Neutral Citation Number: [2019] EWHC 2374 (Admin)

Case No: CO/4162/2018

IN THE HIGH COURT OF JUSTICE
QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT

Royal Courts of Justice
Strand, London, WC2A 2LL

Date: 09/09/2019

Before :

CHARLES BOURNE QC
(SITTING AS A DEPUTY HIGH COURT JUDGE)

- -

Between :

THE QUEEN **on the application of** **ACTEGY LIMITED**	**Claimant**
- and -	
(1) THE ADVERTISING STANDARDS AUTHORITY LIMITED **(2) THE INDEPENDENT REVIEWER OF ADVERTISING STANDARDS AUTHORITY RULINGS**	**Defendants**

- -

Alan Bates and **Will Perry** (instructed by **Lewis Silkin LLP**) for the **Claimant**
Catherine Callaghan QC (instructed by **Bates Wells & Braithwaite London LLP**) for the **Defendant**

Hearing dates: 16 and 17 July 2019

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Approved Judgment

If this draft Judgment has been emailed to you it is to be treated as 'read-only'. You should send any suggested amendments as a separate Word document.

CHARLES BOURNE QC:

Introduction

1. The Claimant applies for judicial review of a decision by the First Defendant ("the ASA") and/or a decision by the Second Defendant ("the IR"), upholding complaints against a newspaper advertisement placed by the Claimant for a medical device, the "Revitive Circulation Booster" which it manufactures and distributes.

2. The Revitive Circulation Booster is the name given by the Claimant to a range of devices which apply neuromuscular electrical stimulation ("NMES") to the soles of the feet, via gel footpads, with electrical stimulation. This case concerns an advertisement for a specific model known as the "DX" ("the device"). The stated purpose of the device is to use NMES to achieve a number of potential therapeutic benefits including improving circulation, reducing swelling in the lower limbs and reducing pain and discomfort in the lower limbs.

3. The device was advertised in the Daily Mail on 7 January 2017 and in The Times on 24 February 2017. Those advertisements made a number of claims for the efficacy of the device. A member of the public complained to the ASA that these claims were misleading. There was a further complaint relating to a claim that the device was being offered at "£50 off" in an advertisement in the Daily Mail on 21 April 2017, but this pricing complaint has no relevance to these proceedings and I therefore make no further reference to it. The advertisement of 21 April 2017 contained the same efficacy claims as the previous advertisements. For that reason it was that advertisement ("the advertisement") which the ASA decided to investigate.

4. Before setting out the facts, it is necessary to explain the regulatory background concerning, first, medical devices and, second, advertisements.

Medical devices

5. Council Directive 93/42/EEC concerning medical devices ("the Medical Devices Directive" or "MDD") harmonises the requirements for placing medical devices on the market in the EU.

6. Medical devices are defined by Article 1 of the MDD as including any apparatus or appliance intended to be used by humans for, inter alia, the treatment or alleviation of an injury or handicap which achieves its principal intended effect otherwise than by pharmacological, immunological or metabolic means.

7. Devices are divided into four classes based on risk to the user where class I is the highest risk, classes IIa and IIb are medium risk and class III is low risk. The device with which this case is concerned has been classified IIa.

8. Article 2 requires Member States to ensure that devices may be placed on the market and/or put into service only if they comply with the requirements of the MDD. Article 3 requires devices to meet "essential requirements" set out in Annex I. These include safety requirements specified in paragraph 1 of Annex I, design requirements specified in paragraph 2 and, by paragraph 3:

> "The devices must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of [their intended uses] …"

9. Paragraph 6a of Annex I further states: "Demonstration of conformity with the essential requirements must include a clinical evaluation in accordance with Annex X." I return to the topic of clinical evaluation below.

10. Article 17 requires relevant devices which meet those essential requirements to bear "the CE marking of conformity" when placed on the market.

11. Article 11 prescribes procedures which must be followed by the manufacturer in order to affix the CE marking to a relevant device. For class IIa devices the manufacturer may choose between a number of procedures. In the present case the Claimant chose the conformity assessment procedure under Annex II of the MDD, excluding section 4.

12. Under that procedure (by section 3 of Annex II), the manufacturer "must lodge an application for assessment of his quality system with a notified body". Article 16 provides for Member States to designate "notified bodies" to carry out such tasks. Section 3.2 of Annex II requires that the manufacturer's quality system must be fully documented, and the documents must meet a number of specific requirements. By Section 3.2(c) the system must include "the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular" several items of information of which one is "the clinical evaluation referred to in Annex X" (as referred to in paragraph 9 of this judgment, above).

13. Annex X in turn describes the clinical evaluation as:

> "… a defined and methodologically sound procedure based on:
>
> 1.1.1 Either a critical evaluation of the relevant scientific literature currently available relating to the safety, performance, design characteristics and intended purpose of the device, where:
>
> - there is demonstration of equivalence of the device to the device to which the data relates, and
>
> - the data adequately demonstrate compliance with the relevant essential requirements.
>
> 1.1.2 Or a critical evaluation of the results of all clinical investigations made.
>
> 1.1.3 Or a critical evaluation of the combined clinical data provided in 1.1.1 and 1.1.2."

14. It is therefore for the manufacturer to obtain and collate the necessary materials including the clinical evaluation. These are then provided to the notified body for assessment.

15. Section 3.3 of Annex II further provides:

> "The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonised standards conform to these requirements.
>
> The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an assessment, on a representative basis, of the documentation of the design of the product(s) concerned, an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.
>
> The decision is notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment."

16. Section 7.2 further provides:

> "For devices in class IIa, the notified body shall assess, as part of the assessment in Section 3.3, the technical documentation as described in Section 3.2(c) for at least one representative sample for each device subcategory for compliance with the provisions of this Directive."

17. So, the notified body does not carry out a clinical evaluation of the device itself, that being a task for the manufacturer. Instead, the notified body carries out an "audit" of the manufacturer's quality system as a whole. As Section 7.2 makes clear, this involves considering samples of the documentation, as opposed to considering all of the documentation.

18. The requirements of the MDD are implemented in the UK by the Medical Devices Regulations 2002 (SI 2002/618). Regulation 45 empowers the Secretary of State to designate "notified bodies", and this function is discharged on his or her behalf by the Medicines and Healthcare Products Regulatory Agency ("MHRA"). Manufacturers are permitted by regulation 46 to choose any notified body to carry out the conformity assessment procedure. The MHRA does not itself carry out such procedures.

19. It should be noted that this regime is concerned with authorising manufacturers to place products on the market, and not with the way in which such products are advertised once on the market.

Advertisements

20. Business-to-consumer advertising in the EU is regulated by Directive 2005/29/EC concerning unfair business-to-consumer commercial practices ("the Unfair Commercial Practices Directive" or "UCPD"). Recital (6) explains that the UCPD seeks to harmonise the laws of Member States in relation to:

> "… unfair commercial practices, including unfair advertising, which directly harm consumers' economic interests and thereby indirectly harm the economic interests of legitimate competitors. In line with the principle of proportionality, this Directive protects consumers from the

> consequences of such unfair commercial practices where they are material but recognises that in some cases the impact on consumers may be negligible."

21. Other recitals emphasize that the UCPD helps to guarantee fair competition and seeks to achieve the proper functioning of the internal market and eliminate obstacles to the free movement of services and goods which could arise from a lack of uniform rules at EU level.

22. The aims of the UCPD are further clarified by recital (14) which states:

> "It is desirable that misleading commercial practices cover those practices, including misleading advertising, which by deceiving the consumer prevent him from making an informed and thus efficient choice."

23. Recital (20) makes clear that self-regulation is to be encouraged:

> "It is appropriate to provide a role for codes of conduct, which enable traders to apply the principles of this Directive effectively in specific economic fields. In sectors where there are specific mandatory requirements regulating the behaviour of traders, it is appropriate that these will also provide evidence as to the requirements of professional diligence in that sector. The control exercised by code owners at national or Community level to eliminate unfair commercial practices may avoid the need for recourse to administrative or judicial action and should therefore be encouraged. With the aim of pursuing a high level of consumer protection, consumers' organisations could be informed and involved in the drafting of codes of conduct."

24. Article 5 prohibits "unfair commercial practices", and these include practices which "are misleading as set out in Articles 6 and 7".

25. That prohibition, as I have explained, is intended to promote competition, not to interfere with it. This is made clear by Article 4, which provides:

> "Member States shall neither restrict the freedom to provide services nor restrict the free movement of goods for reasons falling within the field approximated by this Directive."

26. Article 6 states that a commercial practice is regarded as misleading if it "contains false information" or if it "is likely to deceive the average consumer, even if the information is factually correct" and causes or is likely to cause the consumer "to take a transactional decision that he would not have taken otherwise", in relation to elements including a product's "fitness for purpose" or "the results to be expected from its use".

27. Article 12 makes specific provision about how the misleading or other nature of information can be assessed:

> "Member States shall confer upon the courts or administrative authorities powers enabling them in the civil or administrative proceedings provided for in Article 11:
>
> (a) to require the trader to furnish evidence as to the accuracy of factual claims if … such a requirement appears appropriate on the basis of the circumstances of the particular case;
>
> (b) to consider factual claims as inaccurate if the evidence demanded in accordance with (a) is not furnished or is deemed insufficient by the court or administrative authority. "

28. Enforcement is dealt with by Article 11. It requires that there be adequate and effective means to enforce compliance, including legal provisions by which those with a legitimate interest may take legal action or bring complaints before a competent "administrative authority". It continues:

> "It shall be for each Member State to decide which of these facilities shall be available and whether to enable the courts or administrative authorities to require prior recourse to other established means of dealing with complaints, including those referred to in Article 10."

29. Meanwhile Article 10 contains a further reference to self-regulation by codes of conduct:

> "This Directive does not exclude the control, which Member States may encourage, of unfair commercial practices by code owners and recourse to such bodies by the persons or organisations referred to in Article 11 if proceedings before such bodies are in addition to the court or administrative proceedings referred to in that Article.
>
> Recourse to such control bodies shall never be deemed the equivalent of foregoing a means of judicial or administrative recourse as provided for in Article 11."

30. "Code of conduct" is defined in Article 2 as "an agreement or set of rules not imposed by law, regulation or administrative provision of a Member State which defines the behaviour of traders who undertake to be bound by the code in relation to one or more particular commercial practices or business sectors".

31. "Code owner" is similarly defined as "any entity, including a trader or group of traders, which is responsible for the formulation and revision of a code of conduct and/or for monitoring compliance with the code by those who have undertaken to be bound by it".

32. The UCPD is implemented in the UK by the Consumer Protection from Unfair Trading Regulations 2008 (SI 2008/1277, "the 2008 Regulations"), which reproduce the UCPD's main requirements in slightly different language.

33. Engaging in a commercial practice which is a "misleading action" is made a criminal offence by regulation 9 of the 2008 Regulations. Meanwhile regulation 19 makes it the

duty of weights and measures authorities to enforce the 2008 Regulations, which may also be enforced by the Competition and Markets Authority. Regulation 19(4) provides:

> "In determining how to comply …, every enforcement authority shall have regard to the desirability of encouraging control of unfair commercial practices by such established means as it considers appropriate having regard to all the circumstances of the particular case."

34. The reference in regulation 19(4) to "established means" echoes the use of that phrase in Article 11 of the UCPD (paragraph 28 above).

35. The phrase (used in predecessor legislation) has been interpreted as referring to the system of self-regulation established by the advertising industry in the UK under the auspices of the ASA: see *Director General of Fair Trading v Tobyward Ltd* [1989] 1 WLR 517 at 519 per Hoffmann J (as he then was).

36. The structure of this system as applied to the non-broadcast advertising industry was recently explained by Murray J in *R (Cityfibre Ltd) v (1) the ASA Ltd and (2) the ASA (Broadcast) Ltd* [2019] EWHC 950 (Admin) at [11]-[15]:

"10. The first defendant, the Advertising Standards Authority Limited ("ASAL"), regulates non-broadcast advertising ...

11. … ASAL … is a company limited by guarantee. [It] has a Council comprised of 12 members, two-thirds of whom must be independent of the advertising industry. [The] Council is the Board of the company ... The ASA Executive manages … ASAL … and makes recommendations to [the Council, which is] not bound by those recommendations.

12. ASAL was established in 1962 to provide independent oversight of the self-regulatory system set up by the non-broadcast advertising industry. An industry body, the Committee of Advertising Practice Limited ("CAP"), is responsible for drafting and updating a code known as the UK Code of Non-broadcast Advertising and Direct & Promotional Marketing ("the CAP Code") and for writing authoritative guidance on the rules in the CAP Code. The members of CAP are organisations representing advertisers, agencies, the media and other intermediaries …

13. …

14. … CAP … is a company limited by guarantee, and … is independent of the ASA. Members of … CAP … agree, through their Memorandum and Articles of Association, that they will promote compliance with [the Code] by their members and take action, where appropriate, to secure compliance where a member fails to observe the … Code.

15. The ASA promotes and enforces standards for non-broadcast … advertising by reference to [the Code]. The ASAL Council acts as the "jury" that decides whether an advertisement has breached the CAP Code …"

37. As Murray J also noted at [18], the ASA is a non-statutory body which is independent of both the government and the advertising industry. It has been repeatedly held (as it was in *Cityfibre*) to be amenable to judicial review.

38. The CAP Code does not have the force of law. However, section 3 of the Code (edition 12), entitled Misleading Advertising, states (at page 16) that the ASA "may take the Consumer Protection from Unfair Trading Regulations 2008 into account when it rules on complaints about marketing communications that are alleged to be misleading". Appendix 1 to the Code gives more detail of the "factors" in the 2008 Regulations to which the ASA will have regard, e.g. explaining that marketing communications will be regarded as misleading if they are "likely to deceive consumers" and "likely to cause consumers to take transactional decisions that they would not otherwise have taken".

39. Section 3 of the Code provides in particular:

> "3.1 Marketing communications must not materially mislead or be likely to do so.
>
> …
>
> 3.7 Before distributing or submitting a marketing communication for publication, marketers must hold documentary evidence to prove claims that consumers are likely to regard as objective and that are capable of objective substantiation. The ASA may regard claims as misleading in the absence of adequate substantiation."

40. Section 12 of the Code is entitled *Medicines, Medical Devices, Health-Related Products and Beauty Products*. It provides in particular:

> "Objective claims must be backed by evidence, if relevant consisting of trials conducted on people. Substantiation will be assessed on the basis of the available scientific knowledge.
>
> Medicinal or medical claims and indications may be made for … a CE-marked medical device."

41. Although the CAP oversees sanctions operated by its members, enforcement of the Code may in practice consist simply of the ASA publishing its ruling. The media, who agree to be bound by the Code, will not publish an advertisement which does not comply with the ruling (and the terms and conditions on which media organisations accept advertisements typically require compliance with all relevant regulation including codes of practice). Other organisations similarly will not co-operate with a non-compliant advertiser, e.g. Royal Mail which will not allow bulk mailing discounts in such cases.

42. The role of the IR is described in an ASA document entitled Non-broadcast Complaint Handling Procedure. Paragraph 49 states:

> "The Independent Reviewer of the Rulings of the ASA Council will consider requests for a review of Council decisions against ads."

Such a request is to be made in writing within 21 days of notification of the ASA's ruling, with "a full statement of the grounds for review in a single document". The request must be on the ground either of new relevant evidence or of a "substantial flaw" in the Council's reasoning or the process by which the ruling was made. Any "simultaneous legal action" will prevent the review from proceeding. Essentially the IR's powers are limited to making recommendations, e.g. that Council reconsider its ruling. Paragraph 60 of the procedure provides that the Council must consider such a recommendation but is not obliged to accept it.

43. In summary, then, decisions by the ASA (and recommendations by the IR) are designed to avoid the need to enforce the law contained in the UCPD and the 2008 Regulations, as is contemplated in Article 11 of the former and regulation 19(4) of the latter.

44. As I have said, it is recognised that the ASA's decisions are amenable to judicial review. In *R v ASA ex p The Insurance Service plc* [1990] Tr LR 169, the Court made a ruling to that effect. It quashed a decision because the recommendation by the ASA Executive to its Council had contained a factual error whose effect was that the Council had reached its decision without having regard to a material consideration.

45. There have been a number of judicial review claims against the ASA (and at least two against the IR). In those of which I have been made aware, conventional judicial review grounds of challenge have been applied. So in *R v ASA ex p DSG Retail Ltd* (CO/2432/95 unreported) Popplewell J, explaining that the Court has only a supervisory jurisdiction and will not substitute its judgment for that of the ASA, said:

> "The Court will only interfere on the usual grounds of irrationality, illegality or procedural impropriety. Where there is a band of reasonable interpretation in relation to any particular advertisement, the Court will not interfere simply because another reasonable view can be taken, unless it is shown that the Court's decision is plainly wrong."

46. In this case the Claimant's primary contention is that the ASA's decision should be quashed because it infringed the principle of proportionality in EU law and thereby interfered with the Claimant's right to free movement of goods, although it also relies on irrationality in the alternative.

47. From the explanation of the legal background above, it is clear that if a decision is consistent with the UCPD, it will not offend against the principle of proportionality and will not be an unlawful obstruction of free movement rights. Articles 4-12 in particular, read with recital (6), show that EU law permits and indeed necessitates misleading advertisements to be prohibited, advertisers to be required to furnish sufficient evidence of the accuracy of factual claims and self-regulation in this field by codes of conduct to be encouraged.

48. It therefore seems to me that the EU law ground of challenge must fail unless the Claimant can show that the ASA's decision departed from the requirements of the UCPD and did so in such a way as to interfere with its EU law rights. If the decision did not depart from the requirements of the UCPD, no separate question of proportionality arises. The issue of compatibility with the UCPD is considered below.

49. I shall also deal at greater length below with the Claimant's contention that the ASA's decision was inconsistent with its rights under the MDD, but I note here that authorisation to market a product under the MDD plainly is not authorisation to place a misleading advertisement. Whilst a manufacturer may choose to rely on the same evidence to satisfy requirements of both regimes (as it did in this case), the regimes govern different things.

The facts

50. It is common ground that the Revitive Circulation Booster is a Class IIa medical device for which certification was required, and was obtained, under the MDD.

51. A key piece of evidence which was used to obtain the certification was the clinical evaluation referred to in paragraphs 12-14 above, contained in a Clinical Evaluation Report prepared under the supervision of a Professor Tim Watson ("the CER"). The CER set out a detailed critical review of the available literature and clinical studies relating to the device or other related devices.

52. The Claimant selected the British Standards Institution ("the BSI") to be the "notified body" which would audit its quality system under the procedure referred to at paragraphs 14-18 above.

53. There is no evidence before me of how, precisely, the audit was conducted. I therefore cannot assume that the BSI either did or did not closely examine the contents of the CER in 2016.

54. The BSI issued a CE certificate dated 23 November 2016. This stated:

> "In respect of "Design and manufacture of electrical muscle stimulators for treatment of circulatory disorders of the lower limbs and transcutaneous electrical nerve stimulators (TENS) for the treatment of pain.
>
> on the basis of our examination of the quality assurance system under the requirements of [the MDD] Annex II excluding section 4. The quality assurance system meets the requirements of the directive …".

55. Thereafter the Claimant was entitled to, and no doubt did, affix the CE marking to the device. In this way the Claimant stated that the device satisfied the "essential requirements" set out in MDD Annex I, one of which was that it "must achieve the performances intended by the manufacturer and be designed, manufactured and packaged in such a way" as to be suitable for one or more of its intended uses.

56. The Claimant was permitted to do this by having taken steps including providing the CER and obtaining the BSI's certificate of the conformity of the quality assurance system. The Claimant had thereby done what was required under the MDD to demonstrate conformity with the "essential requirements" including the achievement of the intended performances.

57. It would not, however, be correct to say that the BSI had certified that the device achieved any of its intended performances. It was the Claimant who did that, supported by the CER.

58. As I have said, the device was advertised in national newspapers on dates up to and including 21 April 2017. The relevant advertisement appeared on that date, offering the Revitive DX model for sale by mail order, telephone or online at a price of £149.99. Details of the advertisement included:

    i) A headline reading "Revitive boosts your second heart for fast relief from aching legs & swollen feet!" This will be referred to as "the first claim".

    ii) Text reading "REVITIVE is a drug-free medical device designed to stimulate the muscles in your lower limbs to improve your circulation, which may help to reduce the swelling and, therefore, the pain and discomfort of aching legs, feet and ankles." This will be referred to as "the second claim".

    iii) Text reading "REVITIVE Circulation Booster is a medical device which uses Electrical Muscle Stimulation (EMS) to contract and relax your leg and feet muscles, to boost the circulation in your lower limbs." This will be referred to as "the third claim".

    iv) Under the heading "It's so easy to use", instructions to the user to place both bare feet on footpads and use toe-touch controls and "a typical session lasts from just 20 to 30 minutes – use regularly for maximum benefits".

    v) Four illustrations, all showing a flat disc with two footpads (with feet placed on them in two cases). One is a photograph of a woman (whose age is not obvious but who, it is agreed, is not elderly) using the device.

    vi) References to "ageing population" and "with age" and to the effect of pain on "playing with grandchildren", and references to diabetes, circulatory issues, osteoarthritis, muscle weakness and post-operative recovery.

    vii) An endorsement by the retired cricketer Sir Ian Botham: "I believe using REVITIVE every day could help me stay active for longer!"

    viii) A customer endorsement: "My REVITIVE is invaluable to me. I use it twice a day and can't be without it."

    ix) A reference to a clinical trial: "With REVITIVE, calculations showed blood volume 4 times higher than baseline/at rest in healthy people (Varatharajan et al, 2014, The effect of footplate neuromuscular electrical stimulation on venous and arterial hemodynamics, Plebology, July 4, 20 participants)."

59. This gave rise to complaints to the ASA, which the ASA decided to investigate.

60. By a letter dated 13 June 2017 from Simon Lane, an Investigations Executive, the ASA notified the Claimant of the complaints and the investigation. The ASA never discloses original complaints, but the complaint was summarised under three relevant headings corresponding to the first, second and third claims mentioned at paragraph 58 above.

The question was whether those claims were misleading or could be substantiated, with reference to paragraphs 3.1, 3.7 and 12.1 of the CAP Code.

61. Mr Lane's letter also stated that all medical devices marketed in the EU must have a "CE" marking, and asked the Claimant to confirm the classification of the device for that purpose and to provide a copy of the CE certificate. It stated that it was the Claimant's responsibility to provide the relevant evidence to substantiate the claims made in the advertisement, and that claims for efficacy could not be made on the basis of the CE certificate alone. These requirements are consistent with the CAP Code. The letter also referred to a previous case in which, in 2014, the ASA had ruled that efficacy claims for a similar device were inadequately substantiated, and requested that the Claimant should provide evidence which had not already been considered in the 2014 case, including the Varatharajan paper which was referenced in the advertisement. The letter enclosed copies of CAP guidance relating to medical devices, health claims and substantiation of health claims.

62. It is common ground that the ASA was right to say that claims for efficacy could not be made on the basis of the CE certificate alone. Such a certificate is needed in order for a medical device to be marketed at all, but it does not by itself achieve the substantiation of any claims which any advertisement may make in relation to the device.

63. A director of the Claimant, Roseanna Penny, responded by letter dated 28 June 2017. She confirmed that "Revitive is a Class IIa Medical Device" and enclosed the BSI certificate to which I have referred. She explained that the CER for the range of devices had been updated since the 2014 ASA investigation and enclosed a copy of the up to date CER, noting that some papers were also covered by the previous one but others were not.

64. Ms Penny's letter made two concessions. She agreed that the word "fast" (in the first claim) should be removed, and that pursuant to a previous ruling it was necessary to use "conditional language" in relation to aches, pains and swelling and that this, in the advertisement in question, had "been lost in part".

65. With those caveats, Ms Penny's letter invited the ASA "to consider both product specific evidence and the body of evidence contained in the Revitive CER", and went on to discuss the substantiation of each of the three claims. The letter made reference to two papers or studies, namely a pilot study by Ravikumar et al in 2017 using Revitive, and a study by Babber et al in 2016 on the effect of the Revitive mechanism on walking distance in patients with Peripheral Arterial Disease. Ms Penny also referred to, and attached, the paper by Varatharajan et al in 2014 on the effect of Revitive on blood flow in the lower legs.

66. By an email dated 3 November 2017 Mr Lane asked Ms Penny whether there was a CE certificate specifically for the Revitive Circulation Booster, noting that the certificate supplied did not refer to the specific device. By her reply on 8 November 2017 Ms Penny explained that the certificate was based on an audit of the materials including the CER, and that the CER provided the basis for claims relating to the device in question.

67. On 16 November 2017 Mr Lane sent the ASA's draft recommendation to the Claimant for comment. The draft recommendation was to uphold the complaint. It maintained

the point that the CE certificate "did not identify the specific device being advertised and did not state what 'conditions of use' had been authorised for it". It also found, in any event, that the three claims in the advertisement had not been substantiated and made specific criticisms of the analysis of studies in the CER.

68. Ms Penny responded on the Claimant's behalf by a letter dated 27 November 2017. She invited the ASA to remove any suggestion that the CE certificate was in some way deficient. She asked the ASA to highlight "where in the CAP Code that it is stated that adequate evidence for efficacy claims, aside from CE Certification from a notified body should be held by advertisers on medical devices". She sought to rebut the criticisms of the CER and of some of the specific studies, referred to Profesor Watson's expertise in electrotherapy and requested that a suitably qualified independent expert in that field be appointed to review the CER. She took issue with the ASA's interpretation of the advertisement e.g. as to the mode of use of the device and the notion that the advertisement targeted older patients with health conditions.

69. Mr Lane provided a response by email on 9 February 2018. He stated:

> "We have received confirmation from the MHRA that it satisfies their requirements for a CE certificate to provide a general description of the scope of several products. Thank you for raising that and we have therefore amended the wording of the draft recommendation to reflect."

The response also made a correction to the ASA's interpretation of the Varatharajan study. Otherwise, however, the previous position was maintained. A further draft recommendation, similar to the first save for the points of correction which had been expressly referred to, was provided with an invitation to provide any final comments by 23 February 2018, later extended.

70. Ms Penny sent a further detailed response on 2 March 2018, repeating and/or expanding on the points which she had made previously. Mr Lane responded on 21 March 2018, maintaining his position and indicating that the recommendation had been sent to the Council. On the following day there was a further exchange of emails which did not change the position.

71. On 11 April 2018 the ASA published its ruling, which is the first decision under challenge in this claim.

72. The ruling:

i) interpreted the advertisement as meaning that the device would boost circulation in the lower limbs and was likely to help with relieving symptoms of pain or discomfort from swollen or aching legs, feet or ankles, particularly in those who were diagnosed with osteo arthritis, diabetes, muscle weakness or were recovering from an operation;

ii) noted that it was incumbent on an advertiser to hold adequate evidence for efficacy claims in addition to CE certification;

iii) noted that the advertisement was for the DX model of the device, but the CER was for a "family of devices" and "did not identify any specific models"; that

technical differences between models could affect the outcome of treatment; and that if testing was not on the advertised model, the Claimant needed to explain how and why the tested and advertised models were equivalent for the relevant patient groups;

iv) noted a lack of correspondence between the advertised mode of use and one of the reviewed studies, plus small sample sizes, small numbers of studies showing clinically significant results and quality or other issues with the trials which the CER had noted, plus other methodological issues in the view of ASA;

v) noted that whilst the CER said that the device could provide pain relief as a secondary outcome because of its similarity with TENS devices, the differences between the devices meant no such effect could be assumed;

vi) took the view that the shortcomings of the studies were "significant limitations to the adequacy of the evidence, given that consumers would make a decision based on the ad to buy the device for regular, long-term use at home"; and

vii) concluded that the evidence overall was not sufficient to support the claims and therefore "that the ad breached the Code".

73. By a letter dated 29 April 2018, the Claimant requested the IR to review the ruling. The request was accompanied by a table setting out 11 issues. For reasons explained below, I do not need to reproduce these.

74. The IR, Sir Hayden Phillips, responded in a letter dated 7 July 2018. Before setting out more detailed reasoning, he summarised his position in these terms:

> "I have considered the arguments you have put to me at considerable length but I am sorry to say that I do not believe that you have made out a persuasive case that the Council's ruling is either irrational or indefensible. I cannot therefore find a substantial flaw in the decision itself or in the rationale of the ruling or in the process by which it was made. I am not able therefore to invite the ASA Council to reconsider its ruling."

75. It is convenient to consider the position of the IR before that of the ASA.

The parties' submissions relating to the IR

76. Mr Bates, representing the Claimant, explained at the hearing that the view had been taken that it was necessary for the Claimant to request a review by the IR and to await its outcome because the ASA might otherwise respond to an application for permission to seek judicial review with an assertion that the Claimant had failed to avail itself of an alternative remedy.

77. The Claimant's Statement of Facts and Grounds explains that the IR is named as Second Defendant in case he is, for the purposes of the present claim, properly to be treated as a person separate from (rather than an internal mechanism of) the ASA.

78. Nevertheless, discrete grounds of challenge to the IR's decision have not been advanced. Mr Bates' skeleton argument begins with the words "This claim is a challenge to a decision of the … ASA …", and that is how the case has been argued.

79. Ms Callaghan QC, who represents both Defendants, points out that no discrete challenge is levelled against the IR's decision. She submits that the case against the IR should be dismissed for that reason, without more.

80. However, Ms Callaghan asserts a further significance to the IR review process, namely that the Claimant in this judicial review should not be permitted to raise arguments about the ASA's decision that were not put to the IR.

81. Although there have been judicial review claims against the IR, as I have said, I doubt that it was necessary to make the IR a Defendant in this case. His powers, as I have explained, are limited to making (or refusing to make) recommendations. If these proceedings led to the ASA's decision being quashed, an omission to challenge the IR's rejection of a review request would not resuscitate that decision.

82. However, I do not accept Ms Callaghan's submission that the scope of the IR review request necessarily limits the scope of the judicial review claim. She relied on *R (Sainsbury's Supermarkets Ltd) v Independent Reviewer* [2014] EWHC 3680 (Admin) in which Wilkie J at [138] said that the Court in that case had to focus on the IR's decision and could not consider points which were not before the IR. In my judgment, that was because the judicial review claim was directed against the IR's decision only, and the ASA in that case was merely an interested party.

83. There may of course be cases in which, upon an application for permission to seek judicial review, the Court may consider that the failure to advance a particular ground in a review request was a failure to pursue an alternative remedy. Here, however, the Court has already granted permission to the Claimant to advance certain grounds of challenge against the ASA's decision, and therefore those grounds can be advanced.

84. Nor do I think that the absence of discrete arguments aimed at the IR's reasoning necessarily leads to the failure of the claim against him. He found no substantial flaw in the ASA's decision. If this Court were to find such a flaw, it is at least possible that the Court would then conclude that the IR's decision was unlawful for the same reason. It would depend on the facts.

85. What is clear, at least in the present case, is that if the claim against the ASA fails and therefore the ASA's decision survives, then the claim against the IR will also fail (1) because of the lack of discrete grounds and (2) because such claim would in any event be academic.

86. I therefore go on to consider the grounds of the claim against the ASA.

The grounds of claim

87. Pursuant to the permission decisions of 16 November and 20 December 2018, the surviving grounds (formerly numbered 1, 2 and 4) are:

i) The ASA maintains a test or approach for assessing whether or not efficacy claims made for a medical device in an advertisement are substantiated which is not required by the CAP Code and is anyway disproportionate and/or unreasonable.

ii) The ASA applied a disproportionate, irrational and/or unfair approach and/or standard when assessing whether or not there was adequate substantiation for the efficacy claims made in the advertisement.

iii) The ASA's conclusion that the efficacy claims made in the advertisement were not adequately substantiated was irrational.

88. The second and third of these grounds both impugn the rationality of the specific decision, though the second ground also alleges disproportionality and unfairness. I shall therefore consider them together.

The first ground

89. As I have explained above, the EU law ground of challenge to the ASA's general approach must fail unless the Claimant can show that that approach departs from the requirements of the UCPD (which include, in Article 12, a requirement that traders furnish evidence as to the accuracy of factual claims) in such a way as to interfere with its EU law rights.

90. I note also that the Claimant is expressly not challenging the lawfulness of the CAP Code, of which section 12 requires that objective claims must be backed by evidence, if relevant consisting of trials conducted on people.

91. The "test or approach" applied by the ASA, which is said by the Claimant to have exceeded permissible limits, is apparent from the following points in its decision (by reference to page numbers inserted in manuscript on the decision included in the Core Bundle):

i) A requirement either for testing to have been carried out using the models advertised on the relevant patient groups, or for "a satisfactory explanation of how and why the devices used in testing and the subjects who participated were equivalent to the devices being advertised and applicable to the patient groups being addressed" (paragraph 5).

ii) Although the CER reviewer had concluded that there was sufficient evidence to support the claims made, the ASA formed its own view based on the methodology of trials on which the reviewer had commented, leading to a conclusion of "significant limitations to the adequacy of the evidence" (paragraph 11).

iii) In relation to the separate studies relied on by the Claimant, the ASA formed its own view of the adequacy of the evidence with regard to factors such as the age range of participants, the sample size, the presence or absence of a control group and the stated aim of the trial (paragraphs 12-14).

92. As I have said, article 12 of the UCPD and section 12 of the Code impose lawful requirements for evidence to be held and made available. That leaves open the question of what evidence will suffice for the purpose of those provisions.

93. Mr Bates contended that the ASA imposes an excessive burden on advertisers by requiring, in effect, that efficacy of a medical device be demonstrated only by high quality studies, for example studies using a fully blinded random control group, relating to all patient groups to whom the advertisement is addressed. He argues that the ASA impermissibly failed to inquire whether the available evidence, taken as a whole, provided sufficient substantiation notwithstanding the limitations of each individual item of evidence.

94. This excessive approach, Mr Bates argued, may be traced back to the CAP guidance on substantiation of health, beauty and slimming claims, which states in respect of new or "breakthrough" claims that:

> "… sound data, relevant to the claim made, should be collated to form a body of evidence. The 'totality' of this evidence is important; marketers should not ignore sound data that does not support the 'new' claim."

95. The guidance contains a further section entitled "Quality of data" which notes that there should usually be "at least one adequately controlled human study". It sets out recommended criteria for "sound individual studies", commenting on the need for control methods and randomisation, sample sizes and methodology reflecting the normal proposed usage of a product.

96. In my judgment, neither that guidance nor the Decision in the present case indicates that evidential requirements are being imposed which exceed what is contemplated by the UCPD.

97. It is self-evidently necessary, in the public interest, for there to be assessment of the quality of evidence, regardless of its quantity. Where claims for the efficacy of medical devices are concerned, neither the terms of the UCPD nor the principles of free movement more generally are inconsistent with a requirement for evidence consisting of studies which are both rigorous, in respect of study methodology, and relevant, in respect of equivalence of devices and correspondence between the test parameters and the types of user and types of use contemplated by an advertisement.

98. Since this approach does not go beyond what is contemplated by the UCPD, for the reasons explained above there can be no attack on the proportionality of the approach.

99. Mr Bates also sought to argue that his first ground of challenge is supported by competition law. This is on the basis that the ASA (by itself or in conjunction with the CAP) is an "association of undertakings" for the purpose of the prohibition on anti-competitive agreements in Article 101 TFEU and/or section 98 of the Competition Act 1998.

100. However, it is agreed in the Claimant's Statement of Facts and Grounds (paragraph 72) that agreements to enforce standards of conduct across an industry may be lawful if they are reasonable and proportionate regulatory rules in the public interest (see *Wouters v Algemene Raad van de Nederlandse Order van Advocaten* [2002] 4 CMLR

27). For the reasons I have explained, the Claimant is unable to show that the ASA's general approach fails any test of proportionality.

101. Moreover I am not persuaded that the Claimant has identified any association of undertakings, although this issue was not explored before me in any great depth. An "undertaking" for this purpose must be engaged in an economic activity, regardless of its legal status: see *SAT Fluggesellschaft v Eurocontrol* [1994] 5 CMLR 208 at [18]. This is to be contrasted with activity of a regulatory or public interest nature, which seems a more apposite description of the activity of the ASA.

102. Finally it is contended in the Claimant's Statement of Facts and Grounds (paragraph 71) that the need for controls on advertising to be proportionate is highlighted by the parallel MDD regime. Where that regime helps to ensure the free movement of goods by authorising marketing of devices throughout the EU, its effect should not be undermined by "additional regulatory barriers".

103. The short answer is that the UCPD regime, which is wholly separate from the MDD regime, both permits and requires advertising controls. It seems to me that reference to the MDD regime has more relevance to the second ground of challenge.

104. Having found that the ASA's approach in general is proportionate because it does not depart from the requirements of the UCPD, I also find, unsurprisingly, that it satisfies the test of rationality. It cannot be said that no reasonable regulatory authority could impose a requirement of rigorous and relevant evidence to substantiate claims made for the efficacy of medical devices.

<u>The second and third grounds</u>

105. These grounds challenge the specific approach taken by the ASA to the present case, as opposed to its general approach to advertisements for medical devices. Mr Bates however acknowledged that there is a degree of overlap between all three grounds of challenge because the specific approach was very much informed by the general approach.

106. The focus is now on the ASA's treatment of the evidence supplied by the Claimant to substantiate its claims for the Revitive device, i.e. the CER and a small number of other papers.

107. Before I come on to the issues about scientific methodology, it is convenient to consider the Claimant's contention that the ASA made some specific factual errors.

108. First, the Claimant relies on the fact that in its initial draft recommendation the ASA maintained the view that the CE certificate did not cover the advertised device: see paragraphs 67-69 above. Mr Bates points out that whilst this was corrected in the next draft, there was no other consequential change to the reasoning. He seeks to draw the inference that, in the absence of any amendment to the reasoning, the inference may be drawn that no weight was given to the fact of certification.

109. In my judgment that inference cannot be drawn. The draft wording did not need further amendment because the ASA's decision ultimately was based on its review of the evidence concerning the effectiveness of the device. Just as it did not treat CE

certification as proof of effectiveness, it cannot be assumed to have previously drawn any detailed practical conclusion from a lack of certification.

110. Second, the ASA's decision at paragraph 5 stated: "… whilst the CER referred to a 'family of devices', it did not identify any specific models." Mr Bates points out that this is factually incorrect, because the front page of the CER makes specific reference to "Revitive 2469 MD, 2836AA, RMV, RIX AND RLV". It has now been explained that "RLV" identifies (for stock control purposes) the "DX" model which featured in the advertisement.

111. It is notable that the Claimant did not make this objection in response to the first or second draft recommendations or in its request for review by the IR.

112. This may reflect the fact that in my judgment, although the words quoted above were factually incorrect, the error was not material. It was not material because none of the studies relied on by the Claimant involved the DX model. The ASA therefore did not overlook any material in the CER or elsewhere which dealt directly with the advertised model. The different models have different technical specifications, and these differences appear to be relevant to effectiveness. My attention was drawn to material posted on the Claimant's website (though it has since been removed or changed) stating that, compared with other models, the DX "has a more limited intensity range … and it is therefore suitable only for those people with very mild symptoms".

113. I return below to the ASA's reasoning in respect of the equivalence of devices, but it does not seem to me that the erroneous sentence proved to have any practical significance.

114. Turning to the more general attack on the ASA's reasoning, the Claimant emphasizes that the CER was prepared with the involvement of an independent expert, Prof Watson. He is Professor of Physiotherapy at the University of Hertfordshire, is described as a leading authority in the field of electrotherapy technology and has extensive experience in evaluating research materials in his field.

115. Prof Watson is also the author of an expert report upon which the Claimant relies in these proceedings. Mr Bates told me that the purpose of this evidence was to identify respects in which the ASA had not properly understood the CER. In his report Prof Watson explains that there is no standardised method for assessing the efficacy of medical devices. In his view the randomised controlled trials ("RCTs") which are the method of choice for assessing the efficacy of pharmaceutical treatments may be unsuitable or difficult or impossible to achieve when assessing non-pharmaceutical medical devices. For example, treatment with the Revitive device involves inducing muscular contraction in the patient. If such contraction is physically obvious to the patient, then it will be difficult or impossible to achieve "blinding" in which patients do not know whether they are in a group which has received the treatment or are in a control group which has not. He also makes the point that large sample sizes do not necessarily ensure high quality for a trial and that there are ethical issues around recruiting more people for a trial than is necessary. It is therefore to be expected that evidence relating to a medical device may come from across the hierarchy of evidence types and may well not consist solely of the most highly regarded RCT type.

116. In the CER, the evidence was evaluated using two quality tools: the Cochrane Risk of Bias tool and the GRADE evaluation. The latter assigns a starting quality grade based on high quality RCTs and then adjusts or "downgrades" the quality assessment to "medium", "low" or "very low" quality depending on the presence or absence of particular factors such as design limitations suggesting a high likelihood of bias, or indirectness of evidence (e.g. where what is tested is merely related to, but not the same as, what is advertised).

117. Prof Watson contends that in the assessment of medical devices, shortcomings (and thus lower grades) in trials are commonplace and do not, per se, lead to a conclusion that the findings of the research cannot be relied upon. In his experience, "Cochrane reviews" of quality in this area almost always contain statements such as "additional high quality trials involving larger patient numbers are needed".

118. Therefore, whilst the CER reviewers noted shortcomings in the evidence, the overall conclusion of the review was that there was sufficient evidence to support the claims being proposed for the Revitive family of devices.

119. The ASA reached the opposite conclusion, giving the reasons summarised above for finding the evidence insufficient. Prof Watson's view, in summary, is that the ASA in objecting to trial methodologies and sample sizes and to a lack of evidence of equivalence of devices, applied standards which were unreasonably exacting and more exacting than would be normal in this scientific field. Evidence of "moderate" or "low" quality should not be equated with no evidence.

120. The Defendant was given permission to rely upon expert evidence in response, from Dr Ben Heller, a Principal Research Fellow in the Centre for Sports Engineering Research who also has extensive research experience in the field of electrical stimulation devices. A question was raised in the third witness statement of Ms Penny about the relevance of Dr Heller's expertise but this was not pursued before me.

121. Dr Heller takes issue with much of what Prof Watson says. He argues that convincing placebo effects can be produced in a number of ways and therefore randomisation and blinding are readily achievable in trials of devices such as the Revitive device. Dr Heller gives his opinion on what weight can or cannot be placed on studies of "moderate" or "low" quality. He reviews the evidence in the CER (and the further papers relied on) in this way, arriving at the overall conclusion that it supports a conclusion that the Revitive device may temporarily improve circulation in the lower limbs but is insufficient to support a conclusion that it reduces swelling or reduces pain or discomfort.

122. Dr Heller also explains that trials on Revitive devices other than the DX model cannot be assumed to provide evidence of the effectiveness of that device. See also paragraph 112 above.

123. In Dr Heller's view, the approach set out in the CAP Substantiation Guidance is consistent with that of the general scientific community. He considers that the ASA was right not automatically to accept the CER conclusions or the CE certificate as justifying the claims in the advertisement, and that it adopted an appropriate approach and reached reasonable conclusions. His only criticism of the ASA which I noted was that it would have been preferable for it to appoint an independent expert to review the evidence, as

it did in the previous case in 2014 to which I refer at paragraph 61 above (report paragraph 7.15).

124. The Claimant filed a supplemental report by Prof Watson in response, making a number of points including an argument that Dr Heller had misunderstood an aspect of how the Revitive device is used, which could undermine his views on equivalence of devices.

125. The Defendant then filed Dr Heller's response to the response (and to some of the factual evidence), maintaining and in some cases further explaining his position on the issues raised.

126. In the end the expert evidence, notwithstanding its considerable volume and high level of detail, was of limited assistance to me in deciding this claim for judicial review. None of it was tested by cross-examination, and to do so would have been a very lengthy process which would have been out of proportion to its usefulness. And, when receiving expert evidence, the Administrative Court will be alert to the danger of allowing parties to supplement either the reasoning in the decision under challenge or in the material which was before the decision maker.

127. Overall, I am not persuaded that the ASA adopted an approach on the facts of this case which was unlawful for any of the reasons advanced by the Claimant.

128. It is common ground that the evidence used to substantiate the claims made in the advertisement was subject to significant limitations. Faced with the experts' competing views as to the overall impact of those limitations, I cannot decide which is the better view. However, the Claimant has failed by a wide margin to demonstrate that the ASA's approach was inconsistent with accepted scientific practice or that the ASA did not properly understand the CER. The experts agree that it is necessary to assess the totality of the evidence. In my judgment, that is what the ASA did, and it did not simply base its decision on the fact that there was no single high-quality RCT study. I reach that conclusion based on a straightforward reading of the decision itself, which in my view is properly interpreted as a survey of the evidence as a whole with reference to particular issues leading to a cumulative conclusion, rather than just a series of discrete points. That conclusion could be fortified by the witness evidence of Mr Lane (and of Ms Eldridge in relation to the ASA's general approach), although once again I exercise caution in relation to after-the-event evidence about the decision making process.

129. The issues which the ASA identified – equivalence of devices, mode of use and consumer groups targeted, methodological issues including blinding and sample sizes – were genuine issues acknowledged by both experts. Dr Heller's evidence at least shows that there is expert support for the conclusions reached by the ASA on those issues. I therefore consider that those conclusions were rational in the *Wednesbury* sense. I see no unfairness in the way in which they were reached. I have already explained why I do not consider that a proportionality test needs to be applied but even if it were, it would not produce a different result. The ASA's analysis of the evidence was in pursuit of the legitimate objective of consumer protection, was a suitable or appropriate means of pursuing that objective and was necessary in that it was not more restrictive than any alternative and suitable means of pursuing that objective, no other such alternative having in fact been identified.

130. Nor was there any legal error in the ASA's refusal to be persuaded of the device's effectiveness by its CE certification. It was, in the end, common ground that such certification for the purposes of the MDD does not automatically satisfy the requirements of the UCPD, not least because of the considerable differences in the way in which the evidence is assessed for the purposes of those two regimes. It was therefore lawful for the ASA to carry out its own assessment.

131. The second and third grounds of challenge therefore fail.

Conclusion

132. In the absence of a meritorious ground of challenge to ASA's decision, the claim against both Defendants is dismissed.