

# Open and transparent decision making in medicines governance

## Purpose of this procedure:

---

The aim of this procedure is to ensure that the Area Drug and Therapeutics Committee (ADTC) and its medicines governance subgroups, members and individuals contributing to the ADTC or subgroup are aware of the NHS Lothian policies relating to good business conduct.

## The Procedure:

---

### Procedure for ADTC

#### Step 1

The ADTC and its subgroups must ensure that appropriate support is in place to enable their decision making processes to be robust, open and transparent and that members are made aware of the relevant NHS Lothian policies.

#### Step 2

It is normal practice at the start of meetings for the chair to note requirement to declare interests. This can be included on agendas as a standing item. Any person having anything to do with the committee (as a member, attendee, someone submitting evidence) can declare interests. Interests can be declared verbally, and may also be reflected in the body of a paper or a presentation that has been prepared by a person with an interest. If a committee member has declared an interest at another time, and that interest has a bearing on what is discussed at the meeting, then the member should still declare the interest at the meeting.

#### Step 3

Where there is a declared personal specific interest, the individual is not permitted to be involved in the discussion or the decision-making on that item. The chair may ask the person to leave the room when the item is being discussed. Where there is a declared non-personal interest, the chair can exercise judgement, based on the nature of the interest and the subject being discussed, as to whether the individual should have their involvement in the discussion limited.

#### Step 4

The chair will be mindful of the need to preserve quorum, and will implement strategies to ensure quorate decision making.

#### Step 5

If the chair has an interest, he/she should pass the role of chair of the meeting to someone else for the affected item of business. The chair's interest must then be treated in the same way as any other declared interest.

### Step 6

Where an individual is seeking an addition or amendment to a board recommendation and declares an interest in a therapeutic agent, and is the only NHS Lothian specialist, the following steps will be taken:

- The committee will seek objective evidence from other sources.
- The chair will identify any potential conflict before the meeting, and may request expertise in the subject matter from a specialist from a different NHS board area who has no conflict of interest in the agent. That expert could attend the meeting to give evidence, but would not be a member.

### Step 7

Record the interests in pharmaceutical companies by providing a register of interests form (Appendix 1) to members on an annual basis.

### Step 8

The ADTC and its subgroups will publish their registers of interests on the ADTC membership page of the NHS Lothian internet.

### Step 9

The ADTC and its subgroups will manage records and registers of interests in line with Scottish Government and board guidance and best practice.

## Procedure for Individuals

### Step 1

Adhere to the [seven principles of public life as set down by Lord Nolan](#) - honesty, integrity, accountability, leadership, openness, selflessness and objectivity.

### Step 2

Read, understand and comply with the NHS Lothian guidance on [Applying the Principles of Good Business Conduct](#) and recognise the duty of registering interests, and the duty of declaring interests.

### Step 3

A guide to the kinds of interest which should be declared is included in Appendix 1 ([Definitions of declared interests](#)). It should be noted that if individuals have interests not specified in these notes but which they believe could be regarded as influencing their advice they should declare them.

### Step 4

Complete a register of interests form (Appendix 1) on an annual basis, and provide an updated form to the ADTC and/or its subgroups throughout the year if required, if, and as soon as circumstances change.

## Associated materials/references:

---

NHS Lothian [Applying the Principles of Good Business Conduct](#)

NHS Lothian [Corporate Policies](#)

NHS Lothian [Safe Use of Medicines Policy and Procedures](#)

[Standards of Business Conduct for NHS Staff. NHS Circular: MEL \(1994\)48. The Scottish Office. 29 April 1994.](#)

[Corporate Guidance in the NHS: Supplementary Guidance. NHS Circular: MEL 1994\(80\). The Scottish Office. 2 August 1994.](#)

[The 7 principles of public life. An overview of the 'Nolan principles', which are the basis of the ethical standards expected of public office holders. Committee on Standards in Public Life 31 May 1995.](#)

[Ethical Standards for Providers of Public Services – guidance. Committee on Standards in Public Life. June 2014.](#)

[The Code of Practice for the Pharmaceutical Industry. Association of the British Pharmaceutical Industry \(ABPI\). Prescription Medicines Code of Practice Authority \(PMCPA\). Updated annually.](#)

[A Common Understanding. Working Together for Patients. Guidance on Joint Working between NHSScotland and the Pharmaceutical Industry. The Scottish Government. November 2012.](#)

[Conflicts of Interest. Joint statement from the Chief Executives of statutory regulators of health and care professionals. 8 August 2017.](#)

[Policy on Declaration of Competing Interests. Scottish Intercollegiate Guidelines Network \(SIGN\). 2015.](#)

[SMC policies: Code of practice on declarations of interest and Standard explanation of declarations of interest. Scottish Medicines Consortium \(SMC\). March 2018.](#)

## Appendix 1

## Register of Interests Form for use by ADTC and its subgroups

Committee members are required to complete this on an annual basis.

It should also be updated throughout the year if required, if, and as soon as circumstances change.

Name of the individual and the position held in NHS Lothian
<b>What is the nature of the interest being declared?</b>
Please refer to NHS Lothian guidance on <a href="#">Applying the Principles of Good Business Conduct</a> and also to the definitions provided below.
<b>Personal specific:</b>
<b>Personal non-specific:</b>
<b>Non-personal specific:</b>
<b>Non-personal non-specific:</b>

- ✓ I declare that the information I have given is correct and complete.
- ✓ I understand that if I knowingly provide false information this may result in disciplinary action and I may be liable for prosecution and civil recovery proceedings.
- ✓ I understand this form is a public record, and it will be made available for audit or other inspection, or disclosure under the Freedom of Information Act.

Name .....

**Signature** .....

Date .....

## Definitions of declared interests

(Reference: [SMC policy: Standard explanation of declarations of interest. Scottish Medicines Consortium. March 2018.](#))

The following is intended as a guide to the kinds of interest which should be declared. **It should be noted that if individuals have interests not specified in these notes but which they believe could be regarded as influencing their advice they should declare them.** Individual interests should be declared and examples are detailed below. It should also be noted that, in line with Standing Financial Instructions, the interests of a spouse/partner/cohabitee or close relative should also be declared, if known.

## Personal interests

A personal interest involves payment to the individual personally, for example:

- Consultancies - any consultancy, directorship, position in or work which attracts regular or occasional payments in cash or kind.
- Fee-paid work - any work commissioned by the pharmaceutical industry for which the member is paid in cash or kind.
- Shareholdings - any shareholding in or other beneficial interest in shares of the pharmaceutical industry. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence or financial management.
- Disproportionate expenses/hospitality provided by a pharmaceutical company.
- Other relevant interests: e.g. a Chief Investigator or Co-Chief Investigator of a company funded clinical trial or a Principal Investigator who is likely to benefit from authorship of a resulting publication, participation on an Advisory Board arranged by the pharmaceutical industry regardless of payment.

*If a clinical expert is aware that a product under consideration is or may become a competitor of a product manufactured, sold or supplied by a company in which the expert has a current personal interest, he or she should declare an interest in the company marketing the rival product.*

## Personal specific interests

*Clinical experts should declare a personal specific interest if he or she has at any time worked on the product under consideration and has personally received payment for that work, in any form, from the pharmaceutical industry. Experts should also declare a personal specific interest if he or she has participated on an Advisory Board arranged by the pharmaceutical company.*

### **Personal specific interest that is no longer current**

*If the interest is no longer current (last three years), the expert may declare it as a **lapsed** personal specific interest.*

### **Personal specific interest as a result of significant involvement in the development of a product**

*Note that a personal specific interest as a result of significant involvement in the development of a product, e.g. Chief Investigator or Co-Chief Investigator of a clinical trial, or through authorship of a core publication on the product, **never lapses**.*

---

Document owner: Lead Pharmacist, Medicines Management Team

Version: 3.0

Status: APPROVED

Authorised by: ADTC

Date of Authorisation: 2 August 2019

Review Date: August 2021

### **Personal non-specific interests**

*Clinical experts should declare a personal non-specific interest if he or she has a current personal interest in the pharmaceutical company concerned which does not relate specifically to the product under consideration.*

### **Non-personal interests**

A non-personal interest involves payment which benefits a department for which an individual is responsible, but is not received by the individual personally, for example:

- Fellowships - the holding of a fellowship endowed by a pharmaceutical industry.
- Support by the pharmaceutical industry - any payment, other support or sponsorship by the pharmaceutical industry which does not convey any pecuniary or material benefit to a member personally but which does benefit his/her position or department, e.g.
  - a grant from a company for the running of a unit or department for which a member/expert is responsible;
  - a grant or fellowship or other payment to sponsor a post or a member of staff in the unit for which the member/expert is responsible. This does not include financial assistance for students;
  - the commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible. Individuals are under no obligation to seek out knowledge of work done for or on behalf of the pharmaceutical industry within departments for which they are responsible if they would not normally expect to be informed.

### **Non-personal specific interests**

*Clinical experts should declare a non-personal specific interest if he or she is aware that the department for which he or she is responsible has at any time worked on the product but the expert has not personally received payment in any form from the pharmaceutical industry for the work done.*

### **Non-personal non-specific interests**

*Clinical experts should declare a non-personal, non-specific interest if he or she is aware that the department for which he or she is responsible is currently receiving payment from the pharmaceutical company concerned which does not relate specifically to the product under consideration.*