BHTA CODE OF PRACTICE

For the healthcare & assistive technology products and services industry





BHTA Code of Practice for the Healthcare & Assistive Technology Products and Services Industry

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BHTA Code of Practice for the Healthcare & Assistive Technology Products and Services Industry

Introduction

BHTA's Code of Practice is approved by the Trading Standards Institute under its Codes Approval Scheme. This means the Code Members are licensed to display the combined BHTA TSI Approved Code logo shown on the front cover of this document, and customers can be confident they will be treated fairly. Consumers are private individuals buying goods or services other than for business purposes.

In addition to requirements for contracts with such consumers, this Code also covers business to business contracts, which have been included herein because of the nature of the business carried out. Most of the companies signed up to the Code will sell to a mixture of customers, some private consumers, some businesses, and some public bodies (such as the NHS and Social Services) but the principles involved, particularly in regard to assessment of the users of products and to the need for good after sales support are similar. Where the member provides services paid for by the NHS or other government body, which are provided, for example, to NHS patients free of charge and the patient sees this as being part of an NHS clinic or service (eg Prosthetic and Orthotic services) then sections 8-12 do not apply as practice in this area is governed by the contract that companies have with the NHS. Other examples might be where equipment is provided free of charge by a Local Authority or Education body.

The Code is reviewed annually, with input from external organisations, to ensure its effectiveness.

1. General Scope / Principle / Purpose of the Code

- 1.1 This Code of Practice governs the behaviour of companies (Code members) that have registered to abide by the criteria herein. It operates for sales conducted in the United Kingdom. BHTA, as the Code Administrator, acts as the Regulator for the Code.
- 1.2 In examining a company's behaviour against this Code, only the clauses relevant to that company and its products, the goods that it sells, and its services will be taken into account.
- 1.3 The Code is intended to reflect a philosophy of care and support for customers. Code Members will make themselves aware of pertinent legislation, to ensure they do not offer, stipulate, infer or imply anything in their terms and conditions of contract which provides the customer with less protection or a worse deal than that provided by law, and to ensure that the terms in their consumer contracts comply with the Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013, the Consumer Protection from Unfair Trading Regulations 2008 and the Consumer Rights
- 1.4 Individual persons working in the industry may be registered as competent individuals with a relevant body, such as the Health and Care Professions Council (for qualified occupational therapists, physiotherapists, orthotists, prosthetists), or the Healthcare & Assistive Technology Society. Such registrants will be required to follow a personal Code of Conduct, which will be available on application to the relevant organisation (see useful contacts). As a minimum, this Code expects that individuals will adhere to the Code of Conduct of the Healthcare & Assistive Technology Society.
- 1.5 An undertaking to abide by this Code is currently restricted to, and mandatory for, members of the British Healthcare Trades Association (BHTA). In considering applications for membership, BHTA takes into account the past history of any

directors/partners and will not allow entry by any company where a director, partner or major stakeholder has been involved, within the previous 12 months, in the winding up of a company in such a manner that customers have been disadvantaged. Such companies will therefore be barred from signing up to this Code.

2. Definitions / Terminology

Healthcare Industry

- 2.1 Companies in the healthcare industry, as defined for the purposes of this Code of Practice, will be involved in one or more of the following:
- Supply of assistive technologies, particularly those for elderly and/or disabled consumers
- Supply of externally applied medical devices, and/or services relating to the fitting of those devices
- Supply of equipment and related services necessary for medical and health professionals to carry out their various specialist functions
- Training in the use of assistive technologies
- Training relating to health and safety, such as first aid at work, and manual handling.
- 2.2 The industry (for the purposes of this Code of Practice) does **not** include:
- Pharmaceuticals
- Alternative medicines or therapies
- Dentistry
- GP practice
- Ophthalmology
- Implants

Assistive Technology

2.3 An assistive technology is a product or service that enhances independent living.

Company

- 2.4 The term "company" includes:
- Limited companies
- Partnerships
- Sole traders
- Franchises
- Wholly-owned subsidiaries
- Trading arms of charities

ie, organisations or firms with a commercial, profit-making, interest.

Customer

2.5 Customers may be private individuals, businesses, charities or authorities/agencies such as the NHS as well as private consumers.

Code Member

2.6 Any BHTA member company undertaking to abide by this Code of Practice.

Code Administrator (BHTA)

2.7 The British Healthcare Trades Association (BHTA) is the Administrator for this Code.

3. Over-riding Principles Underpinning this Code

- 3.1 All Code members registered against this Code will adhere to the following principles:
 - a) Compliance with all relevant legislation relating to advertising and marketing, the sale of goods, relevant European Directives/Regulations, consumer rights, disability rights, and data protection.
 - b) They will make themselves aware of pertinent legislation to ensure they do not offer, stipulate, infer or imply anything in their terms and conditions of contract which provides the customer with less protection or a worse deal than that provided by law.
 - c) Where selling products, they will ensure that these are of satisfactory quality and fit for the purpose specified. Their selling techniques will be ethical and they will deliver high standards of service.
 - d) Any claims made by the company and its employees will be honest and truthful, and will not give rise to false expectations. Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous. They must not mislead either directly or by implication.
 - e) They will act at all times in such a manner as to justify public trust and confidence, to uphold the good standing and reputation of the healthcare industry, to serve the best interests of society, and above all, to safeguard the interests of individual customers. They will respect the confidentiality of information obtained and not disclose such information without the consent of the customer concerned or a person entitled to act on their behalf, except where such disclosure is required by law. They will be honest and truthful in all their dealings with customers.
 - f) Products and services will only be supplied where they fulfil a genuine need.
 - g) All communications, verbal and written, will be made in plain language.
 - h) At all times, the vulnerable nature of the customer will be respected. No customer will be coerced in any way. All customers will be given information in an appropriate format, and will have their particular needs taken into account.
 - i) A copy of this Code will be given to anyone who requests it and, where complaints cannot be resolved direct with the company, complainants will be made aware of their right to mediation and arbitration in accordance with this Code and how to initiate such proceedings.
 - j) Members will not disparage the products and activities of other healthcare and assistive technology companies; nor the clinical and scientific opinions of health professionals.

4. Advertising and Marketing

- 4.1 In marketing and promotional activities, in addition to having due regard for current legislation, care must be taken to ensure any gifts related to purchase of a product or service are directly relevant to that purchase and of a nature that cannot be construed as inappropriate or disproportionate.
- 4.2 Advertisements must comply with any relevant <u>code of advertising</u> including:
 - the British Code of Advertising, Sales Promotion and Direct Marketing
 - the Television, Advertising Standards Code
 - the Radio Advertising Standards Code
 - the <u>PhonepayPlus code</u> for all premium rate charged telecommunication services They must also comply with relevant statutory requirements such as the <u>Consumer Protection from Unfair Trading Regulations 2008</u> and the <u>Consumer Credit</u> (<u>Advertisements</u>) Regulations 2004 as amended in <u>2004</u> and <u>2007</u>.
- 4.3 Advertisements must not give misleading indications about price, value or quality, nor about the organisation placing the advertisement, nor about any benefit that may be derived from the product or service offered. The consequence of responding to the advertisement should be clear. Prices, price examples, or price explanations should be given for the products shown in all promotional material intended for consumers, including on websites.

5. Conduct of Staff

- 5.1 Staff must always clearly identify themselves and (when away from the office / company premises) their reason for calling.
- 5.2 Staff must never purport to have medical training where this is not the case, nor claim that their product is endorsed by a trusted body unless this can be evidenced in writing.
- 5.3 As a minimum, staff should be expected to adhere to the provisions of the <u>Healthcare & Assistive Technology Society Code of Conduct</u>.

6. Training of Staff/Ongoing Development

- All staff must be made aware of any legislation pertinent to their role, especially in relation to health and safety, disability discrimination, and consumer rights. They must give due regard to infection control issues, where relevant.
- They must also be informed of any regulations to which they must give due regard in the course of their work, such as building regulations and LOLER (<u>Lifting Operations and Lifting Equipment Regulations 1998</u>).
- 6.3 Staff should not work unsupervised until they are considered competent to do so. They should not be asked to carry out tasks for which they have not received training. It is recommended that regular refresher sessions are held in-house, as a minimum. Registered professionals, such as occupational therapists, physiotherapists, nurses, orthotists and prosthetists, and any individual registered with the Healthcare & Assistive Technology Society are required to receive on-going training to keep their knowledge up-to-date and such registration is an indicator of competence. On-going training must be facilitated.
- 6.4 Companies must maintain a record of training for each member of staff.

- 6.5 Where clinical advice and training is to be given by staff, they must be appropriately qualified.
- 6.6 All staff, in particular those in direct contact with the customer, must be given a copy of this Code and be made aware that the company is required to adhere to the provisions herein.

7. Representation at Point of Sale

- 7.1 Staff must have the appropriate product knowledge to advise and assist purchasers.
- 7.2 A copy of this Code will be made available, free of charge, on request. The BHTA leaflet "Get Wise to Buying Safely" will be given to every consumer to whom a home visit is made, or who buys through distance selling means (or its availability must be clearly mentioned in paperwork which the consumer will receive); and it will be displayed in retail outlets. In addition businesses will display the BHTA Code of Practice poster and the combined BHTA & TSI Approved Code logos (which appear on the front cover of this document).

8. Pre-Contractual and Point of Sale Information

- 8.1 Inappropriate selling tactics must not be used. (Examples of what might be high pressure selling / mis-selling tactics include: unreasonably long stay (for sales in the home); high initial price followed by the offer of a discount (often followed by a telephone call to the "manager"); discount on the condition that the consumer agrees to the sale that day; withholding price information until the end of the sales discussion/visit; alleged limited availability of a product; misrepresentation of the product, price or contract.)
- 8.2 Where a customer's ability, well-being, environment, and/or activities have an effect on the safe use and suitability of a product for the customer's stated purpose, a full assessment of these factors must be carried out, so that an appropriate product can be identified. A record of the assessment must be retained by the company and a copy be made available to the customer on request. This applies to all sales, whether conducted in store, off premises (eg at the customer's home), online, via mail order catalogue or by telephone.
- 8.3 Potential customers should be made aware, where appropriate, of services offered by the Local Authority, NHS, the Employment Service, major charities and other agencies.
- 8.4 Where professional / medical advice should be considered by the customer before purchasing, details of where this assistance might be obtained should be given. If a practitioner is recommended who is contracted to the advising vendor/salesperson, this should be made explicit.
- 8.5 Where VAT relief can apply it should be brought to the attention of the customer, as should details of how this can be obtained.
- 8.6 Terms and conditions of contract must be available in writing and must be legible, comprehensive and written in plain language; the font used should be a minimum of size 12, with large bold print for particularly important terms such as cancellation instructions. In accordance with the Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013 they must include details of the trader's name and geographical address and details of any other trader's name and geographical address on whose behalf the trader is acting. Due regard must be given to the Consumer Protection from Unfair Trading Regulations 2008 and the Consumer Rights

- Act 2015. Where a customer has indicated they have poor eyesight or are confused by paperwork, the salesperson should go through the paperwork with them. A version in large print, Braille, or on audio tape must be provided if requested, within a reasonable timescale. Customers with poor eyesight, or who become easily confused, should consider having a relative, friend or other advisor/carer with them.
- 8.7 Any limitations of the product / service should be made clear and any clear disparity between the goods and / or services for sale and usual consumer expectations must be explained in writing.
- 8.8 Any clear disparity between a customer's stated requirements and the nature of the goods / and or services to be purchased must be pointed out and explained in writing.
- 8.9 Where a product will need to be modified in a way that is not achievable with accessories and where additional fabrication outside routine manufacture is required, the customer must be made aware of this, as the product will be "bespoke" and any changes to terms and conditions as a result of this must be notified to them in writing.
- 8.10 All verbal claims or promises made by the salesperson must be put in writing, either on the contract, or on a separate form.
- 8.11 Pricing information showing the total price and providing a breakdown, where appropriate, of that total showing eg delivery, VAT, credit charges, discount applied, part exchange applied, must be given in writing. Prices must be made available to the customer at the earliest possible stage.
- 8.12 Details of any finance agreement and APR should be explained in such a way that the customer understands how much they will be paying and what the terms of the contract are. Pre-contract information must be sent / presented on its own, allowing time for the consumer to pause and reflect on affordability and to compare credit, before being presented with the agreement to be signed. Consumers must be given the option of paying for Payment Protection Insurance and other insurances up front, rather than these being automatically offered on credit. It must further be made clear that customers have the right to cancel hire purchase and conditional sale agreements and only pay 50%. This does not extend to the insurances mentioned above.
- 8.13 Details of delivery, installation, training, after-sales support, service and warranty should be made available prior to sale.
- 8.14 Delivery and completion dates should be discussed with the customer in advance of ordering / making the purchase and a choice of delivery dates and times should be offered. For mail order and Internet orders, normal delivery times should be indicated. Should it become clear these can not be met, the customer must be informed as soon as practicable, with an honest explanation of the reason for the delay. The customer should have the right to cancel without penalty if the order is not delivered within the stipulated time.
- 8.15 Where tuition / training is necessary for safe use of a product, reasonable and fair tuition / training for its use under the conditions which the purchaser best describes as "normal" for his / her purposes must be offered prior to conclusion of a sale. If such tuition / training is declined, record must be made of that fact and the reasons given.
- 8.16 In particular, tuition in the control of mobility vehicles should be given at the time of purchase and / or on delivery. Tuition levels will vary according to:
 - the user's abilities and experience
 - the type of vehicle
 - the circumstances of use
 - the kind of attendant support expected

Tuition should follow a proper assessment of needs, wishes, abilities and disabilities to enable selection of the most suitable vehicle and specification for user and circumstances. A vehicle should only be sold if the member can realistically expect the user to develop satisfactory control. (A document outlining <u>tuition requirements</u> is available on request from BHTA, as is one which sets out what should be recorded when assessing <u>competency to use a powerchair or mobility scooter</u>.)

9. Linked Goods and Services

- 9.1 If the product will need servicing regularly, an explanation must be given as to what is entailed, and the likely costs thereof should be outlined. It should be made clear whether maintenance is offered / available, or will have to be obtained elsewhere.
- 9.2 Where appropriate, arrangements for insuring the product should be discussed, or leaflets regarding such insurance should be made available. If insurance is discussed, it must be made clear that it is cancellable, the consumer must be given the option to pay for it up front rather than as part of a credit agreement and it must be made clear to whom any refund will be paid in the event of cancellation.
- 9.3 Any optional guarantees / warranties must be explained, including who is offering them and what the benefits are, or leaflets that do this must be provided.
- 9.4 Clear, accurate information on the availability and price of all the above and any other linked goods and services must be provided in writing.

10. Instructions for Use / Manuals

- 10.1 Any instructions for use and manuals should be written in clear language, and those responsible for their production should be aware that versions in large print, or on audio tape, may be requested and this must be facilitated as swiftly as is practicable.
- 10.2 Such instructions/manual must be made available with all new products, and should, if feasible, be made available with second-hand products. The customer's attention should be drawn to user manuals and they should be informed of the need to read them thoroughly.
- 10.3 Depending on the nature of the product, the instructions/manual should cover all or some of the following (this is not an exhaustive list):
 - Product name, description and intended purpose
 - Name of manufacturer and/or supplier
 - Illustration of the product
 - Reference to any variants or accessories
 - General, or detailed, dimensions
 - General, or detailed, description of construction
 - Explanation of how to use it safely
 - Any known limitations
 - Description of maintenance requirements including recommended frequency of servicing
 - Cleaning / decontamination instructions
 - Any specific warnings

11. Cancellation Rights / Protection of Deposits

11.1 If a company offers a cancellation period or returns policy other than that required by the Consumer Contracts (Information, Cancellation and Additional Charges) Regulations
2013, this should be explained to the customer and be clearly defined in the written terms and conditions of contract or shop returns policy.

<u>Consumer Credit Act 1974</u> – Consumers who enter into a credit agreement have a right to a 5 day cooling off period from the date the consumer receives a copy of the executed agreement regardless of whether the visit was pre-arranged.

11.2 Where cancellation rights apply or are offered, the customer must be informed under what circumstances they may cancel and these instructions should be plainly visible in the paperwork given to the customer, for example next to the signature box, and be in large bold type. Where a customer has indicated they have poor eyesight or are confused by paperwork, the salesperson should go through the paperwork with them.

In accordance with the <u>Consumer Contracts (Information, Cancellation and Additional Charges)</u> Regulations 2013 a cancellation form must be provided setting out:

- that a cancellation period applies and the date from which it starts
- the length of the cancellation period
- how to cancel
- 11.3 If a deposit will not be refundable, or will be only part-refundable, this must be made clear when the customer places the order and the reasons for this must be described to them, in writing. If the customer cancels the contract properly full repayment should occur (unless, for example, the goods have been damaged after delivery), and in any circumstance moneys withheld should not amount to more than the net costs or net loss of profit incurred by the Code member.
- 11.4 Where an order cannot be fulfilled and the customer does not wish to accept substitute goods or services, refund must be made speedily and in full and in the case of contracts where cancellation rights apply under the Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013, refund must be made within 14 days of return of the goods or their collection from the customer (whichever is earliest). Vouchers/credit note to the equivalent value must not be offered unless the customer agrees this is acceptable.
- 11.5 Where refundable deposits / advance payments are taken that are not covered under Section 75 of the Consumer Credit Act, or by an online payment service protection, a mechanism such as placing these in a separate account must be in place to ensure that consumers are returned their money without undue delay.
- 11.6 Where a cancellation period applies and a part exchange has occurred, the part exchanged product must not be broken up, disposed of, or sold on until after the cancellation period has been completed.

12. After-Sales Service Provisions

- 12.1 Code members are expected to provide a high standard of after sales service and to ensure a prompt and adequate service and repair policy.
- 12.2 Prompt will normally be taken to mean response and (where appropriate) visit within 3 working days of request, unless otherwise agreed. No customer should be without equipment on which they rely for mobility and/or daily living for more than 14 days.

(Exceptions may occur, for example, where a customer has bespoke needs that cannot be met from normal stock held, or where a hospital/clinic appointments system must be followed, however every effort must be made to keep the period the customer is without mobility to a minimum.)

- 12.3 Guarantees / Warranties must be in writing, and be clear and unambiguous. They do not affect a consumer's statutory rights and all guarantees and warranties used by Code members should carry a statement making this clear. Distributors and retailers must pass on the individual parts and labour guarantee offered by the manufacturer, and abide by the terms contained in the guarantee during its currency.
- 12.4 There must be no high pressure selling of additional warranties, nor any misrepresentation of their costs, coverage and any benefits they provide.
- 12.5 A minimum 3 month guarantee must be offered in respect of all repair work carried out.
- 12.6 It must be explained to the purchaser that no claim will be met under guarantee if the product has been abused in any way, or damaged by neglect, improper use or failure to maintain in accordance with the manufacturer's recommendations, or has been damaged in any accident. Abnormal wear and tear will also be considered when assessing a guarantee claim.
- 12.7 If, after purchase, the customer wishes to sell the product to another consumer, the transfer of a valid guarantee / warranty should be possible and a mechanism should be in place to facilitate this.
- 12.8 Maintenance agreements must be clear and unambiguous and the covered duration must be stated.
- 12.9 If a company has a buy-back policy this must be clear and unambiguous, and be outlined to the customer in writing in advance of the sale taking place. Any reason for not buying back the product, for example because it is single-use, or bespoke, must be stated and the reason made clear. Companies that do not buy back product under any circumstances should be prepared to make available an advice sheet on how to sell the product and advise on the likely second-hand value.
- 12.10 Customers must be given a clear explanation of the basis for charging for repair work not covered by warranty / guarantee and, where practicable, a written estimate in advance, of the anticipated costs of such work. (Customers have the legal right to refund, repair or replacement for goods that are identified as being faulty, as set out in the Consumer Rights Act 2015.)
- 12.11 When work has been carried out, a schedule of the work (labour, parts, etc) should accompany the invoice, detailing a breakdown of costs.
- 12.12 Adequate stocks of components/parts should be held to facilitate prompt service.
- 12.13 Customers should be given details of opening hours, contact telephone numbers and arrangements, if any, for emergencies out of hours.
- 12.14 Reasonable care should be exercised in protecting customers' property whilst in the company's possession and companies should not seek any disclaimers to avoid liability for loss or damage. Companies are advised to ensure they are adequately insured to cover such liability, as well as cover against any claims for death, personal injury and damage to property arising out of the demonstration of goods or their use after sale.
- 12.15 If a company is prepared to remove unwanted products, the terms under which they will do so must be made clear when this is requested, particularly in regard to disposal.

13. Specific Criteria for Particular Methods of Selling / Supply

> Sales Conducted in a Customer's Home ("Off Premises" Sales)

- 13.1 All cold calling is unacceptable and this includes cold calling by telephone.

 Salespersons and / or assessors must not visit without a mutually agreed appointment first being made. The purpose and intent of any visit must be made clear to the customer.
- 13.2 The customer must be provided with literature describing the products and services available, together with actual price examples, or where exact prices are not possible (for example with a bespoke product) with price ranges. This information must be provided in advance of the visit unless this is not feasible for practical reasons (for example if a visit is to be conducted the same day). Prices, pricing examples or price explanations should be given on websites, to enable customers who have Internet access to gain an understanding of these in advance of the visit.
- 13.3 There should be no objection to the customer having a relative, friend or other advisor / carer with them when the salesperson / assessor visits. In certain circumstances this should be encouraged (for example if it is known that the customer has poor eyesight or that they struggle with paperwork).
- 13.4 Salespersons must not use high pressure selling techniques, such as offering inducements to force a quick decision, or knowingly take advantage of vulnerable customers. (Examples of what might be high pressure selling tactics are listed in <a href="clause-state-sta
- 13.5 Salespersons must comply with a customer's request that they leave and no assessment or sale should normally last longer than three hours, other than in exceptional circumstances (for example, if a health services professional is present and is responsible for leading the assessment).

Distance Sales

13.6 When selling over the Internet, via mail order catalogue, or by telephone, information must be provided to the customer before they take the decision to buy, as required by, and set out in the Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013.

Rental Products

13.7 Where product is rented, the terms and conditions of the rental must be clear and unambiguous, including responsibility for any damage to the product, insurance requirements, and, where appropriate, the responsibilities for decontamination / cleaning of the product, and packaging for return.

14. Adverse Incident Reporting

14.1 Where a company becomes aware of an incident involving a product that resulted in, or could have resulted in, serious injury or death of a customer, they must report that incident to the appropriate authority - either the Health & Safety Executive (HSE), or (if it is a medical device) the Medicines & Healthcare products Regulatory Authority (MHRA). (See useful contacts.) All such incidents must also be reported to the manufacturer of the product.

15. Product Recalls and Safety Warnings

- 15.1 Each company must maintain records sufficient to identify to whom they have sold a product, to ensure it can be traced and recovered in the event of a recall for safety purposes, or given appropriate attention if a safety warning is issued necessitating preventive action. Distributors and retailers must comply with manufacturer instructions for product recalls and safety work and must act on these without delay.
- 15.2 Companies selling to agencies such as the NHS and local authorities should advise them of the need to track products, to ensure this can occur.

16. Clauses Relating to Commercial Business / Relationships

Sponsorship

16.1 Where a company sponsors part or all of the salary of a professional employed by the NHS or Social Services, they must have due regard to the employing body's rules regarding sponsorship. No pressure must be exerted on the sponsored individual to favour the sponsoring company's products over any other. At all times, the product supplied should be that which the professional considers is best suited to the client's needs.

Sub-Contractors / Third Parties

16.2 Companies must ensure any sub-contractor, third party, or person carrying out work or representation on the company's behalf upholds the same standards as required herein.

Service/Product Support

16.3 Retailers / distributors who sell into an area of the country where they cannot service / support the product themselves in a prompt and adequate manner, must have in place a third party agreement with an organisation in that area, which meets comparable standards, or there must be a return to manufacturer provision for the product concerned (ie there must be consistent support for the product / customer, whether the customer is local or geographically distant from the seller).

Manufacturers / Persons Responsible for Placing a Product on the Market in the EU

- 16.4 Companies are reminded that they must accept responsibility for the quality, performance and safety of the products they place on the market in the EU and consider whether compliance with relevant safety and testing standards is appropriate. Statements and claims on performance and safety contained in their published literature must comply with any standards they claim to meet.
- 16.5 Such companies, where registered to abide by this Code, must be able to evidence to the Code Administrator, on request, that any of their products carrying a CE mark to indicate compliance with a European Directive, do meet the essential requirements of the relevant Directive. They must be able to provide (or provide access to) a technical file for inspection.
- 16.6 Companies that manufacture and/or import medical devices should ensure spare parts are available for at least five years from date of final manufacture. For all other products, companies must be mindful of their obligation to stock spare parts for a reasonable period of time from date of final manufacture.

16.7 Companies must provide technical training, spare parts lists, and preventative maintenance schedules to anyone requesting them, providing they are satisfied that the enquirer meets any objective criteria they have set for such provision.

> Selling Training

- 16.8 Where training is booked by telephone via administrative staff, those staff must be given a checklist of the minimum information the trainer will require in order to proceed.
- Selling / Providing Services to Authorities / Agencies such as the NHS, Social Services, and the Employment Agency
- 16.9 Companies must give due respect to any codes, regulations, procedures operated by the Authority and to those adhered to by members of the health and care professionals with whom they interact.
- 16.10 They should be aware of complaints procedures in these organisations, so they can advise customers accordingly should there be a problem.
- 16.11 Due regard must be given to the Bribery Act 2010, ie care must be taken to ensure no bribe of any kind (including for example, and without limitation, a facilitation payment, a donation, or excessive hospitality or commission payments) is offered, given to, or placed upon any public servant (eg Local Authority or NHS staff member), or their employer, as an inducement to prescribe, supply, administer, recommend or buy any product or service.

Gifts in the form of promotional aids and prizes, whether related to a particular product or of general utility, may be distributed to members of the health professions and to appropriate administrative staff, provided that the gift or prize is inexpensive and relevant to the practice of their profession or employment. All activity involving sponsorship and hospitality must be considered carefully and steps be taken to ensure it is legal, relevant, proportionate and reasonable. Code members must abide by any guidance issued by the UK public sector on these matters, plus the guidelines on "Interactions with Healthcare Professionals and Healthcare Organisations" set out in Part 1 of the Medtech Europe Code of Ethical Business Practice. (If these conflict with each other, the UK guidance will take precedence for activity in the UK.)

Supply and / or dispensing of Appliances on FP10 Prescription in England and Wales or GP10 Prescription in Scotland

16.12 In addition to giving due regard to the Pharmaceutical Services Regulations and the current arrangements in each country, BHTA members involved in the supply and / or dispensing of appliances are required to abide by the Patients Industry Professionals (PIPs) Forum Collaborative Standards which complement both the service requirements and this Code of Practice; and to give due regard to BHTA's Guidance for DACs on advertisements, competitions and marketing.

17. Complaints Handling

Code Members

17.1 All Code members must have in place a speedy, responsive and user friendly procedure for the resolution of complaints, ie any expression of dissatisfaction regarding the product and / or service supplied. Code members are normally expected to resolve complaints within one calendar month.

17.2 Complainants must be informed to whom within the company they should address their complaint, what information they are required to provide, and the timescales that will apply to dealing with the complaint. These must include targets for initial acknowledgement of notification of a complaint (with advice regarding procedure to be followed in addressing it), as follows:

Telephone call indicating there is a problem – within 2 working days Letter, fax or email – within 5 working days

They must also be informed that should this process fail, they have the right to contact the Code Administrator, BHTA, who will follow the procedure outlined later in this document for conciliation and, if need be, independent arbitration.

- 17.3 Code members should offer maximum co-operation with consumer advisers or any other intermediary acting on behalf of the complainant, such as a Citizens Advice Bureau, or Trading Standards Officer.
- 17.4 Staff must be advised to be professional, courteous, prompt and fair when dealing with a complainant.

Code Administrator (BHTA)

- 17.5 When BHTA receives notification in writing of a complaint against a Code member, it will consider whether the company:
 - has infringed the complainant's legal rights
 - has been guilty of maladministration (including inefficiency or undue delay) in a way that has resulted in the complainant losing money or suffering inconvenience
 - has not complied with this Code of Practice
- 17.6 BHTA can not deal with a complaint if:
 - the complaint is against a company that is not a Code member
 - the complainant has not gone through the company's complaints process and reached stalemate
 - the complaint is being, or has been dealt with by a court, an alternative dispute resolution provider, or similar body
 - the complaint relates to a point in time prior to the company becoming a Code member

17.7 BHTA will:

- Request to see all the complainant's documentation
- Ask the company to report within 7 working days, giving as much evidence as possible
- Look for evidence of any breaches of this Code
- Attempt to settle the dispute by agreement between the two parties within 90 days

There is no charge to the complainant at any stage in the complaints conciliation or the arbitration process described below.

- 17.8 If agreement cannot be reached, the complainant has two options:
 - To take up their own independent court action
 - Referral by BHTA to the Independent Arbitrator (it should be noted that the Arbitrator's decision, to all intents and purposes, is binding)

Where referral to the Independent Arbitrator is chosen, BHTA will pass all the evidence gathered, including copies of all correspondence between the parties and BHTA, to the Independent Arbitrator within five working days. At this juncture, either party may make direct representation of further evidence to the Arbitrator.

> Independent Arbitrator

- 17.9 The objective of the Arbitrator is to arrive at a conclusion that is fair and reasonable in the circumstances, looking at all the evidence presented by both parties. The Arbitrator is an individual who is completely independent from the Code Administrator (BHTA) and from the industry. Technical expertise will be called upon for input as and when this should prove necessary. The Arbitrator's initial reaction will be notified to the parties concerned within seven working days and normally, a conclusion should be reached within fifteen working days. (If further evidence is presented by either party, this may prolong proceedings.)
- 17.10 The Arbitrator's findings (which may, for example, be that the company is not at fault or that the complainant has a valid complaint) will be issued in writing and will give a summary of the facts, the conclusions and reasons for reaching them. The Arbitrator's decision is binding on both parties.
- 17.11 Where a Code member is found to be in breach of this Code, the Independent Arbitrator may require them to do one or more of the following, depending on the circumstances:
 - repay all money paid by the complainant
 - · replace or repair the product without charge
 - pay any costs incurred by the Code Administrator and / or the Independent Arbitrator
 - take all reasonable steps, including any specified actions, to prevent a recurrence of the breach
 - pay compensation to the complainant (the amount to be decided by the Arbitrator based on the evidence and circumstances of the breach)

Each of the above should occur within 30 days, with the exception of specified actions to prevent a recurrence. For these, time limits will be determined on a case by case basis.

18. Sanctions / Disciplinary Action

- 18.1 Where an identified breach of the Code is minor, the Code Administrator will issue a warning and suggest action, if appropriate, to prevent repetition. All serious, or repeated, breaches of the Code will result in the Code Administrator calling upon the Code member concerned to appear before a Disciplinary Committee which will consist of a panel of 3 people, 1 drawn from the relevant industry sector and 2 from appropriate external organisations, with a Chairperson drawn from the external organisations. The Chairperson will have a casting vote in the event of a hung decision.
- 18.2 The nature of the breach will be identified to the Code member in writing, and they will be given the opportunity to offer any evidence in writing in advance of the hearing, which will be on a date arranged/agreed with the Code member.
- 18.3 The Committee's decision may include one or more of the following:
 - no further action be taken
 - the Code member be required to undertake a specified course of remedial action (such as re-training of a particular salesperson)
 - the Code member be issued with a formal warning

- a fine be issued, relating to the amount of work incurred by BHTA and the Independent Arbitrator regarding the complaint, the cost of the Disciplinary hearing, and/or the nature of the offence
- suspension, for a stated period, of the Code member from the register of companies signed up to the Code (and hence from BHTA)
- expulsion of the Code member from the register of companies signed up to the Code (and hence from BHTA)
- 18.4 Where expulsion occurs, a minimum period of twelve months must pass before any application to re-join the register of companies signed up to the Code, and to re-join BHTA, will be considered. If any complaints against the company have been made to BHTA during that time, such application may be rejected for a further period of time.
- 18.5 From establishing that a serious breach has occurred through to final decision of the Disciplinary Committee and instigation of any action should take no more than 90 days. A summary of the decision will be published on the BHTA website and in the weekly newsletter.

19. Monitoring

- 19.1 Every Code member selling goods and/or providing services to consumers will be monitored by at least one of the following means every 12 months (the means will vary depending on the product/service provided details can be made available on request and will be outlined in the Annual Report):
 - mystery shopping exercises
 - independent compliance audits
 - customer satisfaction survey cards

All other Code members will be monitored by independent compliance audits at least once every five years.

19.2 An Annual Report will be published, giving the results of these exercises, the number and nature of complaints received, the remedies recommended and implemented, and the results of any referrals to the Disciplinary Committee.

20. Useful Contacts (correct at December 2017)

To find an Approved Code member: https://www.tradingstandards.uk/consumers

To check the status / credentials of a health professional or individual working in the industry: Health and Care Professions Council

Tel: 0300 500 6184 or visit <u>www.hpc-uk.org</u>

Healthcare & Assistive Technology Society Tel: 020 7702 2141 or visit www.hatsoc.org

Nursing & Midwifery Council

Tel: 020 7631 7181 or visit www.nmc-uk.org

To source a product:
Disabled Living Foundation

Tel: 0300 999 0004 or visit www.dlf.org.uk

To access driving advice and assessment: Driving Mobility

Tel: 01872 672520 or visit www.drivingmobility.org.uk

For assistance relating to consumer rights:

The Citizens Advice Consumer Service

Tel: 03454 04 05 06 or visit www.citizensadvice.org.uk/consumer/

Equality and Human Rights Commission

Tel: 0808 800 0082 or visit www.equalityhumanrights.com

Disability Law Service (DLS)

Tel: 020 7791 9800 (10am-1pm then 2pm-5pm Mon-Fri) or visit www.dls.org.uk

Trading Standards

Look in your Yellow Pages under "local authority" or visit https://www.tradingstandards.uk/consumers/support-advice

To make an adverse incident report:

For medical devices: Medicines & Healthcare products Regulatory Authority (MHRA)

Tel: 020 3080 6000 (switchboard) or visit

https://www.gov.uk/report-problem-medicine-medical-device

For machinery: Health & Safety Executive

Tel: 0845 300 9923 or visit www.hse.gov.uk/riddor/index.htm

21. Pertinent Legislation

The following is not an exhaustive list of all the legislation that might apply to a given circumstance, but is a list of the legislation considered likely to be most pertinent to clauses within this Code of Practice.

<u>Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013</u>: sets out what information must be provided to the consumer, the circumstances in which they have a right to a cancellation period and related information

<u>Consumer Credit Act</u>: requires certain credit and hire agreements to be provided in writing, set out in a particular way, and to contain certain information, It provides cancellation rights for sales in the customer's home (five day cooling off period), regardless of whether the visit was pre-arranged

<u>Consumer Credit (Disclosure of Information) Regulations 2004</u>
<u>Consumer Protection from Unfair Trading Regulations 2008</u>: to ensure that traders act honestly and fairly towards their customers

<u>Consumer Rights Act 2015</u>: sets out the circumstances in which a consumer may receive a refund, repair or replacement for goods; or repeat performance for services

E-Commerce Regulations 2002: for contracts concluded electronically

Trades Descriptions Act 1968

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