



**Policy for Joint Working with the Pharmaceutical Industry
(including Rebate Schemes & Commercial Sponsorship of
Meetings/ Training Events)**

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Printed copies or those saved electronically must be checked to ensure they match the current online version.

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1 Introduction

Purpose of the policy

This document provides a framework to assist the organisation and NHS staff in determining when commercial sponsorship or a joint agreement is appropriate when working with the pharmaceutical industry. It sets out principles and standards which should be applied when NHS Shropshire, Telford & Wrekin Clinical Commissioning Group (STWCCG) and its staff, contractors and agents engage with the pharmaceutical industry. The principles and standards also apply to clinical partners, students and trainees working within NHS Shropshire, Telford & Wrekin CCG

It is recommended that GP practices adapt/adopt the principles contained within the policy. It is expected that members of the Commissioning Support Unit (CSU) adopt the principles contained within the policy

Research and development (R&D) partnerships are outside the scope of these guidance papers.

Definitions:

Commercial sponsorship for the purposes of this policy, commercial sponsorship is defined as including¹:

NHS funding from an external source, including funding of all or part of the costs of a member of staff, NHS research, staff training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, hotel and transport costs (including trips abroad), provision of free services (speakers), buildings or premises.

Commercial sponsorship is distinct from joint working.

Joint working is defined as²: Situations, where for the benefit of patients; organisations pool skills, experience and / or resources for the joint development and implementation of patient-centred projects and share a commitment to successful delivery. Joint working agreements and management arrangements are conducted in an open and transparent manner.

Joint working differs from sponsorship, where pharmaceutical companies simply provide funds for a specific event or work programme.

Responsibility of NHS Employers and Staff

Compliance with the policy is expected by all NHS Shropshire, Telford & Wrekin CCG employed staff, contractors, agents and members of all sub-committees. For the purposes of this policy “employment” includes payments to people in their discharge of CCG responsibilities.

Whilst there is no national guidance on how member practices of CCGs should work with the pharmaceutical industry, there is, however a requirement related to required standards

for public life “the Nolan principles” – which applies to member practices. It is therefore suggested that the adoption of this policy by member practices is in accordance with the requirement of the constitution.³

Therefore, GP practices have the option to adopt this policy for use within the practice. For example, maintaining their own logs of gifts, hospitality or sponsorship. In addition, “Good Medical Practice” published by the GMC sets out standards of conduct expected of all doctors and has specific requirements which relate to commercial sponsorship.⁴

As described in the Standards of Business Conduct for NHS Staff (1993) and Commercial Sponsorship – Ethical Standards for the NHS (2000), NHS employers and employees, and individuals working on behalf of the NHS / CCG need to maintain and demonstrate general standards and behaviours, as defined when dealing with commercial organisations.^{1,3}

Staff must be familiar with this policy and also be aware of NHS guidance, the legal position and appropriate professional codes of conduct, e.g. General Medical Council, Royal College of Nursing, Royal Pharmaceutical Society of Great Britain, General Pharmaceutical Council, Nursing and Midwifery Council, NHS Code of Conduct for Senior Managers and Prescription Medicines Code of Practice Authority (PMCPA) codes.^{5,6}

For those staff groups not covered by a professional code of conduct, the code of conduct as given in the Commercial Sponsorship – Ethical Standards for the NHS (2000) and detailed in Appendix A should be followed.¹

Shropshire, Telford & Wrekin CCG employed staff, contractors, agents staff should be aware that pharmaceutical industry representatives must follow the “ABPI Code of Practice for the Pharmaceutical Industry”.^{7,8}

This code of practice is designed to ensure a professional, responsible and ethical approach to the promotion of prescription medicines in the UK through self-regulation.

A member of Shropshire, Telford & Wrekin CCG employed staff, or a member of a contractor’s or agent’s staff who believes that an industry representative has broken the Code can report their complaint to the Director of the Prescription Medicines Code of Practice Authority (PMCPA) at complaints@pmcpa.org.uk

Shropshire, Telford & Wrekin CCG, is bound by the terms and obligations imposed by the Bribery Act 2010. It is a duty of all CCG employed staff, contractors and agents to consider any gifts, hospitality or sponsorship offered to them, inform their line manager of the offer, and to declare what has been received via the CCGs Gifts, Hospitality and Sponsorship Register as per the requirements set out in the Declaration of Gifts, Hospitality & Sponsorship – Anti-Bribery Policy and Procedure, which is published on the CCG’s website.

Shropshire, Telford & Wrekin CCG has a nominated Local Counter Fraud Specialist, whose role it is to combat and investigate any economic crime committed against the CCG and wider NHS. If you suspect that fraud, bribery or corruption is being committed you can

report these concerns via: <https://www.shropshiretelfordandwrekinccg.nhs.uk/about-us/counter-fraud/>

In the interests of transparency, Shropshire, Telford & Wrekin CCG employed staff, contractors, agents staff should declare any financial interest (e.g. company shares or research grants) or any other conflict of interest (e.g. a relative working for the company in question), which could be considered to influence their impartiality in decision making and the utilisation of NHS funding. Any declarations should be recorded on NHS Shropshire, Telford & Wrekin CCGs register(s) which is published on the CCG's website at <https://www.shropshiretelfordandwrekinccg.nhs.uk/about-us/conflicts-of-interest/>

This policy has been written with due regard for Equality, Diversity and Human Rights strategy <https://www.shropshiretelfordandwrekinccg.nhs.uk/policies/equality-and-diversity-policy/> Staff must familiarise themselves with this strategy and ensure that patients, staff or associates are not unfairly disadvantaged on the grounds of protected characteristics.

This Policy should be read in conjunction with the CCG's Declaration of Gifts, Hospitality and Sponsorship Policy which can be found on the CCG's website at... <https://www.shropshiretelfordandwrekinccg.nhs.uk/policies/gifts-hospitality-and-sponsorship-anti-bribery-policy/>

Commercial Sponsorship from the Pharmaceutical Industry

If members of staff are in any doubt about accepting a gift, hospitality, sponsorship or expenses from the Pharmaceutical Industry they should consult their line manager or a member of the Primary Care Directorate. Staff should also consult the CCG's Declaration of Gifts, Hospitality and Sponsorship Policy which can be found on the CCG's website.

Principles

All offers of sponsorship, funding or gifts from the pharmaceutical industry must comply with the ABPI code of conduct.

Clinical decisions must always be made in the best interest of patients. No sponsorship agreements are acceptable which compromise clinical judgement or that is not in line with local policy or guidelines.

Prior written agreement between authorised NHS Shropshire, Telford & Wrekin CCG's officers (see Appendix C) and prospective sponsors must be obtained for all sponsorship arrangements and include agreed payments.

All agreements must include a break clause enabling the termination of the agreement at reasonable notice.

In any agreement with the pharmaceutical industry, patient and data confidentiality should comply with legal and ethical requirements for the protection and use of patient information and other NHS information.⁹

Use of patient identifiable information must be consistent with Caldicott principles. Appendix B provides a checklist for the assessment of data and confidentiality issues. All agreements must comply with the three crucial values that underpin the work of the NHS – Accountability, Probity and Openness.

Sponsorship agreements which involve several sponsors are to be preferred to those which involve a single sponsor.

As a general rule, sponsorship arrangements involving NHS Shropshire, Telford & Wrekin CCG should be at a corporate rather than individual level.

The promotion of a medicine will not influence any decisions to include the product in the medicines formulary. Promotion of any product should not contradict current NHS Shropshire, Telford & Wrekin CCG guidelines or formulary.

Clinical review services offered by the Pharmaceutical Industry

Pharmaceutical companies sometimes offer clinical based review services to GP practices. In order to ensure that these reviews fit with the strategic priorities of the CCG, and are in line with the formulary, it is strongly encouraged that practices direct companies offering such review services to the Medicines Management Team, so that the overall impact (including potential impact on the prescribing budget) can be assessed.

Staff seeking sponsorship from the Pharmaceutical Industry

It is recognised that CCG staff may look to seek sponsorship from the pharmaceutical industry in order to progress a project or to allow a piece of training to go ahead.

It is recommended that staff should seek advice from the Medicines Management Team in order to progress potential sponsorship requests in line with this policy.

2 CCG authorisation process for offers of gifts, hospitality of sponsorship

All offers of gifts, hospitality or sponsorship in any form to NHS Shropshire, Telford & Wrekin CCG or its staff of £6.00 or greater require authorisation from their line manager. Any offer of sponsorship by the pharmaceutical industry to NHS Shropshire, Telford & Wrekin CCG will require Director level authorisation following advice from the Medicines Management Team and discussion and approval with the Director of Corporate Affairs or the Chief Finance Officer.

Gifts, hospitality or sponsorship offered by the pharmaceutical industry should be entered into the template in Appendix 2 of the Declaration of Gifts, Hospitality & Sponsorship – Anti-Bribery Policy and submitted to the Corporate Affairs Directorate. Whilst this policy is concerned with direct or indirect financial contact with the pharmaceutical industry, it should be noted that gifts, hospitality or sponsorship, which are received from organisations other

than those within the pharmaceutical industry still require logging in the Gifts, Hospitality and Sponsorship Register.

Appendix C details the authorisation procedures and Appendix D gives the criteria for the assessment of commercial sponsorship by the pharmaceutical industry in terms of:

- Meetings and Training
- Funding of members of staff
- Projects (including audits)

A departmental / team log of all offers of gifts, hospitality or sponsorship of a value of £6.00 or greater, whether accepted or refused must be kept and should be declared in the NHS Shropshire, Telford & Wrekin CCG Gifts, Hospitality and Sponsorship Register which is held by the Corporate Affairs Directorate.

In addition, gifts should be declared if several small gifts worth a total of over £50 are received from the same source or closely related sources within a 12 month period. It is important, that where hospitality or sponsorship for meetings is sought, that a number of Pharmaceutical Companies are approached to avoid the same company being used too frequently.

Gifts

The ABPI code of practice 2016 Clause 18 governs the giving of gifts.

No gift, pecuniary advantage or benefit may be supplied, offered or promised to members of the health professions or to other relevant decision makers in connection with the promotion of medicines or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

Health professionals may be provided with items which are to be passed on to patients and which are part of a formal patient support programme, the details of which have been appropriately documented and certified in advance.

The items provided must be inexpensive and directly benefit patient care. They may bear the name of the company providing them. They must not be given out from exhibition stands. They must not be given to administrative staff unless they are to be passed on to a health professional.

See Section 7 of the Declaration of Gifts, Hospitality and Sponsorship – Anti-Bribery Policy and Procedure for further information.

Meetings and Hospitality

The ABPI code of practice 2016 Clause 22 governs meetings and hospitality.⁸

The provision of hospitality is limited to refreshments/ subsistence (meals and drinks), accommodation, genuine registration fees and the payment of reasonable travel costs which a company may provide to sponsor a delegate to attend a meeting.

Hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting i.e. subsistence only.

When meetings are sponsored by pharmaceutical companies, that fact must be disclosed in all of the papers relating to the meetings, and in any published proceedings. The declaration of sponsorship must be sufficiently prominent to ensure that readers are aware of it at the outset.

See Section 8 of the Declaration of Gifts, Hospitality and Sponsorship – Anti-Bribery Policy and Procedure for further information. The policy sets out the parameters under which declarations should be made.

Samples of Medicinal Products

The ABPI code of practice 2016 Clause 17 governs the acceptance of samples of medicinal products.⁸

A sample is a small supply of a medicine provided to health professionals so that they may familiarise themselves with it and acquire experience in dealing with it. A sample of a medicine may be provided only to a health professional qualified to prescribe that particular medicine.

No more than four samples of a particular medicine may be provided to an individual health professional during the course of a year.

Samples may only be supplied in response to written requests which have been signed and dated. An electronic signature is acceptable. Samples must not be provided simply as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

Each sample must be marked 'free medical sample – not for resale' or words to that effect and must be accompanied by a copy of the summary of product characteristics.

3 Access to staff and premises by representative of the pharmaceutical industry

The ABPI code of practice 2016 Clause 15 details the standards expected of representatives of the Pharmaceutical Industry.⁸

First contact by a pharmaceutical company representative should be directed to the personal assistant supporting NHS Shropshire, Telford & Wrekin CCG's Head of Medicines Management.

Appendix F sets out the framework within which pharmaceutical industry representatives may have access to the Medicines Management Team.

Training and Education

Employees should seek authorisation by their line manager before attending events sponsored by the pharmaceutical industry. It must be agreed whether the training should be attended in the employees own time, or during working hours. Attendance at training and educational events must demonstrate a benefit to the priorities of the NHS or CCG.

Managers should be careful to ensure that staff are not pressurised by sponsors of training to alter their own practice to accord with the sponsors wishes where these are not backed up by appropriate evidence.

See Section 9 of the Declaration of Gifts, Hospitality and Sponsorship – Anti-Bribery Policy and Procedure for further information. The policy sets out the parameters under which declarations should be made.

4 Joint working with the pharmaceutical Industry

Joint working between the pharmaceutical industry and the NHS must be for the benefit of the patients or the NHS and preserve patient care. Any joint working between the NHS and the pharmaceutical industry should be conducted in an open and transparent manner.

Due to the significant governance and administrative requirements of joint working, a joint working project will often be of a significant size and duration, generally involving resources in the region of £15,000 - £20,000 and lasting 6 months or more.

It is recommended that every joint working project will have a formal document in place setting out what each party has agreed before the project begins. It should also clearly define the benefits to both parties, of the joint working agreement. Clearly defined, mutually agreed exit criteria must be written into joint working agreements at the outset.

The Department of Health and the Association of the British Pharmaceutical Industry (ABPI) have developed a joint working toolkit.² The purpose of the toolkit is to provide information and give access to tools which will help to with joint working. The toolkit should be utilised When considering joint working arrangements with the pharmaceutical industry or other commercial organisations.

The ABPI have also published a quick start guide ‘Joint Working – A Quick Start Reference Guide for NHS and Pharmaceutical Industry Partners’⁷ which contains a checklist that should be used when developing a joint working project.

Approval / Authorisation for joint working must be sought at officer level (Chief Finance Officer), following consultation with the Primary Care Directorate. Joint working proposals should be authorised by both the Clinical Commissioning Committee (CCC) and the Quality Committee.

5 Examples of potential conflict

The Department of Health published examples of potential conflict of interest in Commercial Sponsorship – Ethical Standards for the NHS November 2000.¹

Appendix G gives details of potential conflict and how to deal with these situations.

6 Monitoring arrangements

Gifts, sponsorship and joint working agreements with the pharmaceutical industry must be notified for inclusion in the NHS Shropshire, Telford & Wrekin CCG Gifts Hospitality and Sponsorship Register. This register of direct or indirect financial contact with the pharmaceutical industry and other third parties is kept for corporate governance reasons and to ensure transparency.

Staff, contractors and agents of the CCG must register any sponsorship and are held responsible for it.

7 Rebate Schemes

Primary care rebate schemes are contractual arrangements offered by pharmaceutical companies, or third party companies, which offer financial rebates on GP prescribing expenditure for particular medicines(s).

Any payments received as a result of the rebate scheme will remain within the prescribing budget unless otherwise agreed by the CCG.

The rebate schemes may cover medicinal and non-medicinal products, appliances and assistive technology. The potential value of the rebate scheme and indirect costs associated with administering the scheme should be considered.

a) Types of rebate scheme

(i) Price discount

In these schemes, the pharmaceutical company would offer a simple discount on the price of the medicine or device (i.e. rather than paying the NHS list price, the NHS would pay a lower percentage of the list price). The agreement with the pharmaceutical company would usually set out the data that the CCG has to supply about the prescription of the drug in order to claim the discount.

(ii) Volume rebate on price schemes

These schemes work in a similar way to simple price discount schemes. However the level of discount received is based on the volume of the medicine or device that is prescribed. These schemes are aimed at increasing the market share of the product.

(iii) Risk sharing schemes

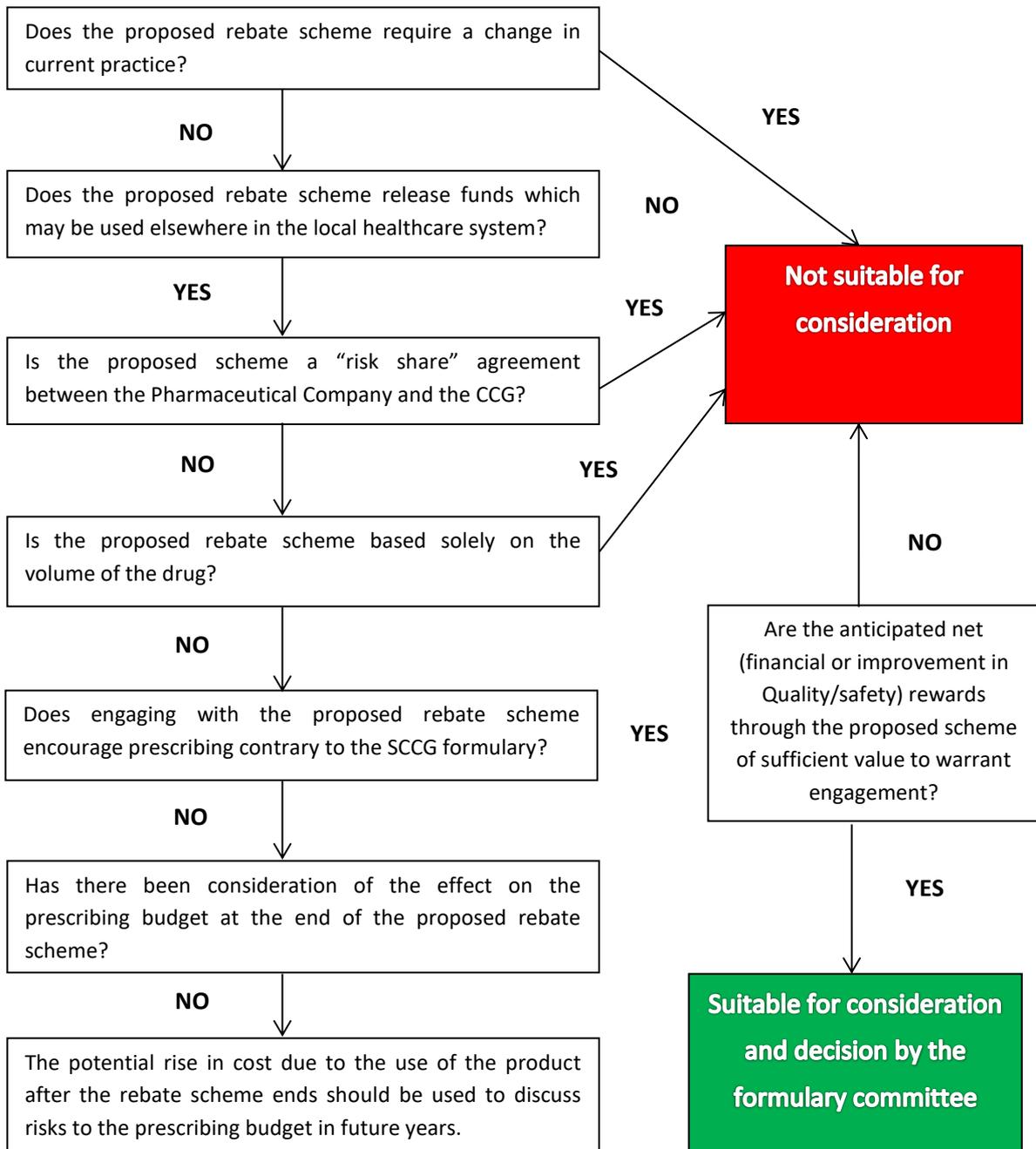
These are agreements between the NHS and pharmaceutical company that aim to reduce the impact on the prescribing budget of new and/ or existing medicines brought about by either uncertainty of the value of the medicine and/ or the need to work within finite budgets.

The agreement should set the scope and realise the mutual obligations between both the NHS and pharmaceutical companies depending on the occurrence of an agreed condition – the ‘risk’. The ‘risk’ varies by situation, and can include pharmaceutical expenditure higher than agreed thresholds. In addition to the above checklist, the potential value of the rebate scheme and indirect costs associated with administering the scheme should be considered.

b) Screening questions when considering a rebate scheme

In entering into such schemes with a pharmaceutical industry partner there are a number of questions which must be asked to ensure that the proposal is in the best interests of both patients and the organisation and the local NHS. All proposals must be treated equally and decisions made will need to stand up to scrutiny if questioned. However, the overarching principle should be that the scheme reduces costs to the CCG without detriment to the quality of patient care.

In the cases where a scheme is agreed the CCG will ensure that the agreement entered into states that the pharmaceutical company which is offering the scheme will not use our engagement in the scheme to promote their company’s activities which are related to this agreement, or in any other promotional activity for their benefit.



c) Process for management

The Medicines Management Team Rebate Lead will screen each viable proposal using the principles outlined above.

The Medicines Management Team Rebate Lead will screen each proposal to filter out any, which clearly do not adhere to the principles above and will then submit the Rebate Contract to the Director of Finance for approval. The contract should be clearly defined, and contain mutually agreed exit criteria.

All rebates will be selected using information from PrescQipp, who review and grade all rebates according to any issues detected by their review board. Grey Rebate schemes will be considered as they have no identified issues. Amber schemes may have some identified issues therefore full consideration is required before joining these schemes. Red schemes are considered Inappropriate and so will not be considered.

If a rebate scheme changes its status during a contract period, an Investigation should be conducted to assess, which changes have occurred and whether this means it is necessary to withdraw from the scheme. If the changes to the rebate do not affect the agreed terms, there is no requirement to withdraw from the Rebate Contract.

d) Schemes accepted following the screening and approval process

The Medicines Management Team will be responsible for undertaking the administration tasks associated with scheme, which have been approved, for example, supply of prescribing volume data.

The Finance Department will be responsible for monitoring rebates, which have been received by the organisation. The funds generated by a rebate scheme will be held in the budget where the saving has been made i.e. the prescribing budget unless otherwise agreed by the CCG.

A list of all current rebates will be published on the CCG website. The drug name, company name and start and end dates for all Rebate Contracts may be published. All other information, however, is not for publication as per the rebate agreement. Note: Advice taken by the London Procurement Programme www.lpp.nhs.uk from DAC Beachcroft LLP has been used to inform the rebate section of this policy.

Further information regarding the use of rebate schemes by CCGs is available from the statement released following the ruling on the Abbott vs Aymes case, which is available on the PrescQipp website.

<https://www.prescqipp.info/~:text=A%20summary%20of%20Abbott%20vs%20Aymes%20and%20an,Wind,%20Chair%20PrescQIPP%20Rebates%20Board%20in%20his%20words.>

e) Final sign-off

All rebate contracts must be signed off by the CCG Director or Deputy Director of Finance.

Appendix A – Code of conduct

Staff and independent contractors working in the NHS should follow existing Codes of Conduct.

Staff, contractors and agents that are not covered by such a code are expected to:

- Act impartially in all their work.
- Refuse gifts, benefits, hospitality or sponsorship of any kind which might reasonably be seen to compromise their personal judgement or integrity, and to avoid seeking exert influence to obtain preferential consideration. All such gifts should be returned and hospitality refused.
- Declare and register gifts, benefits, or sponsorship of any kind, in accordance with time limits agreed locally, (provided that they are worth at least £6), whether refused or accepted. In addition gifts should be declared if several small gifts worth a total of over £50 are received from the same or a closely related source within a 12 month period.
- Declare and record financial or personal interest (e.g. company shares, research grant) in any organisation with which they have to deal, and be prepared to withdraw from those dealings if required, thereby ensuring that their professional judgement is not influenced by such considerations;
- Make it a matter of policy that offers of sponsorship, which could possibly breach the Code be reported to their Board (NHS Trusts/Clinical Commissioning Group/Commissioning Support Service/NHS England Area Team)
- Not misuse their official position or information acquired in the course of their official duties, to further their private interests or those of others.
- Ensure professional registration (if applicable) and/or status are not used in the promotion of commercial products or services.
- Beware of bias generated through sponsorship, where this might impinge on professional judgement and impartiality.
- Neither agree to practise under any conditions which compromise professional independence or judgement, nor impose such conditions on other professionals.
- Be aware of practice that may be in breach of legislation and CCG policies on the strategy for equality and diversity and human rights

Appendix B – Assessment of data and confidentiality issues

Check List	Satisfied	
	Yes	No
<p>If the practice or patient data are to be used, there must be a clear statement included in the Service Agreement regarding:</p> <ul style="list-style-type: none"> • Who will have access to that data and in what form • How, where and by whom that data will be manipulated • The purpose for which the data will be used 		
<p>Each GP should give written consent if their own patients are to be involved if their patient's data is used in any way</p>		
<p>In maintaining confidentiality, if direct contact with patients is required:</p> <ul style="list-style-type: none"> • It is the responsibility of the practice to identify patients who may be eligible to participate • It is the responsibility of the practice to invite patients to participate • Any invitation should indicate that the patient is under no obligation to take part • Prior to patient involvement in the programme, informed consent must be obtained. Consideration should be given to ensuring that patient information is provided in accessible languages and format. 		
<p>If data is aggregated then:</p> <ul style="list-style-type: none"> • The practice must have a clear understanding of the purpose for which such data is to be used • There must be a clearly defined protocol for data management, which includes information on the nature and the ownership of the aggregated data and protocols to govern requests for access to that data • No practice level data should be identifiable from the aggregated data set • The practice should have the option not to share their data as part of the aggregated data set if they wish 		

Before any sponsorship is implemented, the following issues will also need to be addressed.

All principals and other key practice staff must be aware of, and have agreed to participate as appropriate, with the proposed service:

- Agree clearly who is responsible for supervising and reporting on the service to the CCG and other relevant healthcare professionals as appropriate.
- Be satisfied that any information or materials to support the proposed service is valid, evidence based, balanced and non-promotional.

Practices should make arrangements to involve or make patients aware of the sponsorship as appropriate and as early as practically possible.

Practices should agree a process for reviewing the service at appropriate intervals and assessing the success of the service in achieving its stated objectives. Practices may wish to involve patients in this process.

Appendix C – Authorisation procedure for gifts, hospitality and sponsorship from pharmaceutical companies

Please refer to the CCG's Declaration of Gifts, Hospitality and Sponsorship Policy which can be found on the CCG's website at....

<https://www.shropshiretelfordandwrekinccg.nhs.uk/policies/gifts-hospitality-and-sponsorship-anti-bribery-policy/>

All proposals regarding sponsorship should be signed off by a director.

Appendix D – Criterial for assessing offers of commercial sponsorship by the pharmaceutical industry

Meetings and Training

Note the questions below are not the only ones that should be considered when offered commercial sponsorship. NHS Shropshire, Telford & Wrekin CCG staff must consider such offers carefully using the guidance in the main document and this does not replace the authorisation procedure.

	Criterion	Yes	No
1	Is sponsorship of the meeting or provision of training linked in any way (implicit or explicit) to a change in prescribing policy or the recommendation/ endorsement of a particular product (s)		
2	Will the speakers at the meeting/ training course be employed by the pharmaceutical industry (in any capacity)?		
3	Is the subject of the meeting/ training in keeping with NHS Shropshire, Telford & Wrekin CCG's priorities, especially in regard to prescribing?		
4	Will the training course be provided by a recognised independent provider (e.g. a university)		
5	Have all the competing interests by speakers, training providers etc. been declared?		

A positive answer to questions 1 or 2 or a negative answer to any of questions 3 - 5 indicates that the proposed sponsorship should be reviewed by the Head of Department who may wish to consult the Medicines Management Team, who may suggest referral to the Director / Senior Management Team.

Funding for members of staff

Note the questions below are not the only ones that should be considered when offered commercial sponsorship. NHS Shropshire, Telford & wrekin CCG staff must consider such offers carefully using the guidance in the main document and this does not replace the authorisation procedure.

	Criterion	Yes	No
1	Is sponsorship of the meeting or provision of training linked in any way (implicit or explicit) to a change in prescribing policy or the recommendation/ endorsement of a particular product (s)		
2	Is the person involved in the project employed by the Pharmaceutical Industry (in any capacity including secondment)?		
3	Was the job description and selection criteria written by NHS Shropshire, Telford & Wrekin CCG's staff without the influence of commercial sponsors?		
4	Is the subject of the post in keeping with NHS the CCG's priorities especially in regard to prescribing?		
5	Have all the competing interests by all personnel been declared?		
6	Will the post holder be recruited solely by NHS Shropshire, Telford & Wrekin CCG?		

7	Will all the data obtained from the project remain confidential to NHS Shropshire, Telford & Wrekin CCG and practices?		
8	Will access to patient information comply with Caldicott guidance?		

A positive answer to questions 1 or 2 or a negative answer to questions 3 - 8 indicates that the proposed sponsorship should be reviewed by the Head of Department who may seek further advice from the Medicines Management Team who may suggest referral to the Director/Senior Management Team.

Projects (including audits but excluding joint working)

Note the questions below are not the only ones that should be considered when offered commercial sponsorship. NHS Shropshire, Telford & Wrekin CCG staff must consider such offers carefully using the guidance in the main document and this does not replace the authorisation procedure.

	Criterion	Yes	No
1	Is sponsorship of the project linked in any way (implicit or explicit) to a change in prescribing policy or the recommendation/ endorsement of a particular product (s)		
2	Is the person involved in the project employed by the Pharmaceutical Industry (in any capacity including secondment)?		
3	Was the project protocol written by CCG's staff without the influence of the commercial sponsors?		
4	Is the subject of the project in keeping with NHS Shropshire, Telford & Wrekin CCG's priorities especially in regard to prescribing?		
5	Have all the competing interests by all personnel been declared?		
6	Will the project be carried out by personnel recruited solely by NHS Shropshire, Telford & Wrekin CCG?		
7	Will all the data obtained from the project remain confidential to NHS Shropshire, Telford & Wrekin CCG and practices?		
8	Will access to patient information comply with Caldicott guidance?		

A positive answer to questions 1 or 2 or a negative answer to questions 3 - 8 indicates that the proposed sponsorship should be reviewed by the Head of Department who may seek further advice from the Medicines Management Team who may suggest referral to the Director/Senior Management Team.

Appendix E – Guidance on meetings sponsored by the pharmaceutical industry

At meetings to be attended by clinicians the following broad rules should be followed:

- If the meeting involves a specific clinical area and Pharmaceutical Industry support is planned, all relevant companies in line with STW CCG formulary or prescribing guidance should be invited to sponsor the event. This is important to avoid the impression of bias being given. Where there are a large number of manufacturers, a selection should be offered an opportunity. Where meetings are for a non-clinical topic or general audience, a rotation of major manufacturers should be used.
- It is important that a record of this type of sponsorship is held centrally to ensure that at future events alternative manufacturers will be given an opportunity to be involved. The commercial sponsorship form below should be completed. If you have doubts about the appropriateness of any sponsor, or wish to identify potential contributors, please seek guidance from the Medicines Management Team.
- The sponsoring companies may be allowed to set up display stands prior to the event in a suitable space, to mingle with and talk to participants before the event and during coffee and lunch breaks. All display materials and printed hand-outs must be in line with STW CCG formulary, guidance and policies.
- The wording, “supported by an educational grant from *abc drug co*”, may appear once, in typeset no greater than 18 point, at the base of the invitation. Drug company logos and specific product names should not be included on any official materials.
- Drug company representatives will not be allowed to attend the business part of the event unless they would otherwise be entitled so to do as a member of the public.
- No discussion will be entered into with the company about timings, speakers, content or any other aspect of the event that would reasonably be controlled by STW CCG.

**NHS Shropshire, Telford & Wrekin CCG Commercial Sponsorship Form
(Not to be used in the case of Joint Working)**

Name of Sponsor Company:	
Details of Sponsor Company Contact	
Name:	Status/Position:
Phone Number:	Email Address:
Sponsorship received by:	
Date:	Value Approx:

If more than one company is involved, please complete separate forms for each element of sponsorship, but submit with a covering letter explaining the global picture.

Description of Sponsorship: Aims and objectives of project, including key issues to be addressed and duration of project: How does the project benefit patients, contractors, the community and NHS Shropshire & Telford & Wrekin CCG staff?
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Do you have any personal relationship with, or personal business connection with the person/ organisation from which you received the sponsorship declared above? No / Yes If yes, please give details:

Declaration: I declare that the above record represents a complete and accurate statement of the Sponsorship I have offered/ received: Signed: _____ Dated: _____
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Appendix F – Access of staff

The Medicines Management Team will be the point of contact for all pharmaceutical Industry representatives wishing to discuss information pertaining to medicinal products.

Without the involvement of the Head of Medicines Management any agreements reached with NHS Shropshire, Telford & Wrekin CCG staff may be rendered null and void and every effort must be made to secure early consent.

Each company (body corporate, including sub-contractors) should identify one point of contact to ensure consistent communications.

Representatives will be seen **only by appointment**.

A database of appointments will be held and equity of access maintained for all companies.

The proposed subject of the appointment should be advised by e-mail, along with any supporting references. Submission of “formulary packs” is inconsistent with sound environmental policies and the maximum amount of information should be retrievable electronically.

The Medicine Management Team will expect to be given the following information at these meetings:

- Drugs / developments about which the company representative is talking to local GPs, if he/she has access to GPs
- The evidence on which these drugs are being promoted
- The approaches being made to local GPs.

Due to the priority that must be allocated to NHS work, from time to time it may be necessary to change appointments, in which case every effort will be made to offer an alternative appointment.

A mobile phone number must be left at the time of booking.

Appendix G – Examples of potential conflict

Below are some examples of the sorts of situations of potential conflict and how they could be dealt with. These have been taken from Commercial Sponsorship – Ethical Standards for the NHS Department of Health November 2000.

A. A clinician wishes to include a new drug in the Shropshire, Telford & Wrekin CCG Formulary, which is manufactured by a company with which he has links e.g. company shares or a research grant.

The Medicines Optimisation Committee should require declarations of interest from clinicians submitting proposals for new products to be added to formularies and ensure the decision is based on clinical and cost effectiveness information.

B. A pharmaceutical industry representative wishes to present the case for a new product being included in a Trust Formulary e.g. the SATH formulary

The Trust should establish and adopt a reasonable policy on approaches from industry representatives. Industry representatives should be required to sign up to compliance with such a policy before being given access to any meetings.

C. Offer from a company to provide for training of staff.

Employers should be careful to ensure that staff are not pressurised by sponsors of training, to alter their own activity to accord with sponsors' wishes, where these are not backed up by appropriate evidence. Training provided by industry may be above board if it is unbiased has mutual benefit for both the NHS and the sponsoring company, is evidence based and the hospitality is appropriate. However participants should assess whether they may be influenced unduly and also bear in mind what benefits the company might derive (e.g. exposure to NHS, professional contacts, potential allies to use later, names of who to influence, often without the participants realising).

D. A manufacturer of ostomy equipment offers to sponsor a stoma nurse post in an NHS Trust.

The Trust should not accept the sponsorship if it would require the stoma nurse to recommend the sponsor's products in preference to other clinically appropriate appliances, nor if it requires the Trust to recommend patients to use a particular dispensing service or to withhold information about other products. Existing contracts containing any such provisions should, where possible, be urgently renegotiated.

E. A manufacturer of a particular type of Nicotine Replacement Therapy offers to provide their product at a reduced rate to a Health Action Zone.

This arrangement is acceptable provided that there is a clear clinical view that these products are appropriate to particular patients and there is no obligation to also prescribe these products to other patients for whom an alternative product would be at least as beneficial.

- F. *A pharmaceutical company offers to provide starter packs at a discounted price.*
This type of sponsorship is acceptable, but should always be declared in order to avoid any suspicion that subsequent prescribing might be inappropriate and linked to the provision of starter packs.
- G. *A catering company offers to provide discounted products to an NHS Trust.*
This agreement is acceptable, but should be routinely declared to the CCG.
- H. *High tech home health care provider offers to supply equipment at reduced rate in return for business linked to a specific product.*
CCG contract negotiators should advise the company that any contract will not prejudice the provision of the most appropriate service to patients, and will not bear any relation to other contracts.
- I. *Manufacturer offers to pay the travelling costs or accommodation costs for clinicians invited to a conference to view medical products.*
Only clinicians with a specific working interest in the medicines should attend and the travel costs incurred should be paid for by the trust, unless the Chief Executive/Director of Finance gives approval for the potential supplier to take responsibility for the costs. Such decisions should be taken at least at Director of Finance level.

References

1. Commercial Sponsorship: Ethical Standards for the NHS (Department of Health Guidance) November 2000
2. Moving beyond Sponsorship Joint working between the NHS and Pharmaceutical Industry Department of Health August 2010
3. <https://www.england.nhs.uk/wp-content/uploads/2017/07/standards-of-business-conduct-v2.pdf>
4. General Medical Council Financial and commercial arrangements and conflicts of interest April 2013 http://www.gmc-uk.org/static/documents/content/Financial_and_commercial_arrangements_and_conflicts_of_interest.pdf
5. The Code: Standards of conduct, performance and ethics for nurses and midwives <http://www.nmc-uk.org/Publications/Standards/The-code/Introduction/>
6. Standards of conduct, ethics and performance <http://www.pharmacyregulation.org/spp>
7. ABPI – A quick start reference guide for NHS and pharmaceutical industry partners. http://www.abpi.org.uk/our-work/library/guidelines/Documents/joint_working_handbook.pdf#search=oint%2520working%2520quick%2520reference%2520nhs
- 8 The Interactive ABPI Code of Practice for the Pharmaceutical Industry 2016 <http://www.pmcpa.org.uk/thecode/InteractiveCode2016/Pages/default.aspx>
9. Confidentiality: NHS Code of Practice (2003) [https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200146/Confidentiality - NHS Code of Practice.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/200146/Confidentiality_-_NHS_Code_of_Practice.pdf)