NHS
Borders

Title	**Drugs and Therapeutics Industry Engagement Policy**
Document Type	**Policy**
Issue no.	**1**
Issue date	**January 2018**
Review date	**January 2021**
Distribution	**Area Clinical Forum, ADTC, all clinical boards and support services for onwards distribution to staff.**
Prepared by	**NHS Borders Pharmacy Department**
Developed by	**Short Term Policy Working Group; no changes 2018**
Equality & Diversity Impact Assessed	**January 2013; January 2015; January 2018**
Approved by	**G.P Sub Group** **Area Drugs and Therapeutic Committee, NHS Borders Executive Team.**

Contents

1.0 Introduction

The Scottish Government Health Directorate (SGHD) published Circular HDL(2003)62 and associated guidance entitled 'A Common Understanding: Guidance on Joint Working between NHS Scotland and the Pharmaceutical Industry'. This SGHD guidance promotes consistency of approach across the NHS in Scotland through a model framework to ensure responsibility, transparency and probity in the joint working process.

NHS Borders is committed to providing high quality, safe and innovative healthcare and acknowledges the benefits and opportunities arising from collaboration between the NHS, the pharmaceutical industry and other clinical suppliers with due cognisance of appropriate policies and guidelines. However, all relationships between the NHS and suppliers, or potential suppliers, must be conducted in an appropriate, transparent and cost effective manner. To ensure this is the case, NHS Borders has developed this document that will act as a stand alone policy to be adhered to by staff and will also be incorporated as a section of the Standards of Business Conduct for NHS Staff within the NHS Borders Code of Corporate Governance.

This policy provides additional guidance on matters that are specific to joint working with clinical suppliers. For all other issues in relation to clinical suppliers, including hospitality and acceptance of fees, the appropriate sections of the code and accompanying policies apply (e.g. NHS Borders Endorsements Policy).

This section of the code has been developed to provide direction to all employees regarding their conduct and activities when working with suppliers of clinical products. The overall requirement is to ensure all such interactions are conducted in accordance with the Standards of Business Conduct for NHS Staff.

2.1 Registration and Declaration of Commercial Interests

Individuals involved in the development or consideration of any proposal must declare any potential conflict of interest they or their immediate family may have the list below illustrates the type of involvement that could constitute a declarable commercial interest:

- Involvement in any paid or voluntary work to support the pharmaceutical company's activities, such as: lecturing on a drug, involvement in focus groups etc
- Shareholding or directorships in companies
- Research or educational grants/acceptance of educational support
- Consultancy work
- Speaking at industry sponsored events
- Sponsorship or support of any clinical or professional activities such as; audit support, sponsorship of posts

- Any relationship which risks or appears to risk conflict between private interest and NHS duties

These must be registered whether they occur within the employee's working day or otherwise.

The requirement to register interests is applicable to all NHS Borders employees, contractors working directly for the board, holders of honorary contracts and research partnerships.

Interests should be declared on appointment or when the interest is acquired. Any change in circumstances (either acquisition of an interest, amendment to an interest or termination of an interest) should be declared within 4 weeks of the change occurring.

A register of interests will be held for all board members and interests declared will be open to public inspection and will be retained for a period of 5 years from when the individual ceased to have the declared interest.

Declarations should also be made at relevant meetings and this may affect the level of participation in some circumstances.

If suppliers of clinical products approach NHS Borders staff, including honorary contract holders for advice, this may be construed as a commercial interest, in potential conflict with public duties. Therefore, all individuals providing comparable advice to the Board, for example through their participation in advisory committees, must declare any relevant interests and must withdraw or modify their participation, as necessary, in meetings, consultation exercises etc. Advisory Committees include (this list is not exhaustive):

- Area Clinical Forum
- Area Drugs and Therapeutics Committee
- Tissue Viability Group
- Groups with a specialist interest in specific therapeutic topics
- Guideline development committees/groups
- Managed Clinical Networks
- Research Ethics Committees
- Borders Formulary Committee
- Medicines Resource Group
- Any other Sub-Groups/Committees of the above

Chairs of Committees/groups such as those above should actively seek declarations of interest at the commencement of meetings and/or on a quarterly basis.

This requirement to declare an interest also applies to any individuals, including patient and lay representatives, who provide advice and/or influence decisions made by the above.

Staff should be aware that the requirements for declaration at meetings are also applicable to independent primary care contractors directly involved with NHS decision-making on the procurement of medicines and other clinical products, those undertaking research and development and those participating in Board Committees, for example, on issues related to medicines management for NHS Borders.

Community pharmacists and other independent primary care contractors who have commercial relationships with a wide range of suppliers, will require to declare relevant interests if they are involved with Board committees where particular products are being considered for inclusion in local policies.

In situations where external speakers are invited to NHS Borders events, or speakers are sponsored by any external company, a speaker declaration and conflict of interest statement must be completed.

3.1 Requirements of NHS Borders staff when meeting with representatives of Clinical Suppliers

Ethical informed representation of a company's products is accepted and reasonable assistance will be given to representatives so that professional staff may have the benefit of information proffered by pharmaceutical and related companies. Meetings between NHS personnel and representatives of clinical suppliers can provide an opportunity for raising awareness and information sharing, such as advance notification of new clinical products, education/training and support for clinical research. The benefits of this exchange are recognised for both parties. However, interactions must follow the procedure outlined within this guidance and, where appropriate, the Association of British Pharmaceutical Industry (ABPI) Code, therefore:

- Meetings should only involve those whose roles justify their participation
- Individuals should obtain approval from their line manager/clinical director or equivalent before participation. It is acceptable to arrange prior approval up to an agreed level of interaction, as part of the annual job planning, performance review or appraisal process, as appropriate for different professions.
- Only senior staff should participate in one to one meetings with representatives.
- Staff taking part in such meetings should ensure there is a clear understanding of the purpose of the meeting, including the aims and the potential outcomes which benefit the NHS and patients.
- No commercial commitments should be made during the course of such a meeting. Any appropriate recommendations should be referred to the Procurement Department/Pharmacy Department or to managers of other areas that order products directly.
- Employees should keep a personal log of attendance at all such meetings and this should be made available to their line manager/

- Any information provided at such meetings should be critically evaluated. In the case of pharmaceuticals, the ABPI Code governs the approval of promotional materials, directs that statements should be evidence based and restricts distribution to 'persons who can reasonably be assumed to have a need or interest in the information'. If staff are in any doubt or need any assistance, they should refer to the following contacts within the BGH Pharmacy:
    1. Formulary Pharmacist
    2. Senior Pharmacist Medicines Management
    3. Lead Clinical and Development Pharmacist
    4. General Medicines Governance advice can be sought from the Medicines Governance Lead

4.1 Requirements of representatives when meeting healthcare staff

Industry representatives are advised of the following requirements which relate to interactions with NHS Borders staff; Board employees are also expected to ensure they adhere to these requirements:

4.2 Visits to NHS Borders premises

Visits to NHS Borders premises or GP Surgeries should only be made to keep a previously agreed appointment. Representatives should not tour the area looking for staff to discuss products with and should not enter clinical areas without a prior appointment with or agreement of a consultant, senior nurse manager or professional head of department.

- Price comparisons with other products should not be used in a misleading manner. The Pharmacy Service is available to help in interpretation of such information for GP practices and NHS Borders staff.
- Junior medical staff should be visited only when a senior staff member is present (specialist registrar, consultant or associate specialist for medical staff or equivalent for other professions).
- Nursing staff should be visited only with the approval of the relevant manager or professional lead.
- For any product discussed within the Board, representatives should describe the status of the product (in relation to the Scottish Medicines Consortium and Borders Joint Formulary), both when arranging the meeting and at the outset of the discussion. Including any existing restrictions in use.
- Only products within the Borders Joint Formulary may be actively promoted.
- Distribution of promotional materials for Formulary medicines should be in accordance with the ABPI Code.

4.3 Pharmaceutical Industry attendance at NHS Borders meetings/educational events in a non- sponsorship role

Process supporting NHS Borders in relation to the following guidance documents:

- A Common Understanding – Guidance on joint working between NHS Scotland and the Pharmaceutical Industry
- Best Practice Guidance on Joint Working between the NHS and Pharmaceutical Industry and other relevant commercial organisations', DOH 2008.)

Purpose of joint working

Joint working must benefit patients or the NHS and must preserve patient care. This means that there must be a clearly defined outcome which is expected and agreed before industry involvement with a particular project/initiative.

If anyone from the Pharmaceutical Industry is invited to attend an NHS Borders meeting of any type or level, e.g. GP practice/hospital department/hospital directorate/Board level, the content of the meeting should first be scrutinised to ensure that no confidential issues or sensitive information are under discussion whether of a clinical or financial nature.

The purpose of their attendance should also first be agreed with all attendees, taking into account the purpose of joint working, as defined above (see 'A Common Understanding – Guidance on joint working between NHS Scotland and the Pharmaceutical Industry', NHS Scotland, 2003 and 'Best Practice Guidance on Joint Working between the NHS and Pharmaceutical Industry and other relevant commercial organisations', DOH 2008.)

If the criteria for joint working cannot be met then this agreement must not be given and members must adhere to this on all occasions.

As part of the agreement about their attendance, members must agree whether the Pharmaceutical Industry attendee can receive papers related to the meeting.

The Pharmaceutical Industry attendee can only attend for the relevant agenda items of the meeting that have met the criteria for joint working and must leave the meeting before other business is discussed.

If any invited speakers are to be present, who are not group members, and the group feels that the criteria for joint working have been met, then the invited speaker must still be asked if they agree to the Pharmaceutical Industry being present, if they do not agree then the Pharmaceutical Industry member cannot attend the meeting. If the invited speaker does agree to their attendance they should be asked if they are willing for the attendee to receive copies of their presentation if these are being made available to all other attendees.

4.4 Gifts/hospitality

There is a need to ensure that members of staff are not influenced by the provision of gifts or hospitality. The only ones which may perhaps be accepted are calendars, diaries or items of similar small intrinsic value and relevant (as specified in the ABPI Code of Conduct). If there is any doubt, the advice of a general manager must be sought or the offer politely declined. Any hospitality/gifts must be secondary to the purpose of any company sponsored events or meetings.

It is recognised that companies may sponsor promotional meetings/lunches but no inappropriate inducements should be offered to staff (see ABPI Code of Conduct.) It is important that the number of such meetings is not excessive and this is left to the discretion of Practice Managers and Prescribing Leads. When company sponsorship at any level is provided it is unacceptable for the speakers/presenters to be chosen solely by the company. The NHS Borders Manager/lead or Practice Manager organising any such meeting must ensure that they have the freedom to select or reject any company suggested/sponsored speaker, particularly if there is any likelihood that names may have been selected because of their known partiality towards the company or product. As in section 2.0 the sponsorship of meetings must be declared prominently at the outset.

Existing local policies/practice should not be criticised by representatives in meetings with staff and any comparisons with drugs or other products must be based on properly controlled published studies.

If support to attend educational meetings/conferences is accepted by an individual clinician this must be agreed with the line manager and recorded on the donations form or probity section of consultant appraisal folder.

If educational events are organised with any level of company sponsorship the event must not contain promotional activity as an integral part of the programme.

4.5 Funding of equipment/staffing

Where free equipment, equipment on loan or funding of staffing resource is offered by pharmaceutical company representatives, this must be approved by the Area Drugs and Therapeutics Committee prior to commitments being made.

5.1 Samples

This refers to pharmaceuticals or any other clinical product including dressings, sundries, products for wound care, continence, dietetics, and stoma care, equipment and devices. Samples should not be accepted as the Board may be liable for the quality of items utilised in patient care. Exceptions are highlighted below:

There are specific exemptions from the above restrictions:

- Medicines provided as part of a clinical trial.
- Co-ordinated 'assessment' of certain products (e.g. equipment or devices) or supply of a single sample for demonstration purposes.
- Supply of clinical monitoring equipment (e.g. glucometers, glucose testing strips, insulin pen devices or insulin pumps for use by newly diagnosed diabetic patients) as part of an individual evaluation of patient acceptability.
- Assessment of specifically identified products within the stoma service to meet the needs of individual patients.

While it is recognised there may be value in gaining pragmatic experience in this way, supplying samples for these purposes should be:

- in response to a written request, dated and signed
- discussed and agreed with pharmacy/procurement/other relevant managers
- for wound management products; such provision and acceptance of samples must be approved by the NHS Borders Tissue Viability Group
- subject to appropriate disclaimers to avoid liability on the part of the Board

Any Devices or equipment on trial or loan to NHS Borders should be inspected, approved and regulated via normal NHS procedures to include:

- completion of a 'Form of indemnity for equipment on loan'
- completion of training in use of the equipment to the required standards

6.1 Printing of Guidelines

On occasion, the industry may offer to sponsor the printing of clinical guidelines, leaflets etc. This is acceptable provided the following criteria are met:

- The funding should be restricted to printing costs only.
- More than one supplier should have the opportunity to give support through an unrestricted educational grant in discussion with national procurement.
- Clinical and editorial matters must be under NHS control and developed by a local NHS group, involving relevant clinicians.
- Recommendations must be in line with local NHS Borders Joint Formulary or corresponding clinical product catalogues or policies.
- Generic names for medicines should be used throughout, unless otherwise specified in the Borders Joint Formulary.
- Only NHS logos should appear on printed documents.
- Acceptance of the sponsorship should be acknowledged on the printed document e.g. "Printing supported by an unrestricted educational grant from ……." The declaration of sponsorship should be sufficiently clear that readers are aware of it at the outset.

- ❖ Approval of such documents should proceed through the Area Drugs and Therapeutics Committee

7.0 Industry sponsored research/clinical trials

All clinical trials undertaken in NHS Borders require approval of the Borders Research Ethics Committee and if these trials involve the use of medicines, these must be discussed with a senior pharmacist as soon as possible before the trial is approved or commenced. This is important as products involved in trials may not be appropriate for inclusion in local Formularies.

NHS Borders aims to improve the quality and safety of patient care by advancing clinical practice. The Board recognises the support that industry provides to research, with the resultant benefits of interaction between NHS staff and their industry counterparts representing companies who supply clinical products for use in clinical trials.

Research partnerships need to meet the rigorous requirements of clinical relevance and governance as set out in current guidelines and legislation. Please see NHS Borders policy.

Any research undertaken within NHS Borders or with the involvement of NHS Borders staff must be formally assessed and approved by the NHS Borders Research Ethics Committee.

All industry sponsored research/clinical trials should be registered as an interest by the Head of Department, the Principal Investigator and any staff actively involved in the research project. This requirement applies equally to Pharmacy Departments who are in receipt of 'fee for service' in support of clinical trials.

On conclusion of the sponsored research/clinical trial period, the clinical product may be proposed for extended commercial use. The appropriateness of this development should be ascertained by a Peer Review Group, with membership drawn from relevant senior clinical and management personnel who are independent of the trial participants. This Peer Review Group will determine, in liaison with the appropriate Board Committee (e.g. Tissue Viability Group, Borders formulary Committee, Area Drugs and Therapeutics Committee), if the development supports the clinical/financial strategies of the Board in promoting high quality, safe and cost effective patient care.

If a product is subject to transfer from a research setting to commercial use, this should be planned through a formal agreement for service development, and should be subject to the normal process of Scottish Medicines Consortium (SMC) and ADTC approval with agreed funding identified through the Medicines Resource Group (MRG), (if there is potential for this it should be identified under 'horizon scanning' to the MRG at the start of the research project).

Medicines are subject to a separate process of 'managed introduction', given the role of (1) the regulatory authorities in marketing authorisation at a European or UK level; (2) the Scottish Medicines Consortium; and (3) the NHS Borders Area Drugs and Therapeutics Committee.

Trial subjects/patients should be informed that the Board cannot guarantee that a new medicine will be available in clinical practice following clinical trial activity, compassionate use prescribing or 'expanded access' programme (or equivalent). Such availability is dependent on marketing authorisation and national guidance (e.g. Scottish Medicines Consortium and/or National Institute for Health and Clinical Excellence (NICE)), in addition to individual patient circumstances.

Market research activities, post marketing surveillance studies, clinical assessments and the like must be conducted with a primarily scientific or educational purpose and must not be disguised promotion.

In the event that this activity would involve a non-Formulary medicine appropriate submission to the Borders Joint Formulary Committee is essential.

NHS prescribing should be conducted in line with accepted prescribing policies in acute services or primary care.

8.0 Intellectual Property Rights (IP)

Anyone entering into a joint working or sponsorship agreement must ensure that any intellectual property rights arising are properly protected for the benefit of the Board, in accordance with NHS MEL (1998) 23 – Policy Framework for the Management of Intellectual Property within the NHS arising from Research & Development and NHS HDL (2004) 09 – Management of Intellectual Property in the NHS.

9.1 Partnership working at corporate level

In developing a joint working agreement at corporate level, consideration should be given to the following:

- The costs and benefits of any arrangement.
- Likely impact on purchasing decisions across the NHS structure i.e. primary and secondary care, with such decisions being based on best clinical practice and value for money paying due heed to legislative constraints.
- Joint working linked to the purchase of particular products or services, or to supply from particular sources, is not permitted unless as a result of an open and transparent tendering process for a defined package of goods and services. In particular, no sponsorship, funding or resources should be accepted from a supplier who is actively engaged, or shortly to be engaged, in a potential supply to the Board unless it can clearly be demonstrated that the sponsorship has not influenced the procurement

- A requirement that all participants observe Data Protection legislation and respect patient confidentiality.
- The employment or seconding of any person as a result of the agreement is covered by relevant NHS provisions e.g. MEL(1994)48.
- Participants are made fully aware of the duration of the project with a clear definition of (1) the 'exit strategy' and (2) the implications for both patients and the service once the project comes to an end.
- The need for 'registration of interest' with any such agreement.

Any possible partnerships should always be discussed with the relevant line manager, head of profession/clinical director or equivalent, and local pharmacy and procurement teams before proceeding beyond the initial stages.

Procurement (and in the case of medicines, pharmacy) will work with suppliers to establish the best arrangements for the supply of clinical products, in line with Business Standards, Code of Conduct, purchasing legislation and the Board's Standing Financial Instructions (SFIs).

No commercial relationships can be entered into other than by staff with formal delegated authority. Any discussion on commercial matters should be referred to the relevant Procurement or Pharmacy team.

10.1**Appendix**

10.2 **Glossary of Terms**

ADR	-	Adverse Drug Reaction
AHP	-	Allied Health Professional
APEL	-	Accreditation for Prior Experience and Learning
BCAT	-	Borders Community Addictions Team
BCT	-	Borders Crisis Team
BJF	-	Borders Joint Formulary
BNF	-	British National Formulary
CPD	-	Continuing Professional Development
CHN	-	Community Health Nurse
CMP	-	Clinical Management Plan
DMP	-	Designated Medical Practitioner
DOH	-	Department of Health
EMIS	-	Egton Medical Information System
HEI	-	Higher Education Institution
HPC	-	Health Professions Council
IP	-	Independent Prescriber
ISD	-	Information Services Division
KSF	-	Knowledge and Skills Framework
MHET	-	Mental Health for the Elderly Team
MHRA	-	Medicines and Healthcare products Regulatory Agency
NES	-	NHS Education for Scotland
NMC	-	Nursing & Midwifery Council
NMP	-	Non Medical Prescribing
NPC	-	National Prescribing Centre
PDP	-	Personal Development Plan
PI	-	Prescribing Indicators
PRISMS	-	Prescribing Information SysteM for Scotland
RPSGB	-	Royal Pharmaceutical Society of Great Britain

10.3 Links to Useful Documents

NHS Borders Intranet Links:

NHS Borders Code of Corporate Governance
http://intranet/resource.asp?uid=11506

Borders Joint Formulary http://intranet/microsites/index.asp?siteid=65&uid=1

NHS Borders Medicines Intranet Microsite
http://intranet/microsites/index.asp?siteid=5&uid=1

NHS Borders Non Medical Prescribing Intranet Microsite
http://intranet/microsites/index.asp?siteid=341&uid=1

NHS Borders Tissue Viability Intranet Microsite
http://intranet/microsites/index.asp?siteid=478&uid=1

External Links:

Circular HDL(2003)62 and associated guidance entitled 'A Common Understanding: Guidance on Joint Working between NHS Scotland and the Pharmaceutical Industry
http://www.scotland.gov.uk/Publications/2003/12/18625/29970

ABPI Code of Practice for the Pharmaceutical Industry Second 2012 Edition
http://www.abpi.org.uk/our-work/library/guidelines/Pages/code-2012.aspx

Scottish Medicines Consortium
http://www.scottishmedicines.org.uk/Home

Best Practice Guidance on Joint Working between the NHS and Pharmaceutical Industry and other relevant commercial organisations', DOH 2008
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082370

NHS MEL (1998) 23 – Policy Framework for the Management of Intellectual Property within the NHS arising from Research & Development
http://www.cso.scot.nhs.uk/IP/mel%20(1998)%2023.doc

NHS HDL (2004) 09 – Management of Intellectual Property in the NHS.
http://www.sehd.scot.nhs.uk/mels/HDL2004_09.pdf

10.4 **Bibliography**

Special thanks must be mentioned to NHS Greater Glasgow and Clyde for sharing their Standards of Business Conduct on which some sections of this policy have been based.
The GG&C Standards of Business Conduct can be viewed at:
http://library.nhsggc.org.uk/mediaAssets/Procedures/nhsggc_code_of_conduct_staff.pdf

INDEX

N

P

R

S

T

V

W