Commercial Sponsorship and Joint Working with the Pharmaceutical Industry Policy

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Document Control Sheet

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Document amendment History

Version No.	Date	Brief Description
		This policy supersedes all the individual organisation, commercial, Sponsorship and Joint Working with the Pharmaceutical Industry Policy

The formally approved version of this document is that held on each NHS organisation's website:

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

Contents

1 PURPOSE

The purpose of this policy is to:

1.1 assist the NHS organisation in achieving its objectives and delivery of national and local priorities by building effective and appropriate working relationships with the pharmaceutical industry where deemed appropriate.

1.2 ensure the NHS organisation and its staff respond consistently to approaches from the pharmaceutical industry and that the interests of patients, the public and the NHS organisation are maintained.

1.3 ensure staff comply with NHS organisation commercial sponsorship standards and their own professional codes of conduct, and that representatives of the pharmaceutical industry comply with the Association of British Pharmaceutical Industry (ABPI) Code of Practice for the pharmaceutical industry; and

1.4 inform and advise staff of their main responsibilities when entering joint working arrangements with the pharmaceutical industry. Specifically, it aims to:

1.4.1 assist NHS employers and staff in maintaining appropriate ethical standards in the conduct of NHS business.

1.4.2 highlight that NHS staff are accountable for achieving the best possible health care within the resources available.

1.4.3 highlight that NHS staff may be vulnerable to marketing techniques that may attempt to show some pharmaceutical companies in a more favourable light than is appropriate.

2 SCOPE

2.1 This document is intended as a policy for all NHS organisations in Shropshire Telford and Wrekin Integrated Care System and its staff who are involved in working with the pharmaceutical industry. It is intended to complement individual organisation Policies on Standards of Business Conduct and Managing Conflicts of Interest.

2.2 While it recognises that GP practices and PCNs are providers in their own right, the policy would encourage practices to adopt this policy.

2.3 Department of Health Guidance encourages NHS organisation and their staff to consider opportunities for joint working with the pharmaceutical industry, where the benefits that this could bring to patient care and the difference it can make to their health and wellbeing are clearly advantageous. Such advantages are to be clearly stated and evidenced to support such claims. The pharmaceutical industry is also able to be

transparent about expected commercial gain of such initiatives.

2.4 It is important to recognise that a partnership already exists between the NHS and the pharmaceutical industry. Clear guidance is required to ensure that such arrangements are fully transparent and deliver maximum benefits for patients and the health economy. Positively engaging with companies may lead to larger, longer-term collaborations that meet the needs of all parties including the pharmaceutical industry.

2.5 The benefits of greater collaboration must be weighed against any potential risks. It is essential therefore that all projects are subject to the widest scrutiny to enable likely pitfalls to be highlighted at an early stage.

2.6 It is vital to ensure that the business priorities of commercial organisations do not lead to a distortion of local priorities or investment. Upfront disclosure of expected commercial return will help negate this risk. Where a return on investment is expectedby the pharmaceutical industry to be product sales this must be in line with the NHS organisation prescribing policies and investment priorities as well as the ABPI Code of Practice.

2.7 It should be noted that the same principles should also apply to other commercial organisations that provide products and services.

3 APPLICABILITY

3.1 For the purposes of this policy, the term 'staff' refers to all employees of all the above listed NHS organisations on this policy and those personnel not directly employed by them but who sit on working group committees.

3.2 The GP practices though are providers in their own right are encouraged to adopt the policy, in particular the advice to GP practices contained in Appendix 1: Advice to GP practices regarding support provided by the Pharmaceutical Industry.

4 TERMINOLOGY

Certification

This is required for the following:

- the written agreement for donations and grants.
- educational material for the public or patients issued by companies which relates to diseases or medicines.
- material relating to collaborative working.
- material and items for patient support.

Certification must be carried out by a designated signatory on behalf of the pharmaceutical company. This must be a registered medical practitioner, or a pharmacist registered in the UK or alternatively, in the case of a product for dental use only, a UK registered dentist, and must not be the person responsible for developing or drawing up the material.

Commercial Sponsorship

Means 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.

Joint Working

Means situations where, for the benefit of patients, organisations pool skills, experience and/or resources for the joint development and implementation of patient centered projects and share a commitment to successful delivery.

Medical and Educational Goods and Services (MEGS)

Means donations or grants for a legitimate health or educational purpose with no expectation of anything in return for providing the support. They are provided to healthcare organisations to either benefit patients or benefit the NHS, whilst maintaining patient care.

Sponsorship

This can be considered for the following:

- audit work
- research
- publications
- training and other educational resources
- provision of facilities (i.e., for meetings/seminars/training); or
- provision of free services (i.e., speakers), however

Sponsorship will not be accepted for:

- pharmaceuticals, diagnostics, appliances, diagnostics, or equipment which may influence a change in prescribing behaviour; or
- direct funding of staff/employees or contractors for services commissioned by these organisations while applicable.

5 SAMPLES

Sample products should only be accepted to assess their physical properties. They will not be used to treat patients. Samples provided can only be provided to a health professional in response to a written request, which has been signed and dated (ABPI Code of Practice).

6 OUTSIDE OF WORK ACTIVITIES

Individuals who fail to disclose relevant interests, outside employment or receipts of gifts, hospitality, sponsorship, or entertainment as required by the NHS organisation's Employment Policy, Standards of Business Conduct Policy, and Managing Conflicts of Interest Policy or the Standing Orders and Prime Financial Policies may be subject to disciplinary action.

7 RESEARCH AND DEVELOPMENT

7.1. Clinicians undertaking sponsored research or post-marketing surveillance must be guided by their patient's best interests and not be influenced by any sponsorship.

7.2. All research must be approved by the appropriate research and ethics committees.

8 REBATE SCHEME

8.1. Primary care rebate schemes are contractual arrangements offered by pharmaceutical companies, or third-party companies, which offer financial rebates on GP prescribing expenditure for medicines(s). ***Refer to appendix 2 for more information***.

9 SPONSORSHIPS

For staff attending conferences and courses, the following process should be followed:

9.1 approval must be sought from line managers before accepting commercial sponsorship to attend relevant courses and conferences.

9.2 managers must be satisfied that the acceptance will not compromise purchasing or commissioning decisions or influence prescribing; and a record will be made of all sponsorship by completing a Gifts, Hospitality and Sponsorship Form, which can be found on each organisation staff intranet

(please see the Gifts and Hospitality Policy for more information).

9.3 no payment may be offered or paid to individuals to compensate merely for the time spent in attending events/meetings.

9.4 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 their organisation's medicine management lead. Staff should also consult their organisation's Declaration of Gifts, Hospitality and Sponsorship Policy.

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 staff 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.

Use of patient identifiable information must be consistent with Caldicott principles.

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.

Generally, sponsorship arrangements involving NHS organisation 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 medicine's formulary.

Promotion of any product should not contradict current NHS Shropshire Telford & Wrekin ICS guidelines or formulary.

9.5 Clinical review services offered by the Pharmaceutical Industry- ***see information in appendix 1.***

10 MEDICAL AND EDUCATIONAL GOODS AND SERVICES

NHS staff may seek Medical Educational Services and Grants (MEGS no promotional funding) 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 their organisation's Medicines Management Team in order to progress potential sponsorship requests in line with this policy.
Donations and grants must:

10.1 not be accepted by individuals.
10.2 be prospective in nature.
10.3 not be an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines or bear its name.
10.4 have a written agreement in place for each donation or grant which must be certified.

11 EDUCATIONAL MEETINGS AND TRAINING ARRANGED BY THE ORGANISATIONS

11.1 Industry representatives organising meetings are permitted to provide appropriate hospitality and/or meet any reasonable, actual costs, which may have incurred.
11.2 It must be clear that the sponsorship does not imply the NHS organisation endorsement of any product or company. There should be no promotion of products apart from that agreed in writing.
11.3 Where an educational or training event is being considered and sponsorship is being sought, all relevant manufactures/companies should be approached to avoid any suggestion of preferential treatment.
11.4 There will be prior written agreement of the content of the meeting/event and the identity of the speakers and nature of the displayed promotional material agreed including, where possible, a breakdown of agreed costs.
11.5 Where training is being provided by the industry, the NHS organisation must be satisfied that training complies with the ABPI Code of Practice, and guidance complies with current evidence based, NHS and local prescribing guidance.

The company cannot promote its products through the work it is supporting by direct advertisement except by manning a promotional stand at the sponsored meeting/event. This stand will be manned at the registration area and will preferably be in a separate area to that of the main meeting.

11.6 Sponsorship should not compromise purchasing, commissioning decisions or prescribing advice. Refer to individual NHS organisation policies for more guidance: Procurement Policy; Fraud, Corruption and Bribery Policy; Standards of Business Conduct Policy; and Managing Conflict of Interest

Policy.

12 CLINICAL ACCOUNTABILITIES

12.1 Clinical aspects of projects must always remain under local control.

12.2 The development of prescribing guidelines and protocols will be developed via the usual Integrated Medicines Optimisation Committee (IMOC) processes.

13 CONFIDENTIALITY AND DATA PROTECTION

Where access to, or processing of patient confidential data is required all staff, will comply in line with Information Governance Policies

14 CONFLICTS OF INTEREST, PAYMENTS, AND HOSPITALITY

14.1. All staff will comply with their individual organisation Standards of Business Conduct Policy and Managing Conflicts of Interest Policy.
14.2. Clinical staff must comply with their own professional codes of conduct.
14.3. Pharmaceutical companies are required to conduct themselves within the legal framework for the promotion of pharmaceutical products – the ethical code of the ABPI.

15 DOCUMENTATION

15.1 Other related policy documents

- Fraud, Corruption and Bribery Policy
- Gifts and Hospitality Policy
- Procurement Policy
- Standards of Business Conduct Policy
- Managing Conflicts of Interest Policy

15.2 Legislation and statutory requirements

- Public Contracts Regulations 2006 (as amended)
- Bribery Act 2010

15.3 Best practice recommendations

Document	Owner	Website Link
The Code of Practice for the Pharmaceutical Industry 2021	Association of theBritish Pharmaceutical Industry	https://www.pmcpa.org.uk/the-code/2021-interactive-abpi-code-of-practice/

Notes on Joint WorkingBetween Pharmaceutical Companies and the NHS and Others for the benefit of Patients.		https://www.networks.nhs.uk/nhs-networks/joint-working-nhs-pharmaceutical/documents/ABPI_Code_Guidance_Notes_joint%20working.pdf
Joint Working: A ten-step process		https://www.abpi.org.uk/partnerships/working-with-the-nhs/joint-working-a-toolkit-for-industry-and-the-nhs/joint-working-a-ten-step-process/
Ethical standards forproviders of public services	Department ofHealth	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/336942/CSPL_EthicalStandards_web.pdf

The NHS organisation will view instances where this policy is not followed as serious and may take disciplinary action against individuals, which may result in removal from office in accordance with the provisions of the organisation's constitution and/or dismissal. The following policies, will apply to breaches of this policy where appropriate:

- Whistleblowing Policy
- Disciplinary Policy
- Fraud Corruption and Bribery Policy

Appendix 1 – Advice for ICB commissioned services (including GP Practices and PCNs) regarding support provided by the pharmaceutical industry.

ICB commissioned services in NHS Shropshire Telford and Wrekin should consider adopting the following best practice guide when entering discussions about joint working with Pharmaceutical Industry

The Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry allows for medical and educational goods and services (MEGS) to be provided by pharmaceutical companies to healthcare organisations, such as GP surgeries and hospital departments, in order to enhance patient care and benefit the NHS. MEGS must not be provided to individuals or as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

The provision of such services is strictly regulated through the ABPI Code of Practice and theconditions under which companies can offer and provide these services is summarised below.

In addition to ensuring the pharmaceutical company and any sponsored healthcare professionals adhere to the ABPI Code of Practice, GP practices should also consider whether the service on offer will genuinely improve the care of patients of the practice:

- Will the service in question help to address a clinical priority for the practice, PCN or the ICB?
- What are the potential benefits and risks for patients and for the practice? – (e.g., is it likely that prescribing costs, pathology costs, referrals or admissions will change? Will patients have better health outcomes, are better informed about their condition, or be inconvenienced in any way?)
- What are the insurance arrangements for the industry personnel delivering the service?
- Are arrangements for access to patient records consistent with other activities within the practice and other information governance arrangements?
- Ensure any recommendations that relate to medicines are in line with the local formularyapprovals.
- Ensure results of any work including ownership and next steps are agreed and clearly documented to provide an audit trail.

We would strongly advice practices seek advice from the Medicines Management Team or with ICB Information Governance Function before agreeing to participate in clinical/therapeutic review services offered by third parties.

An agreement is attached to the bottom of this document for use when entering

joint working with a company.

The ABPI Code of Practice gives the following guidance to companies offering such services.

1. The involvement of a pharmaceutical company in such activities must be made clear to relevant health professionals and/or practice staff.

2. The involvement of a pharmaceutical company in therapy review services should also be made clear to patients if materials for patients are provided in connection with the service. (e.g., it must be obvious on any information for patients on healthcare or medicines that the material is sponsored by a pharmaceutical company). If there are no material for patients this would be a matter for the relevant professional.

3. Companies should consider using staff other than medical/generic representatives when offering MEGS as these goods and services must not be linked to the promotion of products. This means that representatives must not promote the company's products AND offer a service at the same visit, although they could indicate that a service is available and provide materials e.g.an introductory letter.

4. If a change in medication to one of the company's products is agreed at a promotional visit the representative may not, then offer a therapy review service to facilitate the change as this would be seen as a way for the company to ensure that the agreed change would in fact be made.

5. If the goods and services require patient contact, for example either directly or by identification of patients from patient records and the like, then medical representatives must not be involved. Only an appropriately qualified person, for example a sponsored registered nurse or pharmacist, may undertake activities relating to patient contact and/orpatient identification.

6. Neither the company nor its medical/generic representatives may be given access to data/records that could identify or be linked to patients.

7. Sponsored health professionals should not be involved in the promotion of specific products.

8. The remuneration of those not employed as medical representatives but who are sponsored or employed as service providers must not be linked to sales in any area or to sales of a specific product may not include a bonus scheme linked to such sales.

9. Companies must ensure that patient confidentiality is always maintained, and that data protection legislation is complied with.

10. Service providers must operate to detailed written instructions provided by the company. The written instructions should set out the role of the service provider and should cover patient confidentiality issues.

11. Service providers must take reasonable steps to ensure that they do not mislead as to their identity or that of the company they represent.

12. A recipient of a service must be provided with a written protocol to avoid misunderstandings as to what the recipient has agreed. The identity of the sponsoring pharmaceutical company must be given. (e.g., a GP allowing a sponsored registered nurse access to patient records should be informed in writing of any data to be extracted and the use to which those data will be put).

13. Any printed material designed for use in relation to the provision of services must be non-promotional and must identify the sponsoring pharmaceutical company.

14. Companies are recommended to inform relevant parties such as Primary Care organisations of their activities where appropriate. This is particularly recommended where companies are proposing to provide services which would have budgetary implications for the organisations concerned.

15. Switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine is simply changed to another, without clinical assessment, are prohibited under the ABPI Code of Practice. Companies may promote a straightforward switch but may not help to implement it in any way.

16. A therapeutic review (as distinct from a switch service) which aims to ensure that patients receive optimal treatment following a clinical assessment is a legitimate activity for a pharmaceutical company to support and/or assist. A genuine therapeutic review should include a comprehensive range of relevant treatment choices for the health professional and should not be limited to the medicines of the sponsoring pharmaceutical company. The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational grounds.

AGREEMENT BETWEEN THE PROVIDER PRIMARY CARE PRACTICES AND THE PHARMACEUTICAL COMPANIES.

Primary Care to the Pharmaceutical Companies:

- We recognise and acknowledge that as businesses a key aim for you is the generation of revenue and a return on investment.
- We acknowledge the pharmaceutical sector is a key stakeholder in the health economy.
- We recognise and acknowledge the important contribution the pharmaceutical industry has made to the health of the nation over decades, with regards to the development of new treatments and medications, and innovations in patient care.
- We seek to work with you for the good of our patients, in an open, honest, and transparent manner, acknowledging that at times we may have to step back from a piece of work for ethical and business reasons.
- We will endeavour to create time for good quality clinical discussions around medications and treatments as well as patient pathways, and value-based proposals in conjunction with colleagues as appropriate.

Pharmaceutical Companies to Primary Care:

- We recognise and acknowledge that you are driven by a desire to provide the best outcomes for your patients, and that such outcomes are driven by clinical as well as value-based considerations.
- We recognise and acknowledge the importance of Primary Care's role in the delivery of excellent quality for patients and we will endeavour to support this work by being mindful and respectful of the limited time clinicians and managers have.
- We acknowledge and respect any decisions made regarding medications, treatments or patient pathways made by clinicians and colleagues considering national and local guidelines and principles and that we will only promote medications, treatments or patient pathway that are in line with such guidelines and principles.
- We acknowledge our work should be focused on ICB priorities.
- We seek to work with you for the good of your patients, in open, honest, and transparent manner.

Appendix 2- Rebate Scheme Guidance

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

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

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 NHS STW must 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.

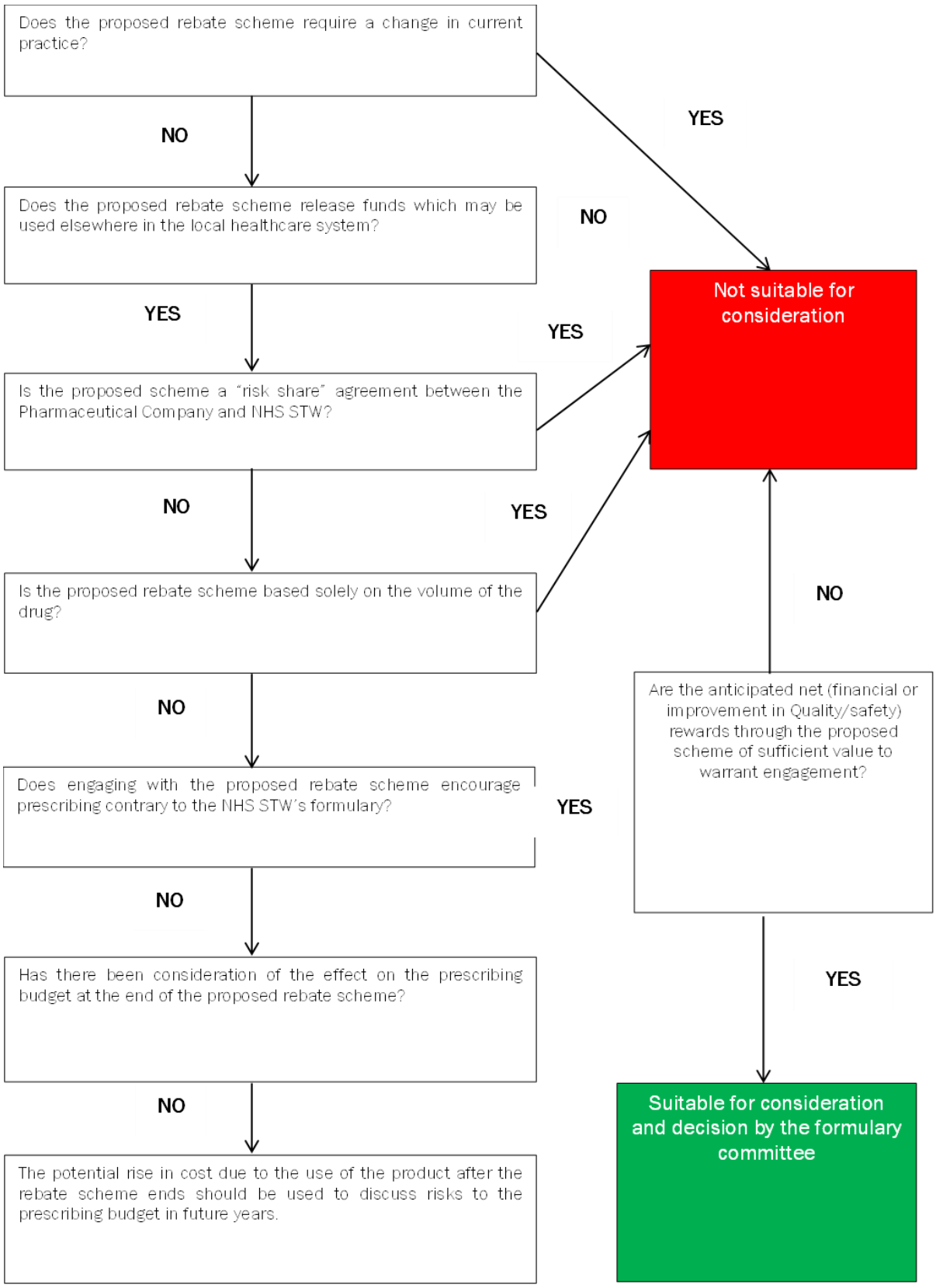
The agreement should set the scope and realise the mutual obligations between both the NHS and pharmaceutical companies depending on the occurrence if an agreed condition – the 'risk'. The 'risk' varies by situation and can include pharmaceutical expenditure higher than agreed thresholds. In addition 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 such schemes with a pharmaceutical industry partner there are several 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 NHS STW without detriment to the quality of patient care.

In the cases where a scheme is agreed, NHS STW will ensure that the agreement entered 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.


Does the proposed rebate scheme require a change in current practice?
YES
NO
Does the proposed rebate scheme release funds which may be used elsewhere in the local healthcare system?
NO
YES
YES
Not suitable for consideration
Is the proposed scheme a "risk share" agreement between the Pharmaceutical Company and NHS STW?
NO
YES
Is the proposed rebate scheme based solely on the volume of the drug?
NO
NO
Are the anticipated net (financial or improvement in Quality/safety) rewards through the proposed scheme of sufficient value to warrant engagement?
Does engaging with the proposed rebate scheme encourage prescribing contrary to the NHS STW's formulary?
YES
NO
YES
Has there been consideration of the effect on the prescribing budget at the end of the proposed rebate scheme?
Suitable for consideration and decision by the formulary committee
NO
The potential rise in cost due to the use of the product after the rebate scheme ends should be used to discuss risks to the prescribing budget in future years.

c) Process for management

The ICB 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 Chief Finance Officer (CFO) for approval. The contract should be clearly defined and contain mutually agreed exit criteria.

Where possible rebates will be selected using information from PrescQipp, who review, assess, 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.

Other independent rebate schemes will be given consideration, to facilitate a fair and appropriate process for non-prescqipp assessed schemes, each scheme will be assessed on its own merits, consideration will be facilitated via a panel of appropriate people. All documents pertaining to the scheme should be presented to allow robust decision making. Once a scheme has been assessed and a decision made to join the scheme the CFO will sign the rebate contract if their approval is given.

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 NHS STW.

A list of all current rebates will be published on the NHS STW 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 NHS STW 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 NHS STW Chief Finance officer (CFO) or the Deputy CFO if the CFO is not available however the rebate contract will correctly reflect the contract approvers title.

Appendix 3 – 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, (if 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 must 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/ICB/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 NHS STW policies on the strategy for equality and diversity and human rights.

Appendix 4 – Authorisation procedure for gifts, hospitality and sponsorship from pharmaceutical companies

Please refer to individual organisation Declaration of Gifts, Hospitality and Sponsorship Policy,

NHSSTW: Approved Documents Policy (shropshiretelfordandwrekin.nhs.uk)

SaTH

SCHT

RJAH

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

Appendix 5 – 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 organisation 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's ICS priorities, especially regarding 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 organisation 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 organisation's staff without the influence of commercial sponsors?		

4	Is the subject of the post in keeping with the NHS/ organisation's priorities especially regarding prescribing?		
5	Have all the competing interests by all personnel been declared?		
6	Will the post holder be recruited solely by NHS organisation?		
7	Will all the data obtained from the project remain confidential to the NHS organisation and practices (where applicable)?		
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 organisation's 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 NHS organisation's staff without the influence of the commercial sponsors?		
4	Is the subject of the project in keeping with the NHS organisation's priorities especially regarding prescribing?		
5	Have all the competing interests by all personnel been declared?		
6	Will the project be carried out by personnel recruited solely by the NHS organisation?		
7	Will all the data obtained from the project remain confidential to the NHS organisation (and practices where applicable)?		
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 6 – 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 ICS 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 many 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 ICS formulary, individual organisation guidance and policies as appropriate.
- 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 the NHS organisation.

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 staff?

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:

Appendix 7 – Access of staff

The Medicines Management Team of each of the NHS organisation 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 or Chief Pharmacist or designated staff, any agreements reached with 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**.

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.

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.

Appendix 8 – 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 Formulary, which is manufactured by a company with which they have links e.g. company shares or a research grant.*
   The Integrated 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, or 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 if 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 as appropriate.

H. *High tech home health care provider offers to supply equipment at reduced rate in return for business linked to a specific product.*
NHS organisation 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.