



Healthcare
Improvement
Scotland

SMC
Advice on new
medicines

Standard explanation of Declarations of Interest

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www.scottishmedicines.org.uk

If members or clinical experts have interests not specified in these notes but which they believe could be regarded as influencing their impartiality they should declare them.

Personal Interests

A personal interest involves payment in cash or kind to the member personally. The main examples are:

- a. Consultancies: any consultancy, directorship, position in or work for the pharmaceutical industry which attracts regular or occasional payments in cash or kind.
- b. Fee-Paid Work: any work commissioned by the pharmaceutical industry for which the member is paid in cash or kind.
- c. 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/expert has no influence or financial management.
- d. Disproportionate expenses/hospitality provided by a pharmaceutical company.
- e. 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.

Non-Personal Interests

A non-personal interest involves payment which benefits a department for which a member or clinical expert is responsible, but is not received by the member/expert personally. The main examples are:

- a. Fellowships: the holding of a fellowship endowed by the pharmaceutical industry.
- b. 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/expert 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.

Members/experts 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.

Notes for clinical experts

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 If the interest is no longer current (last three years), the expert may declare it as a lapsed personal specific interest.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

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.

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.

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.

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.

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Declarations of Interest Frequently Asked Questions (FAQs)

Note that answers should be viewed as a guide, if in doubt consult the Secretariat.

Q1	I recruited patients into a company sponsored trial and prescribed the medicine under review but did not receive personal payment, is this a personal interest?
A1	This is a non-personal specific interest unless you are likely to benefit personally in some other way e.g. by being a Chief Investigator or Co-Chief Investigator or a Principal Investigator who is likely to benefit from authorship of a resulting publication.
Q2	I was paid to participate on an Advisory Board for the medicine under review six years ago, does the personal interest still apply?
A2	No because involvement was more than three years ago this is classed as a lapsed personal specific interest. (However, note that a personal specific interest as a result of significant involvement in the development of a product, or through authorship of a core publication on the product, never lapses).
Q3	What constitutes a significant involvement in the development of a product?
A3	This includes pre-clinical and clinical development e.g. being a Chief or Co-Chief Investigator of a company funded clinical trial or being paid to provide scientific advice.
Q4	I participated on an Advisory Board for the medicine under review but didn't receive/accept payment, is this a personal interest?
A4	Yes as this might reasonably be perceived as possibly affecting your impartiality.
Q5	I participated on an Advisory Board for the medicine under review but passed payment to charity, is this a personal interest?
A5	Yes as this might reasonably be perceived as possibly affecting your impartiality.
Q6	I directly advised the Company on their SMC submission but didn't receive payment, is this a personal interest?
A6	Yes as this might reasonably be perceived as possibly affecting your impartiality.
Q7	I was paid to take part on an Advisory Board for the medicine under review but in a different indication, is this classed as a specific interest?
A7	Yes as the interest relates to the same product.
Q8	I received travel expenses from Company X to attend a conference, is this a personal interest?

A8	Such expenses should be declared, however would not be considered as a personal interest unless the expenses were disproportionate.
Q9	I attended a conference sponsored by a number of companies and received travel expenses from my department, do I need to declare an interest?
A9	No.
Q10	I attended a conference satellite meeting in relation to the medicine under review, is this a personal interest?
A10	Not unless disproportionate expenses/hospitality were provided by the pharmaceutical company.
Q11	Company X paid my registration fee to attend a conference, is this a personal interest?
A11	Yes. This would be considered a non-specific interest unless directly related to the medicine under review.
Q12	I have a personal specific interest in a medicine that is a direct competitor to the product under review, should I declare this?
A12	Yes as this also represents a personal interest in the medicine under review.
Q13	I am a member of SMC/NDC and have a personal specific interest in the medicine under review, can I take part in proceedings?
A13	As a general rule, members with a relevant personal specific interest will not be allowed to take part in discussions.
Q14	I am a SMC clinical expert and have a personal specific interest in the medicine under review, will my responses be considered by SMC?
A14	It is important that clinical expert responses used in SMC assessment of a medicine are perceived as being impartial. SMC is therefore unable to use responses from experts who have a personal specific interest.
Q15	After what time period do interests lapse?
A15	Personal specific interests lapse after a period of three years unless they are as a result of significant involvement in the development of a product, in which case they never lapse. Personal non-specific and non-personal interests normally lapse after 12 months.

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