

A Common Understanding 2012 Working Together For Patients

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GUIDANCE

ON JOINT WORKING BETWEEN NHSSCOTLAND
AND THE PHARMACEUTICAL INDUSTRY



**The Scottish
Government**
Riaghaltas na h-Alba

GUIDANCE ON JOINT-WORKING BETWEEN NHSSCOTLAND AND THE PHARMACEUTICAL INDUSTRY

Throughout this document:

“Staff” refers to all employees of an NHS Board.

The Association of the British Pharmaceutical Industry (ABPI) is the trade association representing companies researching, developing and manufacturing medicines. Membership is voluntary. The *ABPI Code of Practice for the Pharmaceutical Industry* sets standards for the promotion of medicines to health professionals as well as covering interactions with health professionals. It also applies to a number of areas that are non-promotional including the provision of information about prescription-only medicines to the public and relationships with patient organisations. It is a condition of membership to agree to comply with the ABPI Code. In addition, non-member companies also agree to comply with the Code. The Code applies to members of the ABPI and, in the context of this document, non-member companies are encouraged to meet the requirements of the Code. It is administered by Prescription Medicines Code of Practice Authority (PMCPA).

“Pharmaceutical industry” includes companies developing, manufacturing and supplying pharmaceutical products; this includes ABPI members and non-members.

“Independent contractors” include general medical practitioners, community pharmacists, general dental practitioners and optometrists.

The following should not be regarded as being within the scope of this document:

- Research
- Procurement
- Sponsorship

These are covered by existing guidance

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CHIEF EXECUTIVE'S FOREWORD

Scotland is a world-leading centre for innovation in health through joint-working between government, NHSScotland, Industry and the Research Community.



The Scottish Government is committed to ensuring that patients in Scotland receive medicines of established cost-effectiveness and therapeutic value. Medicines are an integral part of all aspects of clinical care provided in NHSScotland. The Scottish Government also recognises that effective joint-working amongst all of the stakeholders involved in contributing to the care of patients is essential to the provision of quality healthcare.

The Quality Ambitions set out in the *Healthcare Quality Strategy for NHSScotland* are key to achieving the most effective use of medicines in delivering the highest quality of care for patients. These are:

- mutually beneficial partnerships between patients, their families and those delivering healthcare services;
- no avoidable injury or harm from the health care they receive;
- the most appropriate treatments will be provided at the right time to everyone who will benefit, with no wasteful or harmful variation.

Appropriate and constructive joint-working between NHSScotland 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. This is recognised in the recent Statement of Intent for Innovation in Health which was announced by the Cabinet Secretary.

The revision of the Scottish Government's guidance - *A Common Understanding* - is timely as it provides an up-to-date guide on joint-working between NHSScotland and the pharmaceutical industry. This guidance should be applied to any joint-working envisaged and will assist in developing local joint-working projects.

I appreciate the contribution made by those involved in creating this updated guidance and commend it to all NHS staff entering into joint-working arrangements with the pharmaceutical industry.

**Derek Feeley,
Director-General Health & Social Care, Scottish Government,
and Chief Executive of NHSScotland**

CHAIRMAN'S FOREWORD

The original Common Understanding document was the first of its kind to be produced in the United Kingdom. A *Common Understanding (2003)* aimed to define a productive relationship between NHSScotland and the pharmaceutical industry, by setting out the principles by which appropriate joint-working could be achieved.



A great deal has changed within NHSScotland since 2003 in terms of the modernisation of healthcare delivery systems, a renewed clinical approach, much greater involvement of patients and public, increased multi-disciplinary working and a clearer understanding of the real benefits of a focus on quality and outcomes.

The pharmaceutical industry has the capacity to play a significant role in this renewed focus on quality and outcomes by assisting with the development and appropriate use of therapies, the provision of educational materials and the refinement of business systems that support clinical activity. Some examples of the many successful joint-working projects involving NHSScotland and the industry are included elsewhere in this document.

A Common Understanding 2012 - by better defining an agreed framework for cooperation between NHSScotland and the pharmaceutical industry - 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 these guidelines will ensure that collaboration forms part of a robust, transparent and outcome-focused approach that will undoubtedly create substantial benefits for NHS patients.

In developing *A Common Understanding 2012*, we have involved as wide a range of stakeholders as possible, in an effort to establish a genuinely inclusive approach. We have suggested principles to be applied when considering joint-working so that agreements will be robust and outcomes measurable. Finally, we have tried to ensure that a wide range of possible situations and scenarios have been considered - so as to provide as much guidance as possible for NHSScotland staff.

It is our sincere hope that all parties will be prepared to utilise the national approach of the *A Common Understanding 2012*, rather than to rely solely upon a plethora of local rules and guidelines.

There will always be room for local decision-making, but it is our considered view that the broad-based framework encapsulated in this document provides the best chance of successful and sustainable joint-working on behalf of patients and public in Scotland.

Ian Mullen OBE, BSc, DL

EXECUTIVE SUMMARY

This document 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.

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.

Each joint-working project will involve careful preparatory work in order to create a robust joint-working agreement. That agreement, and the delivery of the programme that it governs, will be expected to be fully compliant with the Standards and Codes of both NHSScotland and the ABPI.

Nothing in this document removes the requirement for staff to meet the Standards and Codes of NHSScotland and the industry.

CASE STUDY 1:

THE SCOTTISH MEDICINES CONSORTIUM – SMC and ABPI

“The SMC/ABPI partnership is an excellent example of a true partnership that has had immense benefits for patients in Scotland as a result of early access to clinically effective and cost-effective new medicines.”

Professor Angela Timoney, Chair, Scottish Medicines Consortium (SMC)

CASE STUDY 2:

SCOTTISH NEURO ENDOCRINE TUMOUR GROUP GUIDELINES – Scottish Neuro Endocrine Tumour Group and Novartis Pharmaceuticals

“This project has demonstrated a good working relationship between the clinicians and industry which has helped to develop effective clinical guidelines.”

Dr Nicholas Reed, Consultant Oncologist, Beatson Oncology Centre, Glasgow

CASE STUDY 3:

SIGN RESPIRATORY GUIDELINES – Scottish Intercollegiate Guidelines Network; Scottish Respiratory Industry Group; National Advisory Group for Respiratory Managed Clinical Networks; Asthma UK

“Collaborative work, such as the regional workshops, brings a unique opportunity to link evidence, priorities and direct benefits for patients. The workshops allow all stakeholders to influence asthma priorities in different regions across Scotland.”

Dr Keith Brown, Chair, Scottish Intercollegiate Guidelines Network (SIGN)

BACKGROUND

A Common Understanding, Guidance on Joint-working between NHSScotland and the Pharmaceutical Industry, was published by the then Scottish Executive in 2003 and was the first guidance on joint-working between NHSScotland and the pharmaceutical industry.

One of the governing principles of NHSScotland involves the recognition that a modern, clinically effective Health Service should include effective co-operation with others in order to deliver the *Healthcare Quality Strategy for NHSScotland*. All joint-working must be for the benefit of patients but may also be of mutual benefit to the organisations concerned. The relationship between the NHS and the pharmaceutical industry should therefore be built on mutual respect and trust.

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.”

This guidance aims to encourage innovation in joint-working by highlighting examples of good practice and the establishment of a model joint-working framework that will help ensure common understanding, responsibility, transparency and probity in the process.

NHS Circular MEL (1994) 48, entitled *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.

Guidance on collaboration between healthcare professionals and the pharmaceutical industry has been produced by senior representatives of the pharmaceutical industry and healthcare community. All staff should familiarise themselves with this guidance which can be found at:

<http://www.abpi.org.uk/our-work/library/guidelines/Pages/collaboration-guidance.aspx>

CASE STUDY 4:

MRSA CSSTI (COMPLICATED SKIN AND SOFT TISSUE INFECTION) MANAGEMENT EVALUATION - NHS Greater Glasgow & Clyde; Pfizer

“We recognised before this study was undertaken that there was the theoretical potential for earlier discharge of patients with MRSA CSSTI, either on oral antibiotics or utilising our OPAT (Outpatient Parenteral Antibiotic Therapy) services. This project provided us the opportunity to gather the data we needed to answer that question.”

Professor John E Coia, Consultant Clinical Microbiologist, Director Scottish Microbiology Reference Laboratories, Glasgow

VALUES

Three crucial public service values must underpin the work of the health service as set out in *Standards of Conduct, Accountability and Openness*.

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 NHSScotland duties and in dealing with the assets of NHSScotland.

Accountability: All actions of those who work in NHSScotland 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 NHSScotland. The ABPI Code also requires openness, transparency and the declaration of relevant financial transactions.

CASE STUDY 5:

RHEUMATOID ARTHRITIS STOP SMOKING CAMPAIGN - NHS Fife, Fife Rheumatic Diseases Unit; Pfizer Limited; NRAS (National Rheumatoid Arthritis Society)

“Many individuals with RA (Rheumatoid Arthritis) are not aware of the impact smoking may have on their disease or the services that are available to help them stop. We hope this campaign will educate people on the additional risks of smoking and empower them to make positive steps towards giving up.”

Dr Helen Harris, Consultant Rheumatologist, Fife Rheumatic Diseases Unit, Whytemans Brae Hospital

CASE STUDY 6:

GRAMPIAN RISK ASSESSMENT & INTERVENTION (GRANITE) - NHS Grampian: Grampian Cardiovascular MCN and Peterhead Health Centre; AstraZeneca UK Limited.

“The GRANITE screening software effectively identified a patient population within the Peterhead practice who had a probable high 10-year CVD risk requiring intervention.”

John C Stout, GP lead, Managed Clinical Network (MCN) Cardiology, Grampian

PRINCIPLES

VALUE FOR PATIENTS

- 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.
- 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.

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 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.

WORKING WITH THE INDUSTRY

- There are genuine areas of common ground for industry and healthcare professionals, with shared aims and objectives. Pharmaceutical industry staff working in joint projects are stakeholders in health care. In working together, both sides can access a broader range of knowledge and expertise and ultimately ensure high quality patient care.
- 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 ABPI Code of Practice 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 Boards' websites.
- 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.
- NHS Boards 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 Boards involved.
- Care should be taken to ensure that NHS Boards 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 NHSScotland, 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. NHSScotland staff must ensure that all undertakings are in keeping with the governance arrangements of their NHS Board.
- 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 NHSScotland.
- 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.
- 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 public liability and professional indemnity arrangements of the NHS Board concerned. If necessary, advice should be sought to confirm this.
- The Scottish Health Informatics Programme Blueprint on Health Records Research in Scotland 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 HDL(2004)09 *A Framework and Guidance on the Management of Intellectual Property in NHSScotland*, and NHS MEL (1998) 23 *Policy Framework for the Management of Intellectual Property within the NHS*.

CASE STUDY 7:

SPECIALIST REGISTRAR (SPR) TRAINING - Dr Hill; Scottish Respiratory Industry Group (SRIG); Scottish Thoracic Society; NHS Education for Scotland (NES)

“The ABPI Scottish Respiratory Industry Group’s support for Spr (specialist registrar) training is appreciated. Industry has a lot to offer trainees with strengths in areas which complement the core training provided.”

Dr Adam Hill, Consultant Respiratory Physician & Associate Post Graduate Dean South East Scotland, Royal Infirmary of Edinburgh

CASE STUDY 8:

CANCER SERVICE REDESIGN IN NHS GRAMPIAN - NOSCAN and Novartis Pharmaceuticals

“Industry support, in this case has enabled the development of innovative care within a local setting which fits a direction of travel of care consistent with patient needs.”

Peter Gent, Manager NOSCAN (North of Scotland Cancer Network)

PROCESS

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

Terms of Reference (TOR) describe 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.

The Idea

[Use the checklist in Appendix A and refer to the Principles - Working with the Industry section on page 10]

Does the proposed project meet the joint-working principles?
Is this the right partnership to provide the skills required to deliver the expected outcomes for patients?



The Proposal

[Use the framework in Appendix B]

- Develop Terms of Reference to define the nature and scope of the project, how it will be monitored, who will have independent oversight and what you aim to achieve
- Create a Project Initiation Document (PID)
- Create a draft Joint-working Agreement (to include financial arrangements, agreed exit strategy, oversight, and process if any aspects of the project need to be altered)
- Draw up a draft Project Delivery Plan (to include project reporting and progress milestones)



Approval

[Submit the PID, draft Joint-working Agreement and draft Project Delivery Plan]

- To the lead NHS Board
- To the Pharmaceutical Company/Companies compliance officer



Agreement

[Both parties should sign the Joint-working Agreement and publish it on the websites of both the Board and pharmaceutical company/companies]



Commence the Project



Evaluate

[Assess progress and report on achievement of outcomes at agreed stages in the project. Under the Joint-working Agreement, alterations to the project activities and programme may need to be resubmitted for **approval**]



Completion

[Prepare and publish a final report on the project including full assessment of outcomes and benefits to patients, NHSScotland and the pharmaceutical companies involved]

ACKNOWLEDGEMENTS

2012 WORKING GROUP MEMBERSHIP

Ian Mullen OBE, DL (Group Chairman)	Chairman NHS Forth Valley
Sandra Auld	Operations Director ABPI Scotland
Professor Marion Bennie	Professor of Pharmacy Practice Strathclyde Institute of Pharmacy and Biomedical Sciences
George Brechin	Chief Executive, NHS Fife
Paul James	Director of Finance, NHS Greater Glasgow and Clyde
Dr Keith McIntyre	General Practitioner, NHS Greater Glasgow and Clyde
Laura McIver	Chief Pharmacist, Healthcare Improvement Scotland
David McLaren	Patient and Public Representative (NHS Forth Valley)
Marion MacLeod	National Co-ordinator of Scottish Practice Management Development Network, NES
Professor Alison Strath	Principal Pharmaceutical Officer, Scottish Government
Diane Thomson	Government Affairs Manager, Pfizer
Dr Hester Ward	Medical Director, National Services Scotland
Alison Wilson	Director of Pharmacy & Accountable Officer, NHS Borders
John Macgill	Secretary to the Group

“I am extremely grateful to colleagues for their invaluable and informed input, their commitment and dedication and their unfailing determination to ensure that A Common Understanding 2012 becomes the definitive blueprint for joint-working between the Pharmaceutical Industry and NHSScotland.”

Ian Mullen

APPENDIX A: JOINT-WORKING CHECK LIST

		Yes	No
1.	Is the main benefit of the project focused on the patient?		
2.	Will both the pharmaceutical and NHS partners pool skills, knowledge and resources?		
3.	Is there a proportionate contribution of overall resources (taking into account people, finance, equipment and time) from all parties involved?		
4.	Is there a shared commitment to successful delivery of the project by all parties involved?		
5.	Will the project deliver benefits for all parties involved: for patients, industry and the NHS?		
6.	Are all partners committed to, and have in place, a medium via which a summary of the Joint-working Agreement can be made public prior to implementation, e.g. published on the organisation's website?		
7.	Will the patient outcomes of the project be measured and documented?		
8.	Will the project be managed by a joint project team comprising NHS representation and pharmaceutical industry?		
9.	Do all parties and their respective organisations have appropriate skills and capabilities in place to manage the project thus enabling delivery of the outcomes?		
10.	Do all partner organisations have clear procedures in place for reviewing and approving joint-working projects?		
11.	Are all partners clear on the respective signatories for Joint-working Agreements?		
12.	Is there an agreed exit strategy/contingency arrangement?		

If the answer to ANY of the questions 1 to 6 inclusive is No, the project is not a true joint-working (JW) arrangement and should not be viewed as such. Appropriate steps to address the outstanding areas should be taken before proceeding further under the guise of JW.

If the answer to ANY of the questions 7 to 11 inclusive is No, steps should be taken at the outset to address this or risk the proposal failing to achieve approval.

APPENDIX B: A JOINT-WORKING PROJECT PLANNING FRAMEWORK

Please address as many elements listed below as are relevant as this framework, when completed, can be used to write a project initiation document (PID) appropriate to your organisation's submission, review and approval process.

1. Joint-working project summary

1.	Names of the parties entering the joint-working agreement	
2.	Names of the lead representative of each party	
3.	Summary of intended aims/ objectives	
4.	Summary of expected outcomes	
5.	Exact nature of the joint-working proposal	
6.	What are the potential conflicts of interest?	
7.	Start date	
8.	Finish date	
9.	How will the benefits be sustained following completion of the project?	
10.	Exit strategy	

2. Resources and costs

1.	Overall cost of the joint-working project	
2.	What are the direct and indirect resource/cost commitments by each partner?	
3.	How will the resources/costs be monitored and recorded?	
4.	List valid and relevant information on cost effectiveness (has value for money been shown?)	

3. Governance arrangements

1.	Who has been consulted prior to the joint-working project and how was this done?	
2.	How will patients be informed of the joint-working?	
3.	Decision-making process of the project	
4.	Operational and management arrangements	
5.	Does the proposal conform with the standards of business practice of the NHS Board concerned?	
6.	How does the project relate to, and fit with, existing systems of care in the primary and secondary care sectors?	
7.	Has the project been piloted or are there plans to do this? How would this be done?	
8.	Has the proposal been compared with other joint-working proposals currently on offer?	

4. Monitoring and evaluation

1.	Management of the project format/process	
2.	Who has designated responsibility at each stage of the proposal? - please list	
3.	Detail of the variables to be measured to establish benefit	
4.	On completion of the project how will it be evaluated in terms of benefits?	
5.	What have been the learning outcomes/opportunities?	
6.	Audit arrangements and setting metrics	

5. Data and patient protection

1.	What interests do the company and the NHS have in relation to the joint-working proposal - where do these interests coincide?	
2.	What are the potential conflicts of interest?	
3.	Does the NHS “own”, either solely or collectively, the data generated by audit and monitoring of the joint-working?	
4.	Who has access to the data and in what form, i.e. aggregation and anonymisation criteria? (Bearing in mind the Data Protection Act)	
5.	Will the data be used for commercial reasons?	
6.	What are the research and development issues?	
7.	Written contract between parties clearly stating obligations of confidentiality, security standards and limits use of information to purpose specified in contract	
8.	For clinical services, what are the professional indemnity and liability arrangements that the provider has in place?	

6. Declaration of interests (see below)

YES

NO

If YES, Please tick one box in (A) and in one box in (B)

(A) Personal

Specific

Non-specific

(B) Non-Personal

Specific

Non-Specific

Signature: _____ Date: _____

“PERSONAL” implies that you (or your spouse) receive direct payment for services or hold shares in the relevant company concerned or a competitor.

“NON-PERSONAL” implies that your Unit benefits by receiving funding from the company but you did not benefit personally.

“SPECIFIC” implies that you received payment relating to the particular issue under consideration.

“NON-SPECIFIC” implies that payment was not related to the specific issue under consideration but have, for example, undertaken work or given advice on other products made by the relevant manufacturer.

This system is used by the Scottish Medicines Consortium and other national drug regulatory bodies.

APPENDIX C: EXAMPLES OF POTENTIAL CONFLICTS

It may be helpful to give staff/independent contractors some examples of instances giving rise to potential conflicts of interest and how these could be managed. Examples are given below:

- A. **A clinician wishes to include in the Formulary a new medicine, manufactured by a company with which he has links, e.g. company shares, research grant.**

The Area Drug and Therapeutics Committee should require declarations of interest from clinicians submitting proposals for new products to be added to formularies and ensure the decision is based on clinical and cost-effectiveness information.

- B. **A pharmaceutical company representative wishes to present the case for a new product to be included in a formulary.**

Health Board formulary submission process should be followed with necessary declarations of interest being made

- C. **Offer from a company to provide training of staff/independent contractors.**

Training provided by industry is acceptable if it is unbiased, is evidence-based and the hospitality is appropriate.

- D. **A pharmaceutical company offers to sponsor a clinical employee/independent contractor in an NHS Board.**

This does not fit the joint-working criteria and should follow the Board's sponsorship policy. Participants should be aware that any payments to NHSScotland staff must be declared under the ABPI Code of Practice though no individual recipient is named.

- E. **Sponsored attendance at conferences and symposia, should be agreed and registered by the employer and a report on the benefits to patient care and/or service provision shared with colleagues.**

Attendance of more than one member of any clinical team must be considered carefully to ensure that patient care is not compromised. Participants should be aware that any payments to NHSScotland staff must be declared under the ABPI Code of Practice. Any payment must be declared and recorded by the recipients employer.

APPENDIX D: PRESCRIPTION MEDICINES CODE OF PRACTICE AUTHORITY

The ABPI Code of Practice for the Industry was introduced in 1958. Copies of the Code are available from the PMCPA, www.pmcpa.org.uk or by calling 020 7747 8885. It covers and extends beyond legal requirements in the UK.

The Association of the British Pharmaceutical Industry (ABPI) established the Prescription Medicines Code of Practice Authority (PMCPA) in 1993 to operate the Code of Practice for the pharmaceutical industry at arm's length from the ABPI itself.

The PMCPA is responsible for the provision of guidance, advice and training on the Code as well as for the complaints procedure.

Compliance with the Code is obligatory for ABPI member companies and, in addition, about 60 non-member companies have voluntarily agreed to comply with the Code and to accept the jurisdiction of the Authority.

The Code covers the advertising of medicines to health professionals and administrative staff/independent contractors and also covers certain non promotional areas such as information about prescription only medicines made available to the general public.

It covers:

- journal and direct mail advertising;
- the activities of representatives including detail aids and other printed material used by representatives;
- the supply of samples;
- the provision of inducements to prescribe, supply, administer, recommend or buy medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind;
- the provision of hospitality;
- the organisation of promotional meetings;
- the sponsorship of scientific and other meetings including payment of travelling and accommodation expenses;
- the declaration of payments to health care and patient organisations;
- the provision of medical and educational goods and services;

- the provision of information to the general public either directly or indirectly, including by means of the Internet;
- all other sales promotion in whatever form, such as participation in exhibitions, the use of audio-cassettes, films, records, tapes, video recordings, electronic media interactive data systems and the like.

Complaints submitted under the Code are considered by the Code of Practice Panel, which consists of three members of the Code of Practice Authority acting with the assistance of independent expert advisers where appropriate. Both complainants and respondents may appeal to the Code of Practice Appeal Board against rulings made by the Panel. The Code of Practice Appeal Board is chaired by an independent legally qualified Chairman; it includes independent members from outside the industry who must be in the majority for the consideration of any case.

In each case, where a breach of the Code is ruled, the company concerned must give an undertaking that the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in the future. An undertaking must be accompanied by details of the action taken to implement the ruling. Additional sanctions are imposed in serious cases.

Complaints about the promotion of medicines or other activities should be sent to the Director of the PMCPA, 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT; 020 7747 8880 or by email, complaints@pmcpa.org.uk.

The Authority can also be contacted for informal advice on 020 7747 1415 or 020 7747 1405.

APPENDIX E: EXAMPLES OF JOINT-WORKING PROJECTS AND PROGRAMMES IN SCOTLAND (Case Studies)

1. Scottish Medicines Consortium/Association British Pharmaceutical Industry (SMC/ABPI)
2. Scottish Neuro Endocrine Tumour (SCONET) Guidelines
3. Scottish Intercollegiate Guidelines Network (SIGN) Respiratory Guidelines
4. MRSA Complicated Skin & Soft Tissue Infection (CSSTI) Management Evaluation
5. Rheumatoid Arthritis Stop Smoking Campaign
6. Grampian Risk Assessment & Intervention (GRANITE)
7. Specialist Registrar (SPR) Training
8. Cancer Service Redesign in NHS Grampian

1. SCOTTISH MEDICINES CONSORTIUM

Name of Collaboration

Scottish Medicines Consortium (SMC) and Association of the British Pharmaceutical Industry (ABPI)

NHSScotland Partner

SMC

External Partner

ABPI

Aim of the work

The SMC came into being in 2001, providing guidance to the NHSScotland Boards on the clinical and cost effectiveness of all newly licensed medicines. In establishing the early systems and processes the SMC worked collaboratively with the ABPI establishing a formal forum in 2002, known as the SMC User Group.

What was done?

Three industry representatives are full members of SMC with the lead representative also Chairing the SMC User Group Forum. This Group comprises representatives of the pharmaceutical industry with knowledge of Health Technology Appraisals, who meet quarterly with representatives of the SMC Executive, the New Drugs Committee (NDC), pharmacy and health economic assessors and the secretariat. The aim of this Group is to provide a forum for industry and NHS stakeholders involved in the SMC to jointly identify, address, resolve and improve process and methods issues arising in relation to pharmaceutical company submissions and interactions with the SMC. Selection of industry members for the UGF is via an open and transparent process.

Supporting quote from lead clinician

“Partnership working with the pharmaceutical industry has been a major component of SMC’s success. There were expected to be challenges for Scotland, as a small country, in achieving the participation of a global industry in its HTA process. Industry partners have, however, been integral since the outset in setting up the ways of working as well as participating fully in the decision-making process. This allows the industry as a whole to be sure that due process is being followed and that decisions are being made fairly and to objective criteria. The SMC ABPI partnership is an excellent example of a true partnership that has had immense benefits for patients in Scotland as a result of early access to clinically effective and cost-effective new medicines.”

Professor Angela Timoney, Chair, Scottish Medicines Consortium

Outcomes Delivered:

- **Patients benefit** from the rapid review of new medicines leading to early access in some instances
- The **NHS benefits** from a robust process of review which provides guidance on the cost effectiveness of new treatments for NHSScotland
- **Pharmaceutical companies benefit** from the ABPI contribution to the evolution of SMC policy, methods and process, subsequent communication back to industry and support in adhering to the agreed way of working.
- **NHSScotland benefits** by utilising their limited resources in the most cost-effective treatments.

2. SCOTTISH NEURO ENDOCRINE TUMOUR GUIDELINES

Name of Collaboration

SCONET (Scottish Neuro Endocrine Tumour) Guidelines

NHSScotland Partner

SCONET Group

External Partner

Novartis Pharmaceuticals

Aim of the work

To have a clear patient pathway that would ensure patients are identified and receive access to the most efficient and effective care whilst ensuring equity across Scotland (Scotland has a large geographical area, with some rural hospitals, and accounts for 8% of UK population).

What was done?

- Identified the key health care professionals (HCP) and gained their commitment to support the development of patient pathway. This was for all stages. This included Radiology, Pharmacy, Oncology, Endocrinology, Surgery, Pathology.
- Organised and facilitated the Guideline meeting.

Supporting quote from lead clinician

“The Scottish Neuro Endocrine Tumour Group (SCONET) is in the process of developing the first Scottish Neuro Endocrine Guidelines which are expected to be finalised by April 2012. The guideline will ensure the equitable management of patients with this rare disease across Scotland and support integration of newer treatments as they are licensed. This project has demonstrated a good working relationship between the clinicians and industry which has helped to develop effective clinical guidelines.”

Dr Nicholas Reed, Consultant Oncologist, Beatson Oncology Centre, Glasgow

Outcomes Delivered:

- The **patients benefit** by receiving the most appropriate management and treatment for their disease in their locality, in a timely manner
- The **prescribers benefit** by having a clear patient treatment pathway
- The **payors benefit** by having a rare cancer service that ensures both equitable and appropriate patient management

3. SIGN RESPIRATORY GUIDELINES

Name of Collaboration

Scottish Intercollegiate Guidelines Network (SIGN)/ABPI Scottish Respiratory Industry Group (SRIG)

NHSScotland Partner

SIGN/National Advisory Group (NAG) for Respiratory Managed Clinical Networks

External Partners

Asthma UK Scotland/ABPI Scottish Respiratory Industry Group (SRIG) [including the following companies: AstraZeneca, Boehringer-Ingelheim, Chiesi, GSK, MSD, Napp and Novartis]

Aim of the work

Implementation of the SIGN/British Thoracic Society Guidelines: SIGN 101, British Guideline on the Management of Asthma: A national Clinical Guideline.

What was done?

A steering group (SIGN/NAG/Asthma UK/SRIG) has been set up to deliver an implementation process for the guideline; this will involve three regional workshops, match funded by SIGN and SRIG which will run during May 2012 with the following aims, objectives and outcomes.

AIMS AND OBJECTIVES OF THE DAY:

- An opportunity to consider the asthma priorities
- An opportunity to share examples of asthma good practice and models of service delivery
- To help design the benchmark criteria to facilitate implementation
- An opportunity to influence future improvement planning process
- To inspire and motivate continued focus on the delivery of care to patients with asthma
- An opportunity to network with colleagues from your region

EXPECTED OUTCOMES:

- Agreed asthma priorities
- Clear understanding of any regional variations
- Increased knowledge of different clinical and service models to help deliver good practice
- Benchmark criteria to support future implementation

Supporting quote from lead clinician

“Collaborative work, such as the regional workshops, brings a unique opportunity to link evidence, priorities and direct benefits for patients. The workshops allow all stakeholders to influence asthma priorities in different regions across Scotland.”

Dr Keith Brown, SIGN Chair

Outcomes Delivered:

- **Patient benefit:** Improved service, improved access to the service, improved health outcomes
- **NHS benefit:** Improved service, equity of service across all Health Boards (HBs) within Scotland, which will be benchmarked and monitored.
- **Company/Companies benefit:** Joint-working project to support improved delivery of care within a Long Term Condition (LTC) where inequality of care is evident across HBs, this will include benchmarking and monitoring of improvement. Better understanding of how health is being managed and improved in asthma.
- **Societal/wider NHS benefit:** Improved service, equity of service across all HBs within Scotland, which will be benchmarked and monitored.

4. MRSA MANAGEMENT EVALUATION

Name of Collaboration

MRSA CSSTI (Complicated Skin and Soft Tissue Infection) management evaluation

NHSScotland Partner

NHS Greater Glasgow and Clyde

External Partner

Pfizer

Aim of the work

To establish a robust methodology for reviewing the hospital records of patients with confirmed MRSA related CSSTIs to better understand the scale and impacts of the problem and explore early discharge as a potentially significant factor in the solution.

What was done?

Robust methodology agreed by three lead clinicians and an independent research organisation based on a 15-month retrospective review of the hospital records of patients with confirmed MRSA CSSTIs. A representative sample of 173 eligible patients was identified, along with the relevant therapy areas and types of infection and the management of their condition analysed in detail.

Supporting quote from lead clinician

“We recognised before this study was undertaken that there was the theoretical potential for earlier discharge of patients with MRSA CSSTI, either on oral antibiotics or utilising our OPAT (Outpatient Parenteral Antibiotic Therapy) services. This would have obvious benefits for the patients who could return home earlier, and for the hospitals involved by allowing them to make the most appropriate use of available bed resources. However, we did not have the data to accurately assess the true extent of that potential. This project provided us the opportunity to gather the data we needed to answer that question.”

Professor John E Coia Consultant Clinical Microbiologist Director Scottish Microbiology Reference Laboratories, Glasgow

Outcomes Delivered:

For the patient

- The work identified that the median attributable length of stay until discharge was 15 days and that 29 patients (or 26.4%) were potentially suitable for discharge on oral therapy or OPAT (Outpatient Parenteral Antimicrobial Therapy).
- This, in turn, indicates that a significant number of patients may benefit from spending less time in hospital and resume their normal lives more quickly.
- Also of benefit to patients may be the positive contribution the findings could make to new thinking in the control and management of MRSA CSSTI.

For the NHS

- It was established that MRSA CSSTI accounted for 4,352 bed days, equating to 9 beds per day.
- Barriers to early discharge identified included management buy-in, clinician confidence, the need to monitor outcomes, provide support and develop new models of care.
- However, the proportion of patients who may benefit shows the potential for helping reduce infection, reduce costs through shorter stays, meet RTT targets and cut waiting lists.
- If a 25% reduction in HCAI could be achieved in surgical, orthopaedic, gynaecology and urology patients combined, 8,000 additional patients could be treated every year.

For Pfizer

- Further strengthen the company's relationship with NHS Greater Glasgow and Clyde.
- Insight gained into local customer and patient needs.

5. RHEUMATOID ARTHRITIS STOP SMOKING CAMPAIGN

Name of Collaboration

Rheumatoid Arthritis Stop Smoking Campaign

NHSScotland Partner

NHS Fife/Fife Rheumatic Diseases Unit (FRDU)

External Partners

National Rheumatoid Arthritis Society (NRAS)/Pfizer

Aim of the work

- Drive public and healthcare professional awareness of the Rheumatoid Arthritis (RA) and smoking campaign in Fife;
- Raise public understanding of the impact smoking may have on RA disease activity and treatment efficacy;
- Encourage RA patients to recognise the link between RA and smoking and seek professional advice.

What was done?

At a preliminary meeting Rheumatology Consultant raised the idea of creating an image that reflected the link between RA and smoking, e.g. using cigarettes as part of the hand image. Set up a discussion group of healthcare professionals, Chaired by Consultant Rheumatologist to discuss the current issues and challenges around RA and smoking and review a selection of creative concepts for the Disease Awareness Campaign – Establishment of patient pathways in smoking and RA to improve the management of these patients. Engaged with NRAS, to develop and distribute a Detailed Patient Evaluation survey to a selection of patients in order to gain their perspective on the campaign. Interestingly, the creative concepts which provided empowering positive messages were rated more highly than the more hard-hitting concepts. Developed materials based on this feedback: A3 posters, patient leaflets, postcards, patient factsheet, NRAS publication. The Consultant Rheumatologist completed an audit before and after campaign. NHS Fife and NRAS contacted to collate results from campaign.

Supporting quote from lead clinician

“Many individuals with RA are not aware of the impact smoking may have on their disease or the services that are available to help them stop. We hope this campaign will educate people on the additional risks of smoking and empower them to make positive steps towards giving up.”

Dr Helen Harris, Consultant Rheumatologist at Fife Rheumatic Diseases Unit, Whytemans Brae Hospital

“We are delighted to be working together with NHS Fife and Pfizer to create a campaign which truly responds to the needs of patients in Fife. It is over 30 years ago since I developed RA and at the time, I smoked. I do now wonder if this was the trigger, or one of the triggers, which led to me developing RA.”

Ailsa Bosworth, CEO of NRAS

Outcomes Delivered:

Patient benefits

Raise awareness of the link between rheumatoid arthritis and smoking. Results at 4 weeks of launch include:

- **4 pieces** of coverage achieved: *The Courier*, Dunfermline Press, Kingdom FM & Tay FM,
- **289,660** media impressions have been secured,
- **300** hits on NRAS website,
- Over **100** impressions on Facebook and 205 views on NHS Fife staff intranet.

NHS benefits

Increase throughput to stop smoking services to increase number of quitters and improve symptoms of RA and adherence to anti-tnf (tumour necrosis factor) medications. Results: 35 referrals from rheumatology clinic at 4 weeks of launch to stop smoking services. In terms of RA symptoms “early results suggest we expect a reduction in DAS and improvement in medication adherence.”

Dr Helen Harris

Benefits to Pfizer

- To further enhance our reputation and trust within NHS Fife
- To use insights gained to continue to help us improve our services
- To use the opportunity to develop our understanding of customer and patient needs
- To strengthen our collaborative reputation and review appropriate use of medicine

6. GRANITE

Name of Collaboration

Grampian Risk Assessment & Intervention: GRANITE

NHSScotland Partner

NHS Grampian, specifically Grampian Cardiovascular MCN and Peterhead Health Centre

External Partner

AstraZeneca UK Limited

AstraZeneca provided a Sponsorship Grant for this collaborative working programme

Aim of the work

Targeted case-finding for cardiovascular disease (CVD) prevention may be preferable to universal screening. Quality Improvement Scotland (QIS) has recommended that identification of high-risk individuals is needed. In this study, probable CVD risk in patients within the 40-70 years age range who were not on the CHD, Diabetes and Stroke registers and who were not already receiving statins was analysed using a predictive software toolkit which utilised the Assessing cardiovascular risk using SIGN (ASSIGN) risk calculator.

What was done?

AstraZeneca provided software to help the practice ensure that primary and secondary prevention patients were identified. The AstraZeneca Clinical Services Team provided the capacity to run initial clinics for the secondary prevention patients. The patients had their cholesterol measured and a treatment intervention was prompted if this was appropriate according to the protocol. The software included permission to use ASSIGN risk scoring to identify patients suitable for primary prevention.

Supporting quote from lead clinician

“Targeted CVD primary prevention identifies high-risk patients in a cost-effective manner. Structured assessment clinics identify and address unhealthy lifestyle and CVD risk factors. The GRANITE screening software effectively identified a patient population within the Peterhead practice who had a probable high 10-year CVD risk requiring intervention.”

John C Stout, GP lead, Managed Clinical Network Cardiology, Grampian

Outcomes Delivered:

- Targeted screening and levels of deprivation given equitable access to care;
- Cost-effective targeting of primary prevention patients;
- Right patients on the right drugs at the right time;
- A scalable pilot that can be replicated in other local Health Boards with the potential to reduce health inequalities in areas of deprivation.

Ref 1. <http://www.GRANITE Project Evaluation>

7. SPECIALIST REGISTRAR TRAINING

Name of Collaboration

Specialist registrar training (Spr)/Scottish Respiratory Industry Group (SRIG) [including the following companies: AstraZeneca, Boehringer-Ingelheim, Chiesi, GSK, MSD, Napp and Novartis]

NHSScotland Partner

- Dr Adam Hill, Consultant Respiratory Physician & Associate PG Dean SE Scotland (Quality Management), Department of Respiratory Medicine, Royal Infirmary of Edinburgh
- NHS Education for Scotland (NES)

External Partner

- Scottish Thoracic Society (STS)

Aim of the work?

To develop a high quality, co-ordinated and equitable training programme for specialist registrars across Scotland. Easier access to high quality and accredited training that will improve the quality of patient care throughout Scotland.

What was done?

A representative from SRIG sat on the steering group that develops the training programme to fulfil the above objectives. They will be one of 12 members of the group. It is anticipated that the training will be delivered through 6 meetings annually. The cost of each meeting is approximately £1200.00. Subsistence level catering will be provided by SRIG and all other expenses and resources, including the time of those clinicians delivering the training, will be met by STS. On occasion, there may be funding to bring an international speaker to STS events. This budget will be provided by both partners. From SRIG this will be by member companies and from STS will be from NES funding.

Supporting quote from lead clinician

“The SRIG support for SpR training is appreciated. Industry has a lot to offer trainees with strengths in areas which complement the core training provided.”

Dr Adam Hill

Outcomes Delivered:

12 SpR training meetings have been supported by SRIG since 2010. An SRIG member has attended planning meetings to ensure member companies have been represented. This has allowed clear communication on what the pharmaceutical companies involved can and cannot participate in. This has helped build a fruitful alliance between the Deaneries involved and SRIG. There has also been easier access for SpR's to high quality and accredited training that will improve the quality of patient care throughout Scotland.

8. CANCER SERVICE REDESIGN IN NHS GRAMPIAN

Name of Collaboration

Cancer service redesign in NHS Grampian

NHSScotland Partner

NOSCAN (North of Scotland Cancer Network)

External Partner

Novartis Pharmaceuticals

Aim of the work (what was the collaboration seeking to achieve)

The objective of this programme is to co-ordinate the delivery of the administration of bisphosphonates (Zometa) in community hospitals in NHS Grampian. A framework will be developed to determine a service model for delivering bisphosphonate and in the future other cancer treatments outside of the cancer centre.

What was done?

- Novartis supported the funding of a nurse to deliver and evaluate training and cover travel expenses of community nurses during training;
- Novartis supported the delivery of the educational programme in the community.

Supporting quote from lead clinician

“Industry Support in this case has enabled the development of innovative care within a local setting which fits a direction of travel of care consistent with patient needs.”

Peter Gent NOSCAN manager

Outcomes Delivered:

- Bisphosphonates are now administered safely in more than half of the community hospitals (7/13);
- Patients are benefiting from receiving their treatment locally, which enhances their quality of life;
- The number of times patients attend Aberdeen Royal Infirmary for review have been reduced or eliminated, which freed capacity for the hospital to provide other patient services;
- The skills of nurses in community hospitals have been optimised, and they can now benefit wider range of patients with other conditions requiring IV treatments;
- This project is creating a safe and appropriate infrastructure which allows the delivery of other cancer treatments;
- More patients are accessing Zometa and staying on Zometa because the service can now cope with the delivery and the capacity.



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