-4 days.

ii. As the visit was made to the opposite party headquarters and the cool sculpting machine has been installed at different cities for providing the services the inspection of the machine was not provided to the Official.

14. The opposite party was given another opportunity of hearing on 7th February 2024 to submit any further documents or clarifications, the opposite party made the following submissions and submitted no further documents in support of their claims:

i. Drew reference to the submissions dated 06.02.2024 on the Investigation

ii. The opposite party is a company that ensures transparency in its advertisements.

iii. The CoolSculpting machine is installed at the opposite party's specific clinics only not in all of its outlets.

iv. CoolSculpting machine is approved by the US FDA and has License No.: IMP/MD/2022/000601 for the import in India issued by the Central Drugs Standard Control Organization (CDSCO).

15. As per Section 2(28) of the Act –

"misleading advertisement" in relation to any product or service, means an advertisement, which—

(i) falsely describes such product or service; or

(ii) gives a false guarantee to, or is likely to mislead the consumers as to the nature, substance, quantity or quality of such product or service; or

(iii) conveys an express or implied representation which, if made by the manufacturer or seller or service provider thereof, would constitute an unfair trade practice; or

(iv) deliberately conceals important information

16. As per Clause 4 of the Guidelines for Prevention of Misleading Advertisements and Endorsements for Misleading Advertisements, 2022 issued by the CCPA, the conditions of non-misleading advertisements are as under-

Conditions for non-misleading and valid advertisement. –

(1) An advertisement shall be considered to be valid and not misleading, if–

(a) it contains truthful and honest representation;

(b) it does not mislead consumers by exaggerating the accuracy, scientific validity or practical usefulness or capability or performance or service of the goods or product;

(c) it does not present rights conferred on consumers by any law as a distinctive feature of advertiser's offer;

(d) it does not suggest that the claims made in such advertisement are universally accepted if there is a significant division of informed or scientific opinion pertaining to such claims;

(e) it does not mislead about the nature or extent of the risk to consumers' personal security, or that of their family if they fail to purchase the advertised goods, product or service;

(f) it ensures that the claims that have not been independently substantiated but are based merely on the content of a publication do not mislead consumers;

(g) it complies with the provisions contained in any other sector-specific law and the rules and regulations made thereunder.

17. CCPA has carefully examined the response submitted by the opposite party, the submissions made during the hearings, the written submissions made by the opposite party, DG Investigation report and concludes that:

I. The Cool Sculpting machine manufactured by ZELTIQ Aesthetics Inc. has been approved by the US-FDA to be only used on the upper arm, bra fat, back fat,

banana roll, submental area, thigh, abdomen, and flank, or "love handles" part of the human body. Further, the test conducted to acquire the clearance of US-FDA does not include any test being done on individuals of Indian Demographic. Also, US-FDA have cleared the use of the Cool Sculpting machine for specific parts in different countries for example-

a. In the U.S. the CoolSculpting procedure is FDA-cleared for the flank (love handle), abdomen, and thigh.
b. In Taiwan, it is cleared only for the flank (love handle) and abdomen.

(*As clearly indicated by the opposite party on Page 3 of its consent form*)

Hence, in the absence of the test being conducted on the Indian demographic and no specific declaration by US-FDA with respect to the usage of the CoolSculpting procedure in India, making picturization in the advertisement and claiming that it can be used on the whole body is misleading and a violation under Section 21 of the Consumer Protection Act, 2019.

II. As the cryolipolysis procedure has gained popularity in the last few years for fat reduction and the manufacturer of the CoolSculpting machine ZELTIQ Aesthetics Inc has taken due approval of the US-FDA, the opposite party has taken undue advantage of the popularity of the procedure and the goodwill of the manufacturer in misleading the consumers in reducing the fat from whole of the body despite being well aware of the side effects of the procedure.

18. Further during the hearing on 07.03.2024, the representative of the opposite party made the following submission:

"The CoolSculpting procedure is used in India for fat reduction by many major key players in the Indian Market."

19. With the increasing popularity of cosmetic procedures, including fat-reducing treatments, it has come to the attention of the CCPA that certain cosmetic and beauty wellness companies and clinics in India are utilizing fat-reducing machines, such as the Cool Sculpting devices, manufactured outside India and holding approvals from authorities in other countries. Further, they are making exaggerated claims regarding the effectiveness of the machine/ device which are outside the scope of the approval given to them.

20. As per the Consumer Rights enshrined under Section 2(9)(ii) of the Act states that the consumer has-

"the right to be informed about the quality, quantity, potency, purity, standard and price of goods, products or services, as the case may be, so as to protect the consumer against unfair trade practices"

21. Further, CCPA as established under Section 10 (1) of the Act states that- *"The Central Government shall, by notification, establish with effect from such date as it may specify in that notification, a Central Consumer Protection Authority to be known as the Central Authority to regulate matters relating to*

violation of rights of consumers, unfair trade practices and false or misleading advertisements which are prejudicial to the interests of public and consumers and to promote, protect and enforce the rights of consumers as a class."

Also, Section 18(1)(a) of the Act states:-

> *"The Central Authority shall protect, promote and enforce the rights of consumers as a class, and prevent violation of consumer rights under this Act."*

22. As per Section 2(1), advertisement means "*any audio or visual publicity, representation, endorsement or pronouncement made by means of light, sound, smoke, gas, print, electronic media, internet or website and includes any notice, circular, label, wrapper, invoice or such other documents*"

23. In view of the above, and in light of the protection of consumer rights, the CCPA holds the following observations with respect to the US-FDA approved Cool Sculpting procedure/ machine holding License No.: IMP/MD/2022/000601 for the import in India issued by the Central Drugs Standard Control Organization (CDSCO):-

A. Any person or company using such CoolSculpting machine will disclose the following prominently in its advertisement itself or separately in its disclaimer-

   i. Particular areas of the body where it targets the fat- reduction;
   ii. Works only in individuals with Body Mass Index (BMI) of 30 or less;
   iii. Every inclusion and exclusion as stated in the US –FDA approval of the CoolSculpting fat-reducing procedure/ machine.

B. Any person or company using such CoolSculpting machine will mention "*The CoolSculpting Procedure is used for treatment of the focal fat deposits and not weight loss"* in its advertisement as well as on the consent form in such a manner which is easily accessible and readable to the consumers.

C. Any person or company using such CoolSculpting machine will make claims with respect to its efficacy and usage in accordance to the approval granted to it.

D. Any person or company using such CoolSculpting machine shall ensure that pertinent information regarding the absence of testing conducted on the Indian demographic and the lack of specific endorsement by the US Food and Drug Administration (FDA) regarding the utilization of the CoolSculpting procedure in India is provided to the consumer prior to availing the service of CoolSculpting.

24. It may be mentioned that the CCPA under Section 21 (2) of the Act in respect of false or misleading advertisement may impose a penalty which may extend to ten lakh rupees. Further, Section 21(7) of the Act, prescribes that the following may be regarded while determining the penalty against false or misleading advertisement:-

a. The population and the area impacted or affected by such offence;
b. The frequency and duration of such offence.

And, for every subsequent contravention, the penalty may extend up to fifty lakhs rupees.

25. The aforementioned misleading advertisement was visible on the Facebook page of the opposite party which has a significant amount of followers around 6.8 lakhs. Hence it can not be ignored that misleading advertisement has a wide reach among consumers.

26. In view of the above the CCPA hereby passes the following directions to the opposite party:

(i) The opposite party shall withdraw all the misleading advertisement regarding CoolSculpting Procedure from all print/ media/ social media platforms if it's not in consonance to the para 23 above.

(ii) The opposite party to strictly comply with the CCPA observations made in para 23 above.

(iii) The opposite party shall pay the penalty of ₹ 3,00,000 for publishing a false or misleading advertisement with respect to 'Cool Sculpting' and submit a compliance report of the directions of this order within 15 days.

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Rohit Kumar Singh

Chief Commissioner

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Anupam Mishra

Commissioner