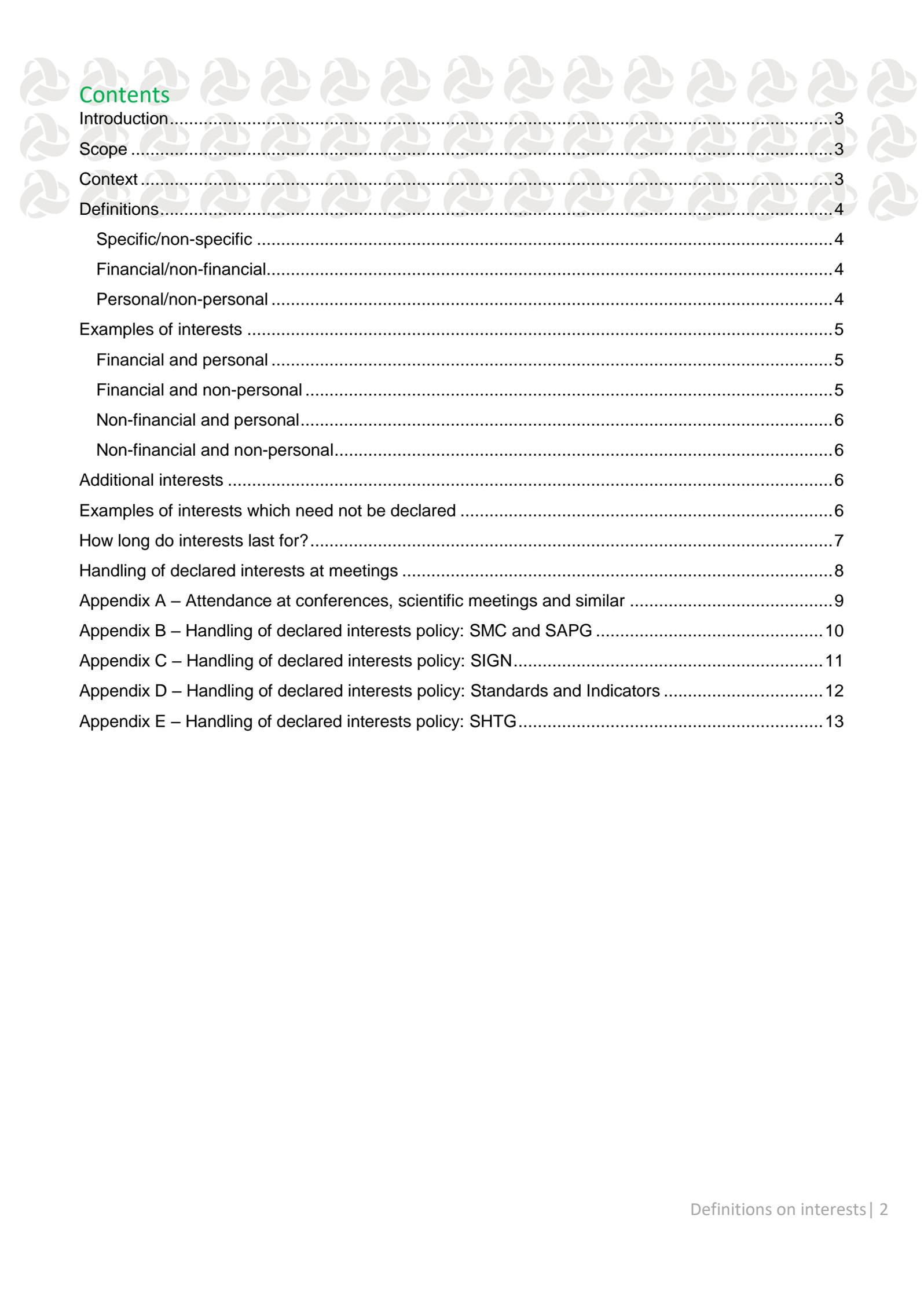
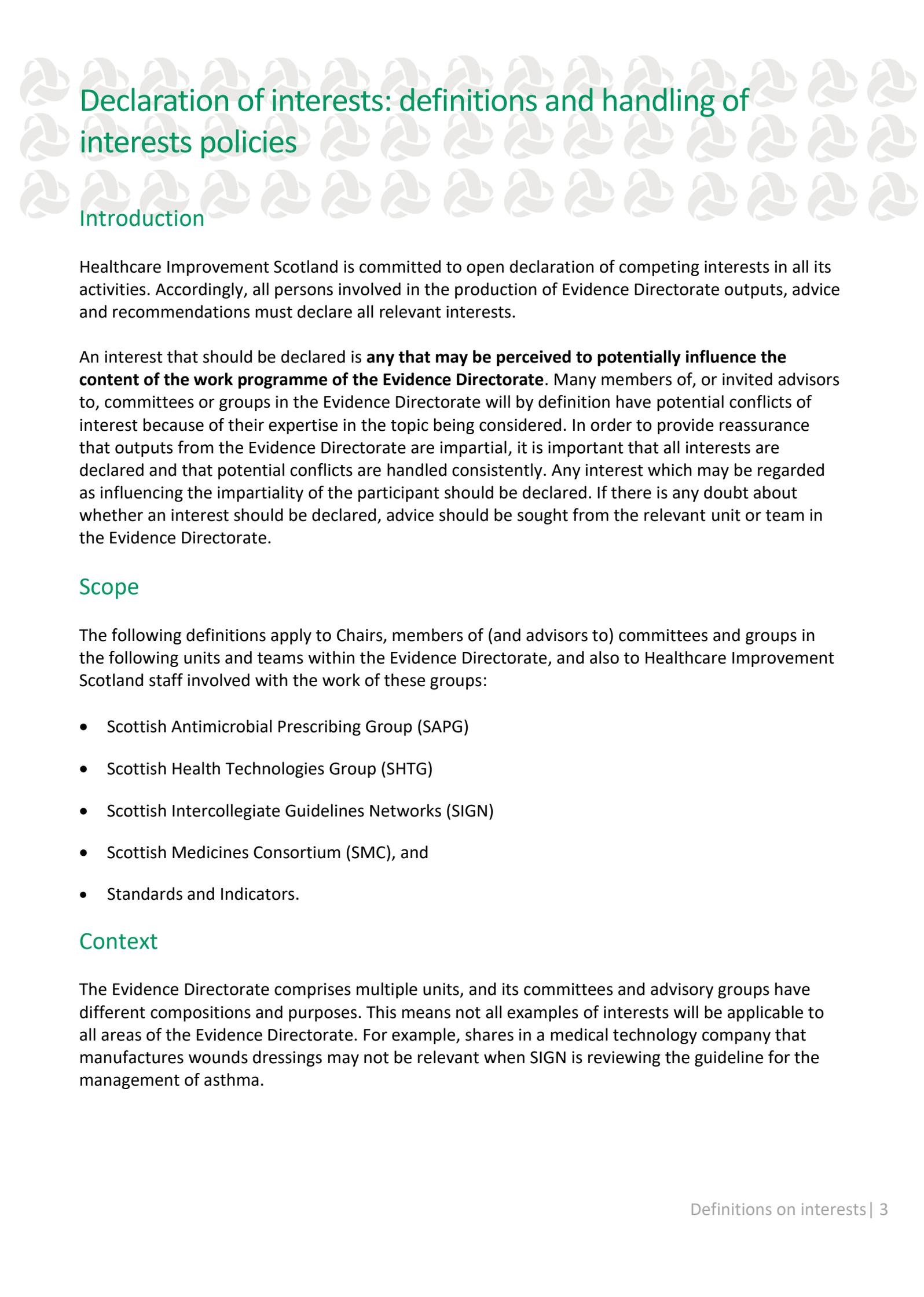


Declarations of interest: definitions and policies for handling of interests at meetings



Contents

Introduction.....	3
Scope	3
Context.....	3
Definitions.....	4
Specific/non-specific	4
Financial/non-financial.....	4
Personal/non-personal	4
Examples of interests	5
Financial and personal	5
Financial and non-personal	5
Non-financial and personal.....	6
Non-financial and non-personal.....	6
Additional interests	6
Examples of interests which need not be declared	6
How long do interests last for?.....	7
Handling of declared interests at meetings	8
Appendix A – Attendance at conferences, scientific meetings and similar	9
Appendix B – Handling of declared interests policy: SMC and SAPG	10
Appendix C – Handling of declared interests policy: SIGN.....	11
Appendix D – Handling of declared interests policy: Standards and Indicators	12
Appendix E – Handling of declared interests policy: SHTG.....	13



Declaration of interests: definitions and handling of interests policies

Introduction

Healthcare Improvement Scotland is committed to open declaration of competing interests in all its activities. Accordingly, all persons involved in the production of Evidence Directorate outputs, advice and recommendations must declare all relevant interests.

An interest that should be declared is **any that may be perceived to potentially influence the content of the work programme of the Evidence Directorate**. Many members of, or invited advisors to, committees or groups in the Evidence Directorate will by definition have potential conflicts of interest because of their expertise in the topic being considered. In order to provide reassurance that outputs from the Evidence Directorate are impartial, it is important that all interests are declared and that potential conflicts are handled consistently. Any interest which may be regarded as influencing the impartiality of the participant should be declared. If there is any doubt about whether an interest should be declared, advice should be sought from the relevant unit or team in the Evidence Directorate.

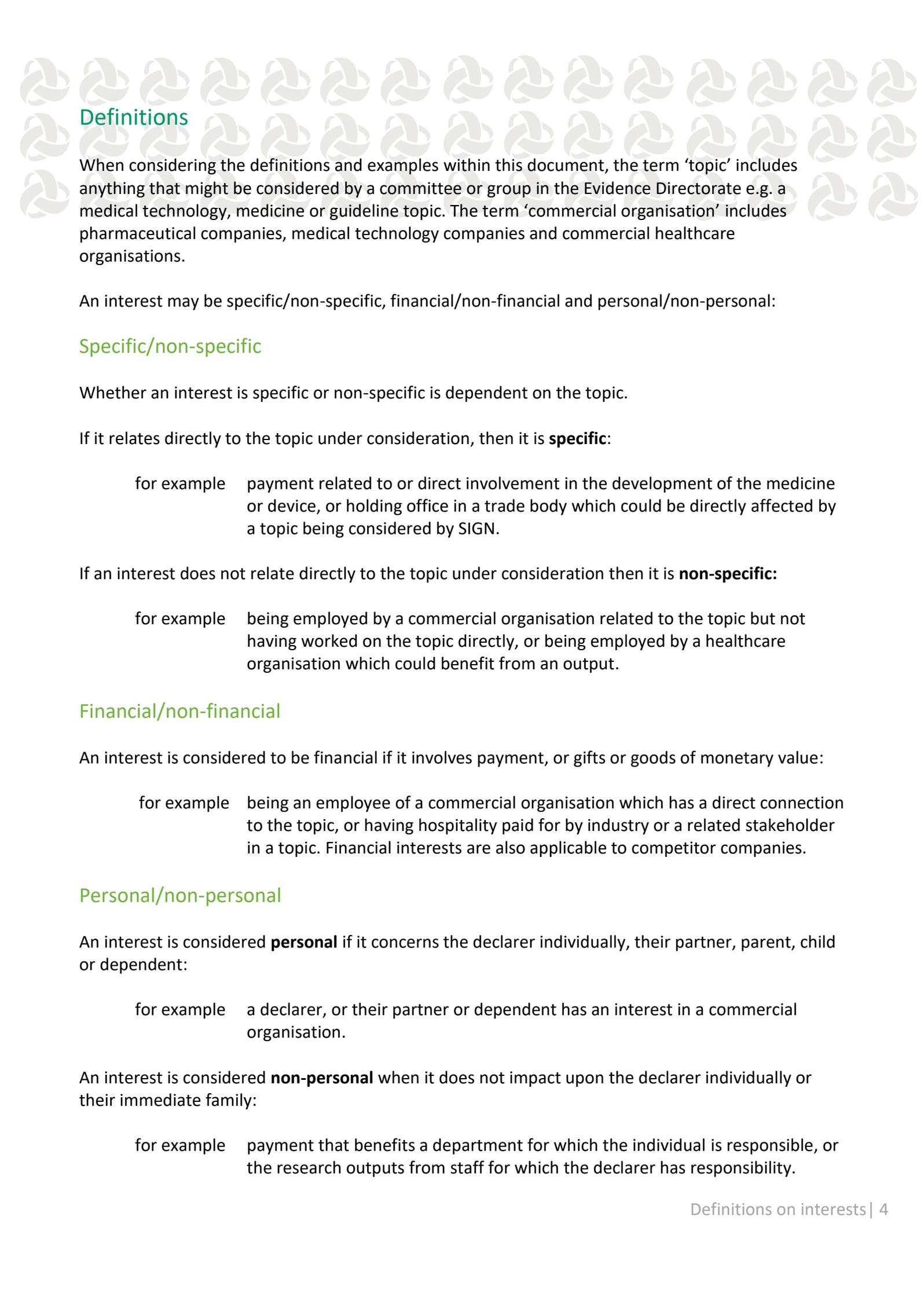
Scope

The following definitions apply to Chairs, members of (and advisors to) committees and groups in the following units and teams within the Evidence Directorate, and also to Healthcare Improvement Scotland staff involved with the work of these groups:

- Scottish Antimicrobial Prescribing Group (SAPG)
- Scottish Health Technologies Group (SHTG)
- Scottish Intercollegiate Guidelines Networks (SIGN)
- Scottish Medicines Consortium (SMC), and
- Standards and Indicators.

Context

The Evidence Directorate comprises multiple units, and its committees and advisory groups have different compositions and purposes. This means not all examples of interests will be applicable to all areas of the Evidence Directorate. For example, shares in a medical technology company that manufactures wounds dressings may not be relevant when SIGN is reviewing the guideline for the management of asthma.



Definitions

When considering the definitions and examples within this document, the term ‘topic’ includes anything that might be considered by a committee or group in the Evidence Directorate e.g. a medical technology, medicine or guideline topic. The term ‘commercial organisation’ includes pharmaceutical companies, medical technology companies and commercial healthcare organisations.

An interest may be specific/non-specific, financial/non-financial and personal/non-personal:

Specific/non-specific

Whether an interest is specific or non-specific is dependent on the topic.

If it relates directly to the topic under consideration, then it is **specific**:

for example payment related to or direct involvement in the development of the medicine or device, or holding office in a trade body which could be directly affected by a topic being considered by SIGN.

If an interest does not relate directly to the topic under consideration then it is **non-specific**:

for example being employed by a commercial organisation related to the topic but not having worked on the topic directly, or being employed by a healthcare organisation which could benefit from an output.

Financial/non-financial

An interest is considered to be financial if it involves payment, or gifts or goods of monetary value:

for example being an employee of a commercial organisation which has a direct connection to the topic, or having hospitality paid for by industry or a related stakeholder in a topic. Financial interests are also applicable to competitor companies.

Personal/non-personal

An interest is considered **personal** if it concerns the declarer individually, their partner, parent, child or dependent:

for example a declarer, or their partner or dependent has an interest in a commercial organisation.

An interest is considered **non-personal** when it does not impact upon the declarer individually or their immediate family:

for example payment that benefits a department for which the individual is responsible, or the research outputs from staff for which the declarer has responsibility.

Examples of interests

The following lists detail combinations of financial/non-financial, and personal/non-personal interests. The list is not considered to be exhaustive. Whether interests are specific or non-specific will change depending on the topic.

Financial and personal

A financial, personal interest relates to a financial interest which will have a direct impact on the declarer, their partner or a dependent. Examples include, but are not limited, to:

- Employment, payment for self-employment, consultancies or other fee paid work by a healthcare organisation, commercial organisation, or specialist society.
- Shareholdings in a relevant industry e.g. pharmaceutical or medical technology company.
- Any consultancy, directorship, position in or work for the pharmaceutical or medical technology industry which attracts regular or occasional payments in cash or kind.
- Any fee paid work commissioned by the pharmaceutical or medical technology industry for which the individual is paid in cash or kind.
- The declarer holds a fellowship endowed by a relevant industry or commercial organisation.
- Expenses or hospitality provided by a commercial organisation for attendance at a conference or an invited lecture. See appendix A for detailed guidance on conference attendance.
- Being a director of a corporate body (this is a non-financial interest if no fee paid).
- Any allowance received in relation to membership of any relevant organisation.

Financial and non-personal

Financial, non-personal interests often relate to support from a relevant industry or commercial organisation which does not convey any financial or material benefit to a declarer personally but does benefit their position or department. Examples include but are not limited to:

- An employee of the declarer holds a fellowship endowed by industry or a commercial organisation.
- Grants from a commercial organisation for the running of a unit or department for which an individual is responsible.
- The commissioning by a commercial organisation of research or other work by, or advice from, staff who work in a unit for which the declarer is responsible.

- Any payment, other support or sponsorship by the pharmaceutical or medical technologies industry which benefit the declarer's position or department

Non-financial and personal

- Being a chief investigator or co-chief investigator of a trial funded by a commercial organisation or a principal investigator who is likely to benefit from authorship of a resulting publication.
- Participation on an advisory board arranged by a commercial organisation.
- An individual has done research work relating to a particular product, or class of products. Although the research has not been funded by any particular commercial organisation, the research has taken a particular line, e.g. in relation to the safety of the products, or their efficacy.
- An individual has made public statements (either favourable or unfavourable) about a particular commercial organisation, or product, or class of products or about a competitor's product or class of product.
- Having the illness or condition, or has a family member who has an illness or condition relevant to the topic or who has experienced a severe reaction or other problem as a result of treatment or intervention with a product under discussion.
- Participation in or connection with, a voluntary organisation or relevant advocacy group that would have an interest in the outcome of a discussion.
- Membership of, or holding an office in, relevant organisations including but not limited to: other public bodies, clubs, and societies.

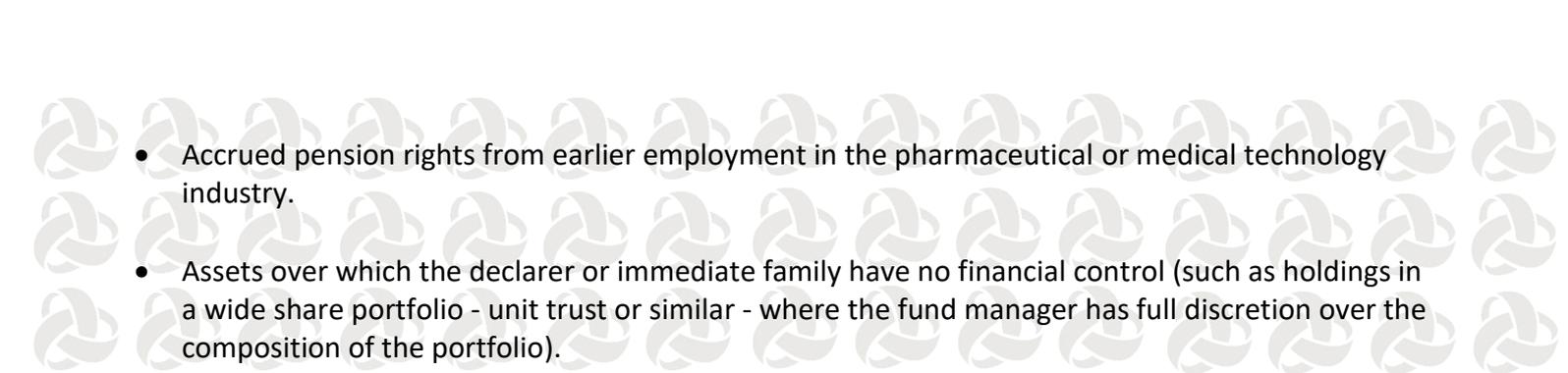
Non-financial and non-personal

- An individual's department has done research work relating to a particular product, or class of products under consideration.
- Commissioning of research or other work or advice from staff who work in a unit for which the individual is responsible. It is not necessary for the declarer to seek out information from their department or colleagues if they would not normally expect to be informed.

Additional interests

- Matters which could reasonably be perceived as affecting the individual's impartiality relating to persons who are closely connected to the declarer but not an immediate family member.
- Any other matter that could affect an individual's impartiality, or that could reasonably be perceived as affecting their impartiality.

Examples of interests which need not be declared

- 
- Accrued pension rights from earlier employment in the pharmaceutical or medical technology industry.
 - Assets over which the declarer or immediate family have no financial control (such as holdings in a wide share portfolio - unit trust or similar - where the fund manager has full discretion over the composition of the portfolio).
 - Financial assistance for students.

How long do interests last for?

- All current interests should be declared.
- *Specific, personal, financial* interests from the past 3 years should be declared.
- *Specific, non-personal, financial* interests from the past 12 months should be declared.
- *Personal, non-financial* interests that have arisen from a publication or a public statement do not expire and remain current interests.
- *Non-personal non-financial* interests that have arisen from an employee or someone you are responsible for, writing a publication or making a public statement expire if that person leaves your employment, or you are no longer responsible for them.
- *Personal, non-financial* interests that have arisen from a non-paid advisory role to a company **do expire**. These interests expire after 3 years if the interest is specific and after 12 months if the interest is non-specific.

Handling of declared interests at meetings

The different units and teams in the Evidence Directorate have different purposes. For example SMC, SAPG, and SHTG hold meetings that have a topic in one agenda item usually dealing with a consistent question: should a medicine/technology be accepted for use in NHSScotland? This consistency in the question being asked allows these groups to be very clear as to when someone should or should not be allowed to participate, as these 'narrow' topics allow a greater potential for bias to be exerted.

In contrast, groups such as SIGN and Standards and Indicators have topic specific groups which will deal with a topic over approximately 1–2 years. These topic specific groups will deal with many individual points to produce recommendations for guidelines and standards supporting best practice. Due to this broader level of application, and because these units consider only medicines or processes already approved for use in NHS Scotland, it can be of benefit to include the expertise of someone who would be excluded from other meetings within the directorate.

Despite these differences the principles for managing the interests should be consistently followed, and operationally there are commonalities in how some interests are handled.

The following interests **always allow** participation by the declarer:

- Specific, non-financial, non-personal.
- Non-specific, non-financial, non-personal.
- Non-specific, financial, non-personal.

The following interest **always excludes** the declarer from taking part:

- Specific, financial, personal.

See appendices B-E for specific guidance on how interests are handled at each unit or team's meetings.

Appendix A – Attendance at conferences, scientific meetings and similar

The Evidence Directorate and its units recognise that conferences, scientific meetings and other events associated with healthcare, medicines or related matters may receive some form of sponsorship either directly, or indirectly via a special fund, from industry and research. The importance of being able to receive advice from leading experts who are able to keep themselves up to date with developments at the cutting edge of science is also recognised, and this is done mainly through attendance at educational and scientific events and meetings. It is therefore essential to set out rules for attendance at these and similar events as questions may be legitimately raised as to whether participation in the event, or even attendance, will compromise an individual's impartiality in any way.

The nature of the events that fall within the scope of declarations of interest and the industry sponsorship received can vary widely from, at one extreme, a conference sponsored by a single company to launch a product to, at the other extreme, a scientific meeting organised by a learned society that has received some financial support from a number of companies paid into a dedicated meeting fund. Between these extremes there are many variations in events and funding that may occur.

Expenses or hospitality provided by a commercial organisation should be declared. Expenses or hospitality beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences might reasonably be perceived as affecting an individual's impartiality and would constitute a personal financial interest.

Where a learned society holds an international conference that is funded by a number of different companies, it will generally be acceptable for the individual to accept such an invitation and to receive payment of expenses, although in such instances declaration of attendance and receipt of funding must be made in the normal way. Benefits of this nature paid to an immediate family member that also benefit the individual (e.g. a company pays their flight costs so that they can attend a conference with a family member) must be declared as the individual's own interest. However, there is no requirement to declare educational conferences and similar events attended by immediate family members.

If an individual attends an educational conference or similar and takes part in a 'satellite' meeting sponsored and arranged by specific companies, this could be a personal interest depending on the opinion expressed by the individual during the meeting or if a consensus statement was generated. If in doubt, this must be raised with the Chair of their group at the earliest possible opportunity, who will be able to provide further guidance.

The situations described are not exhaustive and individuals should always seek advice from the Chair of their group if they are in any doubt about whether or not they should attend, or whether, having attended, they need to declare attendance as an interest.

Appendix B – Handling of declared interests policy: SMC and SAPG

Interest			Action	Policy upheld by:
Specific	Financial	Personal inc. family	Do not participate in discussion. Withdraw from meeting table to designated area within meeting room. Not eligible to vote, if applicable.	Chair or their Healthcare Improvement Scotland staff nominee. The Chair or member of staff must ask individuals to take the specified action when they have self-declared and risk breaching the policy.
Specific	Financial	Non-personal	Participate, eligible to vote, if applicable.*	As above
Specific	Non-financial	Personal inc. family	Do not participate in discussion. Withdraw from meeting table to designated area within meeting room. Not eligible to vote, if applicable.	As above
Specific	Non-financial	Non-personal	Participate, eligible to vote, if applicable, unless exceptionally the Chair rules otherwise.	As above
Non-specific	Financial	Personal inc. family	Do not participate in discussion unless invited to by the Chair. Remain at the table. Not eligible to vote, if applicable.	As above
Non-specific	Financial	Non-personal	Participate fully, can vote if applicable	As above
Non-specific	Non-financial	Personal inc. family	Do not participate in discussion unless invited to by the Chair. Remain at the table. Not eligible to vote, if applicable.	As above
Non-specific	Non-financial	Non-personal	Participate fully, can vote if applicable	As above

* If the individual has personal knowledge of the intervention either through his or her own work, or through direct supervision of other people's work, he or she should not participate in discussion but may remain at meeting table. At the Chair's discretion they may be invited to answer questions from other members but is not eligible to vote.

Appendix C – Handling of declared interests policy: SIGN

Interest			Action	Policy upheld by:
Specific	Financial	Personal inc. family	Do not participate in the evidence review or discussions on the key questions related to the conflict of interest.	Decisions on participation are agreed by SIGN Senior Management Team (SMT) and upheld in meetings by the guideline development group Chair and Programme Manager.
Specific	Financial	Non-personal	Participate unless exceptionally the Chair rules otherwise on advice from SIGN SMT.	As above
Specific	Non-financial	Personal inc. family	Participate unless exceptionally the Chair rules otherwise on advice from SIGN SMT.	As above
Specific	Non-financial	Non-personal	None required	As above
Non-specific	Financial	Personal inc. family	Participate unless exceptionally the Chair rules otherwise on advice from SIGN SMT.	As above
Non-specific	Financial	Non-personal	Participate unless exceptionally the Chair rules otherwise on advice from SIGN SMT.	As above
Non-specific	Non-financial	Personal inc. family	Participate unless exceptionally the Chair rules otherwise on advice from SIGN SMT.	As above
Non-specific	Non-financial	Non-personal	None required.	As above

Appendix D – Handling of declared interests policy: Standards and Indicators

Interest			Action	Policy upheld by:
Specific	Financial	Personal inc. family	Do not participate in discussion. In exceptional circumstances the Chair may allow participation in discussion or to answer questions from members.	Policy upheld in meetings by the development group Chair and Programme Manager.
Specific	Financial	Non-personal	Participate unless exceptionally the Chair rules otherwise on advice from S&I/K&I SMT.	As above
Specific	Non-financial	Personal inc. family	Participate unless exceptionally the Chair rules otherwise on advice from S&I/K&I SMT.	As above
Specific	Non-financial	Non-personal	None required	As above
Non-specific	Financial	Personal inc. family	Participate unless exceptionally the Chair rules otherwise on advice from S&I/K&I SMT.	As above
Non-specific	Financial	Non-personal	Participate unless exceptionally the Chair rules otherwise on advice from S&I/K&I SMT.	As above
Non-specific	Non-financial	Personal inc. family	Participate unless exceptionally the Chair rules otherwise on advice from S&I/K&I SMT.	As above
Non-specific	Non-financial	Non-personal	None required	As above

Appendix E – Handling of declared interests policy: SHTG

Interest			Action	Policy upheld by:
Specific	Financial	Personal inc. family	Do not participate. In exceptional circumstances the Chair may allow participation in discussion or to answer questions from members.*^	Decisions on participation are agreed by SHTG Executive Group and upheld in meetings by the Chair, Unit Head and Programme Manager.
Specific	Financial	Non-personal	Do not participate. In exceptional circumstances the Chair may allow participation in discussion or to answer questions from members.*^	As above
Specific	Non-financial	Personal inc. family	Do not participate. In exceptional circumstances the Chair may allow participation in discussion or to answer questions from members.*^	As above
Specific	Non-financial	Non-personal	Participate unless, exceptionally, the Chair rules otherwise on advice from SHTG Executive Group.	As above
Non-specific	Financial	Personal inc. family	Participate unless, exceptionally, the Chair rules otherwise on advice from SHTG Executive Group.	As above
Non-specific	Financial	Non-personal	Participate unless, exceptionally, the Chair rules otherwise on advice from SHTG Executive Group.	As above
Non-specific	Non-financial	Personal inc. family	Participate unless, exceptionally, the Chair rules otherwise on advice from SHTG Executive Group.	As above
Non-specific	Non-financial	Non-personal	None required	As above

* For health technologies (excluding medicine) there may be limited number of experts in Scotland with relevant knowledge and experience of the technology being considered. Under these circumstances those with interests which normally exclude them from proceedings may need to be consulted.

^Patient representative organisations will not be excluded. It is expected that patient representative organisations will have specific interests in medical technologies. Despite this, the SHTG is interested in the contribution that these organisations can make to the HTA process to ensure that patient opinions are gathered.