1. Purpose of policy

To outline the NHS GG&C management processes for maintaining and updating the Adult Medicines Formulary, namely Formulary appeals,section reviews and New Drug Assessments.

2. Formulary Review Process

2.1. Adding medicines to the Formulary
Medicines may be added to the Formulary via the following mechanisms:

- Evaluation by Scottish Medicines Consortium (SMC) with local consideration by the Area Drugs and Therapeutics Committee (outlined in Managed Entry of New Medicines).
- Following a successful Formulary appeal (process outlined below in Section 3: Formulary Appeal Processes).
- If the medicine is outwith SMC remit, and a decision on Formulary status is considered necessary, then a New Drug Assessment (FORM NDA) may be completed, submitted to the Medicines Policy & Guidance (MPG) team and considered by the Medicines Utilisation (MU) sub-committee of the Area Drug and Therapeutics Committee (ADTC), see section 3 below.

2.2. Removing medicines from the Formulary
Medicines may be removed from the Formulary via the following mechanisms:

- Automatic removal from the Formulary following discontinuation or withdrawal of medicine
- Following a recommendation made during a Formulary Section Review (see below)
- Following a successful Formulary change appeal

The following groups may also make direct recommendations to the ADTC regarding the potential review of medicines within the Formulary via communication with the MU sub-committee:

- Acute Services Prescribing Management Group
- Primary Care Prescribing Management Group
- Managed Clinical Networks
- Regional Specialist Interest Groups (SIGs)

- Antimicrobial Management Group
- Safer Use of Medicines sub-committee
- Medicines Cost Effectiveness Group
- Mental Health Drug & Therapeutics Committee
- Mental Health Prescribing management Group

2.3. Formulary section reviews

In order to ensure that the Formulary reflects current practice, the aim is to have a rolling programme of Formulary section reviews. In general, the review programme is approved by the MU sub-committee of ADTC with input from the Medicines Policy & Guidance team. Formulary section reviews may also be initiated following:

- Approval of a new local clinical guideline by MU Sub-Committee
- Upon the request of a Specialist Interest Group or Managed Clinical Network
- Following the publication of related NICE or SIGN guidance

2.3.1. Prior to a review, the MPG team will identify and approach relevant clinicians and other health professionals inviting them to participate in the section review or nominate alternative persons.

The MPG team will support the review process with the provision of relevant information to inform discussion.

It is preferable for a section review to be carried out in a single meeting by a multidisciplinary expert panel. Quorum for minimum persons constituting this panel has been agreed and consists of:

- Minimum of two consultants in the relative specialty who should represent views of their peers from sites across the geographical area of NHS GG&C (i.e. acute sites in the North and South of Glasgow and the acute sites in the Clyde area of the Health Board)
- Minimum of one General Practitioner or primary care prescriber (if impact in primary care)
- Minimum of one specialist pharmacist, if in post
- Minimum of one representative from paediatrics, which may be a pharmacist or clinician, if significant difference in treatment approach between paediatric and adult patients
- Minimum of one representative from the Primary Care Prescribing Team
- Minimum of one representative from the MPG Team

In the event that the multidisciplinary expert panel does not include a General Practitioner, a section review may still take place (providing that quorum has

been met otherwise). However, the recommendations of the review will not then be considered by ADTC or its sub-committees until they have been reviewed by GPs in an appropriate manner (e.g. consideration at a Community Health Partnership GP Forum).

The MPG Team will liaise with the other panel members to coordinate meeting and agree a chair. If the section review is being led by a specialist group with an existing chair, the chair should be made aware of the process for ratification of suggestions arising from a section review.

Section reviews recommendations may include suggestions to delete medicines from the Formulary, move medicines between Preferred List and Total Formulary, amendments to current Formulary restrictions (ensuring that they still remain within any restriction placed on use by the SMC) or additions or changes to prescribing notes. However, additions of medicines to the Formulary resulting from recommendations of a section review cannot be automatically processed without the specific agreement of the Medicines Utilisation sub-committee or ADTC.

All recommendations will be considered by the MU Sub-committee and ultimately by ADTC.

2.3.2. Assigning Preferred List or Total Formulary status

The GGC Adult Medicines Formulary consists of two tiers. Though all medicines in both these tiers are considered Formulary, they have a slightly different focus.

Preferred List:

First-line agents for use within a class of medicines or for a particular therapeutic use area. These medicines are primarily intended for non-specialist prescribers or junior staff members across all sectors (community, primary care and acute services).

Total Formulary:

Second-line agents and medicines for specialist initiation/ use are generally found in this tier of the Formulary.

Criteria for a Preferred List medicine, as agreed by ADTC are:

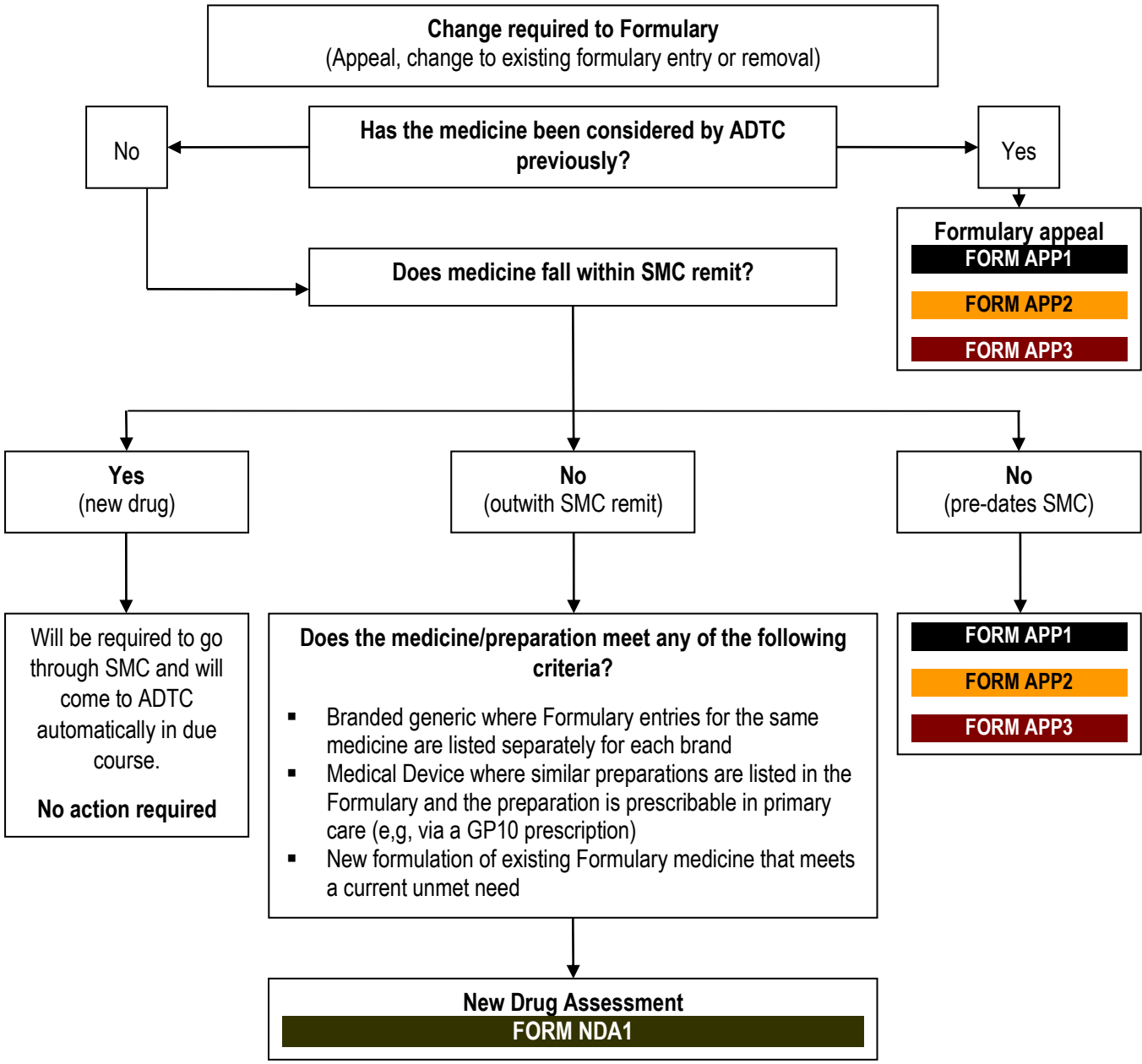
1. Medicines must be suitable for initiation in primary care or in hospital by non-specialist prescribers for common medical conditions
2. Medicines must be approved by the Area Drug and Therapeutics Committee for use within NHSGG&C
3. Medicines/indications/formulations must either pre-date the existence of the Scottish Medicines Consortium (SMC), be accepted for use by SMC or fall outwith SMC remit.
4. Medicines must have demonstrable comparable or superior efficacy within class
5. The medicine's safety profile should be well established, which means that no new medicines (indicated by ▼) will be included unless it is a new class of medicine and/or has demonstrated considerable advantages over existing preferred list medicines and is appropriate for initiation in primary care
6. Where several medicines in a class exist, and efficacy has not been shown to vary greatly across the class, the lowest cost medicine will be selected. If there is no or little cost difference between medicines, the medicine(s) most commonly prescribed will be selected.
7. Where necessary, relevant Managed Clinical Networks or similar groups will be consulted as to which Formulary medicines of a class are considered most appropriate for general prescribing, and hence inclusion in the Preferred List.

2.4. Declared interests in the pharmaceutical industry

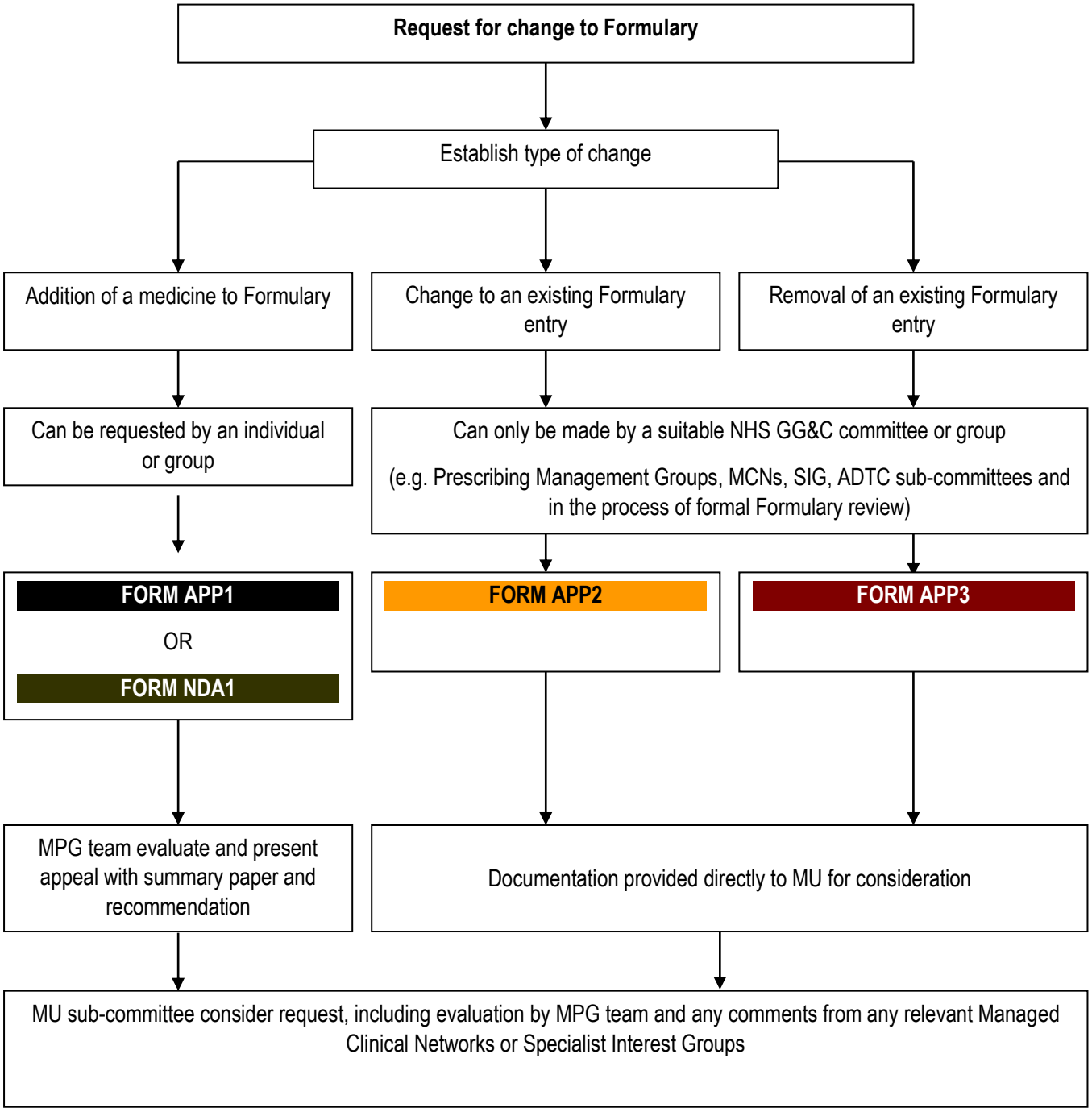
All relevant interests in the Pharmaceutical Industry must be declared in writing by all section review panel members (Appendix 1). Persons with personal specific interests are still able to comment, but the interests will be flagged up when the recommendations of the review panel are considered by the MU Sub-committee.

3. Formulary Appeals Processes

Overview of the process- can a change request be submitted (Figure 1)



Overview of the process- which form to use and further progression (Figure 2)



3. Formulary Management

The NHS GG&C Adult Medicines Formulary appeal processes allow relevant NHSGG&C staff, advisory groups or managed clinical networks the ability to either have a medicine considered for inclusion in the Formulary, to have the restrictions or positioning within the Formulary amended or to have the medicine removed from the Formulary. Requests will be considered by the Medicines Utilisation (MU) sub-committee of Area Drugs and Therapeutics Committee (ADTC).

Whether a Formulary appeal can be submitted considers previous formulary decisions, advice from the Scottish Medicines Consortium (SMC) or NICE Multiple Technology Appraisals endorsed by Healthcare Improvement Scotland (HIS).

There are four related appeal processes (see Figure 1 above):

1. Request to have a medicine re-considered for formulary inclusion
2. Request to have a change made to an existing Formulary entry
3. Request to have a medicine or preparation removed from the Formulary
4. Request for an assessment to be conducted on a new medicine/preparation where there is no automatic route for Formulary inclusion (e.g. outwith remit of SMC).

Who is able to submit an appeal (individuals or groups) depends on the type of request (see Figure 2 above).

Unlicensed medicines: Unlicensed medicines (i.e. medicines with no UK marketing authorisation) are generally not included in the Formulary, but unlicensed preparations are occasionally referred to. For specific medicines where the BNF, national guidelines or other specific references mentions an off-label use and this is in keeping with the recommendations of local specialists, a formulary change request to include such details in the prescribing notes can be submitted.

3.1. Criteria for submission of appeal or New Drug Assessment

A request to have a Formulary decision reconsidered or for an amendment to an existing Formulary entry can only be made if at least 1 year has passed since the medicine was last considered by ADTC. In addition, if the medicine is subject to SMC or NHS HIS advice, then the appeal or amendment must not contradict that advice.

Only relevant healthcare professionals working within NHS Greater Glasgow and Clyde, or appropriate Managed Clinical Networks, groups and committees can submit appeals or requests for amendments. The appeals process is not open to the pharmaceutical industry or general public.

3.2. Criteria for a New Drug Assessment

A New drug Assessment will only be required for new medicines or preparations that are considered to be outwith the remit of the SMC. Typically, these medicines will fall into one of the following three categories:

- The medicine is a branded generic where Formulary entries for the same medicine are listed separately for each brand
- A Medical Device where similar preparations are listed in the Formulary and the preparation is prescribable in primary care (e,g, via a GP10 prescription)
- A new licensed formulation of existing Formulary medicine that meets a current unmet need

3.3. Declarations of interests

The Formulary appeals process is intended to operate in an open and transparent manner in accordance with NHSGG&C guidance on declared interests (see Appendix 1). All staff involved in the submission of an appeal or change request must declare any potential conflict of interests in the relevant sections of the documentation. Where the appellant has a conflict of interest, the MU sub-committee will still consider the appeal but will be mindful of the declared interest.

3.4. Submission process

Having identified the correct process using figures 1 and 2 for guidance, the relevant documentation (available here) should be completed in full and returned to the MPG team (where possible, electronically via the ggc.medicines@ggc.scot.nhs.uk email address).

Although individuals can request an addition to the Formulary, it is advisable that they obtain and document wider peer support for their appeal. This will enable wide acceptance and implementation of formulary choices across NHS GG&C.

The Medicines Policy and Guidance (MPG) team will acknowledge receipt of the appeal or NDA and advise on the timescale for a decision (see section 3.8 timelines).

The appeal/ NDA will then be managed by the MPG team, who will ensure that it is considered by MU sub-committee.

3.5. Evaluation of appeal or New Drug Assessment

The MPG team lead on the evaluation and assessment of the appeal/NDA on behalf of the MU sub-committee and will:

- Summarise the case made by the appellant
- Critically appraise the evidence base supporting the appeal/NDA
- Clarify aspects of the appeal with the appellant
- Consider wider clinical evidence relating to the medicine and its intended use that was not submitted as part of the appeal/NDA to ensure a balanced consideration has been made
- Seek further expert advice where necessary
- Present the appeal/NDA to the MU sub-committee and provide them with a summarised assessment of the submitted and gathered evidence and supporting information.

As part of the evaluation process, where an appropriate Managed Clinical Network (MCN) or Specialist Interest Group (SIG) exists but is not listed as supporting the appeal, advice from that group will be sought (unless the appeal has originated from the MCN/SIG). This advice will typically be sought via the group Chair and based on the responses to the following questions to promote consistency

An appeal/NDA has been received by the Medicines Utilisation sub-committee) for [name of medicine] for the treatment of [indication] in [restriction or proposed patient subgroup as appropriate].

1. Are there any NHS GG&C or national guidelines that would support or are contrary to this appeal?
2. Do you feel that there is currently a significant unmet need that the inclusion of this medicine on the NHS GG&C Adult Medicines Formulary would address? (please give details)
3. Other medicines available from this indication on the Formulary are described in the appeal (including their comparative cost). Where the appeal medicine is more expensive than the Formulary alternatives, please describe the benefits validating this increased cost.
4. If included in the Formulary, how many patients in NHS GG&C would be eligible for treatment with this medicine?
5. Would you like to highlight any further aspects that you think are relevant to this appeal e.g. service implications?
6. Do you support the Formulary appeal/NDA for this medicine?

3.6. Decision process

The MU sub-committee consider the appeal/NDA and the MPG team assessment and agree a decision. The decision may be to uphold the appeal/NDA, including restrictions on use where appropriate; reject the appeal/NDA or defer the appeal/NDA while further information or clarity is sought. Where the appeal/NDA has been deferred, the expectation is that it will be reconsidered at the following meeting of the MU sub-committee.

3.7. Communication of decision

Following consideration by the MU sub-committee, the MPG team will inform the appellant of the outcome of the appeal/NDA at the earliest opportunity, either by email, by telephone or in person. If the appeal/NDA results in a change to the GGC Formulary, this will be made within 14 days of the MU decision. Decisions which result in the inclusion of a new medicine (as opposed to a change in positioning or restriction) will also be included as part of the Formulary Update communication which follows each MU meeting.

3.8. Timelines

The MPG team try to ensure that appeals/NDAs received are processed and considered within a single MU meeting cycle, which usually will result in a decision within 2 months of submission to the MPG team. However there may be other considerations which may result in a longer timescale. These may include the timing of when the appeal was received in relation to the timing of the next MU sub-committee meeting; current formulary appeal workload; MU sub-committee request for further information or clarification.

3.9. Documentation

The Formulary Appeal and New Drug Assessment request documentation is available via the Formulary Appeals page on the GGC Medicines website www.ggcmedicines.org.uk/formulary-appeals/.

Appendix 1: Guidance on interests to declare

All persons involved in formulary section reviews or submitting an appeal must declare any relevant interests in the pharmaceutical industry at the time of the review/ appeal.

The following is intended as a guide to the kinds of interest which should be declared. Where a member is uncertain as to whether an interest should be declared he or she should seek guidance from the MPG team or the Chair of the relevant committee/ sub-committee.

1.1. Personal interests

A personal interest involves payment to the member personally. The main examples are:

- Consultancies: any consultancy, directorship, position in or work for the pharmaceutical industry 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.

Personal Specific Interests:

An individual must 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. If the interest is no longer current, the member may declare it as a lapsed personal specific interest.

Personal Non-specific Interests:

An individual must 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.

1.2. Non-personal interests:

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

1. Fellowships: the holding of a fellowship endowed by the pharmaceutical industry.
2. 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 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 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:
An individual must 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 member has not personally received payment in any form from the pharmaceutical industry for the work done.

Non-personal Non-specific Interests:
An individual must 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.