

# British Society for Allergy and Clinical Immunology

---



## A CODE OF PRACTICE FOR DECLARING AND DEALING WITH CONFLICTS OF INTERESTS

### **1. Background**

The Royal College of Physicians set a precedent in 1986 with the publication of a report 'The Relationship between Physicians and the Pharmaceutical Industry.' This document and similar documents by 'The British Thoracic Society (BTS)' and by 'The National Institute for Health and Clinical Excellence (NICE)', have informed the policy set out in the BSACI Code of Practice for declaring and dealing with conflicts of interest.

### **2. General Principles**

The goal of the BSACI is to improve allergy care through education, training and research.

The BSACI is a charitable professional organisation and has the responsibility to ensure that patients receive the best independent advice. In contrast the biomedical industry whilst clearly serving a socially beneficial function also needs to make a profit in order to satisfy the requirements of shareholders and be able to invest in new research. Collaboration of first class clinical research units with biomedical industry can yield important therapeutic advances. Likewise commercial sponsorship and collaboration with industry can be of great benefit to research and education for members of a professional society such as the BSACI. Thus the BSACI and the biomedical industry share certain goals, but their roles and responsibilities are different and subject to different pressures. Physicians and healthcare workers as well as their professional bodies should therefore conduct themselves carefully in their relationship to this group of industries. It is important that the BSACI acts responsibly in upholding professional independence and safeguarding the interests of patients. As such its activities must be kept open to public scrutiny and must be free from commercial or personal interests especially in relation to allergic and immunological diseases.

This code of practice has been agreed by the BSACI in order to avoid any public concern that pecuniary or other interests might prejudice the advice of the BSACI and the arrangements that govern relationships of the board and the committees.

### **3. Scope**

This document sets out to give guidance for relations between the biomedical industry and BSACI members, especially its committee members and guideline developers.

This code of practice covers the following individuals:

- Chairman and Trustees of the Society
- All employees and associates of the Society
- Members of the Society who sit on BSACI standing Committees, Guideline Committees and Specialist Advisory Groups and other ad-hoc Committees that may be convened by the BSACI;
- Clinicians, patients or other experts who are invited to attend/participate in BSACI Committee meetings, irrespective of whether they are members of the Society.

Definitions:

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.

If members or employees or expert advisors have interests not specified in this Code but which they believe could be regarded as either influencing their advice or role or be perceived to influence their advice or role, they should declare them.

### **4. Activities where conflicts of interest may arise**

Common activities of the society where conflicts of interest may arise:

- Production and dissemination of guidelines (especially for the management of patients with allergic diseases)
- Production and dissemination of patient leaflets
- Educational activities including conferences, training workshops, scientific meetings, short courses
- Production and dissemination of Educational Materials
- Awards to individuals for achievements in Allergy
- Research in Allergy
- Information given to the Media on behalf of the BSACI
- Information given to the Government of governmental agencies on behalf of the BSACI

## **5. Interests which should be declared**

**5.1. Personal pecuniary interests** involve a current personal payment, which may either relate to the manufacturer or owner of a product or service being evaluated, in which case it is regarded as ‘specific’ or to the industry or sector from which the product or service comes, in which case it is regarded as ‘non-specific’; for example:

1. Any consultancy, directorship, position in or work for a healthcare industry that attracts regular or occasional payments in cash or in kind, both those which have been undertaken in the 12 months preceding the meeting at which the declaration is made and which are planned but have not taken place.
2. Any fee-paid work commissioned by a healthcare industry for which the individual is paid in cash or in kind, both those which have been undertaken in the 12 months preceding the meeting at which the declaration is made and which are planned but have not taken place.
3. Any shareholdings, or other beneficial interests, in shares of a healthcare industry that are either held by the individual or for which the individual has legal responsibility (for example, children, or relatives whose full Power of Attorney is held by the individual)
4. Expenses and hospitality provided by a healthcare industry company for accommodation, meals and travel to attend meetings and conferences, both which have been undertaken in the 12 months preceding the meeting at which the declaration is made and which are planned but have not taken place.

5. Funds which include investments in the healthcare industry that are held in a portfolio over which individuals have the ability to instruct the fund manager as to the composition of the fund.

No personal interest exists in the case of:

- Assets over which individuals have no financial control (for example, wide portfolio unit trusts and occupational pension funds) and where the fund manager has full discretion as to its composition (for example, the Universities Superannuation Scheme)
- Accrued pension rights from earlier employment in the healthcare industry.

**5.2. Non-personal pecuniary interests** involve payments or other benefits that benefit a department or organisation for which an individual has managerial responsibility, but which is not received personally – for example:

- The holding of a fellowship endowed by the healthcare industry.
- Any payment or other support that does not convey any pecuniary or material benefit to an individual personally but that might benefit him or her. Examples include:
  - i. a grant from a company for the running of a unit or department for which a member is responsible
  - ii. a grant or fellowship or other payment to sponsor a post or member of staff in the unit for which a member is responsible
  - iii. the commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible

### **5.3. Uncertainty about the need to declare**

In the case of uncertainty whether to declare an interest it should be declared.

## **6. When should interests be declared and what action is required?**

**6.1.** It is a requirement for all members of the Society's Committees to complete a Declaration of Interest (DoI) form on appointment, and then annually. Forms are collected by the BSACI office at the end of January of each year. **By signing this form, you are asked to confirm that you have read the policy document 'Code of practice for declaring and dealing with conflicts of interests' by the BSACI, before completing the DoI.**

**6.2.** If a form is not received before the first meeting in the year of the respective committee the member is due to attend, the member will be asked to either present a form on the day, or stand down temporarily until a form is received.

- 6.3.** The forms themselves will be kept in the room during each Committee meeting for reference. **Please note that the completed forms will be held by the Society, and be available for scrutiny, for the duration of membership of the relevant Committee (or, in the case of a Guideline Committee, for as long as the Guideline remains current).**
- 6.4.** Declarations of Interest will be a standing agenda item at each meeting of the Committee, receipt of forms 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).
- 6.5.** 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 Executive Committee, and in such an unlikely situation, an individual may be asked to step down.
- 6.6.** 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 BSACI 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.

## **7. Confidentiality**

Members of Guideline Committees will be asked to sign a Confidentiality Agreement. This is attached as Annex 2.

## **8. Educational activities**

### **8.1. Publication of guidelines and other educational material**

Biomedical companies sometimes provide financial support for educational material, which is produced independently by BSACI members. Unconditional educational grants from the biomedical industry to allow dissemination of completed guidelines, non-promotional educational material, support for publications, website material, etc. may be considered acceptable. It would be advisable for this to involve several companies.

All educational material produced by the BSACI should be created by BSACI members independently. As such BSACI members should be aware that it is undesirable to use ghost written chapters or first drafts written by biomedical companies as it may compromise unbiased documentation. Any input from a company must be transparent and clearly stated. It is unacceptable for material that has been influenced by a biomedical company to appear to be independent.

## **8.2. Website links**

Links to other websites that may contain information on industry, or those that are supported by industry are used on the members section of the BSACI website only. No industry-sponsored information appears on the public BSACI website. Links to patient information services on other websites are only agreed if they are non-promotional and are not sponsored by industry. The BSACI website has a disclaimer which states that BSACI is not responsible for content of sites external to BSACI.

## **8.3. Support of meetings**

The BSACI welcomes support from the biomedical industry for its annual meeting as well as for other short courses which helps to reduce the costs for participants. However individuals or meetings should not be compromised by accepting sponsorships. Many companies have promotional stands which the BSACI welcomes. In addition sponsorship is also welcome for specific items such as travel expenses for overseas speakers or other aspects of a meeting, however sponsoring companies should not be involved in deciding the choice of speaker or content of a symposium and the company name should not be attached to the event, unless the company has organised the symposium and paid for speakers. This is then declared as a company symposium in the programme for each meeting.

## **8.4. Research support**

Companies may provide a variety of research support, including sponsoring fellowships, hospital or general practice nurses or specific equipment. This is welcome however in all biomedical studies it is of prime importance that recruitment, time scales and analysis of data is conducted in an academically independent manner, always giving precedence to the welfare of any involved patients and aiming for the highest qualitative standard. All biomedically funded research should adhere to the ABPI guidelines<sup>1 and 2</sup>. In addition sponsorship proposals should be scrutinised using the questions asked by the Royal College of Nursing<sup>3</sup>.

## References

<sup>1</sup>Relationships between the medical profession and the pharmaceutical industry. The Association of the British Pharmaceutical Industry. London, March 1998.

<sup>2</sup>The Association of the British Pharmaceutical Industry. Code of Practice for the pharmaceutical industry. London, 2006

<sup>3</sup>Guidelines on commercial sponsorship of nursing posts. Royal College of Nursing.

## Annex 1

### Declaration of interests during the meeting and implications

NATURE OF INTEREST	DESCRIPTION	INVOLVEMENT IN DISCUSSION
Personal Specific	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.*
Lapsed personal specific interest	As above but the interest is not longer current	Can take part in proceedings
Personal non-specific interest	Current personal interest in the biomedical company concerned which does not relate specifically to the product under discussion	May take part in the proceedings unless, exceptionally, the chair rules otherwise.
Current personal interest	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.*
Non-personal specific	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.*
Non-personal, non-specific	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 Chair rules otherwise.

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



British Society for Allergy and Clinical Immunology

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 Standards of Care Committee members, BSACI Trustees and other members of BSACI Committees, especially those involved with guideline development, and BSACI staff and associates.

1. I undertake to BSACI 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 any BSACI Committee
  - c. Not disclose any confidential information to any commercial industrial party without the prior written consent of BSACI and in the event that such disclosure is permitted I shall ensure that such party is fully aware of and agrees to be bound by these undertakings
  - d. Not disclose the deliberations of any BSACI guideline Committee to any other person without the explicit consent of the Chair of the 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 BSACI or the Standards of Care Committee or any other guideline committee provided that the source of such information was not bound by, or subject to, a confidentiality agreement with BSACI;  
or
  - c. I am required to disclosure by any court of competent jurisdiction or any government agency lawfully requesting the same, provided that BSACI is notified in advance of such disclosure;  
or
  - d. Is approved for release by prior written authorisation from BSACI

Signed .....Date.....

Print name.....

### Annex 3: When is it necessary to declare an interest?

	Declaration on appointment	Annual declaration	Declaration at advisory body meeting	Declaration in evidence publication
BSACI executive and council members	Yes	Yes	Yes (if relevant)	Yes (if relevant)
BSACI SOCC members	Yes	Yes	Yes	Yes
BSACI PAC members	Yes	Yes	Yes	Yes
BSACI members of committees not specified above	Yes	Yes	Yes (if relevant)	Yes (if relevant)
BSACI employee	Yes	Yes	Yes	Yes
Evidence contractor	Discuss with BSACI	Not relevant	Yes	Yes
Expert adviser	Not relevant	Not relevant	Yes	Yes
BSACI advisory body member	Yes (except adhoc groups)	Yes (except adhoc groups)	Yes	Yes

SOCC = Standards of Care Committee; PAC = Paediatric Allergy Committee

### Annex 4: Declaring interests at an advisory body meeting

Type of interest	Action
Personal specific pecuniary	Declare and withdraw
Personal non-specific pecuniary	Declare and participate (unless, exceptionally, the chair of the advisory body rules otherwise)
Personal family specific interest	Declare and withdraw
Personal family non-specific	Declare and participate (unless, exceptionally, the chair of the advisory body rules otherwise)
Non-personal specific pecuniary interest	Declare and participate, unless the individual has personal knowledge of the intervention or matter either through his or her own work, or through direct supervision of other people's work. In either of these cases he or she should declare this interest and not take part in the proceedings except to answer questions
Non-personal non-specific pecuniary	Declare and participate (unless, exceptionally, the chair of the advisory body rules otherwise)