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Dear Colleagues

This guidance is currently under review by the author.

Guidance For Healthcare Staff Within NHS Grampian On Working With The Pharmaceutical Industry And Suppliers Of Prescribable Healthcare Products, Version 4

This document has been risk assessed by the author and deemed appropriate to be used during this review period. A copy of the risk assessment can be provided on request.

If you have any queries regarding this, please do not hesitate to contact the Medicines Guidelines and Policy Group (MGPG) email at gram.mgpg@nhs.scot

Yours sincerely

Jodie Allan

Professional Secretary of MGPG, NHSG



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

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ı	Executive Sign-Off	
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The Pharmaceutical Industry And Suppliers Of Prescribable Healthcare

Products

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

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Subject Guidance

Key word(s): Guidance, pharmaceutical industry, healthcare products, joint working,

representatives

Policy

application:

NHS Grampian

Purpose: To provide guidance to healthcare staff on how the NHS can work

collaboratively with the Pharmaceutical Industry and Suppliers of

Prescribable Healthcare 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 three years or sooner if

current treatment recommendations change.

Revision History:

Date of change	Approval date of document that is being superseded	Summary of Changes (Descriptive summary of the changes made)	Changes Marked* (Identify page numbers and section heading)
		Minor update to wording and formatting throughout.	Pages 2 - 10
		Numbering if sections and contents page added.	Pages 2 - 10
		Introduction. Minor update to wording and structure of section. Updated link to new ABPI code of practice.	Pages 2 - 3
		Section 3 – Values - New Section.	Page 3 - 4
		Section 4 – Principles - Updated to include full details from supporting document.	Pages 4 - 6
February 2023	March 2015	Updated Scottish Health Informatics Programme Blueprint on Health Records Research in Scotland to The Scottish Government publication "A Health and Biomedical Informatics Research Strategy for Scotland"	Page 6
		Updated Grampian Medicine Management Group to Grampian Area Drug and Therapeutics Committee	Page 7
		Updated Grampian Joint Formulary to Grampian Area Formulary	Page 7
		Section 8 - Consultation Group - New section.	Page 7
		Appendix 1 - Update to content, wording, order of bullets and formatting.	Pages 8 - 10

Guidance For Healthcare Staff Within NHS Grampian On Working With The Pharmaceutical Industry And Suppliers Of Prescribable Healthcare Product

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

1. Introduction And Scope Of Document

Appropriate and constructive joint-working between NHS Scotland and the pharmaceutical industry has the potential to encourage the development of new products and services that are evidence-based, that better match the needs of patients and that make a greater contribution to sustainable, quality improvement in care.

Together For Patients - Guidance On Joint-Working Between NHS Scotland and the Pharmaceutical Industry" provides a guide on joint-working between NHS Scotland and the pharmaceutical industry (where 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"). It seeks to support NHS staff in taking forward ideas for joint-working projects, from assessing the idea, through delivering the programme of work, to measuring its benefits, to evaluating it and bringing the programme of work to a close. It 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 substantial 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.

All collaborative joint-working involving the pharmaceutical industry should comply with the relevant codes of conduct for both healthcare professionals (<u>Standards of Business Conduct for NHS Staff</u>) and the pharmaceutical industry (<u>Association of the British Pharmaceutical Industry (ABPI) Code of Practice for the Pharmaceutical Industry (2021)</u>).

NHS Circular MEL (1994) 48 <u>Standards of Business Conduct for NHS Staff</u>, specifies the general standards which should be maintained by all staff working in the NHS.

All healthcare 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 evolve 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.

Within the NHS there is a culture which emphasises the use of protocols, guidelines and patient group directions as well as utilisation and compliance with a formulary. 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 Scottish Medicines Consortium (SMC).

Finally, the Freedom of Information Act continues to create greater transparency around prescribing. Both the pharmaceutical 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.

2. Scope Of Document

This document seeks to support joint-working between NHS Scotland and the pharmaceutical industry.

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.

As such the following activities are out with the scope of this document:

- Research
- Procurement
- Sponsorship.

3. Values

Three crucial public service values must underpin the work of the health service as set out in the NHS Scotland document <u>Standards of Conduct, Accountability and Openness</u>.

• **Conduct**: An absolute standard of honesty and integrity should be the hallmark of all personal conduct of staff/independent contractors and suppliers in decisions affecting patients, including the use of information acquired in the course of NHS Scotland duties and in dealing with the assets of NHS Scotland.

- Accountability: All actions of those who work in NHS Scotland must be able to stand the test of parliamentary and public scrutiny, including issues of propriety and professional codes of conduct.
- Openness: Openness and transparency are key values of NHS Scotland. The ABPI Code also requires openness, transparency and the declaration of relevant financial transactions.

4. Principles

Value for patients

- All joint-working between the pharmaceutical industry and NHS Grampian must be of measurable benefit to patients and be compatible with the principles of the NHS Scotland Quality Strategy.
- All joint-working projects must promote and enhance equitable access to evidence-based healthcare.
- The costs and benefits of any joint-working agreement for patients, NHS
 Grampian and the pharmaceutical industry must specifically address and assess
 the value for patients, the NHS and the pharmaceutical companies involved.

Business Standards and Transparency

- 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 NHS Grampian and the pharmaceutical industry should not be represented as endorsement by NHS Grampian of any specific medicine or technology.
- The pharmaceutical industry must comply with the relevant code of practice at all times. All NHS Grampian staff and independent contractors must comply with NHS (and relevant professional bodies') codes of conduct. NHS Grampian and the pharmaceutical industry must work towards a common compliance framework to ensure that projects do not experience undue administrative delay.
- Under the <u>Bribery Act 2010</u> 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 person or organisation proves otherwise.
- Healthcare professionals should not achieve any personal financial benefit from joint-working.

Working with the industry

- 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 with the first annual declaration of payments to be made in 2013 for payments in 2012.
- Unacceptable practice in any aspect of joint-working should not be tolerated.
 Challenge any behaviours that seem inappropriate and report any suspected contraventions of the <u>ABPI Code of Practice</u> to the Prescription Medicines Code of Practice Authority (PMCPA).

Good Governance

- 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 Grampians website.
- 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 NHS Grampian without explicit prospective agreement.
- NHS Grampian should establish monitoring arrangements to ensure accountability. An official register of interests should be established as part of the monitoring arrangements and all relevant individuals must subscribe to this. This register should be published on the websites of all the NHS healthboards involved.
- Care should be taken to ensure that NHS Boards do not enter into new jointworking arrangements that would conflict with Scottish Government policy and with recommendations issued by the Scottish Medicines Consortium (SMC) or NHS Healthcare Improvement Scotland (HIS).
- 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. An exit strategy and plans for future funding of the post and/or service must be agreed from the outset. NHS Grampian staff must ensure that all undertakings are in keeping with NHS Grampian governance arrangements.
- Clinical aspects of care, including the development of guidelines and protocols is the responsibility of NHS Grampian and, should always remain under NHS Grampian 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.
- Prior to the use of any patient identifiable information NHS Grampian <u>Caldecott Guardian</u> advice must be sought. Where patient identifiable information is used, it must be done in line with <u>The Data Protection Act</u> (2018) which is the UK's implementation of the General Data Protection Regulation (GDPR) which ensures 'data protection principles' are adhered to in respect of the use of personal data. Patient identifiable information should be removed from data, to respect and preserve patient confidentiality.
- 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.
- Activities undertaken as part of joint-working should be covered by the NHS
 Grampian public liability and professional indemnity arrangements. If necessary,
 advice should be sought to confirm this.
- The Scottish Government publication "A Health and Biomedical Informatics
 <u>Research Strategy for Scotland</u>" should be adhered to as best practice in
 handling patient information.
- Products originating from intellectual property within the NHS or affiliated bodies are covered by <u>HDL(2004)09</u> A Framework and Guidance on the Management of Intellectual Property in NHS Scotland and <u>NHS MEL (1998) 23</u> Policy Framework for the Management of Intellectual Property within the NHS Arising from Research and Development.

5. Process

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

- Terms of Reference (TOR) 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 (PID) 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.

6. Register Of Declarations Of Interests

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

7. Healthcare

A joint-working project may comprise a number of activities including, but not limited to:

- 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.

8. Consultation Group

Name	Role
Lesley Coyle	Associate Director of Pharmacy, NHS Grampian
Samantha Fenwick	GP Partner Holburn Medical Group and LMC Medical
	Director Grampian
Emma Houghton	GP and Associate Medical Director Primary Care and Hosted Services NHS Grampian
Karen Simpson	GP Insch Medical Practice, Garioch Cluster Clinical Lead and Aberdeenshire Primary Care Prescribing Group GP Representative



Appendix 1 - Considerations for NHS Grampian Staff and Independent Contractors Regarding Contact with the Pharmaceutical Industry and Suppliers Of Prescribable Healthcare Products

Pharmaceutical industry representatives are encouraged to work within the <u>ABPI</u> Code of Practice for the Pharmaceutical Industry.

NHS Grampian employed healthcare professionals and independent contractors may require to interact with pharmaceutical industry representatives to obtain information. This would be considered reasonable where the topic/subject is relevant to their role and scope of practice and prior line management approval has been sought.

The following recommendations are made to all NHS Grampian staff and independent contractors working under NHS terms and conditions in their dealings with the pharmaceutical industry.

Any partnership with the pharmaceutical industry 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. Healthcare professionals should request pre-arranged appointments with pharmaceutical representatives at a mutually convenient time.
- As far as possible, visits 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. Should a healthcare professional agree to meet a pharmaceutical representative without a prior appointment this should not result in any disruption to NHS Grampian services.
- It is recommended that hospital junior medical, pharmacy or nursing staff and primary care pharmacy teams only meet with pharmaceutical representatives at the discretion of the appropriate consultant, nurse or manager.
- 2. Healthcare professionals are advised, when deemed necessary, to request prescribing and cost information from an appropriate NHS Grampian representative, rather than from pharmaceutical representatives.
- To ensure relevant local information is taken into consideration when determining cost/benefits.
- NHS Grampian Medicines Management department are available to help in interpretation of such information for GP practices.
- Clinical pharmacists are able to provide this information within the hospital.

- 3. When considering involving pharmaceutical companies in sponsoring of educational events/training the guidelines laid down within NHS Grampian Corporate Governance Frameworks should be adhered to.
- The full detail of the <u>Standards of Business Conduct for NHS Staff</u> should be adhered to. The sponsoring company may be invited to attend any sponsored event and display information regarding its medicines/products, but it must be clear that NHS Grampian is not endorsing or promoting the company or its medicine/products.
- Hospitality must be secondary to the purpose of a 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 products not recommended by the SMC. The sponsor should also be advised that NHS Grampian staff are required to conform to the Grampian Area Formulary for their prescribing choices and therefore the pharmaceutical industry sponsor should not be advocating use of non-formulary products.
- 4. Prescribers (primary and secondary care) should not request samples of non-formulary medicines or products from pharmaceutical representatives.
- The decision to approve new products for inclusion on the Grampian Area Formulary is made by the NHS Grampian Formulary Group following submissions from clinicians both in hospital or primary care.
- 5. 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.
- Healthcare professionals 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 drug or product. 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.

- 6. 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 (if medicines, prescribable healthcare products and appliances are involved) or Equipment and Medical Devices Group (if equipment or medical devices 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.