

<b>MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY</b>		
<b>AGENCY PROCEDURES</b>		<b>Ref: HR017/06</b>
<b>Title: Dealing with Conflicts of Interests in the Medicines and Healthcare products Regulatory Agency</b>		
	<b>Signed</b>	<b>Date</b>
	<b>Agreed by: Rebecca Starling</b>	19/02/2014
	<b>Agreed by: Cathy Potgeiter</b>	19/02/2014
<b>Effective date</b> 20/02/2014	<b>Review date</b> 20/02/2016	<b>Page 1 of 12</b>

## **1 SCOPE**

- 1.1 As civil servants, Medicines and Healthcare products Regulatory Agency (agency) staff should:

Conduct themselves with integrity, impartiality and honesty.

Endeavour to deal with the affairs of the public sympathetically, efficiently, promptly and without bias or misadministration.

Not misuse their official position or information acquired in the course of their official duties to further their private interests or those of others, and should not receive benefits of any kind from a third party which might reasonably be seen to compromise their personal judgement or integrity.

- 1.1.2 Given the nature of the agency's business, particular care and transparency is necessary in relation to potential conflicts of interests in both the pharmaceutical and medical devices industries.
- 1.1.3 This SOP excludes funding made available to staff members at NIBSC from Pharmaceutical/Medical Devices organisations. These payments are assessed in accordance with the agency's (Institutional) Col Policy.

## **2 POLICY**

- 2.1 Agency staff are civil servants, and as such must not misuse their official position or information acquired in their official duties to further their private interests or those of others. Where a conflict of interests arises, civil servants must declare their interest to senior management.

- 2.1.1 Civil servants must not receive gifts, hospitality or benefits of any kind from a third party that might be seen to compromise their personal judgement or integrity.

- 2.1.2 The agency has decided that in the interests of openness and accountability and to protect staff and the agency from possible accusations of inappropriate

behaviour, it is necessary to maintain a register of all financial interests in the pharmaceutical and healthcare (medical devices) industries held by staff and members of their immediate family and also of any other relevant interests.

- 2.1.3 All members of agency staff, including the Corporate Executive Team and non executive directors, are required to immediately declare any financial or other interests as and when they arise. Failure to comply with this SOP could result in disciplinary proceedings against the staff member.
- 2.1.4 For the purposes of the SOP, staff members include permanent and temporary staff, casuals and short-term contract appointees and people on secondment from other organisations. Immediate family means spouse or partner and members of the family living in the same household. Members of the immediate family will therefore include any dependant children and adult children or other relative (such as parent) living in the same household.
- 2.1.5 As set out earlier, in addition to declaring financial interests, members of staff should also consider whether there is any other matter which could be regarded as affecting their impartiality. A member of staff with a close connection to an individual who is not an immediate family member (such as an adult child no longer in the same household) whose work or other interests are closely associated with the pharmaceutical or healthcare (medical devices) industry, must include in their annual declaration any information they know about that person's interests that might be perceived as presenting a potential conflict of interest.
- 2.1.6 The agency has decided that staff members may not hold direct financial interests in the pharmaceutical and healthcare (medical devices) industries. Newly appointed staff will be required to dispose of such interests before taking up employment with the agency. Similarly, staff may not hold any employment or directorships in the pharmaceutical or healthcare (medical devices) industries, nor carry out consultancy or other private work for those industries.
- 2.1.7 The agency policy on holding and declaring other interests in the pharmaceutical and healthcare (medical devices) industries by staff members and their immediate family is addressed in paragraph 3 below.
- 2.1.8 There is no restriction on agency staff holding interests in other sectors of the financial market as long as they could not be construed as presenting a potential conflict of interest. Such interests held either by a staff member or a member of his immediate family need not be declared (but see paragraph 3.4 below for circumstances in which other interests must be declared).

## 2.2 Timing

- 2.2.1 Following interview, successful candidates will be required to complete the conflict of interests form prior to receiving the terms and conditions of employment and are unable to start employment without completing the form. Candidates must dispose of any interests before commencing employment with the agency.

## 3 SPECIFIC

- 3.1 This SOP sets out the agency policy on the declaration of interests held by agency staff (including casual/temporary workers) and their family members. The policy is particularly concerned with interests in the pharmaceutical and healthcare (medical devices) industries but is intended to cover all interests that may give rise to a conflict or an appearance of bias. The policy supersedes all previous rules on declaring and managing interests that applied to staff. It also reflects the rules on declaring and managing interests in the pharmaceutical industry set out in EU legislation that was implemented in the UK in November 2005.
- 3.1.1 The policy requires all agency staff to declare interests that may give rise to a conflict of interest. In particular, staff must declare all financial interests in the pharmaceutical and the healthcare (medical devices) industries held by them or members of their immediate family and in addition staff should declare any other matter that might be regarded as affecting their impartiality. Staff will be required to dispose of direct financial interests (e.g. shares) in the pharmaceutical and medical devices industries on appointment. Agency staff may not hold any employment or directorships, or undertake any consultancy work with or for the pharmaceutical or healthcare (medical devices) industries, or receive any grant or other payment.
- 3.2 **Newly Appointed Staff**
- 3.2.1 Newly appointed staff must declare any previous employment in the pharmaceutical or healthcare (medical devices) industries and any interests held, when an offer of employment is made. All financial interests must be disposed of before commencing employment.
- 3.2.2 In order to comply with the agency policy, direct financial interests must be disposed of in a way that renders them and the control of and benefit from them, inaccessible to the staff member. In most cases, sale of the asset will be the most effective means of disposal. Certain other means of disposal – such as so-called “blind trusts” – may be suitable only if it can be demonstrated that the staff member no longer has any influence over the asset, its retention or disposal, or any financial benefit deriving from it. HR will advise on the suitability of proposals other than sale for the disposal of such holdings.
- 3.2.3 Staff who, when employed by a pharmaceutical or healthcare (medical devices) industry, or involved in another capacity (such as an investigator in a clinical trial), were involved in the development of a specific medicinal substance, medicinal product or medical device, must declare this interest. This will include work undertaken on the specific product and on products in the same class developed by competitor companies. Decisions about the implications of such declarations on the tasks that staff may undertake will be made by line managers in conjunction with HR but in such cases may limit indefinitely the duties that such staff may undertake.
- 3.2.4 Staff who, when employed by a pharmaceutical or healthcare (medical devices) industry were not significantly involved in the development of individual products will not be permitted to work on products from that company until two years has elapsed from the date of leaving the company.

### 3.3 Existing Staff

- 3.3.1 Existing staff of the agency are prohibited from holding financial interests in the pharmaceutical or healthcare (medical devices) industry. Staff are required to complete and update as necessary, a conflict of interest form declaring relevant interests immediately they arise and as defined in the SOP. Staff will be reminded about this requirement and the definition of financial and other interests on an annual basis.
- 3.3.2 This SOP describes situations that staff are most likely to encounter but should not be assumed to be comprehensive. If in doubt about whether a circumstance or holding should be declared, staff should seek the advice of their line manager who may need to discuss this with HR. Exceptionally, discussion, in confidence, of personal family financial affairs may be with someone other than the direct line manager as long as that person is in the direct line management chain.

### 3.4 What to Declare

- 3.4.1 Staff must declare the following:

Direct financial interests in the pharmaceutical or healthcare (medical devices) industries (whether held directly or via another shareholding or partnership business) held by staff members and their immediate family. The Annex sets out the definition of pharmaceutical and healthcare (medical devices) industries for the purposes of this SOP. Direct financial interests to be declared include stocks; share holdings; equity; bonds, partnership interests as well as any intellectual property rights e.g. patents, copyrights and royalties from such rights.

Interests in other sectoral areas (e.g. IT, catering) must be declared if the staff member works in that area or, for example, is responsible for negotiating contracts for provision of services in that area;

Any other financial benefit paid to the individual such as salaries, consultancies, fee paying work;

Indirect financial interests in the pharmaceutical and healthcare (medical devices) industries held by staff members and their immediate family such as payment that benefits a department or organisation for which an individual is responsible (e.g. fellowships, grants from the pharmaceutical or medical devices industry, payment from the pharmaceutical or medical devices industry for research) but not received by the individual personally;

Staff member's previous employment (at any time and in any capacity and any consultancy, partnership, membership of a steering committee, non-executive directorship paid or unpaid, or similar involvement) in or for the pharmaceutical or medical devices industry;

Staff member's previous direct involvement (in any capacity including consultant, clinical trial investigator, adviser) in the development of a particular medicinal product or medical device;

Gifts and hospitality received from the pharmaceutical or medical device industry

or their agents by staff members including travel costs and accommodation. Fees for speaking at conferences are the subject of a separate agency SOP, GEN006/04;

In addition to the above, staff should declare any other interests which might be regarded as affecting their impartiality (see paragraph 2.1.5) Another example might be where a staff member is asked to assess a product for which a close friend has had a major development responsibility.

3.4.2 All relevant financial interests must be declared. There is no lower limit below which a financial interest is not declarable, except for low value individual or team gifts (see paragraph 3.10 for further advice).

3.4.3 Assets over which the member of staff and/or, his/her immediate family have no financial control (such as holdings in a wide share portfolio, Unit Trust or similar, where an independent Fund Manager has full discretion over the composition of the portfolio, or accrued pension rights from earlier employment in the pharmaceutical or healthcare (medical devices) industry) are excluded and do not need to be declared. However, funds held in a portfolio in which the member of staff and/or, his/her immediate family have the ability to instruct the Fund Manager as to the composition of the fund must be declared. Holdings in such portfolios by staff members may have to be disposed of.

3.4.4 Staff are only required to declare matters of which they are aware.

### 3.5 **Implications of relevant interests held by immediate family members (and other closely connected persons)**

3.5.1 Immediate family members of agency staff and closely connected persons are not barred under this policy from holding interests and/or working in the pharmaceutical or healthcare (medical devices) industries but these may have an impact on the duties that the staff member may undertake. Line Managers in conjunction with HR will make decisions about the implications of such declarations on the tasks that staff may undertake.

### 3.6 **Interests Held in Competitor Products**

3.6.1 Sometimes, a member of staff may be asked to work on a product from a company which is a rival to a company that either the staff member has worked for in the past or in which a family member or other closely connected person has or had a financial interest. As set out above, agency policy does not prevent family members or closely connected persons from holding financial interests or working in the pharmaceutical industry or healthcare (medical devices) industry. However, in these circumstances, it may be necessary to limit the duties of a member of staff. The line manager in conjunction with HR will make decisions about the implications of such declarations on the tasks that staff may undertake.

### 3.7 **Other matters that may be perceived as creating a Conflict of Interest**

3.7.1 It is not possible to set out all the circumstances in which a conflict of interest might be perceived and if in doubt, staff members should always disclose the circumstances to their line manager and complete a conflicts of interests form, immediately it arises. Some examples of circumstances that might arise are set out in paragraph 3.4.

### 3.8 What is “Insider Dealing”?

3.8.1 “Insider dealing” is defined as use of knowledge gained by a staff member from official duties used to benefit the value of their own or a family member or closely connected person’s private investments. Staff gaining information which is not publicly available and is price sensitive in relation to any company’s shares or other securities of companies are prohibited, by law, from trading in those or encouraging others to do so.

3.8.2 Specifically this means that staff must not:

Use any information acquired in the course of their work to advance their financial interests or those of others;

Have financial interests in companies which have extensive interests in areas associated with their official business.

### 3.9 Gifts, Hospitality and Entertainment

3.9.1 All staff must take great care over accepting offers of gifts, hospitality and entertainment that are in any way linked to the agency’s business. This is to avoid anyone being put in a position where there is a potential or actual conflict of interest or which might be construed in that light.

3.9.2 The guiding principle is that staff must not accept gifts, hospitality or other benefits of any kind from a third party, which might be seen to compromise personal and professional integrity. Corruptly soliciting or receiving any gift or favour is a criminal offence. If in doubt about whether to accept a gift, hospitality or entertainment, the line manager’s advice should be sought.

### 3.10 Gifts

3.10.1A ‘gift’ is here defined as any item of cash or goods, or any service, which is provided for personal benefit at less than its commercial value. Gifts should, in general, be refused, to avoid the appearance of improper acceptance. However, gifts and benefits may be accepted if they are of a trivial or inexpensive nature. This would include items such as:

Low value ‘promotional’ gifts (such as calendars, diaries or other small gifts) inscribed with the provider’s name;

Conventional personal gifts – such as flowers, fruit or confectionery of reasonable value – for someone who has been off work for a long time (for example, through sickness or the birth of a child);

Team or directorate gifts of low value, such as confectionary, intended to be shared by the team.

### 3.10.2 Staff should not accept:

Gifts on a larger scale than those described above;

Goods or services provided by a business contact for personal benefit at nil or reduced cost (for example, building or maintenance work);

Payment by business contacts to subsidise social events (such as Christmas parties).

### 3.10.3 Staff must:

Report immediately to the line manager all offers of unreasonably generous gifts;

Return promptly any unacceptable gifts, with a letter politely explaining the terms of this policy and stating that to accept is not permissible;

Dispose of any gift that cannot be returned (such as perishables) at the discretion of the line manager or above; for example, it might be shared between junior staff or given to charity. In these cases the supplier should also be informed, in writing, of the action taken.

3.10.4 Where a business relationship has developed into personal friendship, which exists outside the business environment, personal gifts may be exchanged (on occasions such as birthdays, Christmas, retirements). This is acceptable provided that the person giving the gift and not their employer pays for any gift. If in doubt, discuss the position with your line manager.

3.10.5 Similarly, the agency's resources may not be used to make personal gifts to business contacts. However, if in exceptional circumstances it is proposed to make a gift, agreement from the line director and either the Chief Executive, Chief Operating Officer or (only in their absence) the Deputy Director Finance must be obtained in advance. It should be made clear that there is no element of inducement involved and that the gift should not be reciprocated.

## 3.11 Hospitality

3.11.1 Staff and business contacts should recognise that it is not normal practice in the agency to 'do business over a meal' and that this should be the exception, rather than the norm. There is a distinction between a working lunch provided in the office and more expensive social functions, travel or accommodation. Any hospitality provided should be modest and necessary for the effective discharge of the agency's business.

3.11.2 Avoid providing hospitality at non-business locations during normal working hours if possible. Disproportionate expenditure should also be avoided. Hospitality such as business meals or drinks outside of normal working hours

can be provided on an appropriate scale. Take particular care to ensure that the provision of alcohol is limited and reasonable.

3.11.3 Staff should accept hospitality only when this can be defended as being in the interests of the agency's business – for example, because significant relationship building is a business aim. For some agency staff, the offer of hospitality – such as invitations to attend Trade Association dinners or invitations to dine when abroad on business – is a routine part of undertaking business. In these circumstances staff should carefully consider whether it is appropriate to accept such invitations, discussing the issue with their line manager if in any doubt. Attendance must always be declared as an interest. In some cases the offer of hospitality is associated with attendance for other business purposes such as invitations to “speakers’ dinners” and provision of overnight accommodation when speaking at a conference. A request to speak at such a conference should be handled through the agency's Conference and Education function in the normal way, with any speaker's fee paid to the agency. The associated hospitality must be declared.

3.11.4 It is particularly important to ensure transparency in dealings with suppliers; staff must not be put in a position where their decision-making might be perceived to have been influenced. The higher the individual's personal responsibility for a business relationship, the greater the level of care needed. Staff are particularly vulnerable if they are involved in any aspects of a contract. Accepting hospitality is particularly sensitive where it is made in a negotiating context (such as when a contract is up for renewal).

3.11.5 If in any doubt about any offer received, staff should contact their line manager first. If staff find themselves in a position where they were not aware in advance that more lavish hospitality was to be provided, and to refuse would appear rude or cause embarrassment, they should accept it. They should, however, report it on return to the office.

### 3.12 Entertainment

3.12.1 Entertainment should only be accepted in exceptional circumstances, with prior written approval. Agency funds should never be used for providing entertainment.

3.12.2 Providing or accepting entertainment, such as tickets to major sporting or cultural events, is even more sensitive: it is likely to be more difficult to justify in terms of furthering the business of the agency so should normally be refused.

3.12.3 Approval will not be given under any circumstances for:

Tickets for any function or event at which the host (the person who issued the invitation) is not present;

Use of a business contact's property (such as a holiday home) for your personal use;

Extension of business trips for personal purposes, paid for by a business

contact.

### **3.13 Expectations of Future Employment**

3.13.1 Staff should not give, or appear to give, advice or take decisions that might be influenced by the hope or expectation of future employment with a particular company or organisation. This is to ensure that a company or organisation does not gain unfair advantage over its competitors. If staff are in discussions with a company about the possibility of future employment, they should inform their line manager if a potential conflict of interest arises.

3.13.2 Applications to HR to take up employment may be approved with specific conditions. Conditions imposed on appointment can apply for up to two years. They include:

A waiting period before staff may take up post;

Restrictions on staff's involvement in dealings with the prospective employer and the agency/department or other government department.

### **3.14 Other Benefits received from Industry**

3.14.1 The agency has a clear policy on accepting offers to attend and speak at conferences and payments made for providing such a service. This includes payment of travel and subsistence costs associated with the event.

### **3.15 Legislative Provisions and other Guidance**

3.15.1 The EU medicines legislation states, " In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry which could affect their impartiality. These persons shall make an annual declaration of their financial interests..."

3.15.2 This SOP should be read in conjunction with the Civil Service Code that gives general guidance on the duties and obligations of all civil servants. In particular, staff must not be involved in any official business that could affect the value of their private investments, or the investments of others close to them. Agency SOP HR007/01 sets out examples of service on committees and private work that may also lead to potential conflicts of interest and should be declared to the line manager. SOP GEN006/04 sets out agency rules for staff invited to address conferences & accepting fees, hospitality and travel costs.

3.15.3 Staff who undertake duties at the European Medicines Agency or similar bodies may also be required to comply with other rules on declaring interests. This does not alter their obligation also to comply fully with the agency requirements on declaring interests.

### **3.16 The Register of Interests**

- 3.16.1 The register of interests will be compiled by HR from the declarations made by newly appointed and current staff members and will be held securely in the agency and will not be made public. It will, however, be made available for review by the agency's Risk and Audit Committee. Each individual member of staff is responsible for ensuring that they update the declaration of interests, including interests held by members of their immediate family as defined in paragraph 2.1.4 above and interests held by other closely connected individuals as defined in paragraph 2.1.5 above. Names of household members and others need not be declared. Names of companies in which staff and members of a household or others have interests must be declared, but not the numbers of shares etc held nor the financial value of holdings.
- 3.16.2 Staff are entitled to see the entries in the register that relate to them and their family members under the data access provisions of the Data Protection Act 1998.
- 3.16.3 Newly appointed staff will be required to complete a full declaration of relevant interests before joining the agency. HR must refer the completed form to the line manager who will decide whether the declaration will have any impact on the duties that they may undertake and endorse the declaration accordingly. The line manager will return the declaration to HR for inclusion in the agency's register. The line manager may, if he or she wishes, keep a copy of the completed form for future reference. The declarations made by members of staff will be held on their personal file. The declarations made by staff will be made available on request to any manager in an individual's line management chain.
- 3.16.4 Each year staff will be reminded of their obligation to complete a further conflict of interests form if there have been any changes to the register or if their circumstances have changed. Staff will also be reminded of the definition of financial and other conflicts of interests. However it is important to note that the onus is on the member of staff to report changes immediately that they happen rather than wait for the annual reminder. Failure to do so may lead to disciplinary action. Where the declaration has changed staff must refer the updated form to their line manager to decide if the updated declaration will have any impact on the duties that they may undertake and endorse the declaration accordingly. The line manager will pass the completed form to HR for inclusion in the agency's register.
- 3.16.5 If a member of staff or a member of his/her immediate family acquires an interest during the year, or if another matter arises which might be regarded as affecting a member's impartiality, an updated declaration must be completed immediately even if a previous declaration has been made. The declaration must be referred to their line manager to decide if the updated declaration will have any impact on the duties that they may undertake and endorse the declaration accordingly. The line manager will pass the completed form to HR for inclusion in the agency's register. Failure to report changes that occur may lead to disciplinary action.

## **4 APPENDICES**

### 4.1 Definition of pharmaceutical industry – Annex A

## 4.2 Guidance for staff on submitting Conflicts of Interest Electronically

**5 REVISION HISTORY**

Issue number	Effective date	Reason for revision	Prepared by
HR003/01	25 March 2002	First Issue	Joanna Billan
HR003/02	01 August 2003	Formation of Medicines and Healthcare products Regulatory Agency	Carrie Woodville
HR003/03	01 March 2005	Changes to RRP Format	Carrie Woodville
HR017/02	01 January 2007	Revision	Joanna Billan
HR017/03	01 October 2009	Revision	Yvette Colbourne
HR017/04	14 February 2011	Changes to electronic COI returns	Jemma Barton / Peter Rimmer
HR017/05	6 April 2012	Reissued with no changes	Peter Rimmer
HR017/06	February 2014	Note regarding external funding to staff members at NIBSC	Rebecca Starling

**6 KEY WORDS**

Pharmaceutical industry, Medical Devices industry, shares, interests, SOP

## Appendix 1

### PHARMACEUTICAL INDUSTRY DEFINITION

In this SOP “pharmaceutical industry” includes:

- Companies, partnerships or individuals whose primary business activity is substantially involved with the manufacture, sale or supply of medicinal products subject to the licensing provisions in the Medicines Act, and EU medicines legislation (this includes products falling within the homoeopathic and traditional herbal medicines registration schemes);
- Trade associations representing companies involved with such products;
- Companies partnerships or individuals who are directly concerned with research, development or marketing of a medicinal product which is being considered by the Commission or one of the Committees or Sub-Committees;
- References to “the pharmaceutical industry” include cases involving a single company.

In this SOP “healthcare (medical devices) industry” includes:

- Companies, partnerships or individuals who are involved with the manufacture, sale or supply of medical devices subject to the EU medical devices legislation;
- Trade associations representing companies involved with such products;
- Companies partnerships or individuals who are directly concerned with research, development or marketing of a medical devices which is being considered for registration;

References to “the healthcare (medical devices) industry” include cases involving a single company.

## Appendix 2

[Link to staff guidance on submitting annual returns electronically](#)