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**TC07005**

**Appeal number: TC/2018/00226**

10 *VALUE ADDED TAX – zero-rating – whether certain equipment was designed solely for use by a handicapped person – yes – appeal allowed*

**FIRST-TIER TRIBUNAL  
TAX CHAMBER**

15

**ACTEGY LIMITED**

**Appellant**

**- and -**

**THE COMMISSIONERS FOR HER  
MAJESTY'S  
REVENUE & CUSTOMS**

**Respondents**

**TRIBUNAL: JUDGE AMANDA BROWN  
JULIAN SIMS**

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**Sitting in public at Taylor House, 80 Rosebery Avenue, London, EC1R 4QU on 17  
December 2018.**

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**Mr Mark Ellis, director of the Appellant for the Appellant**

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**Mr Anharul Qureshi, presenting officer of HM Revenue and Customs, for the  
Respondents**

## DECISION

### Introduction

5 1. The present appeal is brought by Actegy Limited (“**Actegy**”) against a decision of  
HM Revenue & Customs (“**HMRC**”) that certain products marketed and sold as the  
Revitive Medic (“**Medic**”) and the Revitive Arthritis-knee (“**Arthritis-knee**”) (or  
together “**Revitive Devices**”) when sold to individuals suffering from chronic  
10 illness/disability do not qualify to be zero rated pursuant to section 30 and Item 2(g)  
Group 12 Schedule 8 Value Added Taxes Act 1994 (“**VATA**”).

2. Pursuant to the decision that supplies of the Revitive Devices could not be treated  
as zero rated HMRC issued assessments against Actegy in the total sum of £122,543 in  
respect of the Medic and £53,246 in respect of the Arthritis-knee. These sums were  
15 notified as part of a larger assessment the remainder of which was undisputed by  
Actegy.

### Information on the devices

3. The Tribunal was provided with a bundle of documents including marketing  
materials for both Medic and Arthritis-knee. Mr Ellis also provided the Tribunal with  
an overview of the business in connection with the development of the Revitive  
20 Devices.

4. Between 2010 -12 Actegy identified an opportunity to develop a product range  
using electrical muscle stimulation (“**EMS**”) technology. The Tribunal was informed  
that EMS is the technology used for pain relief in TENS machines (used by women in  
labour and for a wide range of pain relief uses).

5. Clinical research was carried out. As part of this research an extensive literature  
review was undertaken as to the effectiveness of the use of EMS in alleviating  
symptoms of patients suffering from five identified conditions: peripheral arterial  
disease (“**PAD**”), chronic venous insufficiency (“**CVI**”), diabetic peripheral  
neuropathy (“**DPN**”), knee osteoarthritis and chronic immobility. The literature review  
30 revealed that EMS had a positive impact on sufferers of these conditions. Sufferers saw  
benefits with reduced swelling, management of pain and improved circulation.

6. Actegy identified that there was supportive research that having an affordable  
device that delivered EMS to patients suffering from the identified conditions  
individually or in combination was an attractive business proposition.

7. The Tribunal were informed that EMS provides electrical stimulation to muscles  
and causes them to contract. When applied through the soles of the feet/the calves EMS  
will help pump blood back up towards the heart. Using a platform of the technology  
purchased from the previous device manufacturer in Korea in 2010, Actegy modified  
the EMS technology by lengthening the pulse of electric stimulation but reducing its  
40 intensity. Actegy holds patents for these modifications. The effect of these

modifications was believed to improve the efficacy of EMS by lengthening the period over which the treatment could be administered.

8. The second phase of the research was to test the modified technology with pilot groups of individuals. The pilots were undertaken in 2013 by and through the Imperial College School of Medicine with PAD, CVI and DPN sufferers. The pilots were all led by Professor AH Davies, Professor of Vascular Surgery and Honorary Consultant Surgeon.

9. The Tribunal were provided with copies of Professor Davies' Study protocols. For the DPN study it was clear that the aim of the pilot was to assess the effect of EMS (as developed and used in Medic) on patients with DPN with the primary outcome measure being the improvement in nerve conduction. Patients were recruited from neurophysiology, diabetic foot and vascular clinics. Similarly the PAD and CVI studies appeared to focus very specifically on the impact of the Revitive Devices on the specific medical conditions identified.

10. In order to market a device which makes any medical claims the manufacturer must obtain certification from the British Standards Institution of the device and the associated claims is. This is a requirement of the Medical Devices Directive EC Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC ("**MDD**"). In order to have a device certified the applicant must prepare and submit for approval a Clinical Evaluation Report ("**CER**"). The CER will address the requirement for clinical evidence of safety and performance. The Tribunal understands that a CER can be prepared on a product basis or for a "family" of related products. They must be continually reviewed, updated and resubmitted, to reflect ongoing research whether in connection with the product itself or more generally into the conditions treated/alleviated by the medical devices concerned. This requires Actegy to be continually aware of research into the efficacy of EMS in connection with the targeted conditions.

11. The Tribunal were provided with the 2015 CER for Medic and Arthritis-knee as part of a wider family of products including those which are no longer marketed and a new variant product which was not formally the subject of the present appeal but on which HMRC had also ruled as not eligible to be zero rated. The CER was produced prior to the launch of the Medic in July 2015 and the Arthritis-knee in July 2016.

12. The CER shows that it was externally reviewed by Professor Tim Watson, Professor of Physiotherapy at University of Hertfordshire and the Expert Reviewer was Professor Deirdre Walsh, Emeritus Professor of Rehabilitation Research, Ulster University.

13. The executive summary of the CER states:

"Revitive is currently intended for use by individuals in the home setting to deliver neuromuscular electrical nerve stimulation in order to:

- Reduce swelling in the legs/ankles/feet – caused by being immobile due to osteoarthritis or an injury
- Improve circulation to reduce or prevent blood-pooling (stasis) – caused by diabetes or by being immobile following surgery
- 5       • Reduce pain and discomfort in the legs/ankles/feet – caused by diabetic peripheral neuropathy or swelling (oedema) due to osteoarthritis or following surgery
- Increase muscle strength to help regain mobility in the legs affected by being immobile due to COPD, osteoarthritis or following surgery
- 10       • Help maintain leg vein health – by increasing circulation, delivering more oxygenated blood and reducing swelling (oedema) in the legs, feet & ankles.

The following intended user groups are considered:

- Diabetes (Type I and Type II, including those with neuropathy)
- 15       • Immobility – post-surgical and sedentary
- Chronic Obstructive Pulmonary Disease (COPD) (including GOLD I-IV where stated) – muscle strength indication only
- Arthritic Disease (osteoarthritis)”

14. The CER narrates the literature reviews undertaken and the clinical data from studies utilising the Revitive Devices which confirms that the EMS therapy delivered through the Revitive Devices is safe and achieves the intended performance. Medic and Arthritis-knee are certified as class IIa devices. Certification enables the product to be marketed and sold across the EU and, through accepted equivalence, in other parts of the world.

15. The MDD also requires that manufactures hold and maintain a Technical File for each product submitted for and certified as a medical device.

16. The Tribunal also reviewed the Technical Files for each of the Revitive Devices. Initially Actegy had provided neither HMRC nor the Tribunal with full copies of the Technical Files. After the hearing the Tribunal requested specific additional sections from the Technical Files and were provided with them, also copied to HMRC.

17. The Technical Files state that they are “prepared for the purpose of demonstrating that the [Revitive Device] complies with the relevant requirement of the EC Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC”.

18. The Technical File for Medic sets out the historical context for the development of the Medic device as follows:

5 “The prior available device “Circulation Booster V2” was first distributed by Actegy Limited in 2007, thereafter Actegy became the legal manufacturer and obtained CE marking for the “Circulation Booster V3” device in 2010. Since 2007 sales of the Circulation Booster indicate a favourable market acceptance of the products.

The Revitive devices represent the next generation of devices from the Circulation Booster, which introduces new features for the user and provide improvements in design and manufacturability of the devices.

10 Revitive is split into 2 categories, Devices designed and developed for our target audience of chronically sick persons of 55+, potentially with more than one disability or ailment, whose symptoms may be treated with the Revitive technology. These units consist of [Medic] ... We also have devices designed for both these population groups and healthy populations ...

15 Revitive is currently indicated for use as a device to administer Electrical Muscle Stimulation, with the purpose of supporting and improving blood circulation, reducing swelling and discomfort, reducing pain, increasing muscle strength and increasing blood oxygenation. Patient clinical needs continue to be determined, and Actegy is evaluating possibilities of additional therapeutic indications of Revitive. Actegy is committed to making Revitive available to all patients who  
20 are likely to benefit from electrical muscle stimulation therapy, and is investing in a clinical program that will explore the potential benefit in selected new adult patient populations.”

19. Section 1.12: “Product “Family” Approach Definition and Justification” lists the symptoms identified in para 13 (i.e, referencing symptoms associated with chronic  
25 conditions together with “injury” and “following surgery”) under the subheading “definition” and by reference to the family of devices including Medic (not Arthritis-knee) but not so limited. The section continues:

30 “[Medic] [has] been developed to service the needs of these individuals **only**. In addition to the medical indications the Revitive family can be used to provide electrical muscle stimulation for the following: Healthy individuals who have a sedentary lifestyle or spend long periods inactive. Revitive may help but were not designed to: reduce swollen feet and ankles; alleviate tired, aching & heavy legs, including cramp; improve circulation, help maintain leg vein health, increase muscle strength in the legs. The RIX  
35 and RLV models are sold to general population as well as patient populations” (emphasis added).

The RLX and RLV models are the pre 2010 models and not the subject of the present appeal. It is not entirely clear from this section whether the “only” individuals for which the Medic was developed are those with the identified chronic conditions or a wider  
40 “patient” population including those who suffer acute conditions (i.e injury or post-surgery) but it was not developed for the wider healthy population to which the RIX and RLV are aimed.

20. Section 1.12 continues: “Revitive devices are intended for use in the home setting without the need for involvement of a clinical professional during treatment. Note: It is expected that patient population groups would use the device in consultation with a health care professional.”

5 21. Section 2.9 sets out the intended user profile and states: “The Revitive family is intended as a device to administer Electrical Muscle Stimulation, with the purpose of supporting and improving blood circulation, reducing swelling and discomfort, reducing pain, increasing muscle strength and increasing blood oxygenation. The intended user profile is based on users who may suffer from immobility, poor  
10 circulation and other related issues due to Diabetes, OsteoArthritis PAD and CVI. ...The device is intended for use worldwide and a typical user may be of any adult age range and is not specific to any demographics of sex, ethnicity or educational background. ... The [Arthritis-knee] is intended for use by the end user in a non-clinical setting and without the need for supervision or intervention of clinician during  
15 treatment”.

22. Section 2.10 lists the indications for use:

“ – reduce swelling in the legs/ankles/feet – caused by being immobile due to osteoarthritis

- 20 - Improve circulation to reduce or prevent blood pooling (stasis) – caused by diabetes
- Reduce pain and discomfort in the legs/ankles/feet – caused by diabetic peripheral neuropathy or swelling (oedema) due to osteoarthritis
- Increase muscle strength to help regain mobility in the legs affected by being immobile due to COPD, osteoarthritis
- 25 - Help maintain leg vein health – by increasing circulation delivering more oxygenated-blood and reducing swelling (oedema) in the legs/feet/ankles”

23. Section 2.11 provides: “The marketed intended use of the individual variant Revitive devices is determined from the complete set of indications for use, however,  
30 labelling of the devices may contain a subset of the indications and the stated intended use as appropriate for the target market and individual features of the device. As the intended user of the Revitive devices is understood to be lay, in order to make it more understandable/accessible for all users, the indications for use as described in the product labelling is written in readily understandable language for the non-medical  
35 professional user. The indications for use are therefore written to reflect the outcome as perceived by the user and as a result of clinical evaluations rather than the strictly medical outcome as defined for the indications for use. ...”

24. The Technical File for Arthritis-knee states that the device “is the latest product within the Revitive Circulation Booster range and is specifically intended to offer  
40 therapy for users who suffer from Osteoarthritis of the knee. The existing range of

5 devices target the symptoms of a number of chronic conditions, but the most commonly medically diagnosed condition is arthritis, or which 90% suffer from osteoarthritis. Given the prevalence of osteoarthritis of the knee and the particular needs of sufferers, it has been identified that there is scope to develop a new device and treatment protocol to better meet these specific needs. As such [Arthritis-knee] will be introduced to allow more specific segmentation of the Revitive target consumer and will address an existing unmet need”.

10 25. The intended user profile of the Arthritis-knee, as specified in section 2.8 of the Technical File, is: “based on users who are seeking to relieve and manage the symptoms of osteoarthritis of the knee, with the purpose of relieving knee-joint pain, leg stiffness, reducing swelling in knees and strengthening leg muscles. It is also suitable for rehabilitation following knee-surgery. The device is intended for use worldwide and a typical user may be of any adult age range and is not specific to any demographics of sex, ethnicity or educational background. ... The [Arthritis-knee] is intended for use  
15 by the end user in a non-clinical setting and without the need for supervision or intervention of clinician during treatment.”

26. Section 2.9 replicates the list for Medic in section 2.10 of the Medic Technical File as set out above.

20 27. Section 2.10 describes the intended use as “a subset of the indicated uses for the device” but essentially replicates and repeats sections 2.8 and 2.9.

28. Consistent with the CER and Technical Files the packaging for the Medic device states that it: “reduces aches and pains in the legs and feet; reduces swollen feet and ankles; alleviates cramp; strengthens leg muscles; actively improves circulation”. It also expressly references “diabetes, osteoarthritis, poor mobility, muscular weakness, post-surgery recovery”. The packaging shows a picture of the device which is a white round plate approx. 40cm in diameter with two black foot shaped pad electrodes through which the modified EMS is delivered. In the centre is a power button, an electronic display and plus and minus control buttons.

30 29. The Arthritis-knee packaging references: “Fight knee pain. Targeted relief and management of Osteoarthritis of the knee. Unique dual action technology helps fight pain from the feet up and the thigh down.” The principal difference between the Medic and the Arthritis-knee is the addition, in the latter device, of two electrode pads which the Tribunal was told are stuck to the leg just above the knee and provide an additional pulse to the lower quadriceps.

35 30. The clinical research continued for the Revitive Devices and full studies were also undertaken in 2017 by Professor Davies in connection with the use of Medic with PAD and DPN.

40 31. A study into the effects of combining electrical stimulation of the calf and thigh muscles in patients with osteoarthritis of the knee was undertaken in 2017 by Mr Alasdair Santini, Consultant Orthopaedic Surgeon at Liverpool University.

32. In correspondence Actegy referenced 4 “pen portraits” for their target audience. Actegy stated: “all our devices are designed to treat symptoms associated with illnesses and disabilities these individuals may suffer from/have. We split them into groups and have named them detailing out severity and number of ailments. We have developed our devices and have started to target specific illnesses across these groups.”

33. The Tribunal was provided with these pen portraits, the relevant excerpt is below:

Segment	Who the users are (condition)
“Sue” Aged 60-75 3+ L/T medical conditions	<ul style="list-style-type: none"> <li>- Controlled diseases</li> <li>- Everyday life impacted</li> <li>- Pain is frequent and may be prolonged</li> <li>- Reduced quality of life as everything is an effort and requires planning just to get through the day</li> <li>- Some functional limitation</li> </ul>
“Mary” Age 75+ 3+ L/T medical conditions	<ul style="list-style-type: none"> <li>- Severe diseases poorly controlled or at end stage; possible risk of death</li> <li>- Everyday life dictated by condition</li> <li>- Rarely leaves house</li> <li>- Pain is constant, brief moments of relief</li> <li>- Dependant on family and external carers</li> <li>- Needs help with everyday basics</li> <li>- Experience loneliness, depression and fear</li> </ul>
“Betty” Age 75+ Only 1-2 L/T medical conditions	<ul style="list-style-type: none"> <li>- Controlled diseases</li> <li>- Viewed as “just aging” – significant muscular atrophy/frail</li> <li>- Rapidly reducing mobility/agility</li> <li>- Gone from being relatively pain and symptom free to having to come with restrictions and discomfort</li> </ul>
“Robert in pain” Age 60 – 75 Only 1-2 L/T medical conditions	<ul style="list-style-type: none"> <li>- Active and keen to remain so</li> <li>- Recurring pain starting to restrict some activities (put down to overdoing it and/or getting old)</li> <li>- Knee and hip joints in pain and requiring surgery</li> <li>- A well-controlled disease of one body system</li> </ul>

34. The Tribunal were also taken, by HMRC, to marketing material produced by Actegy. On the Actegy website the Medic is stated to be suitable for everyone with poor circulation and also for those with osteoarthritis, diabetes, high blood pressure or high cholesterol. The claims to relieve aches and pains etc. reflect those on the packaging and referred to above. The page also extols Medic’s virtues in connection with the alleviation of such ailments and symptoms.

35. HMRC were also very focused on the information produced and supplied to Boots (the high street Chemist) – a “Staff training guide” and not for public distribution. The guide has sections: 1) leg health and circulation; 2) what is the Revitive and how does it work? 3) Revitive Circulation Boosters; 4) when to recommend Revitive; 5)



Frequently asked questions?” In section 2) the document states “Revitive is a clinically proven, drug-free medical device designed to activate the ‘second heart’ (calf muscle) to increase blood flow and thereby improve circulation.” Of the Arthritis-knee the document states that it is “designed to specifically help those with osteoarthritis of the knee or those recovering from knee surgery.”

36. In section 3) the document references the design of the Medic as “to help not just customers with poor circulation, but also those suffering from osteoarthritis, from diabetes, with poor mobility, with muscle weakness and recovering from operations (such as hip and knee replacement). In the comparison it again states: “medically powerful for people with poor circulation as well as those with certain medical conditions and post-surgery recovery”.

37. Section 4 suggests that the Boots staff ask potential customers if they suffer from both symptoms and specific chronic conditions.

38. When asked about the marketing material and the statements made in them regarding design suggested that when marketing the Revitive Devices there was a wider target audience than when the devices were designed. He stated that the devices had been clinically shown to have benefits in a wider population than the chronically sick and such claims had been endorsed by the British Standards Institution. Customers to the website and in Boots were part of the broader population of potential purchasers suffering from symptoms which might be alleviated through the devices and the marketing material facilitated and enabled such customers to make informed decisions.

39. All marketing material states that the devices are Class IIa medical devices such that customers with long term or chronic conditions being able to claim back the VAT paid.

## 25 **Legislation**

40. Section 30 VATA provides:

“(2) A supply of goods or services is zero-rated by virtue of this subsection if the goods or services are of a description for the time being specified in Schedule 8 or the supply is of a description for the time being so specified.”

30 41. Schedule 8, Group 12, Item 2(g) provides:

“The supply to a disabled person for domestic or his personal use, or to a charity for making available to disabled persons by sale or otherwise, for domestic or their personal use, of: ... (g) equipment and appliances not included in paragraph (a) to (f) above designed solely for use by a disabled person.”

## The issue

42. As is apparent from the statutory provisions not all supplies of equipment or appliances falling within Item 2(g) will be zero rated as the zero rating provisions are limited not only by the nature of the goods but also the status of the recipient.

5 43. In the present appeal there is no dispute between the parties that the Revitive Devices are “equipment or appliances”. The parties are similarly agreed that the Revitive Devices do not fall within any of the provisions (a) to (f) of Item 2.

44. Further, there is no dispute that the recipients of the supplies which had been zero rated by Actegy were disabled persons and that the Revitive Devices were for personal use.

45. Therefore the only issue for determination by the Tribunal was whether the Medic and/or the Arthritis-knee were “designed solely for use by a disabled person”.

46. Even within the narrow confines of the dispute there is agreement that the focus of the Tribunal’s attention is on the design of the Revitive Devices and the intention of the design. Whilst ultimate use and marketing may be indicative of the intention of the designers the fact that the devices may be used by those who are disabled does not exclude the devices from being zero rated under item 2(g).

## Case law

47. Actegy referred to no case law and relied on compliance with HMRC’s guidance as the basis for zero rating.

48. Disappointingly, whilst HMRC referenced a number of cases they produced only one paragraph summaries of the cases save for the case of *Pure Independence (UK) Ltd* [2011] UKFTT 611.

49. That case concerned bespoke mattresses and toppers which the Tribunal concluded were zero rated. In his judgement, at paragraphs 55 – 66, Judge Reid reviewed a number of previous First-tier Tribunal judgements concerning the application of Item 2(g). HMRC essentially left this Tribunal to find and read the judgments to which they and Judge Reid referred. This the Tribunal has done.

50. From this review the Tribunal distils the approach that has been adopted previously by the Tribunal. The approach is not binding on this Tribunal as all the decisions are of comparable authority but unless that approach is considered to be wrong it is to be adopted by us.

51. In *Foxer Industries Ltd* (1995) VTD 13817 the Tribunal considered single seater golf buggies. That Tribunal considered a line of previous cases. The Tribunal noted that in many instances there was no evidence available from the designer of the items under consideration such that the intention of the designer had to be discerned from the product itself and its marketing. The Tribunal observed that the historic case law as somewhat difficult to reconcile but the Tribunal was clear in its view that the focus of

attention must be on the observable intention of the designer assessed by reference to objective criteria. The Tribunal considered that the requirement that the items be designed solely for disabled persons was a requirement that there be a specific design purpose. The fact that items were capable of use by a wider population was not considered to preclude zero rating but broad usage beyond the target group of disabled persons would be indicative that the design was not specific to disabled persons.

52. In the case of *Joulesave Emes Limited* VTD 17115 the Tribunal considered radiator covers which prevented those unable to move away from the heat of a radiator from being burned by it. That Tribunal heard evidence directly from the designer of the covers and was able to assess his subjective evidence objectively in the context of use and marketing of the covers.

53. In the case of *Medivac Healthcare Limited* VTD 16829 the Tribunal again had the benefit of direct evidence of design objective/intention and was able to assess that evidence in the context of an understanding of the equipment (anti allergen systems), its use and marketing. The Tribunal endorsed the approach identified above in *Foxer*.

54. At paragraph 66 of *Pure Industries* the Tribunal stated:

“What emerges from a review of these cases is that the following, at least, should be considered in order to determine whether the equipment or appliance is designed solely for use by a handicapped person (i) the identification of the designer and his intention; (ii) the function, purpose and actual uses of the finished article; (iii) any advertising and promotional literature and the market in which the product is supplied and its cost; and (iv) the availability and similar products and their comparative cost”.

55. It appears from a review of the cases that access to the designer or those commissioning the designer is comparatively rare but is clearly hugely beneficial. The subjective intention of the designer, which may be self-serving, will be relevant but must be tested by reference to all the available documentary material. In this context the advertising/marketing material will be relevant as will the other factors identified in *Pure Industries* but of particular relevance will be the Technical Files and CER.

### 30 **Parties’ submissions**

56. Actegy contended that the Revitive Devices were designed and developed specifically to treat/alleviate the common symptoms associated with CVI, PAD, DPN and Osteoarthritis of the knee by those disabled by those conditions. The symptoms identified were: leg aches and pains, swollen feet and ankles, cramps, pain when mobile, muscle weakness and stiff knee joints. The Medic which was developed first revealed that, whilst capable of improving muscle weakness and stiffness in the joints, it was not sufficiently targeted for osteoarthritis of the knee sufferers and accordingly the Arthritis-knee included the necessary adaptations to provide that targeted focus.

57. Actegy accepted that the Revitive Devices were capable of use by a wider population than just those suffering the identified conditions but Actegy focused on the pen portraits of the target audience. It was however contended that the marketing

material which supported the wider population use was not sufficient to deny zero rating of the Revitive Devices which, it was submitted, had a specific disabled user group in mind when designed.

58. HMRC contended that the term “designed solely” was extremely narrow and could not include products which disabled individuals might find useful in coping with their disability but were designed with wider application.

### **Discussion**

59. It did not appear to be disputed by HMRC that Actegy was the designer of the Revitive Devices. Had there been any dispute however, the Tribunal considers that Actegy is the designer on the basis that it became the legal manufacturer of predecessor devices which were then modified through the development of patented changes to the EMS used by the devices.

60. The Tribunal had the benefit of hearing from Mr Mark Ellis of Actegy on the subjective intention of design. That intention was then tested by reference to the documentation available.

61. Of particular relevance were: (i) the Technical Files for each product which are required to be produced and maintained pursuant to the provisions of the MDD; (ii) the CER; (iii) the pen portraits; and (iv) product information and marketing material.

62. It is reasonably clear from the statutory test itself, the acceptance by HMRC in the present case and the case law analysis that the focus is on the specificity of design and not on the final use made by a wider population or to the marketing of the products save to the extent that the use and marketing informs the evidence on design.

63. The Tribunal considers the Technical Files, prepared for purposes other than VAT and as part of Actegy’s obligations associated with the MDD classification of the devices, represent the primary source of objective evidence of the design intention.

64. In the present case the Technical Files for each of the devices provided some support for Mr Ellis’s evidence that the Revitive Devices were designed for use by the chronically ill (whom HMRC accept as disabled) relieving specific symptoms suffered by patients with the identified conditions. However, they are not completely unambiguous. As set out in paragraphs 17 – 27 above the Technical Files do explicitly state that the intended use for Medic and Arthritis-knee is by those who are chronically sick suffering from Diabetes, PAD, CVI, PMD and osteoarthritis but there is also reference the alleviation symptoms as arising not only from the identified chronic conditions but also post-surgery or more generally in connection with leg vein health.

65. Having carefully read the Technical Files and the clinical research studies the Tribunal has taken the view that whilst clearly surgery and poor vein health will arise for a number of reasons it is also likely that certainly the identified chronic conditions are likely to cause poor vein health and in some instances lead to the need for surgery. The Tribunal also bears in mind that the Technical File for the Medic also referenced multiple devices some of which Actegy accepts are not eligible to be zero rated. It is

also clear that the clinical research undertaken concerned only patients with the identified conditions. As a consequence of these factors the Tribunal has decided that by reference to the Technical Files the design focus was on the symptoms of sufferers of the identified chronic conditions even though those symptoms also arise as a consequence of other causes.

66. Applying the approach taken by other Tribunals and by reference to the Technical Files alone the Tribunal considers that the modifications delivered through the Medic and Arthritis-knee were designed specifically with the disabled in mind and therefore solely for the domestic use of disabled persons. It is noted in the Technical Files that, in particular the Medic, would have beneficial therapeutic outcomes for anyone suffering from the symptom whatever the root cause of such symptoms but the focus of the literature review and the pilot studies undertaken prior to the launch of the product both support a conclusion that the design objective was focused specifically on individuals suffering symptoms as a consequence of chronic illness/disability. The Technical File 2.8 for Arthritis-knee supports a conclusion that the modification of it as compared to the Medic (i.e. the addition of the thigh electrodes) was solely with sufferers of osteoarthritis of the knee as the focus of the modification. Section 2.8 and 2.10 recognise wider use but not as a design objective.

67. As indicated above, the CER represents the document prepared and submitted to the British Standards Institution for the purposes both of classification as a medical device and for approval of the therapeutic claims associated with the Revitive family of devices including the Medic and Arthritis-knee. This document taken on its own would tend to indicate that the design of the Revitive Devices may not have been solely for the use of disabled persons.

68. The CER references post-surgery use and is focused primarily on the symptoms relieved/alleviated through use rather than the underlying cause of those symptoms. The majority of the document is however focussed on reporting the outcome of the clinical research which, as indicated above, was addressed solely on groups of individuals suffering chronic illness/disability of which the symptoms alleviated by the Revitive Devices are a feature. On balance, the Tribunal considers that the reference to post surgery use and the alleviation of symptoms after injury is a function of the rationale for the document. Firstly, the CER concerns all the Actegy devices and not only Medic and Arthritis-knee in circumstances where, the Tribunal understood, Actegy accepted that not all devices were eligible to be zero rated. Secondly, this document is required in order that the various claims made are approved as technically and clinically sound. Having designed devices to treat the symptoms of certain conditions causing disability (all being chronic illnesses impairing normal life) it is not surprising that Actegy would want to be able to make claims of the therapeutic and clinical effect for sufferers of symptoms arising from acute or non-chronic conditions. The fact that these claims can be, and are, made does not, in the Tribunal's view, disturb the conclusion on specificity of design reached from the Technical Files which themselves recognise that the marketing of the devices is wider than the intended user at the design stage.

69. Mr Ellis, by his email to HMRC dated 15 May 2017, articulated that the design focus of the Revitive Devices was by reference to four pen portraits. His description of the pen portraits places the focus on symptoms and not disability. Certainly taken alone his email gives a solid basis for HMRC's concern that the Revitive Devices were designed with the symptoms and wider population suffering from them in mind. However, by reference to the relevant excerpts of the pen portraits set out above, it is clear that each of the target audience groups stated to be the design (and marketing) focus of the Revitive Devices suffers from one or more chronic conditions rendering them disabled. Whilst the language used in his email was unhelpful to Actegy's case the Tribunal considers the pen portraits themselves are consistent with the conclusions reached on the Technical Files and hence support a conclusion the Revitive Devices were designed solely for disabled persons.

70. The product information and the marketing material undoubtedly promote the Revitive Devices to the widest possible audience including those who are not chronically sick. Had there been no evidence of the design intention (as was the case in many of the previous cases considered by the tribunal) the Tribunal would have concluded that the necessary design intention had not been made out.

71. The question for the Tribunal is therefore whether the marketing material and the product description should act as a sufficient counterweight to the design intention as evidenced in the Technical Files. As set out in paragraph 23 above the Technical File for the Revitive family including the Medic explicitly recognises that as the intended user of the Revitive devices are not intended to be medical professionals "the indications for use as described in the product labelling is written in readily understandable language for the non-medical professional user. The indications for use are therefore written to reflect the outcome as perceived by the user and as a result of clinical evaluations rather than the strictly medical outcome as defined for the indications for use". In light of this the Tribunal considers that the marketing material does not disturb the Tribunal's conclusion of the design intention/objective.

72. The case law is clear that marketing material is relevant and in some cases (where there is no other evidence) will be determinative. In the present case however, it is sufficiently clear that the focus of the clinical literature reviews and the pilot studies for the Revitive Devices was in patients suffering from Diabetes, PAD, CVI, DPN and osteoarthritis of the knee. The modifications to the historic versions of the devices were specifically targeted at those disabled by these conditions.

73. There is undoubtedly a clinical use for the Revitive Devices in acute rather than chronic sufferers and those with similar symptoms arising from non-chronic conditions but the Tribunal has determined that is happy circumstance and not the objective of the design of the Revitive Devices. Whilst not relevant to the conclusion on the design intention of the devices and hence their eligibility to be zero rated it is noted by the Tribunal that customers purchasing the Revitive Devices who are not disabled will, in any event, bear VAT on the purchase of them.

74. Working through the criteria listed in *Pure Industries*:

(1) the identification of the designer and his intention: as stated above the designer is Actegy and the identified intention was that the Revitive Devices be developed specifically and therefore solely for use by disabled individuals.

5 (2) the function, purpose and actual uses of the finished article: the Revitive Devices fulfil the function, purpose and use for which they were designed though recognising that use in a wider population than the target audience is possible.

(3) any advertising and promotional literature and the market in which the product is supplied and its cost: the marketing material is certain aimed at a wider audience but the Tribunal considers for the reasons above that this does not override the conclusion on design. The cost of the Revitive Devices is approx. £200. There was no evidence given the Tribunal on comparative devices or cost and as such the Tribunal cannot consider the impact of cost.

10 (4) the availability and similar products and their comparative cost: as above  
15 neither side led evidence or even made submission as to a comparator market, accordingly the Tribunal has not considered this factor.

### **Decision**

75. For the reasons stated above the Tribunal determines that both the Medic and Arthritis-knee are devices designed specifically for use by disabled persons and therefore are equipment or appliances designed solely for use by such persons.

76. Accordingly, the appeal is allowed and the assessments raised as a consequence of the decision that the Revitive Devices were not of a type eligible to be zero rated are to be withdrawn.

77. This document contains full findings of fact and reasons for the decision. Any party dissatisfied with this decision has a right to apply for permission to appeal against it pursuant to Rule 39 of the Tribunal Procedure (First-tier Tribunal) (Tax Chamber) Rules 2009. The application must be received by this Tribunal not later than 56 days after this decision is sent to that party. The parties are referred to “Guidance to accompany a Decision from the First-tier Tribunal (Tax Chamber)” which accompanies and forms part of this decision notice.

**AMANDA BROWN  
TRIBUNAL JUDGE**

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**RELEASE DATE: 26 FEBRUARY 2019**