NHS
Cheshire and Merseyside

Working with the Pharmaceutical Industry (PI), Dispensing Appliance Contractors (DACs) and Prescribing Associated Product Suppliers Policy

Version 3

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1. 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.

Increasingly Dispensing Appliance Contractors (DACs), suppliers of prescribing support software and intelligence are also working closely with the NHS, clinicians, and commissioning organisations.

It is essential that there are clear procedures for Cheshire and Merseyside Integrated Care Board (ICB) 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.

ICB 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:

2021 Interactive ABPI Code of Practice - Comes into operation 1 July 2021 (pmcpa.org.uk)

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 an ICB staff member believes that an industry representative has broken the Code, they should contact the ICB Chief Pharmacist for information and advice, and who will oversee any complaints being reported.

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

2. SCOPE

This policy covers employees of NHS Cheshire and Merseyside ICB. It also applies to consultancy and all staff remunerated by NHS Cheshire and Merseyside ICB. The ICB strongly recommends that individual GP practices, Primary Care Networks (PCNs) and PCN collaboratives also adhere to the principles outlined within it.

3. POLICY STATEMENT

The aim of this policy is:

- to provide the Cheshire and Merseyside ICB with assurances that all decisions made about medicines and medicines management in relation to pharmaceutical industry, DACs and prescribing associated product suppliers sponsorship, which give mutual advantage, are made within a framework of probity
- to make clear 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), DACs and prescribing associated suppliers.
- to safeguard the interests of the ICB and assure the public interest
- to establish ways that the ICB can work constructively with the Pharmaceutical Industry, DACs and prescribing associated suppliers.

4. 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 the 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 inkind
- Contribution towards the cost ofmeetings
- Provision of medical and educational goods and services.

The ICB maintains and publishes on its website[1] a register of all gifts, hospitality and sponsorship 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 Cheshire & Merseyside ICB Conflicts of Interest Policy[1] and Standards of Business Conduct Policy[1] regarding recording all transfers of value offered in the course of ICB business. Please refer to the full policies for further details.

[1] https://www.cheshireandmerseyside.nhs.uk/about/how-we-work/managing-conflicts-of-interest/

5. DECLARATIONS OF INTEREST

The ICB maintains and publishes on its website a register of declarations of interest in relation to ICB staff and relevant decision making staff. Conflicts might occur with regards to the Pharmaceutical Industry, DACs or prescribing associated product suppliers due to the possibility of individuals having:

- A direct financial interest
- An indirect financial interest
- Non-financial or personal interests
- Indirect Interest.

It is essential that all staff and those contracted to undertake a role on behalf of the ICB to complete a declaration of interest in line with the ICB's Conflicts of Interest Policy and Procedure when requested to do so and notify the organisation of any changes immediately. Please refer to the full policy for details.

6. ATTENDANCE AT SPONSORED CLINICAL TRAINING OR EDUCATION MEETINGS/ EVENTS

ICB employees must also ensure there is an entry made on the ICB Gifts, Hospitality and Sponsorship register regarding attendance at clinical training or education provided by or sponsored by a pharmaceutical company, DAC or prescribing associated product supplier either directly or via a third party arrangement. This should include details of company name, drugs discussed at meetings, and hospitality or other sponsorship provided (see Appendix 4). The ICB Gifts, Hospitality & Sponsorship Register will be available for both ICB and public scrutiny.

Attendance at a sponsored clinical training or education meeting / event that has no material value (e.g., a sponsored webinar), doesn't include hospitality or includes gifts <£6 in line with the ICB Conflicts of Interest Policy and Procedure need not be declared, but colleagues should agree the attendance with their line manager where the meeting / event occurs in work time.

Where there is a value to the training / event that is more generous (e.g., hospitality is included and gifts £6 or over) this should receive prior approval (via Appendix 4) and be declared according to the ICB Conflicts of Interest Policy.

For GP practices, PCNs and PCN collaboratives it is recommended that each practice should maintain their own register of dealings with the Pharmaceutical Industry 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 /PCN Register of Interests should be available for both ICB and public scrutiny.

7. MEETINGS WITH COMPANY REPRESENTATIVES

The ICB does not approve of any 'cold calling' to staff from company representatives. All requests for meetings and contacts by company representatives to staff or members should be done via the dedicated proforma (Appendix 1). All contact should then be via email to the generic communications email address mop-enquiries@cheshireandmerseyside.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 company, consideration should be given to whether this will represent best use of ICB staff or member's time and therefore not all requests can be granted.

All proformas will be logged centrally by the ICB Medical Directorate administration team and held for 12 months for reference purposes.

Occasionally it may be necessary for ICB employees to proactively contact Pharmaceutical Industry representatives for information relating to planned projects GPs and any other clinician members of the ICB who supplier/company 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, DACs, and suppliers of prescribing associated products. 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 ICB and public scrutiny.

GP practices considering meeting with such representatives in their capacity as clinicians at practice level or representing a PCN should also consider whether this will represent good use of their time given the arrangements in place locally through ICB and the Area Prescribing Group for recommendations on new drugs, formulary, and guidelines and on medicines safety.

The process for dealing with contact made from representatives is detailed in Appendix 2.

8. SPONSORSHIP OF MEETINGS/ EVENTS BY PHARMACEUTICAL INDUSTRY, DISPENSING APPLIANCE CONTRACTORS (DACs) and PRESCRIBING ASSOCIATED PRODUCT SUPPLIER REPRESENTATIVES

Please also refer to the ICB Conflicts of Interest Policy and Procedure.

Sponsorship of meetings is not permitted for routine internal meetings of the ICB, only for educational or special events.

In relation to the Pharmaceutical Industry, 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/ events being organised by ICB staff, a form for proposed sponsorship of meeting must be completed and forwarded to the ICB Chief Pharmacist for approval, see Appendix 3. A copy of the approved form should be sent to the ICBs Associate Director of Corporate Affairs and Governance for inclusion on the Gifts, Hospitality & Sponsorship Register, to provide a central overview of ICB events being sponsored.

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 Place Medicines Management Team for advice if you are unsure. Products that are not approved by the ICB or on the formulary should not be promoted. This includes higher cost branded products of medicines which may be on formulary when lower cost generic/biosimilar products are the preferred choice.

If meetings are sponsored by companies or supplier, that fact must be disclosed in all 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 sponsored meetings, the level of access to clinicians or associated staff for the promotion of specific drugs or services by the 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 GP practices, PCNs or PCN collaboratives obtaining sponsorship for practice meetings details of the sponsorship must be kept in a practice register of dealings with the Pharmaceutical Industry, DACs, suppliers of prescribing associated products, which should be available for ICB and public scrutiny.

Meetings of NHS Cheshire and Merseyside Integrated Care Board

The ICB holds meetings of its Board in public, they are often attended by representative of PI, DACs, and suppliers of prescribing associated products. Those representatives

attend meetings in their capacity as members of the public and have no special privileges. They should receive no greater or lesser opportunity to participate in the meeting or engage with individual members of the Board than would any other member of the public.

Members of the Board 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 in these circumstances.

9. JOINT WORKING WITH PHARMACEUTICAL COMPANIES

For the purpose of this policy joint working is defined as situations where, for the benefit of patients, the ICB and one or more pharmaceutical companies' 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.

Joint working between the pharmaceutical industry and the ICB 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.

Any tentative discussion about entering into joint working with ICB staff 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 ICB Place Head of Medicines Management or Chief Pharmacist.

If the proposal is deemed suitable to explore further, the designated lead should provide details on the joint working proposal using the quality standards checklist for considering commercial partnerships. The proposal should then be submitted to and presented at the ICB Medicines Optimisation and Pharmacy (MOP) group by the designated lead for consideration/approval (see Appendix 5) .

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 ICB 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.

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 summarised in Appendix 6

It is recommended that GP practices, PCNs and PCN collaboratives consider the recommendations above and how they can be applied within their organisation . Completion of Appendix 5 is strongly recommended and included on the practice/PCN register of interests. Further advice can be sought from the ICB Chief pharmacist or Place Head of Medicines Management / Lead Pharmacist.

10. 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 ICBs by the Pharmaceutical Industry (PI) 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 the ICB 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.

- Any schemes offered to the ICB will be considered by the Medicines Optimisation and Pharmacy Group and the NHS Cheshire and Merseyside ICB Primary Care Rebate Scheme (PCRS) Assessment/Decision Form completed (Appendix 7).
- The ICB subscribes to PrescQIPP. The PrescQIPP Governance Review Board provides an independent assessment of some schemes. The Medicines Optimisation and Pharmacy Group will consider the outcome of any assessment as part of the decision-making process.
- If appropriate the rebate will be signed off by the ICS Chief Pharmacist or nominated deputy via the ICB Medicines Optimisation and Pharmacy Group.
- 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 but careful consideration will be given to the implications of this type of scheme
- Schemes that are offered throughout the NHS in England will be preferred over schemes that are exclusive to the ICB
- The ICB will hold a register of Primary Care Rebate Schemes that details the accepted rebates. Companies entering into PCRS with the ICB will be aware that the ICB will be subject to the usual requirements under Freedom of Information to disclose information appropriately.

11. TRAINING IMPLICATIONS

It has been determined that there are no specific training requirements associated with this policy.

12. RELATED DOCUMENTS

Legislation and statutory requirements
Bribery Act 2010

Other related ICB policy documents
Conflicts of Interests Policy and Procedure
Anti-Fraud, Bribery and Corruption Policy
Whistle Blowing Freedom to Speak Up Policy
Disciplinary Policy
Standards of Business Conduct Policy
Detailed Financial Policies
All available via: https://www.cheshireandmerseyside.nhs.uk/contact/publication-scheme/

Best practice recommendations
NHS Code of Conduct and Code of Accountability (2004)
Records Management Code of Practice 2021
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
ABPI Code of Practice for the Pharmaceutical Industry 2021

13. MONITORING, REVIEW & ARCHIVING

Monitoring
The Corporate Governance Team will agree a method for monitoring the dissemination

and implementation of this policy.

Review

The Corporate Governance Team will ensure that this policy document is reviewed on an annual basis or earlier if there are changes in legislation, relevant case law decisions, significant incidents and/ or changes to the ICB organisational structure.

Staff who become aware of any change which may affect a policy should advise their line manager as soon as possible. The Corporate Governance Team will then consider the need to review the policy or procedure outside of the agreed timescale for revision.

For ease of reference for reviewers or approval bodies, changes should be noted in the 'Revision' table on the summary page at the front of this document.

Archiving

The Corporate Governance Team will ensure that archived copies of superseded policy documents are retained in accordance with Records Management Code of Practice 2021.

NHS
Cheshire and Merseyside

Appendix 1

Appointment Request Form for Pharmaceutical Industry, DACs, suppliers of prescribing associated products representatives

All sections must be completed prior to consideration of an appointment
Please email to mop-enquiries@cheshireandmerseyside.nhs.uk

Word version available at: https://westcheshireway.glasscubes.com/share/s/e4lkoudaas08g83rtroh4kt7mc

Request Date	
Name of Representative	
Name of Company	
Email/Mobile No.	(We may offer teleconference appointments)
Category of topic(s) you wish to discuss	**Please mark the relevant category/categories**

ICB Commissioning pathways and service development	
Prescribing – please complete additional table below	
Proposed joint working	

ALL requests relating to prescribing please complete (highlight all relevant)

Please mark the relevant category/categories

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**			

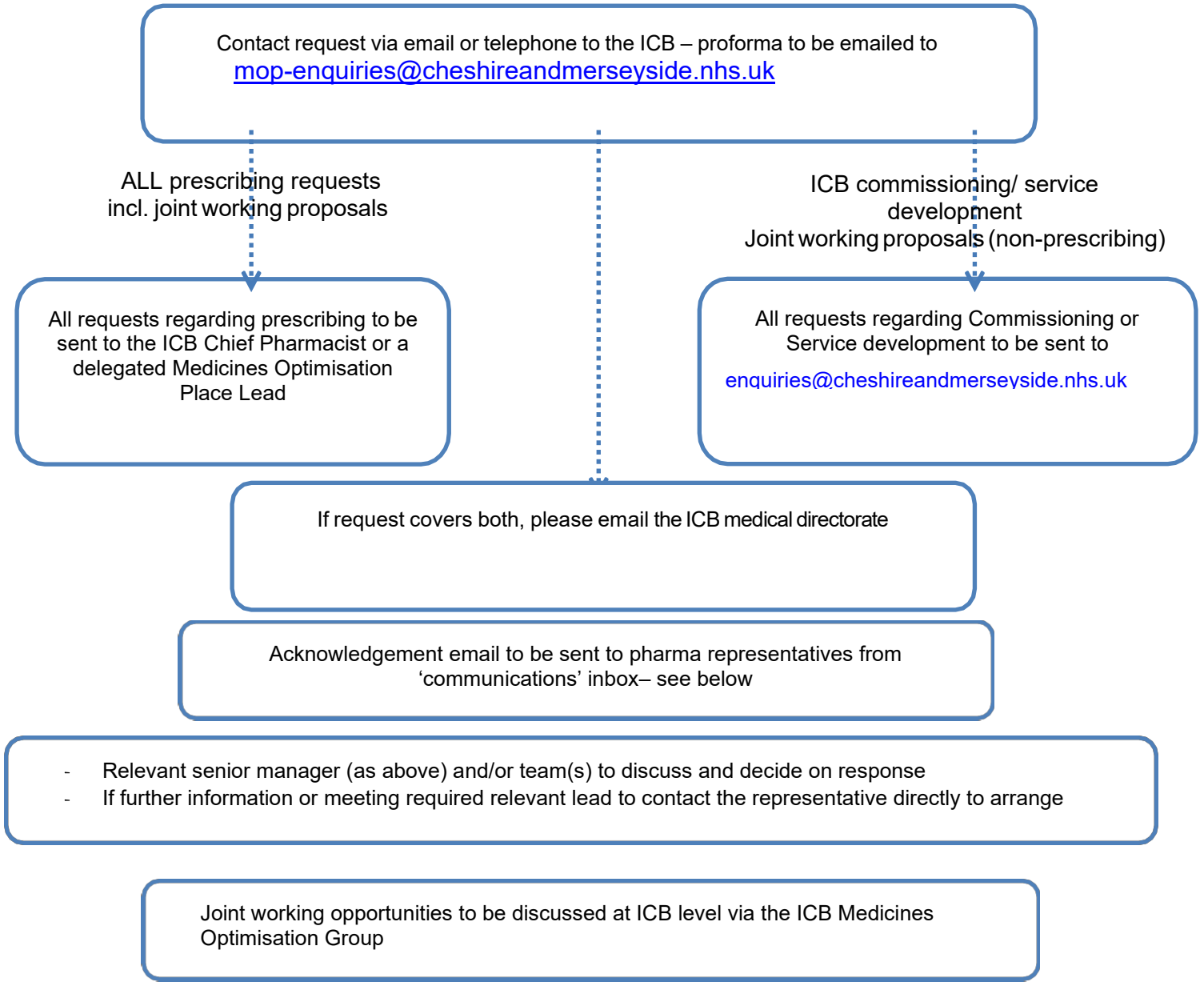
Outline what you wish to discuss and attach relevant pre-reading material	
What is the outcome you hope to achieve from the meeting?	
How long do you anticipate the meeting lasting?	

Office Use Only

Date of last appointment			
To be given an appointment	**Yes** ☐ **No** ☐	**Urgent** ☐ **Routine** ☐	**Time required** ……
Reason if no appointment given			
Details of appointment if applicable			

Appendix 2
NHS Cheshire and Merseyside ICB Process for Dealing with Contact from Pharmaceutical Industry, DACs, Prescribing Associated Product Supplier Representatives

Where possible all initial email correspondence with company representatives should be via the generic ICB mailbox mop-enquiries@cheshireandmerseyside.nhs.uk
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 ICB staff member for their consideration. We will be in contact should we wish to meet or require any further information."

Appendix 3

Request Proforma for sponsorship of a meeting/ event by a pharmaceutical company, DAC, supplier of prescribing associated products.

Word version available at: ***https://westcheshireway.glasscubes.com/share/s/4c6chj4dr6j3e49ar6vg4l1tiq***

Date of sponsorship offer:		
ICB member of staff organising the meeting/ processing sponsorship offer:		
Title and details of Meeting/ Event:		
Target audience:		
Venue:	Proposed date of offer (e.g., date of event):	
Proposed Sponsor(s) details: Include name, address & nature of business		
How many occasions have the company sponsored an event in the last 12 months?		
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.		

Appendix 3

Please confirm that any products or services to be marketed are included on the ICB/place formulary. If unsure, please seek advice from medicines management before proceeding.	Please Tick to confirm
Reviewed & Approved by Line Manager (print name and sign):	Date approved:
Please forward the completed form to the below email for formal approval by the ICB Chief Pharmacist or deputy ***prior*** to the event taking place: mop-enquiries@cheshireandmerseyside.nhs.uk	

Appendix 4

Proforma (ICB internal) for attendance at a sponsored event/ meeting

Word version available at: ***https://westcheshireway.glasscubes.com/share/s/fpo7cmku39bjt44eep2hjurll9***

Name of ICB staff member attending event:	
Job title of staff member attending:	
Title and details of Meeting/ Event (including date & venue):	
Target audience and reason why you are attending:	
Company Sponsor(s) details: Include name, address & nature of business	
Overall Value £……..	
Details of sponsorship: E.g., promotional materials/ information from sponsor handed out, drugs discussed during meeting/ training promotional stands, refreshments provided etc.	
Are products or services being marketed included on the ICB/place formulary? If unsure, please seek advice from medicines management team.	Yes/No
Attendance approved by line manager (print name and sign):	Date approved:
Please forward the completed form to Chief Pharmacist or Deputy Chief Pharmacist for formal approval via mop-enquiries@cheshireandmerseyside.nhs.uk ***prior*** to the event taking place	

Appendix 5

Quality Standards Checklist for Joint Working with a commercial company or the Pharmaceutical Industry

Word version available at: https://westcheshireway.glasscubes.com/share/s/tmrgvp1bbeht40duam4u71f3sv

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 ICB 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 ICB 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 ICB/place formulary?		

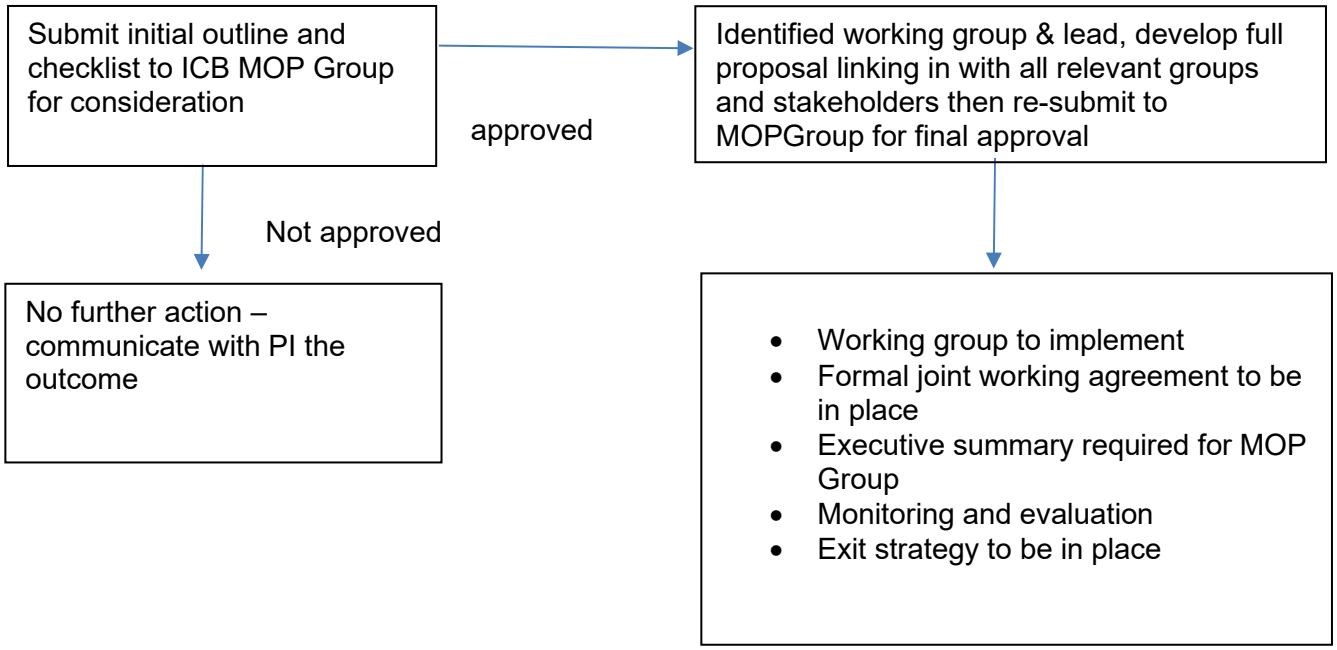
Information and Data considerations		
• Is the sponsorship related to the collection of data?		
• Who will own the data? Please state:		
• Will the sponsor have access to the data?		
• Have the provisions of the Data Protection Act been taken into consideration?		
• Has a DPIA been completed?		
• Who will evaluate the data? Please state:		
• Has an EIA/QIA been completed?		
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 ICB/place formulary?		
○ 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 ICB 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 6

NHS Cheshire and Merseyside ICB Process for Joint Working Opportunities with the Pharmaceutical Industry

Where possible all initial email correspondence with PI representatives should be via the generic ICB Medicines Optimisation and Pharmacy email address mop-enquiries@cheshireandmerseyside.nhs.uk



Appendix 7 NHS Cheshire and Merseyside ICB Primary Care Rebate Scheme (PCRS) Assessment/Decision Form

Word version available at: https://westcheshireway.glasscubes.com/share/s/u7f3e89ce0g1ir7g64tc1glrlk

Product	
Company	
Contact details	

Has the scheme been assessed by the PrescQIPP Pharmaceutical Industry Scheme Governance Review Board?	**Yes/No**
If yes, provide a summary of the final score; comments and overall status	

Question (if any are ticked 'No' then the scheme is less suitable for rebate)	**Yes/No**
Is the product recommended and listed on the APC Formulary?	
The product does not have a negative decision from NICE?	
There is no requirement for a directive or guideline to be given to health care professionals to prescribe the specific product?	
If the product is a medicine, is it licensed in the UK?	
The rebate scheme is not designed to increase off label use of the drug?	
If the product is a device or nutritional supplement, is it contained in the current Drug Tariff?	
The rebate scheme does not require exclusive use of a specific brand?	
The product is not contained in Category A or M of the Drug Tariff?	
The rebate scheme is not linked directly to a requirement for an increase in market share or volume of prescribing?	
The rebate scheme does not prevent consideration of other schemes?	
There is no requirement to submit additional information beyond the volume of prescribing and NIC of the product?	
There is no requirement to collect patient specific data?	

No. of years scheme is available? (Is it >2 years?)	
What is the notice period for the rebate?	Commissioner: Supplier:

The rebate application should provide assurance of resilience of supply, preferably in excess of 6 months' availability at all times	
Estimated potential annual savings for C&M ICB?	
Have any other contractual or legal issues been identified during the evaluation?	

Further information	

Recommendation	
Rationale	
Evaluation carried out by (Name, Title & Date)	
Checked by (Name, Title & Date)	

ICB Decision

This Primary Care Rebate Scheme for ……is proposed for implementation across Cheshire and Merseyside ICB

Signed: Date:

Name: Title:

This Primary Care Rebate Scheme for …… is approved for implementation across Cheshire and Merseyside ICB

Signed: Date

Name: Title:

Appendix 8

Free of Charge (FOC) Medicine Scheme* – request for approval

NHS Cheshire and Merseyside has adopted the principles outlined within NHS England guidance: Free of charge (FOC) medicines schemes – national policy recommendations for local systems.
Provider trusts should use this form to request commissioner approval of free of charge (FOC) medicines supply.

Completion of this form **does not** ensure future commissioning arrangements.
The completed form should be submitted to the NHS Cheshire and Merseyside ICB Chief Pharmacist at: mop-enquiries@cheshireandmerseyside.nhs.uk

All requests submitted to the Chief Pharmacist will be taken to the NHS Cheshire and Merseyside ICB Clinical Effectiveness Group (CEG) for consideration. The outcome of the decision by CEG will be recorded in the minutes and communicated back to the applying trust by the ICB Chief Pharmacist.

** A FOC medicines scheme is defined as an arrangement where a UK licensed, or unlicensed medicine is provided free of charge by a pharmaceutical company to an individual patient or an identified cohort of patients. This definition also includes very discounted medicines offered at a price so low that they are almost free of charge e.g. £1 per pack or schemes offering money back.*

Trust name	Click or tap here to enter text.
Approved drug name (include generic or biosimilar name if known)	Click or tap here to enter text.
Preparation (include strength and formulation)	Click or tap here to enter text.
Pharmaceutical company	Click or tap here to enter text.
UK license status	Click or tap here to enter text.
Clinical indication	Click or tap here to enter text.
Line in therapy and what this replaces (if any)	Click or tap here to enter text.
Regimen (i.e. dose, route, duration and frequency, number of cycles. Include all anticancer drugs and supportive care medication used in combination with FOC drug)	Click or tap here to enter text.
Who is the responsible commissioner for this drug used for this indication? (ICB or NHSE)	Click or tap here to enter text.
Is the medicine available via EAMS? (yes or no)	Click or tap here to enter text.
Does the medicine have a positive NICE FAD? (yes or no) If yes, see national policy recommendations	Click or tap here to enter text.
If the medicine has a positive NICE FAD, does the indication, dose, frequency described in the FOC scheme fall outside of NICE criteria? (yes or no)	Click or tap here to enter text.
Does the medicine have a Patient Access Scheme (PAS) in place? (yes or no) If yes, see national policy recommendations	Click or tap here to enter text.
Estimated number of anticipated patients per financial year	Click or tap here to enter text.

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Funding arrangements agreed with pharmaceutical company for existing patients if drug gains NICE approval	Click or tap here to enter text.
Funding arrangements agreed with pharmaceutical company for existing patients if drug gains NICE approval but the patient does not fit the funding criteria	Click or tap here to enter text.
Funding arrangements agreed with pharmaceutical company for existing patients if the drug does not gain marketing authorisation/ NICE approval	Click or tap here to enter text.
Trust activity please detail number of attendances (outpatient, inpatient, follow-ups) required for the use of the drug	Click or tap here to enter text.
Any other information/supporting evidence (level of evidence, phase of trial, protocol etc.)	Click or tap here to enter text.
Minimum dataset required by the company to administer the FOC scheme	Click or tap here to enter text.
Is this FOC medicines scheme request supported by the trust Medicines Management Committee (or equivalent)? (yes/no)	Click or tap here to enter text.
Requesting clinician	Click or tap here to enter text.

Completed by

Name ..... Date .....

Signature .....

Medicines Management Committee Chair

Name ..... Date .....

Signature .....

Commissioner approved	Yes / No
Rationale for decision	Click or tap here to enter text.
Further comments from commissioner	Click or tap here to enter text.

Decision approved by

Name ..... Date .....

Signature .....