Dear Colleague

This letter authorises the extended use of the following Guidance until 1st December 2019:

Guidance For Health Care Staff Within NHS Grampian On Working With The Pharmaceutical Industry And Suppliers Of Prescribable Health Care Products

The review of this guidance is currently underway and it is expected to be available for use in late 2019.

If you have any queries regarding this please do not hesitate to contact the Pharmacy and Medicines Directorate.

Yours sincerely

Lesley Thomson
Chair of Medicines Guidelines and Policies Group
Guidance For Health Care Staff Within NHS Grampian On Working With The Pharmaceutical Industry And Suppliers Of Prescribable Health Care Products

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Area Clinical Forum
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Signature: 

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Across NHS Boards | Organisation Wide | Directorate | Clinical Service | Sub Department Area
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YES                |                   |             |                 |                   

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Author: Deputy Director of Pharmacy and Medicines Management, Pharmacy and Medicines Directorate

Subject: Guidance

Key word(s): pharmaceutical industry, health care products, joint working, representatives

Policy application: NHS Grampian

Purpose: To provide guidance to health care staff on how the NHS can work collaboratively with the Pharmaceutical Industry and Suppliers of Prescribable Health Care Products and Appliances.

Responsibilities for implementation:

Organisational: Directors of services

Corporate: Clinical Directors

Departmental: Departmental managers

Operational Management Unit: Doctors, pharmacists, specialist nurses and AHPs

Policy statement: This document contains guidance on how the NHS can work collaboratively with the Pharmaceutical Industry and build on mutual respect and trust. A governing ethos of NHS Scotland is the acceptance and recognition that a modern and dependable NHS will be built on effective joint working with others.

Review: This policy will be reviewed at least every two years or sooner if current treatment recommendations change.
This document is also available in large print and other formats and languages, upon request. Please call NHS Grampian Corporate Communications on (01224) 551116 or (01224) 552245.

Responsible for review of this document: Deputy Director of Pharmacy and Medicines Management, Pharmacy and Medicines Directorate

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Guidance For Health Care Staff Within NHS Grampian On Working With The Pharmaceutical Industry And Suppliers Of Prescribable Health Care Products

March 2015

Introduction

The Pharmaceutical Industry is a significant stakeholder in the NHS and contributes by the development of new drug therapies and other related products. There are potential benefits to working with the Pharmaceutical Industry and guidance on joint working has been laid out in the document “A Common Understanding 2012 Working Together For Patients - Guidance On Joint Working Between NHSScotland and the Pharmaceutical Industry” (link) published by the Scottish Government. This document better defines an agreed framework for cooperation between NHSScotland and the pharmaceutical industry and aims to assist NHS staff to achieve the best joint-working outcomes. The document also encourages all parties to be confident that the application of the guidelines will ensure that collaboration forms part of a robust, transparent and outcome-focused approach that will create benefits for NHS patients.

Joint-working is different from sponsorship; it involves the NHS and the pharmaceutical industry each contributing their share of knowledge, skills and resources to support a programme of activity which will deliver measurable benefit to patients. Joint-working is defined as involving: “Situations where, for the benefit of patients, organisations pool skills, experience and/or resources for the joint development and implementation of patient-centred projects and share a commitment to their successful delivery”.

All collaborative joint working involving the Pharmaceutical Industry should comply with the relevant codes of conduct for both healthcare professionals and the Pharmaceutical Industry. (Standards of Business Conduct for NHS and the Association of the British Pharmaceutical Industry (ABPI) Code of Practice (ABPI code of Practice 2014).

NHS Circular MEL (1994) 48 (link) Standards of Business Conduct for NHS Staff, specified the general standards which should be maintained by all staff working in the NHS. All health professionals including independent contractors and locum practitioners working under NHS terms and conditions are covered by the circular. Healthcare professions shall continue to be bound by the codes and standards of their regulators and professions.

There are significant opportunities for both the NHS and the Pharmaceutical Industry as we continue to change our structures and relationships. There is more of an emphasis on discussion with organisations rather than individual prescribers and an increasing emphasis on system-wide working as evidenced within Managed Clinical
Networks and Care Pathways. The Pharmaceutical Industry can have a valuable role to play in development, the appropriate use of therapies, educational materials and the refinement of business systems to support clinical activity.

There is an increasing emphasis on the use of protocols, guidelines and patient group directions and the development of a formulary culture. Changes to the NHS structure over past years has provided the industry with the ability to relate to the organisation at different levels. More direction has taken place on the appropriate use of medicines, particularly in relation to guidance from the SMC.

Finally, the Freedom of Information Act continues to create greater transparency around prescribing. Both the Industry and the NHS have a shared agenda in the development of quality and appropriate prescribing of existing pharmaceutical products. Guidance for NHS Grampian staff and contractors on contacts with pharmaceutical industry representatives is given in Appendix 1.

Joint Working

Principles

- All joint-working between the pharmaceutical industry and NHSScotland must be of measurable benefit to patients and be compatible with the principles of the NHSScotland Quality Strategy ([link](#)).

- All joint-working projects must promote and enhance equitable access to evidence-based health care.

- The costs and benefits of any joint-working agreement for patients, NHSScotland and the pharmaceutical industry must specifically address and assess the value for patients, the NHS and the pharmaceutical companies involved.

- The joint-working agreement should not be seen as an endorsement or promotion of a specific company organisation, medicine or technology.

- The interests of individual patients must be protected, and joint-working should not undermine or conflict with the ethical requirements of any healthcare professional, including the duty of clinicians to provide the treatment considered to be clinically appropriate. Collaboration between NHSScotland and the pharmaceutical industry should not be represented as endorsement by NHSScotland of any specific medicine or technology.

- The pharmaceutical industry must comply with the relevant code of practice at all times. All NHSScotland staff/independent contractors must comply with NHS (and relevant professional bodies') codes of conduct. NHSScotland and the pharmaceutical industry must work towards a common compliance framework to ensure that projects do not experience undue administrative delay.

- Under the Bribery Act 2010, any money, gift or consideration received by an employee in public service from a person or organisation holding or seeking to
obtain a contract will be deemed by the courts to have been received corruptly unless the employee proves otherwise.

- Healthcare professionals should not achieve any personal financial benefit from joint-working.
- Healthcare professionals have a shared responsibility to maintain high standards in any collaboration. Declare all relevant conflicts of interest and always be transparent about any involvement with industry and seek patients’ informed consent where appropriate. Industry will be required to collect and declare anonymised information about the total payment to healthcare professionals for certain services such as speaker fees and participation in advisory boards.
- All joint-working should be underpinned from the outset by robust documentation. An early draft written agreement should lead to a final agreement that is acceptable to all parties and published on NHS Grampian’s website.
- Care should be taken to ensure that staff do not enter into new joint working arrangements that would conflict with Scottish Government policy and with recommendations issued by the Scottish Medicines Consortium or NHS Healthcare Improvement Scotland.
- Where the joint-working arrangement involves the pharmaceutical industry employing or seconding staff/independent contractors to provide services within NHS Grampian, this must comply with Scottish Government policy on public sector healthcare provision and avoid any conflict of interest. Staff must ensure that all undertakings are in keeping with the governance arrangements of NHS Grampian.
- Clinical aspects of care, including the development of guidelines and protocols is the responsibility of the Health Board and, should always remain under local/national NHSScotland control.

Data, Patient Information and Intellectual Property

- There must be clarity from the outset of what data will be collected, and how it will be collected and evaluated to monitor the defined outcomes for the project.
- Reports, or information pertaining to joint-working must not be used or published, or be used for any commercial activity without the explicit permission of NHS Grampian.
- Any patient identification should be removed from data, in line with the Data Protection Act to respect and preserve patient confidentiality and professional codes of conduct. Caldicott Guardian advice must be sought where patient data is to be used or sent outwith the NHS.
Where a joint-working arrangement permitting access to patient-specific information is agreed then access to the data must be limited to use by registered healthcare professionals. The contract must draw attention to obligations of confidentiality, specify security standards to be applied, limit use of information to purposes specified in the contract and reinforce the fact that the contract will be terminated if these conditions are not met.

The Scottish Health Informatics Programme Blueprint on Health Records Research in Scotland should be adhered to as best practice in handling patient information.


Exit Strategies

There must be an agreed and obvious “exit strategy” from the outset to ensure that patient care is not compromised at any stage. Similarly, no recurring financial commitments should be placed upon NHSScotland without explicit prospective agreement.

Where the joint-working arrangement involves the pharmaceutical industry employing or seconding staff/independent contractors an exit strategy and plans for future funding of the post and/or service must be agreed from the outset.

Process

Three documents should be produced as joint-working proposals are developed and submitted.

Terms of Reference describes the purpose and structure of a project, committee, meeting or negotiation, involved in work to accomplish a shared goal. The terms of reference of a project are often referred to as the project charter.

The Project Initiation Document details all the key information required to present a strong business case that outlines the method of achieving the project objectives. The PID will be used to communicate plan with key stakeholders including signatories.

The Joint-working Agreement is the contractual agreement between partners following the approval of the PID, in order to implement the Joint-working project.

Register of declarations of interests

An official register of declarations of interests should be held by NHS Boards as part of the monitoring arrangements and all clinicians (whether employees or independent contractors) must subscribe to this. The level of recording should be agreed locally.
Within the sectors. Within Grampian, a register of declarations of interest should be maintained for all members of Grampian Medicines Management Group, Formulary Group, Medicines Guidelines and Policies Group, Antimicrobial Group, and Managed Clinical Networks. In addition, clinicians requesting a new medicine to be added to the Grampian Joint Formulary must also declare their interests.

**Examples of Joint Working**

A Joint Working project may comprise a number of activities including, but not limited to, the following:

- staff training
- staff and/or patient education
- economic analysis
- nursing services
- facilitation of pathway redesign
- support for guideline implementation
- funding of project staff requirements (e.g. provision of administrative, clinical, analytical health economic and/or management resources by either party)
- secondments
- audit.
Appendix 1

Guidance For NHS Grampian Staff And Contractors
Contact with the Pharmaceutical Industry And Suppliers Of Prescribable Health Care Products Representatives Within NHS Grampian

Introduction:

Pharmaceutical industry representatives are required to work within the ABPI Code of Practice for the pharmaceutical industry. (Standards of Business Conduct for NHS and the Association of the British Pharmaceutical Industry ABPI code of Practice 2014).

Reasonable assistance may be given to pharmaceutical representatives so that professional staff may have the benefit of information offered by the pharmaceutical industry. The following recommendations are made to all NHS Grampian staff and contractors in their dealings with the pharmaceutical industry.

All health professionals, including independent contractors and locum practitioners, working under NHS terms and conditions, are considered to be covered by this guidance. For the purposes of this document, the term ‘staff’ is used as a convenience to refer to all such people.

Any partnership working must protect the interest of individual patients, e.g. guard against the use of any single drug to the exclusion of other reputable medicines in the market.

Recommendations:

1. **Prescribers should request prearranged appointments with pharmaceutical representatives at a mutually convenient time**

As far as possible, visits to NHS Grampian premises should be made to keep a previously agreed appointment. This will allow the appropriate person(s) to be present to discuss the topic. Agreement in advance of the topics to be discussed and the time available is advantageous. Where a prescriber agrees to see a representative without a prior appointment the representative should be sensitive to not causing any disruption to services.

Within hospital it is recommended that junior medical, pharmacy and nursing staff only meet with pharmaceutical representatives at the discretion of the relevant consultant, nurse or pharmacy manager.
2. Prescribers are advised to request prescribing and cost information on product choices from CHP/practice pharmacists or hospital clinical pharmacists, rather than from pharmaceutical representatives.

CHP pharmacists and practice pharmacists are available to help in interpretation of such information for GP practices. Clinical pharmacists are able to provide this information within the hospital. This allows the relevant local information to be used in determining cost/benefits.

3. The North of Scotland Research Ethics Service (NOSRES) must approve all clinical trials undertaken in Grampian.

All clinical trials undertaken in Grampian require the prior approval of NOSRES and if these trials involve the use of medicines, these must be discussed with the appropriate pharmacist as soon as possible before the trial is approved and commenced. Local management approval must be obtained and the study registered with the R&D office. Details of equipment loans during clinical trials and expanded access programmes for trial medicines after completion of the trial should be provided in the ethics application.

4. When considering involving pharmaceutical companies in sponsoring of educational events the guidelines laid down within NHS Grampian Corporate Governance Frameworks should be adhered to.

The full detail of the standards of business conduct for NHS staff should be adhered to. The sponsoring company may be invited to attend any sponsored event and display information regarding its medicines, but it must be clear that NHS Grampian is not endorsing or promoting the company or its medicines.

Hospitality must be secondary to the purpose of the meeting. The level of hospitality offered must be appropriate and not out of proportion to the occasion; and the costs involved must not exceed that level which the recipients would normally adopt when paying for themselves, or that which could be reciprocated by the NHS. It should not extend beyond those whose role makes it appropriate for them to attend the meeting.

The Pharmaceutical industry sponsor(s) should be requested not to promote products pre-SMC approval or those products not recommended by the SMC. The sponsor should also be advised that NHS Grampian staff are required to conform to the Grampian Joint Formulary for their prescribing choices and therefore the pharmaceutical industry sponsor should not be advocating use of non-formulary products.

5. Prescribers in Primary Care should not request samples of non-formulary pharmaceutical products from pharmaceutical representatives.

The decision to approve new products for inclusion on the Grampian Joint Formulary is made by the Grampian Formulary Group following submissions from clinicians both in hospital or primary care. Determination of the benefit/cost effectiveness of a product cannot be made by the use of samples in small numbers of patients.
Therefore, it is recommended that samples of non-formulary products are not requested by prescribers in primary care from pharmaceutical representatives.

6. **Hospital Prescribers should not request samples of medicines for use in hospital inpatient or outpatient departments.**

The decision to approve new products for inclusion on the Grampian Joint Formulary is made by the Grampian Formulary Group following submissions from clinicians both in hospital or primary care. Determination of the benefit/cost effectiveness of a product cannot be made by the use of samples in small numbers of patients. Within secondary care and community hospitals supplies of medicines are made from the pharmacy department, ARI. Samples of medicines should not be requested for use in hospital inpatient or outpatient departments.

7. **NHS Grampian staff should not accept inducements or promote products on behalf of a pharmaceutical company.**

There is a need to ensure that members of staff are not influenced by the provision of gifts or hospitality. Staff must not ask for or accept any inducement, gift or hospitality which may affect or be seen to affect the way you prescribe for, treat or refer patients.

Clinicians may present the results of findings of clinical trials at events sponsored by the pharmaceutical industry. However, the acceptance of the sponsorship should not be seen as NHS Grampian’s endorsement of a specific product or drug. Any mention of the sponsor will be to the company and not specifically to any of its products.

NHS Grampian staff should not accept gifts, hospitality or sponsorship that might place them in a position of conflict between their private interests and that required by their NHS duties.

8. **Free equipment, equipment on loan or funding of a staff resource must not be accepted by NHS Grampian staff without the prior agreement of the appropriate head of service and the Director of Pharmacy and Medicines Management (if medicines, prescribable health care products and appliances are involved) or Chair of Equipment Group (if equipment involved).**

Consideration needs to be given to ensure that any acceptance of equipment or staff time will not divert the service from its primary task of treating patients or disrupt NHS priorities/core functions. Implications of ongoing revenue costs need to be considered.

When the joint working arrangement involves the Pharmaceutical industry employing or seconding employees/independent contractors to provide services within NHS Grampian, this should comply with relevant employment regulations and an exit strategy and plans for future funding of the post and or/service must be agreed from the outset.