

INTRODUCTION

The Code of Ethical Business Practice (“Code”) has been adopted by the Association of British Healthcare Industries (“ABHI”) to set standards for ethical behaviour and to govern ethical promotion and sales practices in the medical devices industry in the UK (“the Industry”). Complaints against the Code are administered and adjudicated by a Complaints Adjudication Committee (the “Committee”). The Committee can convene at any time as part of the complaints process, a “Complaints Panel”, if it feels that a specific complaint against the Code requires expert input and adjudication. Individual members of the “Complaints Panel” can however, be called upon at any time prior to the convening of a specific ‘Panel Hearing’.

Compliance with the Code and with this Procedure, is mandatory for members of ABHI and with companies. It also applies to those companies which, although non-members, have agreed to comply with the Code and this Procedure and the jurisdiction of the ‘Complaints Panel’. “Complaints” made under the Code include direct complaints, as well as indirect complaints made to MedTech Europe and referred to ABHI for adjudication and may also include issues raised in the media or otherwise that fall within the remit of the Code.

The ‘Committee’ and any ‘Complaints Panel’ are not investigatory bodies as such. The procedure dictates however, that they request from the company whose activities are the subject of a complaint (“respondent”), a complete response to any allegations. This may include further information to clarify any outstanding issues.

The Complaints Procedure shall not preclude complainants from having recourse to courts or other tribunals to seek resolution of complaints and any complaints made under the Code. Furthermore, this procedure should not be initiated or should be suspended in case of initiation of formal civil court proceedings with respect to the same subject matter. Where a governmental or regulatory investigation or criminal proceedings are either initiated or threatened against a Member Company with respect to the same subject matter, that company shall notify the Committee Chairman of the same in confidence, who shall then have the discretion whether or not to suspend any relevant proceedings under this procedure.

For the avoidance of doubt, all companies or individuals that wish to utilise this Complaints Procedure, shall not, save in respect of fraud, fraudulent misrepresentation, manifest error or gross negligence by the Committee (or a member thereof) in arriving at a ruling, commence legal proceedings or any analogous contentious or complaint proceedings against ABHI, the Committee, or Panel member, in respect of any loss or damage they may suffer as a consequence of any such ruling.

Reports on cases that are subject to a Committee decision are published and are available on request and on the ABHI Code of Ethical Business Practice website:
www.abhi.org.uk/code-of-ethical-business-practice

Information on cases that are resolved through mediation can be published in a summary report and/or case studies, although the names of the companies or individuals involved will not be disclosed.

Complaints about the conduct of any Member Company under the Code should be submitted to: Telephone: +44 (0)20 7960 4360, E-mail: complaints@abhi.org.uk.

GLOSSARY

‘Committee’; Chairman, Vice-Chairman and Secretariat . The Secretariat shall be represented by the Director, Regulatory and Compliance of ABHI. The Committee members shall be appointed annually by the ABHI Board.

‘Complaints Panel’; The Committee supported by selected and Board ratified experts. The experts shall have appropriate expertise in relevant industry areas and can be extended by external expert assistance as necessary. External expertise can be selected and appointed by the Committee.

DISPUTE RESOLUTION PRINCIPLES

General framework

The procedures set out below are intended to provide an effective and efficient complaint-handling process, the object of which is to ensure compliance with the Code. It is based on principles of proportionality, speed, due process, fairness and transparency.

Rulings are made on the basis that the company or individual making the complaint (“complainant”) has the burden of proving their complaint on the balance of probabilities.

Applicability of the Code

Member Companies must comply with the Code as a minimum standard when:

1. Member Companies interact with Healthcare Professionals and Healthcare Organisations registered and practising in the UK irrespective of where the activity takes place; and/or
2. Activities take place in MedTech Europe Geographic Area¹, irrespective of where Healthcare Professionals and Healthcare Organisations are registered and practicing.

¹ MedTech Europe Geographic Area includes the countries in the European Economic Area as well as those countries where MedTech Europe Member Associations are located.

STRUCTURE AND RESPONSIBILITIES

The Committee

The Committee is responsible for resolving complaints made under the Code. It may also assist in arranging for conciliation and/or mediation between companies when requested to do so.

The Committee shall consist of a Chair, Vice-Chair and ABHI Secretariat support and shall report to the ABHI Board in respect of their activities and the operation and administration of this Complaints Procedure.

Committee members are appointed annually by the ABHI Board, although there is no limit on the length of time that the Chairman and Vice-Chairman may serve in their respective capacities.

The Complaints Panel

The Committee shall identify a number of individuals who can be called upon in the event that a Complaint cannot be resolved by the Committee alone. The individuals shall have relevant industry and healthcare experience and who have expertise for assessing complaints under the Code. This group of individuals shall constitute the 'Complaints Panel'.

The Complaints Panel shall be ratified annually by the ABHI Board, with the names of the members of the Committee and Complaints Panel being published on the ABHI website. There is no limit on the length of time that the Complaints Panel members may serve in their respective capacities.

The Complaints Panel may solicit and obtain additional expert assistance in any relevant field, depending on the specific complaint. This additional expert assistance is determined and appointed by the Committee. External expert advisers who are consulted may be invited to attend a meeting of the Complaints Panel but have no voting rights. Each such expert shall also be required to confirm that they have no conflict of interest in providing expert assistance on any particular case.

General Provisions

All Committee, Panel members and additional experts, shall sign a declaration of confidentiality and independence on their appointment, confirming that they have no conflict of interest in adjudicating on a particular complaint.

COMPLAINTS PROCEDURE

Activities 'pre-complaint submission'

Prior to lodging a formal complaint against a Member Company under this Procedure, the complainant shall first attempt a genuine conciliation with that company, in an attempt to reach an amicable solution.

For complaints between Member Companies, such a genuine attempt at mediation shall be documented and considered a pre-condition of submission. The complainant shall therefore provide sufficient evidence to the Committee to prove such genuine attempts at conciliation have been made.

Any *individual* wishing to make a complaint against a Member Company utilising this Complaints procedure must initially attempt to resolve the complaint utilising that company's internal or external whistleblowing and/or dispute resolution procedures. If, in either case however, no amicable resolution of the complaint can be reached through such means, within a reasonable time frame, the complainant shall be entitled to pursue the matter further directly via this procedure.

Any *individual* or *company* making a complaint under this procedure that is a *non-member* Company of ABHI, shall be required in writing and as a precondition (in the case of a company for a minimum of 18 months, and in the case of an individual for the duration of the procedure), to undertake to abide by the provisions of the Code and of this procedure.

If a complaint is received about a company other than a Member Company, such company will be invited to agree to comply with the Code and accept the jurisdiction of the Committee. In the absence of such agreement however, the complaint will not be accepted for adjudication using this procedure.

Notwithstanding the foregoing, where a complaint is brought in respect of activities undertaken or instigated by a Member Company's parent or other affiliated company which is not itself an Member Company, the Member Company will be deemed as the respondent company for the purposes of this procedure and the complaint will proceed accordingly.

Complaints Procedure

When the Chairman of the Committee receives information from which it appears that a Member Company may have contravened the Code, the Chairman of the Committee shall undertake an initial review of the complaint and will determine (if appropriate, in consultation with the Committee, complainant and/or respondent) whether there is a *prima facie* case to answer.

If, in the view of the Chairman of the Committee, a complaint does not show that there may have been a *prima facie* breach of the Code, the complainant shall be so advised. If the complainant does not accept that view, the following paragraphs of this Section shall apply.

In the event that the Chairman of the Committee determines that there is either a *prima facie* case to answer, or the complainant insists that the complaint is referred for adjudication, the Chairman shall write to the managing director or chief executive or

equivalent, of the Member Company against whom the complaint has been made requesting that it provide a complete response to the matters of complaint.

The respondent company shall provide such a response in writing to the Chairman of the Committee within no more than 20 working days. If no such response is provided by the respondent company within these timescales, the Committee shall make its adjudication on the basis of the information provided by the complainant only.

Following receipt by the Committee Chairman of the respondent company's response, the case shall be referred to the Committee to determine whether or not there has been a breach of the Code.

To assist companies in ensuring that a complete response is submitted, the Committee Chairman may suggest relevant supporting material to be supplied, although it is the responsibility of the respondent to ensure that a full response is submitted. In addition, the Committee Chairman may request (whether at the suggestion of the complainant or respondent or at the behest of the Committee) such further clarifications or documents from either the complainant or respondent within such reasonable timescales as he shall deem prudent and necessary to assist the Committee in making its determination.

As an alternative to proceeding directly to the Committee, the Committee Chairman may offer to facilitate a time-limited mediation between the parties. Such mediation shall be limited to no more than six working weeks but may be extended at the Committee Chairman's discretion.

If the complaint cannot be resolved by conciliation, mediation or by Committee ruling, the Committee Chairman shall convene a Panel, composed of the Committee and appropriate members of the complaints panel and, if necessary, external experts.

Both parties shall make every effort to ensure that relevant personnel are available to participate in the process as and when they are required.

If the complainant is not an Member Company, the Committee Chairman shall suggest the paragraphs of the Code to be addressed, however when the complaint is from an Member Company, the complaint must be signed or authorised in writing by the company's managing director or chief executive or equivalent and must state those paragraphs of the Code which are alleged to have been breached.

Unless the information is disclosed in the complaint, any complainant other than an Member Company will be asked to confirm in writing whether or not they have any commercial, financial or other interest in the matter of complaint or in the company concerned. This can include for example, whether the complainant is an employee or ex-employee, a consultant or ex-consultant. Adjudication of a complaint without this written confirmation will not be permitted to proceed. Such interests will be disclosed to the respondent company and will normally be included in the case report.

When an Member Company advises the Committee Chairman or Committee itself that it may have breached the Code, the Committee Chairman shall treat the matter as a complaint if it relates to a potential breach of the Code or if the company fails to take appropriate action to address the matter. The company's response is invited and the complaints procedure shall be followed.

Alignment with the MedTech Europe Code

In so far as the ABHI Code and MedTech Europe Codes align, at any time during a complaint handling process the Committee Chairman or the “expanded panel” shall be entitled to refer questions of interpretation of the Code in writing, to the MedTech Europe Compliance Panel.

The MedTech Europe Compliance Panel may at its discretion either decline to entertain the matter if it is felt that no question of principle is at issue or accept the interpretation referral, and review and provide guidance on the interpretation of the Code.

Where such a request has been made, the Committee Chairman and the “expanded panel” should consider following and applying any such guidance provided by MedTech Europe unless so doing would conflict with UK law. For the avoidance of doubt MedTech Europe shall not rule on the merits or facts of any particular complaint but only on questions of interpretation of the Code.

Administrative Fees

In addition to the procedural aspects of this section, both parties will be liable to an administrative fee of £500 each, payable on acceptance of the Complaint by the Committee Chairman. Any further legal costs deemed necessary during the procedure shall be notified to the complainant and respondent prior to being used, with those costs payable by Complainant or Respondent depending on outcomes. The parties shall agree at the outset to the terms of mediation and the costs incurred in running the process.

Complaints Arising from Media Criticism

If it appears to the Committee Chairman from media reports, that a Member Company may have breached the Code, the Committee Chairman may, at his discretion, treat such reports as a complaint. This procedure shall be invoked, if it relates to a potential breach of the Code or if the company fails to take appropriate action to address the matter.

The author or editor (as Member) of the relevant media report may be asked if they want to be involved in the case and whether they have any additional information to submit. If the editor or author declines involvement, this is stated in the case report.

A published letter from which it appears that a Member Company may have breached the Code may also at the discretion of the Committee Chairman be treated as a complaint.

Committee and Panel Rulings

Where either the Committee or Panel rules that there is a breach of the Code, the complainant and the respondent shall be advised by the Committee Chairman of such, in writing, of the reasons for the decision. Any decision of the Complaints Panel shall be final, and there shall be no appeals procedure against any rulings.

The respondent company has no more than 20 working days to provide a written undertaking that either;

1. The activity in question (if not already discontinued) will cease forthwith and that all possible steps will be taken to avoid a similar breach of the Code in the future. This undertaking must be signed by the managing director or chief executive or equivalent of the company and must be accompanied by details of the actions taken by the company to implement the undertaking, including dates and timings and training undertaken.

2. That in their opinion, the activity is in compliance with the Code. In this instance, the respondent will provide appropriate evidence to this fact.

In extenuating circumstances, an extension in the time allowed in which to respond may be granted at the discretion of the Committee Chairman.

The respondent company must also pay within twenty working days an administrative charge based on the cost of convening the Committee or Panel and dealing with the complaint as determined by the Committee Chairman.

Where the Committee or Panel rules that there is no breach of the Code, the Committee or Panel shall advise the complainant and the respondent of such in writing and give their reasons for the decision. Where the complaint is from an Member Company, the complainant must pay within twenty working days an administrative charge based on the cost of convening the Committee or Panel and dealing with the complaint as determined by the Committee Chairman.

In addition to the foregoing, the Committee or Panel may impose additional or alternative sanctions on either of the respondent company (in the event of its breach of the Code) or complainant company (in the event of no breach of the Code) as appropriate in respect of any particular complaint. In particular, the Committee or Panel may:

1. Require the relevant company to publish any communication required by the Committee or Panel, including but not limited to explanatory information or statements of future intent or policy;
2. Issue a formal reprimand;
3. Recommend to the ABHI Board to suspend the offender from membership of ABHI for a specified period and impose conditions on readmission;
4. Recommend to the ABHI Board to expel the offender from ABHI;
5. Set time-limits for compliance with any sanction imposed or order made by the Panel in addition to those specified in paragraphs;
6. Order that either party pay the costs of the Panel, in whole or part, having regard to a standard scale published by ABHI and any other matters considered appropriate;
7. Provide for further sanctions in the event of further breaches of or non-compliance with the Code or any order, sanction or requirement of the Panel (including time limits), with or without the right to make further representations before such further sanctions are to take effect.

Case Reports

At the conclusion of any case under the Code, the Committee or Panel shall advise the complainant and the respondent of the outcome and a report shall be published summarising the details of the case.

In a case where the complaint was initiated by an individual, other than in those circumstances where an anonymous or confidential complaint is accepted for adjudication, that individual shall be named in the report. In a case where the complaint was initiated by a company or by an organisation or official body, that company or organisation or official body shall be named in the report.

The respondent company and the product(s) concerned will usually be named in the report

unless the Committee Chairman in his discretion deems this inappropriate. Any information given must not, however, be such as to identify any individual person within such company, organisation or official body.

Where expert assistance has been obtained by the Panel, the report will include the name and qualifications of the expert concerned.

Where guidance has been sought from MedTech Europe, the question raised by the Committee Chairman or the Panel and the guidance received from MedTech Europe shall be included in the report.

Where a company has been required to issue a statement of its corrective actions, the report will reproduce its text and provide details of how the corrective actions statement was disseminated.

A copy of the report on a case is made available to both the complainant and the respondent company prior to publication. Any amendments to the report suggested by these parties are considered by the Committee Chairman, consulting with the other party where appropriate. The Committee Chairman's decision is final.

Full case reports will appear on a specified section of the ABHI Code of Ethical Business Practice website. Access to the relevant section of the relevant ABHI website referring to cases or decisions is unrestricted.

GENERAL PROVISIONS RELATING TO THE PROCEDURE

Amendments to Time Periods

The Chairman shall, in extenuating circumstances and at his discretion, be entitled to grant any party to this Procedure an extension in time or amend any timescales specified in this Procedure to the extent that to do so would be fair and reasonable in the circumstances.

Withdrawal of Complaints

A complaint may be withdrawn by a complainant with the consent of the respondent company up until such time as the respondent company's comments on the complaint have been received by the Chairman, but not thereafter. In either case, the complainant shall pay an appropriate administrative charge.

Charges

The administrative charges referred to in this procedure are determined by the Chairman based on the costs of formally convening the Panel and in dealing with the complaint. Administrative charges are payable only by Member Companies, and these companies are liable for such charges whether they are members of the ABHI or not.

Where two or more companies are ruled in breach of the Code in relation to a matter involving a joint activity, each company shall be separately liable to pay any administrative charge which is payable.

Failure to pay any of the administrative charges provided for in this procedure must be reported by the Chairman or the Panel, to the ABHI Board. In such circumstances, the

Panel shall be entitled to impose or recommend such further sanctions as it deems appropriate, including (but not limited to) those referred to previously.

Anonymity and Confidentiality

Any complainant or respondent shall be entitled to request that any document or information provided to the Panel or Chairman pursuant to this Procedure is not disclosed further on the grounds of confidentiality, in particular to either the complainant or respondent as the case may be or in any case report. The Chairman shall decide with his discretion whether to grant such request, in particular taking into account the ability of either the complainant or the respondent to respond.