

**BTS AND BIOMEDICAL INDUSTRIES POLICY: JOINT WORKING AND FUNDING RELATIONSHIPS
2018**

1. BACKGROUND

1.1 Patients with respiratory disease have benefited from drug innovations and improvements in delivery devices and equipment over the last few decades, and new and better drugs are needed to improve respiratory morbidity and mortality. The combination of a strong and successful biomedical industry and first class clinical research units in the UK has led to important therapeutic advances. It is therefore in the best interest of the patient that opportunities for collaboration with industry are taken where there is the potential for improved healthcare. The British Thoracic Society (BTS) and the biomedical industry (pharmaceutical and devices and equipment companies) share certain goals, but their roles and responsibilities are different and subject to different pressures. BTS has a responsibility to ensure that patients receive the best independent advice so that they may make their own decisions about their health. The biomedical industry has the burden of substantial development costs as well as responsibilities to employees and shareholders that have to be met by sales of their products.

1.2 Commercial sponsorship and collaboration with industry can be of great benefit to research and education. It is important that this is not provided or accepted at the expense of compromising the professional independence of the Society and its members, and its responsibility to safeguard the interests of patients. This policy document aims to reflect the view of the majority of members of BTS on how best to maximise the benefits available to both patients and members without introducing compromise. There will inevitably be sincerely held differences of opinion on some of the more sensitive issues but this should not stop BTS from stating its position. The BTS Board of Trustees reviews this policy annually, assisted by BTS Council, which comprises elected members. The policy may be amended and added to following discussion, debate and review of the latest guidance from other sources such as the Royal Colleges of Physicians, Departments of Health and other relevant bodies. The review in the autumn of 2017 took account of issues relating to the changing clinical service delivery environment, implications for patients and how to address breaches of this policy by members, inter alia.

1.3 In the last decade there have been reviews and recommendations about collaboration with industry that have produced clearer guidance on what is appropriate to ensure the UK utilises the opportunities provided. Active collaboration is encouraged. Recommendations have been produced following a Royal College of Physicians of London Working Party¹ and the Department of Health have produced guidance on Joint Working and a toolkit^{2,3}.

2. SCOPE

2.1 This policy document covers matters that concern the Society directly such as Guideline Groups Committees and BTS conferences including invited speakers. It also covers areas that are more relevant to BTS members in their workplaces, rather than their engagement with the business of the Society – for example, in the way in which research is funded and carried out. Individual issues here can be complex so the guidance in those sections is more general, aiming to raise awareness and highlight general principles rather than attempting to cover all eventualities. The main purpose of this document is to highlight those areas in which the Society seeks to ensure probity and transparency in relation to the work that is undertaken on its behalf by members and staff.

2.2 As far as BTS members are concerned, the main links are with pharmaceutical and devices industries, but the same principles hold for other commercial links, e.g. with medical instrument manufacturers, companies offering consultancies, referral management, contract management, product development, data management and telehealth, and for members providing these services as Directors of Limited Companies.

2.3 The document covers the following areas:

- general principles
- joint working
- involvement of the biomedical industry in the production and dissemination of Guidelines
- commercial support for educational activities
- industry-funded research
- industry sponsored respiratory nurses and clinical assistant sessions by staff working in the pharmaceutical industry
- BTS sponsorship or support for external documents, websites
- membership of BTS Committees or Specialist Advisory Groups (SAGs) by industry personnel
- breaches and potential sanctions
- implications for patients

2.4 All members of the BTS Board of Trustees, all Committees and sub-Committees, Guideline Groups, Steering Committees, Working Parties and Specialist Advisory Groups, as well as members of BTS staff with responsibility for financial matters and procurement are required to declare commercial interests each year. Speakers at BTS conferences and short courses must also provide a list of commercial and/or related interests which will be made available to all delegates and on the BTS website.

2.5 The content of this document applies to BTS members and staff and associates acting on behalf of the Society. BTS also expects non-members working with the Society to adhere to the principles, views and recommendations as outlined in this document.

3. GENERAL PRINCIPLES

3.1 BTS is a charitable professional organisation, open to public scrutiny. This being the case, all its activities must be free from commercial or personal interests, particularly in relationship to respiratory strategy and Guidelines.

3.2 BTS subscribes to the three crucial public service values which underpin the work of the health service. These are accountability, probity and openness².

3.3 ***Declaration of Interests (DoIs).*** To ensure adherence to this policy, the Society asks all concerned to complete an annual on-line Declaration of Interests return. The Honorary Secretary will review each submission annually and will discuss any potential concerns with the Chair(s) of the relevant Committee(s), and, if necessary, with senior BTS Officers and the Board of Trustees. At the beginning of all BTS Committee and other meetings the declared commercial and remunerated interests of all members should be readily available and should be reviewed before the start of the meeting by the Chair of that Committee or Group. This will be the first standing item on the agenda of all meetings. The Chair will ask that all Committee members have completed a submission and will request declaration of any additional interests, which should be recorded in the minutes of that meeting, and added as soon as possible to the on-line records, if this has not already taken place.

3.4 “Interests” include shares, paid consultancies and directorships, travel and accommodation expenses, paid memberships of speakers panels or advisory boards, commercial sponsorship for the member and for the people for whom they are responsible, e.g. Research Fellows, and support for research within their Department including equipment, writing or administrative support. In the case of uncertainty the interest should be declared. If any conflict is considered to exist then the inclusion of the Committee member will be at the Chair’s discretion and should be recorded. For any departure from this policy the Chair will write a short paragraph of explanation for the issue to be discussed at the BTS Board of Trustees.

3.5 In this document, ‘shares’ refers to any shares in the biomedical industry, excluding Unit Trusts, and it refers to shares held by a member or a close family member. A consultancy refers to a paid retainer or agreement between a BTS member and a company with respect of one drug or device, or more generally, usually with a contract for a specific period of time. Consultancy will include ongoing attendance at Advisory Board meetings but would not normally include a situation where an individual is paid for a specific item or for attending or speaking at an occasional meeting. If there is any doubt advice should be sought from the Honorary Secretary or Chief Executive

3.6 Membership of the Society or any of its Committees and Groups is not open to persons who are or have been full or part-time employees of, or paid consultants to, the tobacco industry, or who have received sponsorship or payment in kind from the tobacco industry, at any time during the previous 10 years.

4. JOINT WORKING

4.1 'Joint working' applied to the NHS has been defined by the Department of Health as 'Situations where, for the benefit of patients, organisations pool skills, experience and/or resources for the joint development and implementation of patient-centred projects and share a commitment to successful delivery.'² Joint working is encouraged by BTS and should be mutually beneficial to BTS and industry, but with the principal beneficiary being the patient. Joint working should be conducted in an open and transparent manner. This means that the details of the arrangement are freely available and the rationale for the arrangement are clearly stated. The length of the arrangement, the potential implications for patients and the NHS, along with the perceived benefits for all parties should be clearly outlined before entering any agreement. Where there are reasons to enter into an agreement with confidential components, the reasons for this must be clearly stated. Joint working is distinct from sponsorship, where industry simply provides resources. BTS will apply the principles applied to joint working in all its activities with industry^{2,3}.

5. SINGLE COMPANY FUNDING

5.1 Funding provided in large amounts or repeatedly by only one funder needs to be closely monitored to ensure that the balance of benefit (or projected benefit) is in favour of healthcare. ***BTS will not usually work with sole funders*** and will certainly not sanction single company funding where this monitoring does not occur.

5.2 More broadly, there may be situations where a single organisation provides large or repeated funds for a recipient. In this circumstance it is important that the principles of joint working are applied. The benefits to healthcare should be clearly defined and should outweigh the benefits to funder and recipient. Recipients may be individuals, groups in receipt of project grants, and large centres. Some joint initiatives may have longer term benefits to patients that are difficult to quantify as there may be considerable uncertainty about the outcomes of research. Agreements with biotechnology or venture capital organisations will often have benefits that depend on the success of the project and this is potentially an excellent way to make advances that translate to improved healthcare. In these circumstances, the potential benefits to all parties should be set out to ensure that the balance is in favour of patients. It is unlikely that BTS, as a charitable organisation covering such a wide spectrum of disease, could enter into a single company funding agreement.

6. PRODUCTION AND DISSEMINATION OF GUIDELINES, QUALITY STANDARDS AND CLINICAL STATEMENTS*

6.1 The public has the right to expect that Guidelines and other clinical statements and recommendations produced by a professional Society have been produced in the best interest of the public and patients. For some Guidelines, e.g. for asthma, almost everyone involved in producing the Guidelines will have had some association with the pharmaceutical industry in one way or another, though nearly always with different companies and with no particular

reason to favour any one drug in particular. This may not always be the case, however, and BTS has to ensure that the decisions made by Guidelines Groups, and those producing Clinical Statements and Quality Standards are as independent as possible. The validity of Guidelines and other clinical statements relies on reasonable steps being taken to ensure their integrity.

6.2 BTS guidance is produced by Guideline Groups selected and approved by the BTS Standards of Care Committee. The work of Guideline Groups is supported by BTS Head Office staff. The BTS Guideline production process is accredited by NICE and more detail is included in the BTS Guideline Manual (2016) which is available to view on-line. The Society does not seek and will not accept external funding for the production of any of its clinical guidance (which now also includes Quality Standards and Clinical Statements as well as Guidelines).

6.3 Chairs of Guideline Groups should not have shares in a biomedical company or be retained as a consultant with a company. Before appointment their current and recent (3 years) involvement with commercial organisations will be reviewed by the Chair of the Standards of Care Committee and the Honorary Secretary to ensure that there are no grounds to expect a conflict of interest. All information should be recorded and freely available to all members of the Guideline Group to ensure openness and transparency. Copies of DoI returns for group members will be kept on file at BTS Head Office for the duration of the work of the Guideline Group (and then for the subsequent period of time that the Guideline remains valid).

6.4 All members of Guideline Groups should declare all commercial interests and remuneration from the biomedical industry when approached to be on the Group and on an annual basis for the duration of the work of the Guideline group via the on-line Declaration of Interest submission. Guideline Group members will be invited to update their declarations on a regular basis and at the beginning of any formal committee meeting when requested by the Chair. The declaration forms should be available on the table for Group meetings and interests may be noted within the published Guideline in line with Thorax publication requirements. Interests should include shares and consultancies, commercial sponsorship for the member and for the people for whom they are responsible, e.g. Research Fellows, and support for research within their Department. In the case of uncertainty the interest should be declared.

6.5 Members of any Guideline Groups who have shares or a general consultancy agreement with a biomedical company should not normally take part in discussions about any product from that company, or a main competitor, and should leave the room when such discussions occur. Members receiving a consultancy retainer for a specific product should leave the room when that product or a direct competitor is being discussed.

6.6 The biomedical industry should not in any way finance or be involved in any aspect of developing Guidelines, for example by collecting, reviewing or accessing the literature or determining the content of Guidelines.

6.7 Discussions about Guidelines may lead to commercial sensitivities and should be confidential until such times as they are discussed in open meetings, and subject to a confidentiality agreement (see Appendices 1 and 2 for Code of Practice and confidentiality agreement).

6.8 When Guidelines are in a near final form they are often discussed at an open meeting with a wider professional group. Biomedical company support for such a meeting is not acceptable. The same principles apply when a draft Guideline is made available for public consultation on the BTS website. Members with an interest in the biomedical industry should declare that interest when they return their comments.

6.9 A statement should be included in each Guideline when published to confirm that the Guideline Group members adhered to this BTS policy and provided the required Declaration(s) of Interests, and where appropriate specific interests should be declared. An example of such a statement is “All members of the Guideline Group made declarations of interest in line with BTS policy and further details can be obtained on request from BTS.”

6.10 There may be opportunities for the involvement of biomedical industry after Guidelines have been published. Unconditional educational grants to allow dissemination of completed Guidelines, non-promotional educational material, support for publications etc. may be considered acceptable. The Society’s policy is always for this to involve several companies. Areas of mutual benefit should be discussed and documented for review by the BTS Board of Trustees, which will be the final arbiter and will approve all such proposals.

**NB- all of the above statements (6.1-6.10) apply equally to members of Groups producing Quality Standards and Clinical Statements.*

7. COMMERCIAL SUPPORT FOR EDUCATIONAL ACTIVITIES:

i.e. BTS Summer and Winter Meetings, short courses educational materials, and attendance at scientific meetings.

7.1 *BTS Summer and Winter Meetings, short courses and e-learning*

Pharmaceutical and devices/equipment companies support the BTS Summer and Winter Meetings and short courses in several ways, usually by paying to have exhibition space at the Winter & Summer Meetings (thereby reducing the costs for participants) or by providing equipment for short courses.

7.2 Support for the BTS Summer and Winter Meetings and short courses is welcome. This usually takes the form of exhibiting at the Meetings, with the fees being used to reduce delegate fees. **BTS does not allow sponsored symposia at its Summer and Winter Meetings.**

7.4 *Individual sponsorship to attend scientific meetings*

Although the situation is changing significantly in this regard, a number of people are still able to attend meetings of the American Thoracic Society, the European Respiratory Society and the BTS Winter Meeting as a result of commercial sponsorship. This is valuable to the recipient and the benefit from attending the Meetings should translate into benefits to the recipient that will, in the longer term, benefit patients. Companies which provide such

support often host satellite meetings or symposia. These must never be advertised in a way that they are part of the BTS event. It should not be expected that the individual must attend these if other alternative events are taking place, and companies should be aware of this. Any expectations should be clearly stated to the recipient and the recipient should declare that they have accepted these to ensure transparency of the agreement.

7.5 BTS recognises the value that members gain from commercial sponsorship for national and international meetings.

7.6 All hospitality offered to and accepted by members should conform to ABPI guidelines⁵

7.7 The Chair of the BTS Board (and on some occasions, other Honorary Officers – i.e. Treasurer or Secretary) may need to attend scientific meetings (such as ERS) to undertake BTS duties, both formally and informally. Where this is necessary, BTS will provide funding (travel, accommodation and subsistence and registration fee in line with BTS policy for expenses) for attendance by the Chair (or other Honorary Officer, if attending as a deputy for the Chair) at up to two international meetings per year.

7.8 More generally, individuals must consider whether having financial support to attend a meeting could compromise their position in any way. A useful maxim for members is always to ask themselves whether they would be happy for their patients, employers or the local press to witness the hospitality being received. This would be particularly relevant to meetings that were targeted by a company to discuss or launch an individual drug. In these circumstances there should be a documented assessment of the benefits to both parties and how this is beneficial to improved healthcare. A copy of this should be sent to the Society's Honorary Secretary who will consult with the BTS Officers' Group in the event of any concerns.

7.9 Hospitality and travel arrangements should not exceed that which the individual themselves or their employer would reasonably fund.

7.10 Recipients of such sponsorship must register any such support (via the Declaration of Interest process) if they are on any BTS Committee, sub-Committee, Guideline Group, Quality Standards Group, Clinical Statements group, Steering Committee, Working Party, Specialist Advisory Committee or any other group.

7.11 BTS encourages industry to include BTS members with interests in all sub-specialties and all healthcare professions when providing sponsorship for attending meetings.

7.12 Biomedical companies should provide a documented indication of any expected attendance at company sponsored events to allow recipients to assess if their position has been compromised.

7.13 ***Commercial Support for Educational Materials***

Biomedical companies sometimes provide financial support for educational material, which is produced independently/ not relating to BTS by BTS members. There is a risk, however, that the content of the educational material has been influenced by the biomedical company whilst appearing to be independent.

7.14 Some biomedical companies and writing companies have offered to ghost write chapters or reviews (i.e. writing the document with the intention of attaching the name of a BTS member who has not written the document) or to provide a first draft of an article which would then be published as if written by a BTS member and would appear to be the independent work of that member. This can be seen as an easy way to get a publication for people who are not good writers or are very busy and is often paid very lucratively. This practice has been the subject of litigation in the United States. BTS members should not allow their name to be attached to any review, overview, chapter etc that they have not written themselves and should resist offers of help in the form of first drafts or collation of references.

7.15 Educational material produced by BTS and its partner organisations, including web-based educational tools, might be attractive to commercial organisations in terms of sponsorship opportunities. The same principles should apply to educational material as for all other published material. It is essential that the content should be free of bias and independently created by BTS members. Educational material attributed to BTS members should have been produced independently. Any input from a company must be transparent and clearly stated. It is not acceptable for material that has been influenced by a biomedical company to appear to be independent.

7.16 Where journal supplements and journals are supported by company sponsorship the role played by the company should be clear and unambiguous.

7.17 Any sponsorship of educational materials should be in the form of an unconditional educational grant, ideally provided by a Consortium of companies.

8. INDUSTRY-FUNDED RESEARCH

NB – BTS does not engage in respiratory research. This section is intended to advise BTS members who are engaged in industry funded research about the Society's views relating to proper conduct.

8.1 The biomedical industry carries out clinical research with the help of individuals who may be BTS members and provides financial support for research in a variety of ways.

8.2 A company may provide support for a research project that a Research Fellow and/or supervisor have designed because the company is interested in the scientific question being addressed. Such an arrangement is unlikely to cause problems as long as the initial agreement is clear with respect to finance, intellectual property rights and publication strategy. Companies often wish to see manuscripts prior to publication which is reasonable; they should not be able to veto publication or insist on changes to a manuscript.

8.3 Members may take part in multi-centre studies, designed and organised by a biomedical company, and there are a range of approaches in between this and direct support as in 8.2. A Research Fellow may be asked to help with such a study and some involvement can be useful. In some instances, research fellows are encouraged to piggyback their own

study on to a multi-centre study and here there are certain pitfalls. It is unusual for a study designed specifically for one purpose to be suitable for a second study. The Research Fellow needs to be reassured that there will be a sufficient number of patients for his/her own study, that the add-on study can be designed to answer the question and that they have full access to the data for their study and can analyse it independently.

8.4 Biomedical studies may involve a substantial amount of money and the pressures to achieve results within a given time may be larger than in other situations. This can cause undue and sometimes unacceptable pressures to be put on clinicians and scientists. Commitments with respect to recruitment and time scales need to be realistic.

8.5 At an early stage of product development there may be the opportunity for one or more biomedical companies to work with (usually academic) BTS members to ensure that product development is following the path that is most likely to lead to clinically relevant products. Such associations at the “pre-competitive stage” can lead to the development of whole classes of products (usually pharmaceutical agents) that are then developed further by companies either jointly or in direct competition. At the pre-competitive stage the benefits to medicine are likely to be much less influenced by the commercial pressures and so these associations are to be encouraged. There may be further benefits to medicine from these associations e.g. Biomedical Research Units. It may be helpful, therefore to identify where joint working is at the pre-competitive stage and where this ends.

8.6 Joint-working arrangements may require that some aspects of the research are subject to confidentiality agreements. This is to protect innovative approaches so that companies and individuals benefit from them. Confidentiality agreements should not extend to details of funding or remuneration and should only include those pertaining to the research. If confidentiality agreements the reason for them should be stated.

8.7 All research, whether funded by the biomedical industry or not, should be carried out to the highest standard. Research that is not of the highest quality may give misleading information, which can have deleterious effects on patient care.

8.8 The distinction between the pre-competitive stage and later stages of product development should be considered when entering into joint-working arrangements.

8.9 Biomedically-funded research should adhere to the ABPI guidelines.^{4,5}

8.10 If Research Fellows are to be trained in research methods they need to be involved in all stages of the study design and must be in a position to analyse the data of their own study independently.

8.11 Unreasonable pressure to achieve results leads to poor quality work and increases the chances of research misconduct. Junior research workers can feel unsupported when this occurs, despite the existence of workplace “Whistleblowing” policies. BTS would encourage junior research workers who are members of BTS to find themselves under undue pressure to discuss this with their supervisor initially and if the situation does not improve they should inform the appropriate authorities, whether university, trust or appropriate professional body

or college⁶. Failure to do this when misconduct occurs may mean that the research worker is seen as implicated in the misconduct. Anyone finding themselves in such a situation should try to resolve the problem locally but if that proves not to be possible they should contact the Honorary Secretary of BTS or their Medical Protection Society.

8.12 Confidentiality agreements should not extend to details of funding or remunerations and the reasons that they are necessary should be stated.

9. INDUSTRY SPONSORED RESPIRATORY NURSES AND CLINICAL ASSISTANT SESSIONS BY DOCTORS WORKING IN THE BIOMEDICAL INDUSTRY

9.1 Industry Sponsored Nurses

The biomedical industry has provided financial support for nurses in hospital and in general practice, often in the form of pump-priming. In other situations a nurse employed by a pharmaceutical company may help in some way, *e.g.* in a regular clinic slot. In some of these positions the nurse is in a position to alter the drugs prescribed. The concern, particularly in the latter situation, is that prescribing will be distorted and there is evidence to show a shift towards prescribing drugs produced by the sponsoring company.

9.2 The Royal College of Nursing⁷ suggests that the following questions should be asked when a sponsorship proposal is being considered:

- Does the proposed contract have implications for patient confidentiality and freedom of choice?
- Will the contract compromise or restrict the nurse's clinical judgement?
- Have the views of the post-holder, his/her professional organisation/trade union and the statutory body been sought? The UKCC, for example, does not allow nurses to wear uniform which would draw attention to the sponsorship.
- What benefit will the sponsor receive through entering into such contracts – for example, access to statistics on patient numbers or products or services used, and who will take responsibility for agreeing to such requirements and for collating and disclosing such information to the sponsor?
- What contact will the sponsor expect to have with the post-holder?
- What evidence is there that the commercial sponsor will maintain the sponsorship arrangement and that continuity of care and a quality service is ensured?
- In the event of a sponsor withdrawing from or not maintaining the contract, can the service be maintained, and if not, what arrangements will have to be made to safeguard the service to patients?
- How much experience of the service concerned does the commercial sponsor have?

Recently the RCN have reinforced this guidance in connection with the 2011 Bribery Act⁸.

9.3 Patients have a right to independent advice about treatment that is not influenced by a sponsoring company.

9.4 BTS endorses the approach taken by the Royal College of Nursing and in the Department of Health's best practice guidance on joint working^{3,4,7}.

9.5 BTS has particular reservations about nurses who are in a position to alter medication whilst employed by a pharmaceutical company and recommends that every effort is made to ensure that the nurse's clinical judgement is not restricted or compromised.

9.6 ***Clinical sessions by doctors working in industry***

Doctors in the biomedical industry may do some clinical work, usually an outpatient session, to maintain their clinical skills. The same general considerations apply as for industry-sponsored nurses and similar questions to those above need to be asked.

9.7 It is the responsibility of the doctor from industry and the doctor responsible for the clinical service to ensure that clinical practice is not compromised by this arrangement, particularly in relation to prescribing.

9.8 There should be documentation of the expected benefits to the industry, NHS and patient.

10. BTS SPONSORSHIP AND/OR ENDORSEMENT OF THIRD PARTY DOCUMENTS, ACTIVITIES, GUIDELINES AND WEBSITES

10.1 BTS is sometimes asked to be linked with or to endorse documents or Guidelines produced by commercial companies and/or other bodies. It is also sometimes asked to set up web links to patient information services including some that are sponsored by a pharmaceutical company. In many instances the documents or web sites cover areas of which the Society is generally supportive. BTS has to be cautious, however, since by providing support it may give tacit approval to parts of the document or website with which it is not comfortable and which, in a worst-case scenario, could have medico-legal or financial consequences. This is an area which will need to be reviewed each year to see if this guidance needs to be changed in this fast moving field.

10.2 BTS does not advertise meetings and courses that have commercial sponsorship and does not supply address labels to external organisations for advertising purposes.

10.3 BTS will only consider involvement in externally-sponsored documents or Guidelines if it is fully involved from the outset of the project and is fully engaged in the development of Guidelines. The BTS Guideline Development Manual (2016)¹⁰ provides detailed information in relation to BTS involvement in external Guidelines.

10.4 BTS will not normally choose to endorse Guidelines other than those in which it has been actively involved throughout the production process. When considering whether it should be involved in the production of other Guidelines, the same criteria with respect to the

involvement of the biomedical industry in the production and dissemination of the Guidelines would apply as for BTS Guidelines.

10.5 Links to other websites that may contain information on industry, or those that are supported by industry will not be included on the BTS website. No industry-sponsored information will be featured on the BTS website. Links to patient information services on other websites are only agreed if they are non-promotional and are not sponsored by industry. The BTS website has a disclaimer which states that BTS is not responsible for content of sites external to BTS.

10.6 The decision to include other links not specified in this guidance, or if there is uncertainty, should be first discussed with the Chair of the Board of Trustees or a deputy, who may wish to ask advice from SAG Chairs.

10.7 Links should be reviewed on a yearly basis to confirm that content still complies with 10.5 above.

11. MEMBERSHIP OF BTS COMMITTEES OR SAGS BY INDUSTRY PERSONNEL

11.1 There are certain Committees and/or SAGs which may need to consult with industrial partners e.g. sleep, because of the importance of the interaction with companies that supply mechanical support devices. In addition, the increased opportunities for healthcare professionals in commercial organisations may lead to changes in status for existing Committee members. If a member of a BTS Committee or Group moves to working for a biomedical industry after their appointment, they will be asked to stand down.

11.2 Membership of BTS Guideline Groups, Quality Standards Groups or Groups producing Clinical Statements is not open to employees of the biomedical industry. However, it is important to recognise the difference between directly commercially influenced activities and areas in which the entrepreneurial and business skills of industry could be invaluable. Other public bodies including the government and charities have (with appropriate safeguards in place) embraced the commercial sector in the interests of improving skills and knowledge within their organisations.

11.3 BTS does not wish to be seen as isolationist and too rigid in this respect. Following the general principles and code of practice for the Declaration of interests will allow appropriate interaction to occur. Individual cases will be discussed if they arise by the Society's Board of trustees. The reasons for this will be fully documented and minuted.

12. BREACHES

12.1 There may be situations when interests will not be identified, declared or managed appropriately and effectively. This may happen innocently, accidentally, or because of the deliberate actions of staff or organisations. For the purposes of this policy document these situations are referred to as 'breaches'.

12.2 If a breach is identified it should be notified to the chair of the affected Committee, Guideline Group, Groups producing Clinical Statements and Quality Standards, Steering Committee, Working Party or Specialist Advisory Group and to the Honorary Secretary and Chief Executive.

12.3 If the breach or potential breach is identified the Society will take the matter forward as outlined in its “Complaints and Concerns Procedure”, which can be found in Appendix 3.

12.4 If the breach has been committed by a member of BTS staff the matter will be dealt with in line with the Society’s approved disciplinary processes.

13 **SANCTIONS**

13.1 This document is concerned in the main with the conduct of BTS members, staff and associates when they are serving in some capacity on BTS business.

13.2 If any of these are found to be in breach of the requirements contained herein, and following investigation as outlined Appendix 3, the individual concerned will be required to stand down immediately. The on-line system for collecting DOIs will be amended so that it reads:-

“I declare that I have read and understood the BTS policy on biomedical industries - joint working and funding relationships (2018) and will comply with this and the confidentiality policy as set out in Appendix 2. I also confirm that I have no involvement in the tobacco industry (para 3.6). I understand that the details of my declaration will be made available on the BTS website. I am aware that failure to declare relevant interest(s) may result in me being required to stand down from the Committee/Group concerned”

13.3 If breaches of national legislation or external codes of conduct take place, for example in relation to research activities (much of section 8 of this document refers, for example) or NHS Codes on Conflicts of Interest¹¹, it is anticipated that the employers of the individual concerned will act in accordance with sanctions outlined in national legislation.

14 **Implications for Patients**

14.1 Patients entrust NHS organisations and private providers to deliver high quality care that is free from undue influence.

14.2 To deliver high quality and innovative care organisations need to work collaboratively with each other, local authorities, industry and other public, private and voluntary bodies. Partnership working brings many benefits, but also creates the risk of conflicts of interest as detailed above.

13.3 The British Thoracic Society and the people who work with, for, and on behalf of them want to manage these risks in the right way. Implementation of this guidance will reassure patients and the public and enable greater consistency across the activities of the BTS to minimise any conflict of interest.

13.4 By implementing this guidance BTS staff and the organisations with which we work will understand what to do to take the best action to deliver the best care and protect themselves from allegations that they have acted inappropriately.

References

1. Innovating for Health: Patients, physicians, the pharmaceutical industry and the NHS.
<http://www.rcplondon.ac.uk/research/medicine-and-industry>
NB- this document is being updated at time of preparation of this update. The Society will review its policy when the RCP London statement is available, which may be before the next due date which is November 2014
2. Best practice guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations. Department of Health 2008.
<http://www.dh.gov.uk/publications>
3. Tool kit for Joint Working
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_119052.pdf
4. Code of Conduct: code of Accountability in the NHS (2nd rev ed 2004) Department of Health. www.dh.gov.uk/publicationsandstatistics
5. The Association of the British Pharmaceutical Industry. Code of Practice for the pharmaceutical industry. Updated 2015 http://www.abpi.org.uk/our-work/library/guidelines/Documents/code_of_practice_2015.pdf
6. Report of the Royal College of Physicians. *Fraud and misconduct in medical Research*. London, RCP, February 1991.
7. Guidelines on Commercial Sponsorship of Nursing Posts. Royal College of Nursing
8. Ministry of Justice. The Bribery Act 2010
<http://www.justice.gov.uk/downloads/guidance/making-reviewing-law/bribery-act-2010-guidance.pdf>
9. Commercial sponsorship – ethical standards for the NHS. Department of Health, PO Box 777, London SE1 6XH.
10. BTS Guideline Production Manual , 2013 <http://www.brit-thoracic.org.uk/guidelines-and-quality-standards/>

11. <https://www.england.nhs.uk/wp-content/uploads/2017/02/guidance-managing-conflicts-of-interest-nhs.pdf>

General references

Stonier PD. The pharmaceutical industry and the clinical professions. *J R Coll Physicians Lond* 2000;34:127-31.

Relationships between the medical profession and the pharmaceutical industry. The Association of the British Pharmaceutical Industry. London, March 1998.

Prescription Medicines Code of Practice Authority. *Code of practice for the pharmaceutical industry*. London: PMCPA, 1998.

Ethics in Pharmaceutical Medicine. Report from the Ethical Issues Working Group, Faculty of Pharmaceutical Medicine. *Int J Pharm Med* 1998;12:193-8.

Larkin M. Whose article is it anyway? *Lancet* 1999;354:136.

Editorial. Drug-company influence on medical education in USA. *Lancet* 2000;356:781.

Horton R. The less acceptable face of bias. *Lancet* 2000;356:959-60.

Bero LA. Accepting commercial sponsorship. *Br Med J* 1999;319:653-4.

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Date of last revision: December 2017.

Appendix 1

THE BRITISH THORACIC SOCIETY Code of Practice for

ANNUAL DECLARATION OF INTERESTS 2018

1. Scope

1.1 This code of practice covers the following individuals:

- Chair and Trustees of the Society;
- All employees and associates of the Society;
- Members of the Society who sit on BTS standing Committees, Guideline Committees, Quality Standards Groups, Clinical Statements Groups and Specialist Advisory Groups (SAGs) and other ad-hoc Committees that may be convened by BTS;
- Clinical, patient or other experts who are invited to attend/participate in BTS Committee meetings, irrespective of whether they are members of the Society.

2. Definitions

2.1 The term “Biomedical industry” includes:

- Companies, partnerships or individuals involved in the development, manufacture, promotion, sale or supply of products used in medical practice, including (but not limited to) pharmaceutical products, biomedical equipment and devices.
- Companies, partnerships or individuals involved in the development, manufacture, promotion, sale or supply of products or services which are advertised, promoted or marketed as contributing to the promotion or maintenance of good health.
- Trade associations representing companies involved in the above.

3. Types of Interest and Participation in Meetings

3.1 The following is intended as a guide to the types of interest that should be declared. If a Member has an interest which is not outlined below, but that interest may influence or be perceived to influence their role/advice then this should be declared.

3.2 *Personal Interests*

Those involving a payment to the member personally – for example:

- (i) Consultancies: includes any regular or occasional payment in cash or in kind for consultancy, directorships, or other position with a biomedical company undertaken within the 12 months prior to the declaration being made, or planned but not yet undertaken.
- (ii) Fee paid work: includes work commissioned by a healthcare company for which payment is made in cash or kind undertaken within the 12 months prior to the declaration being made, or planned but not yet undertaken.
- (iii) Shareholdings: includes shares or other beneficial interests in a healthcare company that are held by the individual or for which the individual has legal responsibility (child or relative).
- (iv) Expenses and hospitality: includes expenses provided by a healthcare industry for travel and accommodation for attendance at scientific and educational meetings which have been undertaken in the 12 months prior to the declaration being made, or planned but not yet undertaken.

3.3 **Non-Personal Interests**

Those involving payment which benefits a department for which a member is responsible, but is not received by the member personally – for example:

- (i) Fellowship: held by the member which is endowed by a biomedical company;
- (ii) Support from a biomedical company by way of:
 - a grant: for running of a unit or department for which the member is responsible;
 - a fellowship or grant: provided to sponsor a post or member of staff in the department for which the member is responsible;
 - sponsorship of a post
 - a commission for research work or advice: provided by staff in the department for which the member is responsible
 - sponsorship of equipment.

3.4 A summary of the description of the types of interest and the implications for the meeting are attached at Annex 1.

4. **Confidentiality**

4.1 Members of Guideline Committees will be expected to comply with a Confidentiality Agreement, in line with section 4 of the Policy on BTS, Biomedical industries and Commercial Sponsorship. The Confidentiality Agreement is attached at Appendix 2.

5. **Declaration of Interest Form**

5.1 It is a requirement of the Society's policy document 'BTS and biomedical industries: joint working and funding relationships 2018' for all members of the Society's Committees and Groups to complete an annual Declaration of Interest (DoI) on-line. This policy was first approved at the AGM in December 2000, and has been reviewed and updated annually. It is also posted on the BTS website.

5.2 Members and relevant staff and associates will be asked to declare that they have read and understood the BTS policy document and that they wish their declared interests to be recorded and published on the BTS website. They will also be asked to confirm that they are aware that failure to declare relevant interest(s) may result in them being required to stand down from the Committee/Group concerned.

5.2 The forms themselves will be kept in the room during each Committee meeting for reference and the content of individual declarations of interest for the current year are available on the BTS website. Please note that the returned information will be held by the Society, and will be available for scrutiny for the duration of your membership of the relevant Committee of Group (or, in the case of a Guideline, Quality Standards or Clinical Statements Group for as long as the Guideline remains current).

5.3 Declarations of Interest will be a standing agenda item each meeting of the Committee. Receipt of returns and updates will be minuted and members will be asked at each meeting for any relevant updates to the annual form. The Chair of each Committee must have read all returns before the first meeting of the year takes place. All other members are encouraged to do the same. Until a form has been returned, the member concerned will not be able to speak or vote at the Committee meeting(s).

5.4 The Chair of each Committee may feel that the balance of interests on the Committee has become uneven. In this case s/he should bring this to the attention of the Honorary Secretary and the Chair of the Board of Trustees, and in such an unlikely situation, an individual may be asked to step down.

5.5 If an enquiry is received from any source about a potential Conflict of Interest by an Officer, Chair of a Committee or the staff of the Society, the enquirer will be asked to make the request in writing to the Honorary Secretary of BTS who will follow it up with the Chair of the Committee and the individual member concerned. A response will be given within a reasonable period.

5.6 Members of all Committees are asked to complete the online form by **mid-January 2018 at the latest**, or earlier if there is a meeting of a Committee on which they serve before that date.

5.7 If a form has not been received before the Spring meeting of each Committee or the first meeting, whichever is earlier, the member will be asked to either complete the form on the day, or stand down temporarily until a form is received. Thank you.

Dr Justin Pepperell
Honorary Secretary

December 2017

If you have any queries please email the Chief Executive in the first instance. sheila.edwards@brit-thoracic.org.uk. Tel 020 7831 8778

Annex 1 to the Code of Practice

Declaration of interests during the meeting and implications

NATURE OF INTEREST	DESCRIPTION	INVOLVEMENT IN DISCUSSION
<i>Personal Specific</i>	Member engaged in current and/or ongoing work on the product under consideration and has personally received payment for that work from the industry	Should take no part in the proceedings as they relate to that product*
<i>Lapsed personal specific interest</i>	As above but the interest is no longer current	Can take part in proceedings
<i>Personal non-specific interest</i>	Current personal interest in the biomedical company concerned which does not relate specifically to the product under discussion	Should take no part in the proceedings as they relate to that product*
<i>Current personal interest</i>	Either in the biomedical company concerned which does not relate specifically to the product under discussion or in a company marketing a rival product	Should take no part in the proceedings as they relate to that product*
<i>Non-personal specific</i>	Member is aware that the department for which they are responsible has at any time worked on the product under discussion	May take part in the proceedings <u>unless</u> they have personal knowledge of the product through their own work or the supervision of others in which case they should take no part in the proceedings as they relate to that product*
<i>Non-personal, non-specific</i>	Member is aware that the department for which they are responsible is currently receiving payment from the company which does not relate to the product under discussion	May take part in the proceedings unless the Chairman rules otherwise

* except at the Chair's discretion to answer questions from other members

Appendix 2

British Thoracic Society

Confidentiality agreement

This agreement covers all those who have sight of documents, or are party to discussions, relating to the development of Guidelines before public consultation. This includes Guideline Group members, BTS Trustees and other members of BTS Committees, and BTS staff and associates.

- 1) I undertake to BTS that I shall:
 - (a) keep all confidential information strictly confidential
 - (b) not use any confidential information for any purpose other than participating in the deliberations of the Guideline Group
 - (c) not disclose any confidential information to any third party without the prior written consent of BTS and in the event that such disclosure is permitted I shall ensure that such third party is fully aware of and agrees to be bound by these undertakings
 - (d) not disclose the deliberations of a Guideline Group to any other person without the explicit consent of the Chair of the Guideline Group and the Chair of the Standards of Care Committee

- 2) The undertakings set out in paragraph 1 above ('the undertakings') shall not apply to the use or disclosure of information that:
 - (a) at or after the time of disclosure or acquisition is in the public domain in the form supplied otherwise than through a breach of any of the undertakings; or
 - (b) was lawfully within my possession before its disclosure to me by the BTS Guideline Group provided that the source of such information was not bound by, or subject to, a confidentiality agreement with BTS; or
 - (c) I am required to disclose by any court of competent jurisdiction or any government agency lawfully requesting the same, provided that BTS is notified in advance of such disclosure; or
 - (d) is approved for release by prior written authorisation from BTS.

Appendix 3

DEALING WITH COMPLAINTS AND/OR CONCERNS ABOUT THE WORK OF A BTS COMMITTEE OR GROUP

JANUARY 2018

A. PREAMBLE

1. This procedure has been published to assist in the event of a complaint being made about the conduct of business within one of the Society's Committees or Advisory or Guideline Groups, and/or by individual member(s) and/or the Chair. It is intended to provide the framework for a fair, equitable, transparent and timely response to complaints about conduct of business.
2. The Trustees of the Society recognise that members who assist in the work of the various Committees and Groups do so because they share the ambition of achieving improvements in the care of people who have respiratory conditions. They work often long hours and in their own time, and do not expect rewards or awards. The Society aims to provide a supportive environment which allows those who provide clinical expertise to feel that this is valued by Trustees, BTS members and the wider respiratory healthcare community, and will be processed by skilled and professional head office staff.
3. Trustees expect that minor queries or challenges about the way in which Society business is conducted will be resolved at an early stage by open and direct communication. This procedure has been developed to assist when the situation within a Committee or Group has progressed to the point where additional assistance is needed to achieve a resolution.

B. MAKING A COMPLAINT

4. If an individual wishes to make a complaint about the conduct of business, he or she should raise this first with the Chair of the Committee concerned. The Chair will raise this with the Chair of the Board of Trustees or Honorary Secretary if he or she feels that the issue would benefit from their advice. If the complainant does not feel able to do so (for example, if the subject of the complaint is the Chair), a written approach to the Society should be made to the Chair of the Board of Trustees, via the Society's Chief Executive. (If the complaint is about the conduct of the Chief Executive it should be addressed directly to the Chair of the Board).

The complaint should be in writing, describing what has occurred; and, if possible, what the complainant feels should be done to rectify the situation. The complainant will be advised that the process will involve making a copy of the complaint available to the Chair of the Committee/Group concerned, and an opportunity given to review the complaint accordingly.

C. INITIAL ASSESSMENT PROCESS

5. The Chief Executive (or Chair of the Board, in circumstances outlined in para 4, above), will acknowledge receipt, and will convene a discussion with the Chair of the Board of Trustees and the Honorary Secretary within one week of receipt of the complaint. If one or other of the senior Officers is away, or is already involved in the matter, another Officer or Board member who is not connected with the Committee concerned will be asked to assist.
6. At this initial discussion, decisions will be made about:-
 - Whether the matter can be dealt with relatively quickly by a series of conversations – i.e. will it be possible to broker a resolution at an early stage;
 - If not, who will take forward the conversation with the complainant and the Chair of the Committee concerned. This will usually be the Chair of the Board or Honorary Secretary (the Lead Investigator)
 - The timetable for the discussions and decision /resolution of the complaint.
 - Dealing with Committee business in the meantime, especially if the nature of the complaint appears to warrant a particular course of action.
 - Communicating the situation in the short term to members of the Committee, if this is judged to be necessary. This will usually be done by the Chief Executive on behalf of the Chair of the Board.

D. DETAILED FACT-FINDING

7. The Lead Investigator will arrange to speak to both parties and staff involved within 2 weeks of the receipt of the complaint. The aim will be to seek as much information as possible to inform next steps. He or she will convene a further discussion with the other members of the group as outlined in paragraph 6, above, and will seek further factual information from the lead BTS staff member if required, before making a decision about resolving the complaint.
8. If the Lead Investigator considers it necessary, and at their discretion, the matter will be discussed again by the Officers Group - with the exception of the President and President-elect, who will be held in reserve as the people to whom an appeal might be made. A short factual report may be provided to the President and President-elect so that they are aware that a complaint has been received, but they will not otherwise be involved in discussions at this point.
9. At all times, and applying to all concerned, the following principles should be maintained:-

- The principles of natural justice and transparency. The discussion to find out what has happened will be conducted in the same way with the complainant and the Chair of the Committee or the SAG concerned. The discussions are NOT intended to be adversarial or in the nature of a tribunal.
- All concerned will be expected to maintain confidentiality throughout the process. This is to ensure that the reputation of all concerned, including the Society's reputation and good standing, is protected and not subject to uninformed speculation, or one-sided interpretations of events.
- If a complaint is made which may lead to the Society being threatened with legal action (for example in relation to breaches of Equal Opportunity legislation; accusations of libel or slander) the advice of lawyers will be sought at an early stage.
- If the Society as a whole is accused of a breach of national legislation; of having caused harm by virtue of one of its activities; or if the complaint comes from an external source and is related to a broader issue than conduct of Committee business, the advice and assistance of BTS' lawyers will be sought immediately.
- Notes will be kept as a record but not shared with anyone who is not involved in the complaint or its investigation and resolution

E. RESOLUTION AND APPEAL PROCESS

10. The Lead Investigator may feel that a resolution could be achieved by facilitating a discussion between both parties. If this is the case, attempts should be made to arrange this within two weeks of this decision being conveyed to both parties.
11. In any event, when a decision has been made about how to proceed, this will be conveyed to the complainant and the other party within two working days following the meeting at which the decision is made.
12. It is hoped that the proposed way forward is acceptable to both parties. If not, either has recourse to requesting an overview by the President and President-elect (in tandem) who will review the paperwork and speak to both parties and the Lead Investigator. They will be asked to give their views to the Lead Investigator no longer than 2 weeks after being asked to do so.
13. The final decision about how to proceed will be relayed to both parties no later than 3 weeks after an appeal has been lodged.
14. It is expected that all parties will accept the proposed resolution of the complaint.

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