

**WORKING WITH
THE PHARMACEUTICAL INDUSTRY
POLICY
Version 1.0**



Standard Operating Procedure	St Helens CCG Working with The Pharmaceutical Industry Policy
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26/04/17	POLICY	Introduction of New Policy.	FG&R Committee

POLICY OBSOLETE		
Date	Reason	Approved By

TO BE READ IN CONJUNCTION WITH THE FOLOWING POLICIES:

- Anti-fraud and Corruption Policy
- Whistle Blowing Policy
- Disciplinary Policy
- Code of Conduct for NHS Managers (October 2002)
- Standards of Business Conduct (HSG (93) 5)
- Procurement Policy
- Detailed Financial Policy
- RCGP & NHS Confederation's 'Managing Conflicts of Interest' briefing paper, (September 2011)
- Monitor - Substantive guidance on the Procurement, Patient Choice and Competition Regulations (December 2013)
- <http://www.legislation.gov.uk/uksi/2013/500/contents/made>
- The Bribery Act 2010
- Managing Conflicts of Interest in the NHS (February 2017)
- CCG: Standards of Business Conduct Policy
- CCG: Conflicts of Interest, Gifts and Hospitality Policy
- ABPI Communication July 2015 – Disclosures of Transfers of Value by Pharmaceutical Companies
- ABPI Code of Practice for the Pharmaceutical Industry 2016

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1.0 Introduction

Medicines are the most frequently and widely used NHS treatment and account for over 12% of NHS expenditure. The Pharmaceutical Industry (PI) has always worked closely with the NHS, clinicians and commissioning organisations. The establishment of Clinical Commissioning Groups put clinicians at the centre of commissioning to deliver excellent healthcare by building effective and appropriate working relationships with key partners such as the PI. This means that there is even greater complexity in relation to what could be deemed conflict of interest. It is essential that there are clear procedures for the CCG staff, members and supporting individuals and organisations (including private and voluntary) where there may be potential for a conflict of interest that could affect commissioning decisions related to medicines and associated services.

CCG employees should be aware that as a condition of membership of the Association of the British Pharmaceutical Industry (ABPI), PI representatives must follow the “ABPI Code of Practice for the Pharmaceutical Industry:

<http://www.pmcpa.org.uk/thecode/Documents/Code%20of%20Practice%202016%20.pdf>

The ABPI is an industry body representing pharmaceutical companies in the UK. The ABPI Code of Practice sets a framework of standards for UK pharmaceutical companies, covering the promotion of medicines and requirements for interactions with healthcare organisations and healthcare professionals. The code applies to most of the PI in the UK. It is designed to ensure a professional, responsible and ethical approach to the promotion of prescription medicines in the UK. If CCG staff or members believe that an industry representative has broken the Code, they should contact the Head of Medicines Management for information and advice, they will oversee any complaints being reported.

CCG staff and members should be aware that the nature of marketing and therefore pharmaceutical marketing means that decision making can be influenced in ways where the target may be unaware of being subject to influence. Therefore CCG staff should maintain awareness and accept that this is possible and even probable. This is why full declarations of interests that are open to public scrutiny are important enabling greater objectivity.

2.0 Purpose

The aim of this policy is:

- To provide the CCG Governing Body with assurances that all decisions made about medicines and medicines management in relation to pharmaceutical industry sponsorship, which give mutual advantage, are made within a framework of probity
- To make clear to the membership the relevant principles, process and procedures to follow regarding business conduct and accountability in relation to commercial sponsorship and dealings with the Pharmaceutical Industry (PI)
- To safeguard the interests of the CCG and reassure the public
- To establish ways that the CCG can work constructively with the pharmaceutical industry

This policy covers employees of NHS St Helens CCG. It also applies to consultancy and agency staff remunerated by St Helens CCG. The CCG recommends that member practices also adhere to the principles outlined within it.

3.0 Disclosures of Transfers of Value by Pharmaceutical Companies

From June 2016 the ABPI began publishing a public database declaring benefits that UK pharmaceutical companies give in cash or in kind to healthcare organisations, individual healthcare professionals and any relevant decision makers within a healthcare organisation. These benefits are termed 'transfers of value'.

For individual Healthcare Professionals, transfers of value activities cover:

- Events – registration fees
- Events – Travel and accommodation
- Consultancy Services – fees
- Consultancy Services – expenses

For Healthcare Organisations, requirements cover:

- Activities covered by contract under which organisations provide any type of service on behalf of companies
- NHS joint-working projects
- Donations, grants and benefits in kind
- Contribution towards the cost of meetings
- Provision of medical and educational goods and services

The CCG maintains a register of all gifts and hospitality offered to the organisation and/or individual members of staff – to ensure this is kept up to date and matches the public ABPI database it is important that staff adhere to the NHS St Helens CCG Standards of Business Conduct regarding recording all transfers of value offered in the course of CCG business. Please refer to the full policy for details.

4.0 Declarations of Interest

The CCG maintains a register of declarations of interest in relation to CCG staff and relevant decision making staff.

Conflicts might occur with regards to the pharmaceutical industry due to the possibility of individuals having:

- A direct financial interest
- An indirect financial interest
- Non-financial or personal interests
- Conflicts of loyalty.

It is essential that all staff complete a declaration of interest in line with the NHS St Helens Standards of Business Conduct Policy when requested to do so and notify the organisation of any changes immediately. Please refer to the full policy for details.

5.0 Attendance at Sponsored Clinical Training or Education Meetings

CCG employees must ensure there is an entry made on the CCG Gifts, Hospitality and Sponsorship register regarding any clinical training or education provided by or sponsored by a pharmaceutical company. This should include details of company name, drugs discussed at meetings, and hospitality or other sponsorship provided. The CCG Gifts, Hospitality & Sponsorship Register will be available for both CCG and public scrutiny.

CCG member practices – it is recommended that each practice should maintain their own register of dealings with the PI including any clinical training or education provided by or sponsored by a pharmaceutical company. This should include details of company name, drugs discussed at meetings, and hospitality or other sponsorship provided. The Practice Register of Interests should be available for both CCG and public scrutiny.

6.0 Meetings with Pharmaceutical Company Representatives

The CCG does not approve any 'cold calling' to staff or the membership from PI representatives.

All requests for meetings and contacts by PI representatives to staff or members should be done via the dedicated proforma (Appendix A). All contact should then be via email to the generic email address communications.ccg@sthelensccg.nhs.uk until such a decision has been made that a meeting or direct contact will take place.

In considering requests for meetings with representatives of the PI, consideration should be given to whether this will represent best use of CCG staff or member's time and therefore not all requests can be granted.

All proformas will be logged centrally and held for 12 months for reference purposes.

GPs and any other clinician members of the CCG who PI representatives may contact in their capacity as prescribers or related health professionals should follow good practice and ensure inclusion in a practice register of dealings with the pharmaceutical Industry. The register should include details of the meeting, date, representative and company name, practice members present, drugs and services discussed, hospitality received. This register should be available for both CCG and public scrutiny.

Members of the CCG considering meeting with PI representatives in their capacity as clinicians at practice level should also consider whether this will represent good use of their time given the arrangements in place locally through CCG and Area Prescribing Committee for recommendations on new drugs, formulary, and guidelines and on medicines safety.

The process for dealing with contact from PI representatives is detailed in Appendix B.

7.0 Sponsorship of Meetings

Sponsorship of meetings is not permitted for routine internal meetings of the CCG. Sponsorship may be obtained only for educational or special events.

The ABPI Code states that meetings must be held in appropriate venues conducive to the main purpose of the event. 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. The level of subsistence offered must be appropriate and not out of proportion to the occasion. The costs involved must not exceed that level which the recipients would normally adopt when paying for themselves. It must not extend beyond members of the health professions or appropriate administrative staff.

For sponsored meetings being organised by staff or CCG members (other than for their own GP practice), a form for proposed sponsorship of meeting must be completed and forwarded to the Head of Medicines Management so that an overview of sponsorship of meetings by the CCG can be maintained, see Appendix C.

When seeking sponsorship for a meeting, use of a company with products directly related to the topic under consideration should be avoided as far as possible. Please contact the Medicines Management Team for advice if you are unsure. Products that are not approved by NHS St Helens CCG and on the CCG formulary should not be promoted.

If 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.

Details of the sponsorship should also be highlighted to attendees at the beginning of the meeting.

For PI sponsored meetings, the level of access to clinicians or associated staff for the promotion of specific drugs or services by the pharmaceutical company (before the primary purpose of the meeting commences) must be agreed in advance, (as stated on sponsorship request form). For a sponsored sandwich lunch for example the representative could have a stand with promotional materials and attend the stand to engage with attendees during lunch and before the meeting starts.

Representative/s of the pharmaceutical company sponsoring the meeting should be thanked for the sponsorship ahead of the commencement of the primary purpose of the meeting and then must not remain in attendance at the meeting unless it is a public meeting.

For CCG members obtaining sponsorship for practice meetings details of the sponsorship must be kept in a practice register of dealings with the pharmaceutical industry, which should be available for CCG and public scrutiny.

Meetings of the Governing Body

The CCG holds meetings of its Governing Body in public and is required to do so both by statute and its Constitution. They are often attended by representatives of the

pharmaceutical industry. Those representatives attend meetings in their capacity as members of the public and have no special privileges when they do so. They should receive no greater or lesser opportunity to participate in the meeting or engage with individual members of the Governing Body than would any other member of the public.

Members of the Governing Body may be approached by representatives who seek to engage with them for the purpose of promoting their particular products or canvassing support for products or projects. It is recommended that they politely but firmly decline to engage with pharmaceutical representatives in these circumstances.

8.0 Joint working with Pharmaceutical Companies

For the purpose of this policy joint working is defined as situations where, for the benefit of patients, the CCG and one or more pharmaceutical companies' pool skills, experience and/or resources for the joint development and implementation of patient centered 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.

Joint working between the pharmaceutical industry and the CCG must be for the benefit of patients or the NHS and preserve patient care; the main beneficiary being the patient.

Joint working arrangements must be entered into at a corporate level and not with any individual member of staff or CCG member.

Any tentative discussion about entering into joint working which staff or CCG members may have and consider worth pursuing should first be discussed with their line manager, relevant clinical leads and executive leads as appropriate. There must also be a discussion with the Head of Medicines Management or Senior Pharmacist.

If the proposal is deemed suitable to explore further the designated lead should provide initial details on the joint working outline proposal using the quality standards checklist for considering commercial partnerships and a summary should then be submitted to the Executive Leadership Team (ELT) for consideration (see Appendix D).

If the initial outline is supported a project group should be established to produce a full proposal that will then need to be approved by the ELT.

The length of the arrangement, the potential implications for patients and the NHS, together with the perceived benefits for all parties, should be clearly outlined before entering into any joint working.

When entering into an agreement for joint working, the CCG must also consider the impact once these arrangements are concluded. An effective exit strategy must be in place at the outset of a given project detailing the responsibilities of each party.

A formal written agreement must be in place and an executive summary of the joint working agreement must be made publicly available before arrangements are implemented.

All aspects of confidentiality with regard to patient information must be observed and how this will be achieved clearly stated in the Joint Working Agreement. Confidentiality of information received in the course of duty should be respected and should never be used outside the scope of the specific exercise.

Arrangements for monitoring the operation of the agreement and assessing clinical and financial outcomes should be agreed and clearly stated within the Joint Working Agreement. All assessments of the joint working programme should be made readily available to other NHS organisations and the public.

This process is summarized in Appendix E

9.0 Primary Care Pharmaceutical Rebate Schemes

Primary care rebate schemes (PCRS) are contractual arrangements offered by pharmaceutical companies, or third party companies, which offer financial rebates on GP prescribing expenditure for particular branded medicine(s). Such schemes are increasingly being offered to Clinical Commissioning Groups (CCGs) by the pharmaceutical industry as a means to introduce new drugs into the NHS, or more simply as a tool to increase/ establish market share of existing/new medicine(s).

This policy provides the clarity and guidance for NHS St Helens CCG when considering entering into a primary care rebate scheme.

Rebate schemes are different from national patient access schemes, which are recognised by NHS England to manage entry of new products to the market at a reduced cost. However both approaches serve to protect the 'list price' of the product, which is used as a reference by markets in other countries.

NHS St Helens CCG subscribe to the PrescQIPP NHS Programme who created the PrescQIPP Pharmaceutical Industry Scheme Governance Review Board. The primary output of the board is an assessment, summarising the recommendations for any rebate scheme submitted to them. Each Board Assessment will also include a Red, Amber or Grey status depending on the outcome of the assessment stage. The classification of the three colours is as follows:

Grey – Scheme Considered; No significant reservations

Amber – Scheme Considered; Not fully appropriate

Red – Scheme Considered; Inappropriate

Submitted schemes will need to demonstrate compliance with the following five principles in order to achieve a Grey/Amber Status:

1. The therapeutic initiative has a place in clinical practice
2. The arrangements for the scheme are simple and easy for the NHS to implement.
3. There is a transparent, sensible plan for payment and tracking
4. The governance on what the Scheme is, and is not, going to be used for is robust
5. There is a plan for ongoing review.

NHS St Helens CCG will ensure that the following principles underpin any decision with regards to rebate schemes:

- Any schemes offered will be considered based on the PrescQIPP Pharmaceutical Industry Scheme Governance Review Board assessment
- Any schemes that are considered will need to demonstrate compliance with the five PrescQIPP principles and must have achieved a Grey or Amber Status
- Any schemes offered to the CCG will be considered by a Senior Pharmacist and if appropriate will be signed off by the CCG Director of Finance
- It is preferable for pharmaceutical companies to supply medicines to the NHS using transparent pricing mechanisms that do not create an additional administrative burden to the NHS
- Health professionals should always base their prescribing decisions on assessments of their individual patients' clinical circumstances. The impact of a rebate scheme should never be a consideration
- Any scheme offered should not be exclusive. That is there should be no requirement to limit access of other medicines to patients under the scheme
- Arrangements for the termination of the scheme must be detailed and agreed
- Any schemes that include a requirement for volume thresholds will be considered in line with the PrescQIPP assessment and careful consideration will be given to the implications of this type of scheme

Appendix A

Appointment Request Form for Pharmaceutical Industry Representatives

All sections must be completed prior to consideration of an appointment

Please email to communications.ccg@sthelensccg.nhs.uk

Request Date																									
Name of Representative																									
Name of Company																									
Email/Mobile No.	(We may offer teleconference appointments)																								
Category of topic(s) you wish to discuss	<p>Please mark the relevant category/categories</p> <table border="1"> <tr> <td>CCG commissioning pathways and service development</td> <td></td> </tr> <tr> <td>Prescribing – please complete additional table below</td> <td></td> </tr> <tr> <td>Proposed joint working</td> <td></td> </tr> </table>	CCG commissioning pathways and service development		Prescribing – please complete additional table below		Proposed joint working																			
CCG commissioning pathways and service development																									
Prescribing – please complete additional table below																									
Proposed joint working																									
<u>ALL requests relating to prescribing</u> please complete (highlight all relevant)	<p>Please mark the relevant category/categories</p> <table border="1"> <thead> <tr> <th colspan="2">New Medicine</th> <th colspan="2">Formulary</th> <th colspan="2">Sharing Resources</th> </tr> </thead> <tbody> <tr> <td>Clinical data (efficacy, safety etc)</td> <td></td> <td>Licence extension</td> <td></td> <td>Medicines optimisation collaborative initiative</td> <td></td> </tr> <tr> <td>Budget impact document</td> <td></td> <td>New formulation of existing medicine</td> <td></td> <td>Other collaborative initiative</td> <td></td> </tr> <tr> <td>Pre-licence advanced planning notification</td> <td></td> <td>Efficiency saving</td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	New Medicine		Formulary		Sharing Resources		Clinical data (efficacy, safety etc)		Licence extension		Medicines optimisation collaborative initiative		Budget impact document		New formulation of existing medicine		Other collaborative initiative		Pre-licence advanced planning notification		Efficiency saving			
New Medicine		Formulary		Sharing Resources																					
Clinical data (efficacy, safety etc)		Licence extension		Medicines optimisation collaborative initiative																					
Budget impact document		New formulation of existing medicine		Other collaborative initiative																					
Pre-licence advanced planning notification		Efficiency saving																							
Outline what you wish to discuss and attach relevant pre-reading material																									
What is the outcome you hope to achieve from the meeting?																									
How long do you anticipate the meeting lasting?																									

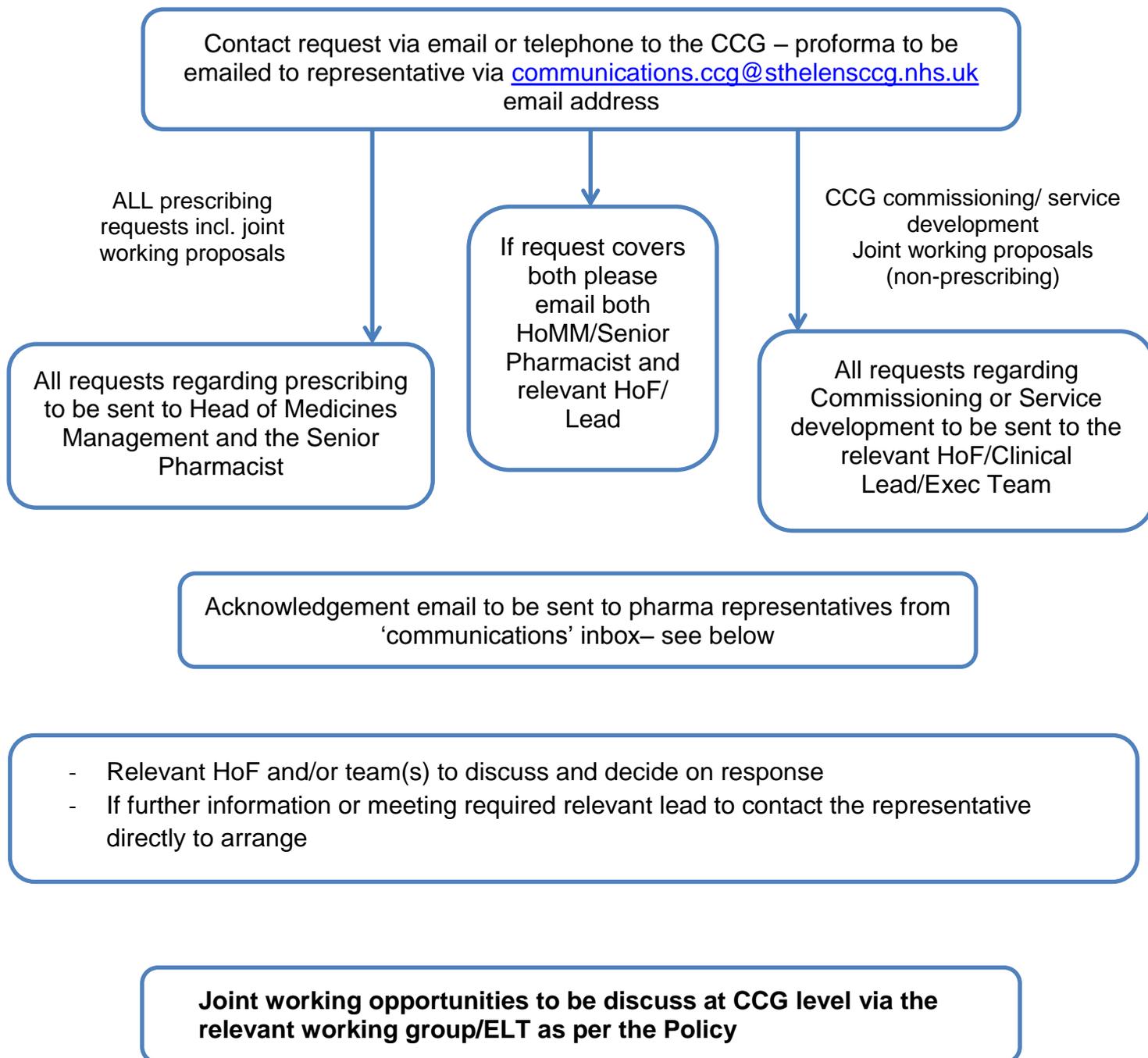
Office Use Only

Date of last appointment	
To be given an appointment	Yes <input type="checkbox"/> No <input type="checkbox"/> Urgent <input type="checkbox"/> Routine <input type="checkbox"/> Time required
Reason if no appointment given	
Details of appointment if applicable	

Appendix B

NHS St Helens CCG Process for Dealing with Contact from Pharmaceutical Industry Representatives

Where possible all initial email correspondence with PI representatives should be via the generic CCG mailbox. No staff details should be given out (names, work emails, and contact numbers) without prior consent from that individual



Standard Acknowledgement to Pharma Contact:

“Thank you for your email. The information has been passed onto the relevant CCG staff member for their consideration. We will be in contact should we wish to meet or require any further information.”

Appendix C

Request Proforma (CCG internal) for sponsorship of a meeting by a pharmaceutical company

CCG Lead or member of staff organising the meeting:		
Title and details of Meeting:		
Target audience:		
Venue:	Proposed date:	
Proposed Pharmaceutical Sponsor(s)		
Representative name(s) and contact details (please list all):		
Details of sponsorship requested. Please include details of whether invoices are to be raised for each sponsor – details to be confirmed with each sponsor.		
Approximate value of sponsorship	Overall Value £.....	Per Sponsor £.....
Details of direct marketing contact at meeting: e.g. whether representative will attend the meeting, have a marketing stand showing product information; which products and or services will be marketed.		
Please confirm that any products or services to be marketed are included on the CCG formulary and/or have been approved for use locally by the CCG. If unsure please seek advice from medicines management before proceeding.		Please Tick to confirm <input type="checkbox"/>
Please forward the completed form to joanne.smith6@sthelensccg.nhs.uk prior to the event taking place Please ensure an entry is made on the gifts and hospitality register as appropriate.		

Appendix D

Quality Standards Checklist for Joint Working with a commercial company or the pharmaceutical industry (Adapted from Harrogate and Rural District CCG policy)

Quality Standards Checklist for considering Joint Working with a commercial company or the pharmaceutical industry		
	Yes	No
Does the scheme have clear aims and objectives?		
Does the sponsorship offer any benefits to the following aspects of health care?		
• Diagnostics and referral? Include details:		
• Investigations and measurements? Include details:		
• Informing and educating patients?		
○ Will the material be checked by the CCG before it is distributed to ensure it is non-promotional and culturally appropriate		
• Informing and educating health professionals?		
○ Will the material be checked by the CCG before it is distributed to ensure it is valid, non-promotional and in line with national and local formulary and guidance?		
Is the sponsorship directly related to patient treatment?		
• Have alternative treatments been considered and evaluated?		
• Has an assessment of the costs and benefits of the package in relation to alternative options been investigated?		
• Has monitoring of the patients been considered as part of the treatment?		
• Has a criteria for success of the project been established?		
• Has patient perceptions been included as part of the criteria?		
• Has a health care professional been designated clinically responsible for the patient at each stage of the package?		
• Has an assessment been made as to how the package fits with existing systems of primary and secondary care?		
• Is the treatment on the current CCG formulary or is CCG approved?		

Information and Data considerations		
• Is the sponsorship related to the collection of data?		
• Who will own the data? Please state:		
• Will the sponsor have access to the data?		
• Have the provisions of the Data Protection Act been taken into consideration?		
• Who will evaluate the data? Please state:		
Is the sponsorship related to any of the following?		
• Provision of clinical products?		
○ Will this encourage the use of a particular product in the future?		
○ Is the product included in the local formulary or is CCG approved?		
○ Will the use of the product limit patient choice?		
○ Is this project intended to increase the market share for a particular product or company?		
○ Will this limit clinical freedom of a prescriber to select the most appropriate product?		
○ Has evidence been provided to support use of this product and has this been independently reviewed?		
• Provision of equipment?		
○ Is the equipment linked to the use of one particular brand of consumables?		
○ Has an assessment been undertaken to establish that it is the best for purpose?		
○ Has the equipment been approved for use locally?		
○ Is there any guidance locally or nationally regarding use of this type of product?		
• Provision of free stationery?		
○ Does the stationery include commercial advertising?		
○ Has the CCG control over the content of the advertising?		
Are there any recurring costs for the scheme?		
Who will be responsible for recurring costs? Please state:		

How does the use of a product impact on other providers in the future e.g. costs, supply, FP10 availability, very specialist etc.

Further Information

Appendix E

NHS St Helens CCG Process for Joint Working Opportunities from PI

Where possible all initial email correspondence with PI representatives should be via the generic CCG email as below

