

HEALTH AND BEAUTY UPDATE

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A: Significant or Pressing Issues

Teeth whitening

The European Council has adopted a Directive on tooth whitening. Once the Directive is published (expected to be any time now), the UK Government will be obliged to amend the Cosmetic Regulations to reflect the content of the Directive within 12 months of the date of publication.

In other words, within 12 months of publication, Regulators will have the green light to enforce the Directive.

The Directive allows dentists to legally supply products for tooth whitening, which release or contain up to 6% hydrogen peroxide. To date, it has been illegal to supply products for the purpose of tooth whitening that contain or release more than 0.1% hydrogen peroxide.

Under the Directive, only registered dental practitioners will be permitted to sell products that release or contain between 0.1% and 0.6% hydrogen peroxide. In addition, the first use of the product by a user must be carried out by a dentist, or under their supervision. These products must not be used by those under the age of 18.

The product must also be labelled as follows:

1. Concentration of H₂O₂ present or released indicated in percentage.
2. Not to be used by a person under the age of 18.
3. To be sold only by dental practitioners.
4. For each cycle of use, the first use to be only done by

dental practitioners or under their direct supervision if an equivalent level of safety is ensured. Afterwards to be provided to the consumer to complete the cycle of use.

It will continue to be lawful for consumers to purchase teeth whitening products that contain or release less than 0.1% hydrogen peroxide from non dental practitioners.

MHRA Warning - SIBUTRAMINE

The Medicines and Healthcare products Regulatory Agency (“MHRA”) issued a warning to consumers in relation to certain herbal products it had found to be laced with a banned substance, sibutramine. MHRA said that products like **Instant Slim**, **ACAI** and **Sport Burner** had been tested and revealed traces of sibutramine.

In issuing the consumer alert, the MHRA advise consumers to look out for products that were approved under the Traditional Herbal Medicinal Products Directive (“THFPD”) as a means to avoid products that may contain controlled substances.

In addition, they urged people not to take any slimming medicines or products brought on-line without consulting a pharmacist or doctor as they risk being supplied with medicines that are not safe or not suitable for them to use.

MHRA explained that **subutramine**, along with **sildenafil**, **gilbenclamide**, **tadalafil**, **vardenafil** or their analogues, or **lignocaine**, is commonly found illegally in botanical

products claiming to aid weight loss or erectile dysfunction.

The following herbal slimming products have been issued with safety alerts from the Swedish Medical Products Agency having been found to contain sibutramine: - **Slimline Soft Gel, Acai Berry ABC, Hygia Fit, Sport Burner, Health Slimming Coffee, Instant Slim, 3X Slimming Powder, Li D Daidaihua and Botanical Slimming.**

The following herbal slimming products have also been found to contain at least one undeclared substance such as sibutramine and/or phenolphthalein: - **Celerite Slimming Tea (Food and Drug Administration - USA) - Pink Lady for Women Capsules (Therapeutic Goods Administration - Australia) - St Nirvana Herbal Slimming capsules (Therapeutic Goods Administration - Australia) - Hong Kong Department of Health: Six Clock Natural Leptin Coffee, Aisam Wellness Sport Burner - Whole Body Encircler, Aisam Wellness Sport Burner - Waist Slimmer, Aisam Wellness Sport Burner - Leg Slimmer, Slimming Capsules, Super Fat Burning Bomb, Super Fat Burning Bomb - Quick Result Slimming, Super Fat Burning Bomb - Abdomen and Waist, Fat 2 and 1 Burners Soft and Hard Gelatin Capsules, Super Fat Burning Bomb - 4th Generation All-Body Slimmer, Super Fat Burning Bomb - 3rd Generation Leg Slimmer, Super Fat Burning Bomb - 3rd Generation All-Body Slimmer, Pro-Trim 8 Slimming Effects (All in One) - For Young Women, Pro-Trim 8 Slimming Effects (All in One) - For Older Women and Leptin HCA Weight Loss Milk Tea.**

B: Alerts:

On-line medicines warning issued

The MHRA has issued a press release warning of the risks of buying medicines online. It talks predominantly about prescription only medicines. However, it also warns that any medicines, whether prescription only or not, if purchased over the internet may not meet UK regulatory and quality standards. They may be past their 'sell-by date' in which case their effectiveness will be reduced.

The MHRA explains that its enforcement team continually monitors internet sites, especially those known to be selling prescription only medicines. Further, it confirms that spot checks are made to see if the internet sites selling prescription only medicines are based in the UK. If so, it is able to take action and a number of prosecutions have taken place. It goes on to explain that it refers overseas sites to the appropriate regulatory body in that country.

In association with the UK government and with other regulatory and health bodies, the MHRA is working to ensure that there is proper guidance to support the safe purchase of medicines over the internet. It is playing a key role in a Department of Health working party on the sale and supply of medicines in the UK which will determine the legal and proper way to buy medicines over the internet.

The above moves are intended to reconcile the increasing trend towards electronic commerce, including the growth of e-pharmacies supplying prescription only medicines, with the protection of patient safety and public health.

C: Enforcement decisions

On-line medicinal treatment services warning

The MHRA has updated its guidance for consumer websites offering medicinal treatment services.

This guidance is intended primarily for companies and organisations which do not hold Marketing Authorisations for medicines but which provide services that may lead to the prescription and supply of a prescription only medicine (POM). However, the content may also be of relevance to anyone who has a website and features a medicine that is prescription only. The guidance seeks to ensure that the content of such websites does not contravene the Advertising Regulations. In particular, it highlights the prohibition by regulation 7 of the Advertising Regulations of advertisements to the public likely to lead to the use of a POM. Sites must not promote POMs to the public as this is in breach of UK medicines advertising legislation.

Voodoo Lily Weight Loss

The European Food Safety Authority (EFSA) approved a weight loss health claim for the Asian botanical, Konjac Mannan.

The Panel considered that in order to obtain the claimed effect, at least 3 g of glucomannan should be consumed daily in three doses of at least 1 g each, together with 1-2 glasses of water before meals, in the context of an energy-restricted diet. The target population is overweight adults.

ACAI

The Advertising Standards Agency (ASA) upheld complaints that claims in relation to ACAI and its ability to reverse ageing, improve energy or manage weight were not capable of substantiation. The advertiser was cleanseanddetox.co.uk. They were held to have provided no evidence to demonstrate that the product could reverse ageing, improve energy, manage weight or provide any other health benefits. On this basis, the ads were held to be misleading. The ASA also took issue with statement on the website such as: “cleanse with ACAI 1200 the number-one antioxidant superfood” and “look good, feel great, reverse ageing, improve energy and manage weight with 100% pure ACAI 1200... FLATTEN YOUR TUMMY AND FLUSH POUNDS OF WASTE”.

The company did not respond to the ASA enquiries, the mobile phone number on the website went through to announce the service, and the claims continue to be made on the website.

Breast enhancement product reprimanded

Volufiline is a product sold on the basis that it helps to enhance breasts.

An ASA adjudication upheld a complaint that claims that Volufiline could give fuller and firmer breasts were not capable of substantiation.

In addition, the ASA challenged whether the ad made unauthorised medicinal claims, because the ad implied the modification of human physiology by way of pharmacological and/or metabolic pathways, and the MHRA confirmed that Volufiline was not licensed in the UK.

The ASA found that there was no documentary evidence in support of the efficacy claims in the ad, and for that reason, it concluded that the ad was likely to mislead.

The ASA also considered that claims like *“Volufiline stimulates adipocyte differentiation and proliferation, and promotes lipid storage leading to an increase of adipocyte volume in the fatty tissue”* and *“up to 8.4% improvement in volume”* implied the modification of human physiology by way of pharmacological and/or metabolic pathways. Because the ASA understood that the product was not licensed by the relevant authorities in the UK, it considered that the ad made unauthorised medicinal claims and concluded the ad was in breach on that point also.

The maker of Volufiline was told that they could no longer make these claims.

Weight loss product reprimanded

A weight-loss drink company have been told that their advertisement is in breach of the advertising codes of conduct.

The ad stated: *“What are the benefits of taking Bios Life Slim? 1. Promotes fat loss 2. Reduces appetite and cravings 3. Improves cholesterol levels 4. Balances blood sugar 5. Reduces fat levels in the blood 6. Regulates bowel function 7. You don’t have to change your eating habits for Bios Life Slim to work”*. A page headed *“90 Day Success Story”* showed photographs of a man at 0 days, 30 days, 60 days and 90 days. Under the *“0 days”* image, text stated *“NECK 18” CHEST 46” WAIST 43”* “. Under the *“90 days”* image, text stated *“NECK 16.5” CHEST 43.5” WAIST 39.5”* “. Text beneath the

images stated *“My name is Paul O’Donnell and throughout my life, I have battled constantly to control my weight. After some real personal challenges in the past few years, my weight ballooned to 251 pounds ... my heaviest ever and I felt dreadful. A friend of mine sent me a birthday present in early July this year and told me it would help me ... HOW RIGHT SHE WAS!!! After only 60 days, I have dropped 29 pounds in weight and lost 8% excess bodyfat [sic] ... not water or muscle, actual FAT!!”*.

Further testimonials stated *“In 90 days of drinking Bios Life Slim my weight dropped by 36 pounds and I lowered my body fat count by almost 10%. It is a truly wonderful feeling! Paul O’Donnell Glasgow”*, *“My friend Christie introduced me to Bios Life Slim and it really works! I love the way it makes me feel, keeps me motivated and gives me energy. Now I can fit into clothes I never thought I would fit in ... again! Darla Sanders Texas”*, and *“I have tried a lot of fat loss products with mixed results, some kept me awake for days. I tried Bios Life Slim and lost 8 kilos in 8 weeks without a massive change to my lifestyle. Chris Large London.”*

The final page of the ad showed before and after pictures of a woman, and was headed *“Darla Sanders Lost 80 pounds and 37.75 inches”*.

The complainant challenged whether:

1. the efficacy claims with regard to the *“benefits”* of the product were misleading and could be substantiated;

2. the efficacy claims with regard to the *“benefits”* of the product were implied medicinal claims for an unlicensed product;

3. the ad breached the Code, because it implied that consumers could not fail and could eat as much as they liked and still lose weight;
4. the testimonials were genuine and could be substantiated; and
5. the claims, in particular those in relation to Paul O'Donnell's testimonial, that consumers could lose weight from specific parts of the body, breached the Code.
6. The ASA challenged whether the claims that users had lost particular amounts of weight were compatible with good medical and nutritional practice.

The owner of the brand was Livelarge. They were told that the ad was in breach of the code and must not appear again in its current form.

The ASA told Livelarge that they should not make efficacy claims for the product that were not substantiated by robust clinical evidence for the product itself, and that they should not make implied medicinal claims.

In addition, the ASA said that they should ensure they held documentary evidence that testimonials were genuine and that they held contact details for the people that gave them. They told them that they should not imply that people could not fail to lose weight, could eat as much as they liked, or that they could lose weight from specific areas of the body. Finally, they told them not to make claims about weight loss that were incompatible with good medical and nutritional practice.

Acne product claims are held not to be misleading

SkinMed Ltd, challenged the maker of Freederm Gel and its product claim that it is "The only spot treatment with an anti-inflammatory". SkinMed said that their product, Aknicare contained four anti-inflammatories. The ASA reviewed the complaint and held that the claim was not misleading.

Freederm's TV ad, for a spot treatment, stated "The only spot treatment with an anti-inflammatory, which helps stop your angry spots. It's unique. Nothing else works like this. Nothing fights spots like Freederm Gel".

The ASA noted that SkinMed Ltd said Aknicare contained four anti-inflammatories: Triethyl citrate, Ascorbyl Palmitate, MSM (Methylsulfonylmethane) and Octadecanoic acid. However, the ASA said that it understood those ingredients were not commonly known to have anti-inflammatory effects. It also noted Aknicare was not a licensed medicine, whereas Freederm Gel was. The ASA noted Freederm Gel contained nicotinamide, an ingredient recognised by the MHRA as an anti-inflammatory. It said it understood SkinMed believed their product had anti-inflammatory ingredients. However, it considered that, because Aknicare did not come under the category of formally licensed medicines, it was reasonable for Diomed Developments to exclude the complainants' product from the comparison.

For this reason, the ASA concluded that the claim "The only spot treatment with an anti-inflammatory ...", particularly in the context of the text "Nothing works like this", was not misleading.

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