BTS and the Biomedical Industry

Policy for joint working and funding arrangements

2023

1. Introduction

- 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.
- 1.2 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.

2. Scope

- 2.1 This policy document sets out how the Society conducts business with the biomedical industry. It covers:
 - General principles
 - Definitions
 - Who does this policy apply to?
 - Declarations of Interest
 - Involvement of the biomedical industry in BTS conferences and educational activities
 - Involvement of the biomedical industry in BTS activities and projects
 - Attendance of BTS members at external conferences and meetings
 - BTS sponsorship of externally produced documents/digital resources
 - BTS and the tobacco industry
 - BTS and research
 - Breaches and Sanctions
 - Review

3. General principles

- 3.1 BTS is a registered charity, a company limited by guarantee, and a professional organisation, open to public scrutiny. This being the case, all its activities must be free from commercial or personal interests, and the principles that underpin all aspects of the Society's work are:
- accountability:;
- independence;
- transparency.
- 3.2 These central principles will govern the Society's relationships with industry as it works to further its charitable aims and objectives.

4. Definitions

4.1 The Biomedical Industry:

This encompasses the pharmaceutical and devices industries, and extends to other commercial companies including medical instrument manufacturers, companies offering consultancies, referral management, contract management, product development, data management and telehealth, and for any individuals providing these services as Directors of limited companies.

4.2 Joint Working:

'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.' ¹

4.3 Non-promotion grants

A grant is an amount of money, awarded for a specific activity, which does not need to be repaid. Non-promotional grants can be made to the Society from a commercial company, for an activity in which the company concerned has no direct involvement in the planned activity or its planning/implementation/outcome.

4.4 BTS conferences and educational activities:

The BTS Winter Meeting, Summer Meeting, BTS short courses, BTS educational materials.

4.5 BTS activities and projects:

This refers to BTS publications (including guidelines, clinical statements, quality standards and other publications) and other projects (including the audit programme, registry programme, and other clinical projects).

5. Who does this policy apply to?

5.1 The content of this document applies to BTS members, BTS staff and associates. BTS also expects others who work with the Society (for example those colleagues who are not BTS members but who are part of BTS committees or groups) to adhere to this overall policy document.

BTS Trustees and BTS senior staff are required to apply this policy in a fair and equitable manner. Queries about the policy should be addressed to the Chief Executive in the first instance.

6. Declarations of interest

6.1 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 are required to declare commercial and other relevant interests each year. To ensure adherence to this policy, the Society asks all concerned to complete an annual online **Declaration of Interests** return in line with the BTS Policy on Declaration of Interests. ²

¹ ABPI Joint working: a toolkit for industry and the NHS 2019 Joint Working - a toolkit for industry and the NHS (abpi.org.uk)

² BTS Declaration of Interest policy <u>Governance Documents and Policies | British Thoracic Society | Better lung</u> health for all (brit-thoracic.org.uk)

- 6.2 Chairs of Guideline Groups, Clinical Statement Groups or Quality Standards Groups should not have shares in any biomedical company or be retained as a consultant with a company. Before appointment a Chair's 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.
- 6.3 Membership of BTS Guideline Groups, Quality Standards Groups or Groups producing Clinical Statements is not open to employees of the biomedical industry.
- 6.4 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 from their role on the BTS Committee or group concerned.
- 6.5 All copies of Declarations of Interest forms for the year submitted from members of the Group concerned are made available to the Chair of the Group before the first meeting, and subsequently visible on the BTS website while the Group is active. The latest Declarations of Interest for the Group at the time the document is published is retained by BTS head office for the subsequent period of time that the document remains valid.
- 6.6 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.
- 6.7 Discussions about Guidelines may lead to commercial sensitivities and Group members should maintain confidentiality about the content of guideline group discussions until such times as they are discussed in open meetings.
- 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. When a draft Guideline or other guidance document is made available for public consultation on the BTS website, respondents to the consultation process should declare their 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."

All members of the BTS Committees and Groups, and BTS staff are required to complete a declaration of interests form each year.

Chairs of Guideline Groups, Clinical Statement Groups or Quality Standards Groups should not have shares in any biomedical company or be retained as a consultant with a company.

Membership of BTS Guideline Groups, Quality Standards Groups or Groups producing Clinical Statements is not open to employees of the biomedical industry.

7. Involvement of the biomedical industry in BTS conferences and educational activities

7.1 BTS Conferences and short courses

Commercial companies support the BTS Summer and Winter Meetings and short courses in several ways, usually by paying to have exhibition space (either onsite or online) at the Winter & Summer Meetings, by paying for a limited range of advertising opportunities or by providing equipment for short courses.

- 7.2 Support of this nature for the BTS Summer and Winter Meetings and short courses is welcome. Funds generated in this way are used to offset costs of the Meeting and so reduce delegate fees. In the case of short courses, the involvement of relevant equipment suppliers to provide the relevant equipment/devices is similarly welcome.
- 7.3 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.
- 7.4 Where the Society seeks industry funding (through a non-promotional grant) to allow attendance for delegates at a BTS meeting (for example through a travel/fellowship scheme), funding must be obtained from 2 or more companies. The companies concerned will play no part in the award of the funds to delegates. Single company support for travel awards of this nature will not be permitted.

BTS does not allow sponsored symposia at its Summer and Winter Meetings.

Where journal supplements, journals or other Conference related items are supported by company sponsorship the role played by the company should be clear and unambiguous.

7.5 BTS Educational Materials

Educational materials produced by BTS, including course documents, web-based educational tools, and other resources, are developed by BTS members and others on behalf of the Society under the auspices of the BTS Education and Training Committee. Only those courses and materials produced in this way will bear the BTS name and branding.

7.6 BTS members may be involved in other educational activities that are supported by industry, and as such will be involved as experts in their own right rather than as representative of BTS. No mention of BTS should be made in any materials connected with such activities.

Sponsorship of the production of BTS educational courses and materials by a single company is not permitted.

Support for the production of BTS materials may be permitted provided funding comes from a consortium of companies (2 or more companies providing non-promotional grants).

- 8. Involvement of the biomedical industry in BTS projects and other activities
- 8.1 BTS projects such as guidelines production, lung disease registries, webinars etc (see definitions above)

The public has the right to expect that Guidelines, Clinical Statements, and other guidance produced by a professional society have been produced in the best interest of the public and patients. It is to be expected that in convening a group of experts to produce a guidance document, many of those involved will have had some association with the biomedical/pharmaceutical industry in one way or another. This means that it is vital that BTS ensures 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 documents relies on reasonable steps being taken to ensure their integrity.

- 8.2 BTS guidance documents (guidelines, clinical statement, quality standards and other guidance documents) are produced by Groups selected and approved by the BTS Standards of Care Committee. The work of these 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 (2022) ³.
- 8.3 It is recognised that there are certain Committees, SAGs or other activities which may need to consult with industrial partners. The intended involvement or consultation with an industrial organisation by a Committee or other group should be discussed in the first instance with the Chief Executive or Honorary Secretary.
- 8.4 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.
- 8.5 There may be occasions on which external funding is sought for a BTS activity (this could include the Lung Disease Registry, the MDRTB CAS service or other activity). Any proposal for external funding to support a BTS activity should be discussed with the Chief Executive and Honorary Secretary in the first instance and the proposal will then require Board approval to proceed. Single company support for a BTS activity will not be approved.

BTS does not seek and will not accept external funding for the production of any of its clinical guidance (which includes Guidelines, Quality Standards, Clinical Statements and any other guidance document).

Membership of BTS Committees and Groups is not open to employees from the biomedical industry. Single company support for a BTS activity will not be approved.

9. Attendance of BTS members at external conferences and meetings

9.1 Individual sponsorship to attend scientific meetings

BTS recognises the value that members gain from commercial sponsorship for attendance at national and international meetings. The value 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. BTS members' involvement in the conference or meeting concerned, or in any sponsored symposia hosted by a company, (whether as a speaker or delegate) will be as an individual in their own right rather than as representatives of BTS. To avoid any misunderstanding, the individual concerned should check with BTS head office before accepting any invitation. 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.

9.2 For BTS members attending external meetings all hospitality offered to and accepted by members should conform to the ABPI code of practice ⁴. BTS members should declare support to attend

³ BTS Guideline Production Manual 2022 <u>Guidelines | British Thoracic Society | Better lung health for all (britthoracic.org.uk)</u>

⁴ ABPI code of practice 2021, Code of Practice for the Pharmaceutical Industry 2021 (abpi.org.uk)

meetings as part of the annual declaration of interest process (see section 6) if they are on any BTS Committee or Group. Hospitality and travel arrangements should not exceed that which the individual themselves or their employer would reasonably fund.

- 9.3 BTS encourages industry to include BTS members with interests in all sub-specialties and all healthcare professions when providing support for attendance at meetings and conferences.
- 9.4 On occasion, the Chair of the BTS Board (and on some occasions, other Honorary Officers, for example the Hon Treasurer or Hon 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.
- 9.5 On occasion BTS may be invited to meetings or events that are held under the auspices of All Party Parliamentary Groups, or by parliamentarians or other third parties and these events will often be supported by single companies. Attendance by a BTS representatives at such meetings is permitted provided the involvement of the company in the support of such an event is clearly stated.
- 9.6 BTS does not nominate representatives to participate in working groups hosted by organisations (such as an APPG or other grouping) for which the work concerned has single company support.
- 9.7 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.

BTS members should declare support to attend meetings as part of the annual declaration of interest process (see section 6) if they are on any BTS Committee or Group.

BTS does not nominate representatives to participate in working groups hosted by organisations (such as an APPG or other grouping) for which the work concerned has single company support.

10. BTS endorsement of externally produced documents/digital resources

10.1 The BTS endorsement policy sets out the criteria for the use of the BTS name and logo on documents and other resources produced by external organisations. ⁵

11. BTS and the Tobacco Industry

11.1 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. If such a connection is uncovered, and if, after a process of investigation between the Society and the individual concerned demonstrates this to have been the case, then membership of the Society will be withdrawn immediately.

⁵ BTS Endorsement Policy <u>Governance Documents and Policies | British Thoracic Society | Better lung health for all (brit-thoracic.org.uk)</u>

11.2 Full details of the Society's position in relation to the tobacco industry is contained in the BTS Position Statement on Tobacco. ⁶

12. BTS and research

12.1 BTS, through the Science and Research Committee will foster, promote and champion high quality respiratory research but BTS does not fund respiratory research.

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.

All research, whether funded by the biomedical industry or not, should be carried out to the highest standard and should adhere to the ABPI code of practice⁷.

13. Breaches

- 13.1 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'.
- 13.2 If a breach is identified it should be brought to the attention of the Chief Executive, who will notify 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.
- 13.3 If the matter concerns the conduct of business of a BTS Committee or group, the process outlined in the BTS Complaints procedure will be followed.
- 13.4 If the matter concerns the conduct of an individual who has failed to make the required declarations in line with the BTS declaration of interest policy, the matter will be investigated by the Hon Secretary and Chief Executive and the individual concerned may be required to step down from their role.
- 13.5 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.

14. Review

14.1 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.

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⁶ BTS Tobacco Position Statement <u>Position Statements</u> | <u>British Thoracic Society</u> | <u>Better lung health for all</u> (<u>brit-thoracic.org.uk</u>)

⁷ ABPI code of practice 2021. Code of Practice for the Pharmaceutical Industry 2021 (abpi.org.uk)

Useful links

AMRC An essential partnership: a guide for charities working with industry, 2014 <u>Download.ashx (amrc.org.uk)</u>

MOVING BEYOND SPONSORSHIP: JOINT WORKING BETWEEN THE NHS AND PHARMACEUTICAL INDUSTRY 2010: joint working toolkit dh.abpi.pdf (networks.nhs.uk)

ABPI code of practice 2021. Code of Practice for the Pharmaceutical Industry 2021 (abpi.org.uk)

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