



ABPI GUIDANCE NOTES ON JOINT WORKING BETWEEN PHARMACEUTICAL COMPANIES AND THE NHS AND OTHERS FOR THE BENEFIT OF PATIENTS

**TAKING INTO CONSIDERATION THE 2008 ABPI CODE OF
PRACTICE FOR THE PHARMACEUTICAL INDUSTRY**

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The Association of the British Pharmaceutical Industry represents more than 70 companies in the United Kingdom producing prescription medicines. Its member companies are involved in all aspects of research, development and manufacture, supplying more than 80 per cent of the medicines prescribed through the National Health Service. The ABPI also represents companies engaged solely in the research and/or development of medicines for human use. In addition, there is general affiliate membership for all other organisations with an interest in the pharmaceutical industry in the United Kingdom.

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1. Purpose of this Guidance

The NHS is under pressure and changing rapidly. Many, including some UK Governments, want the NHS to engage with the pharmaceutical industry on a broader business-to-business agenda.

Pharmaceutical companies that are members of the ABPI are required to comply with the ABPI Code of Practice for the Pharmaceutical Industry 2008 (ABPI Code ¹), which regulates the promotion of prescription medicines and certain other non-promotional activities. The ABPI Code also applies to many non member companies. The ABPI Code states that joint working (Joint Working) with the NHS (health authorities, trusts and the like) is permitted if carried out in a manner compatible with the ABPI Code. The Prescription Medicines Code of Practice Authority (PMCPA) has issued guidance about Clause 18 of the Code and its interpretation which includes mention of Joint Working. The ABPI Code is sometimes interpreted differently by companies, in line with their own understanding of the Code and legal requirements, and taking into account their individual company policies and procedures. This can cause confusion, both between and within companies, and also externally when companies respond differently to similar customer or NHS requests. Individual company governance arrangements are also likely to differ as ultimately, each company is responsible for managing its own activities.

This ABPI guidance seeks to provide a framework and greater clarity for pharmaceutical companies about various aspects of Joint Working, including consideration about how to articulate the benefits of Joint Working to all parties and the sorts of issues that must be considered prior to commencing Joint Working projects. The purpose of this guidance is to support appropriate Joint Working. It extends beyond matters covered by the ABPI Code.

This guidance is not a free-standing 'how to' guide and should be read alongside the relevant national Government policy documents, for example: in England, the Department of Health (DH) "NHS Best Practice Guidance on Joint Working" ²; in Scotland, "A Common Understanding: Guidance on Joint Working between NHS Scotland and the Pharmaceutical Industry 2003" ³ and in Wales, WHC(2005)0016 "Guidance for Partnership Working between NHS Organisations, Primary Care Contractors, the Pharmaceutical Industry and the Allied Commercial Sector in Wales 2004" ⁴.

In England, the Joint Working Toolkit, "Moving Beyond Sponsorship: joint working between the NHS and the pharmaceutical industry" ⁵, produced by the DH and the ABPI in March 2008, provides guidance to help NHS organisations and pharmaceutical companies establish Joint Working projects and is available to all. The toolkit also provides a number of template agreements and other documents required to ensure that the governance arrangements are robust. It is referred to elsewhere in this guidance. As yet, other UK regional governments have not produced similar toolkits. The guidance will be updated as new experience is gained.

This guidance is aimed primarily at Joint Working between pharmaceutical companies and the NHS and is generally written as though the arrangements will be made between a single pharmaceutical company and an NHS organisation. However, it is also intended to cover Joint Working between several pharmaceutical companies and/or several NHS organisations and also to cover Joint Working conducted through third party service providers and/or with suppliers of private healthcare.

Please note that only informal guidance about compliance with the ABPI Code can be obtained from the PMCPA. The decision as to whether any individual Joint Working arrangements comply with the ABPI Code will be determined by the Code of Practice Panel following a complaint and, on appeal, by the Code of Practice Appeal Board. Each case is considered on its own merits. The Panel and the Appeal Board have seen this ABPI guidance. The Medicines and Healthcare products Regulatory Agency (MHRA) has seen this guidance and support its aims. A decision about whether individual Joint Working arrangements comply with UK law would be determined on their own merits.

¹ ABPI Code of Practice for the Pharmaceutical Industry 2008. See <http://www.pmcpa.org.uk>

² "Best practice guidance for joint working between the NHS and the pharmaceutical industry, Department of Health (February 2008) ("DH Joint Working Guidance"). See http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082370

³ A Common Understanding: Guidance on Joint Working between NHS Scotland and the Pharmaceutical Industry 2003. See <http://www.scotland.gov.uk/Resource/Doc/47043/0013545.pdf>

⁴ Guidance for Partnership Working between NHS Organisations, Primary Care Contractors, the Pharmaceutical Industry and the Allied Commercial Sector in Wales 2004. See <http://www.wales.nhs.uk/sites3/Documents/371/WHC%20%282005%29%2016%20%2D%20Partnership%20document.pdf>

⁵ Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry, Department of Health/ABPI (March 2008) ("Joint Working Toolkit"). See http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082840

2. Background to Joint Working

An underlying principle for Joint Working is that the arrangements must bring benefits to patients. The NHS and the pharmaceutical industry share a common agenda to improve patient outcomes through high quality and cost effective treatment and management.

For many years, pharmaceutical companies have demonstrated their commitment to improvements in patient care in a variety of ways, for example, by providing medical and educational goods and services and unrestricted educational grants. More recently, however, the NHS and the pharmaceutical industry have been seeking to extend the nature of these relationships in order to develop higher quality care for patients and improve mutual understanding and trust. For example, Joint Working projects are taking place in some parts of the UK but this experience is by no means universal.

In England the DH published its Joint Working Guidance in February 2008,, thus confirming the Government's wish to see a closer and more mature working relationship between the NHS and the pharmaceutical industry and DH policy on Joint Working was emphasised further in the 'Next Stage Review – High Quality Care for All' (Darzi Report – June 2008):

We will involve the industry systematically to support better forward planning and to develop ways of measuring the uptake of clinically and cost effective medicines once introduced. (3.51)

We want to foster a pioneering health service that makes best use of the talents of NHS staff, the higher education sector and industry. International evidence from continental Europe, North America and the Far East, has demonstrated that patients benefit by bringing together the talents of different sectors. Their skills are harnessed in developing pioneering treatments and service models for patients. (4.42)

By Spring 2009, each PCT will publish its strategic plan, setting out a five year plan for improving the health of people locally. These plans will put into practice the evidence-based pathways of care at the heart of each region's vision. They will show a strong emphasis on partnership working between PCTs, local authorities and other partners (public, private and third sector – including social enterprise) to ensure that local health and wellbeing needs are better understood and addressed. (8.5)

However, for Joint Working to be sustainable in the longer term, it should also bring benefits to both the NHS organisation and the pharmaceutical industry partner, such as cost effective use of NHS resources and increase in shareholder value respectively. These anticipated benefits should be clearly stated and understood at the outset of the project – see Section 7 for examples of the mutual benefits that might apply.

3. Definition and Scope of Joint Working

This guidance applies to Joint Working arrangements between the NHS and one or more pharmaceutical companies. Joint Working is defined in the DH Joint Working Guidance and Joint Working Toolkit as:

Situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery.

The key requirements from this definition are two-fold:

- (i) the Joint Working project must be focused on benefits to patients; and
- (ii) there must be a “pooling” of resources between the pharmaceutical company or companies and the NHS organisation(s) involved. Each party must, therefore, make a significant contribution to the Joint Working project to avoid the arrangement being construed as merely a gift, benefit in kind, donation or some other non-promotional/commercial practice. Resources may come in various forms, including people, expertise, equipment, communication channels, information technology, and finance.

In addition, given the significant governance and administrative requirements involved in setting up proper Joint Working arrangements, it is likely that most Joint Working projects will be of a significant size and duration – as a guideline, generally involving resources (manpower, materials, funding etc) in the region of £15,000 - £20,000 and lasting 6 months or more. Ideas for Joint Working projects can arise from either party, hence pharmaceutical companies (as well as NHS organisations) can pro-actively propose ideas for Joint Working.

There are a number of non-promotional and/or commercial practices that involve interaction with the NHS and healthcare professionals that are not subject to this Joint Working guidance. This is because such practices do not satisfy the definition of Joint Working. These include:

- Clinical trials and company support of investigator or institution-initiated or sponsored studies. These should be reviewed in accordance with applicable laws, regulations and guidance and codes of practice, including the ABPI Code
- Package deals, whereby the purchaser of medicines receives with them other associated benefits, such as apparatus for administration, or nurse support to administer a particular medicine, provided that the transaction as a whole is fair and reasonable and the associated benefits are relevant to the medicines involved. These should be reviewed in accordance with the ABPI Code, in particular Clause 18.1. Please note that deals linked to the purchase of particular medicines, or to supply from particular sources, are not allowed under NHS rules, unless as a result of a transparent tender for a defined package of goods and services⁶
- Meetings and hospitality. These must be reviewed in accordance with the ABPI Code, in particular Clause 19
- Gifts, benefits in kind or pecuniary advantages. These must be reviewed in accordance with the ABPI Code, in particular Clause 18
- Commercial payments to healthcare professionals employed as consultants and advisors. These must be reviewed in accordance with the ABPI Code, in particular Clause 20
- The pro-active offer or provision of medical and/or educational goods and/or services (MEGS) which enhance patient care, or benefit the NHS and maintain patient care. MEGS are provided by a pharmaceutical company to a healthcare professional or NHS organisation in circumstances where there is no “pooling of resources” as required under the definition of Joint Working (i.e. the goods, services or resources behind the project are provided solely or mainly by the pharmaceutical company or its agent/employees). MEGS must be reviewed in accordance with the ABPI Code, in particular Clauses 18.4 and 18.5

⁶ Commercial Sponsorship: Ethical Standards for the NHS, Department of Health, November 2000. See http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005135

- The provision of educational grants to a healthcare professional, institution or organisation (i.e. again there is no pooling of resources). These should be reviewed in accordance with the ABPI Code, in particular Clause 18.1
- Measures or trade practices relating to prices, margins and discounts which were in regular use by a significant proportion of the industry on 1 January 1993
- NHS Tenders conducted in accordance with NHS procurement policy and straightforward sale of goods. Current NHS procurement practices often require that companies not only compete on price, but also that they propose the supply of certain added value goods or services. Even where the supply of such services involves some joint endeavour, the arrangements should still be considered within the scope of the NHS procurement and tender processes
- Other commercial arrangements with the NHS, e.g. risk share or outcome guarantee schemes. These should be reviewed in accordance with the ABPI Code, in particular Clause 18.1 where there is any potential benefit to individual healthcare professionals or associated administrative staff

4. Principles of Joint Working

The following principles will apply to Joint Working:

- All Joint Working must be for the benefit of patients, although it is expected that the arrangements will also mutually benefit the parties
- Joint Working will be conducted in an ethical, open and transparent manner
- Joint Working will take place at a corporate (organisational) level, and not with individual healthcare professionals or NHS administrative staff
- Contracts will be negotiated on fair and reasonable terms, in line with NHS values
- Confidentiality of information received in the course of the arrangement will be respected and never used outside the scope of the project
- All patient identifiers will be removed from data to preserve and respect patient confidentiality in line with the Data Protection Act 1998
- In the interests of transparency, the overall arrangements must be made public, although the parties should consider which parts of the Joint Working arrangements are commercially sensitive
- Joint working is based on mutual trust and respect. Pharmaceutical companies must comply with the ABPI Code at all times. All NHS employed staff should comply with NHS, and relevant professional body codes of conduct at all times

5. 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
- nurse 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

Please see also the good practice examples highlighted in the Joint Working Toolkit.

6. Joint Working Governance

Governance arrangements are explained in the Joint Working Toolkit. It is important to reiterate, however, that Joint Working between the pharmaceutical industry and the NHS must be conducted in an open and transparent manner. This will include entering into appropriate Joint Working agreements, establishing steering groups and consulting with relevant stakeholders about each particular Joint Working project.

If medicines are to be administered to patients as part of a Joint Working project, these must only be used in line with nationally accepted clinical guidance (where this exists).

In order to avoid the inappropriate influencing of prescribers, Joint Working discussions and agreements must take place at an appropriate organisational level within the NHS (e.g. authorised negotiators or signatories of an NHS Trust, Health Board, Primary Care Trust (PCT), and/or NHS commissioning group) and the pharmaceutical company (e.g. senior manager or director level). However, individual GP practices, hospital departments and the like and health professionals are likely to be intimately involved in the planning and implementation of Joint Working projects.

Although pharmaceutical companies and individual GP practices or hospital departments may wish to work together, such projects are unlikely to be recognised as Joint Working projects unless an NHS body (e.g. a PCT or a Health Board) is involved (see Section 16). It is more likely that such activities will fall under some other non-promotional/commercial practice, such as the provision of MEGS.

7. The Mutual Benefits of Joint Working

When developing a Joint Working proposal it is important at the outset to define the anticipated benefits for patients and the parties, and to ensure that both parties are comfortable with the proposals. As Joint Working projects are 'business to business' arrangements it is both reasonable and appropriate for both the NHS body and the pharmaceutical company to consider return on investment (ROI) before committing to any project. Commercial benefit to either party must not be the sole benefit under Joint Working (although it may be under some other commercial practices, e.g. NHS Tenders or package deals).

It has sometimes been a challenge for pharmaceutical companies to articulate the types of benefits that the parties might achieve from Joint Working due to the real and perceived constraints associated with European Community and UK legislation on advertising of medicines and relevant codes, primarily the ABPI Code. Transparency and openness are necessary for appropriate Joint Working.

Examples of the potential benefits to patients, the NHS and pharmaceutical companies are outlined below.

For patients

- Care closer to home
- Fewer hospital admissions
- More equitable and consistent care and access to care
- Better information about conditions and treatment options
- Clearer and improved care pathways
- Better experience of the healthcare system

For the NHS

- Higher quality, more consistent care achieved more rapidly
- Services configured around patients' needs
- Better health outcomes
- Better use of resources, greater value for money, lower costs
- More people treated appropriately (e.g. in line with national guidelines)
- Lower costs of hospital admissions
- Support towards achievement of performance targets
- More creative approaches to problems
- Better cross-sectoral working
- Better skilled personnel

For the pharmaceutical company

- More and/or better use of medicines, including the company's medicine(s)
- Better understanding of customers' and patients' needs
- Improved reputation
- Faster NHS implementation of policy which may be relevant to the company's business

Where Joint Working involves explicit references to a pharmaceutical company's medicine(s), then such arrangements are only likely to be acceptable if they are framed in the context of patient care, the relevant medicine(s) is used appropriately in accordance with nationally accepted treatment guidelines and there is no inducement to prescribe the product(s) concerned.

Activities which are designed to increase the appropriate use of medicines generally in a particular therapeutic area, such as designing and implementing a disease protocol, are acceptable notwithstanding that the pharmaceutical company may benefit from a share of the general increase. This could be articulated in a Joint Working agreement as follows:

"This Joint Working project is intended to create more opportunities for the appropriate use of medicines, including [company x's] medicines in suitable patients in line with [insert treatment guidelines, e.g. NICE/SIGN/AWMSG guidelines, National Service Framework targets, locally agreed protocol]. If this improvement occurs, we are likely to see an increase in prescriptions of [product y] roughly equal to our current proportion of prescriptions in this therapeutic area."

Joint Working projects that increase the use of a pharmaceutical company's particular medicine(s), (as opposed to increasing the use of a class of medicines generally), whilst possible, are more open to challenge and so these arrangements need to be checked particularly carefully to ensure that there is no actual or perceived inducement to prescribe that company's product(s). Acceptable projects are likely to be those which implement national or local guidelines.

If a Joint Working project is linked to an "agreed objective" then defined patient outcomes must be agreed by the parties. Where no "defined" patient outcomes can be agreed (e.g. because there are no recognised patient outcomes for a particular condition), clear arrangements for measuring the objectives of the Joint Working project should be agreed. Templates for such agreements are contained in the Joint Working Toolkit.

8. Measuring Joint Working

The outcome of every Joint Working project should be measured. Dependant on the project, a set of baseline measurements should be established at the outset of the project to track and measure the success of the project aims, particularly patient outcomes. When measuring Joint Working outcomes, the following should be borne in mind:

- If a pharmaceutical company intends to use data to assess the clinical effectiveness of its product(s), it must consider whether other rules may apply to the project, such as clinical trial regulations and/or the need for ethics committee approval
- Measurement should be shared between the NHS and the pharmaceutical company as appropriate. It is likely that the parties will analyse their own data sources and then share and compare results (see Section 14 for further information about measurements involving patient data)
- For longer term projects (> 1 year) patient outcomes should be analysed at least every six months as a minimum to ensure that anticipated patient benefits are being delivered
- Measurement should be conducted at a suitable level within the company to avoid the impression that local sales personnel are unduly influencing a Joint Working project. Second line management or above is a preferable level for this to occur
- If measures relate to changes in the use of one or more medicine(s) in accordance with appropriate local/national guidelines, then the change can be used to estimate the potential benefit to patients and the NHS
- In principle, it is acceptable to conduct retrospective analysis of any measure, including specific product sales and market shares, related to Joint Working. Retrospective in this context means after the project has been completed

Some examples of how the outcomes/success of Joint Working projects may be measured are set out below.

For patients

- Increase in the number of appropriately diagnosed patients
- Decrease in the number of inappropriately diagnosed patients
- Increase in appropriately treated patients
- Decrease in inappropriately treated patients
- Increased access to appropriate medicines
- Reduced inequality of access to appropriate medicines
- Patient satisfaction (change/level)
- Patient reported outcomes
- Increased patient awareness and understanding of diseases/treatments
- Improved patient concordance and adherence to therapy
- Decreased burden of treatment for patients including reduction in side effects or improved management of side effects

For the NHS

- Increase in the number of appropriately diagnosed patients
- Decrease in the number of inappropriately diagnosed patients
- Increase in appropriately treated patients (e.g. in line with national guidelines)*
- Decrease in inappropriately treated patients
- Improvement towards achieving NHS/national targets
- Reduced wastage
- Improved relationship and trust between the NHS and the pharmaceutical industry and/or the NHS and patients
- Patient reported outcomes
- Customer satisfaction (change/level)
 - from the patient perspective (their customers)
 - from the industry perspective (as customers)
- Increased resources for projects
- Increased patient concordance and adherence to therapy
- Reduction in treatment costs or release of budget to enable more patients to be treated by the use of more cost effective medicines

For the pharmaceutical company

- Market expansion with consequent proportionate increase in the appropriate use of specific medicines
- Share of newly diagnosed or existing patients prescribed an appropriate medicine in line with national guidelines*
- Greater use of specific medicines in line with national guidelines*
- Improved reputation
- Improved relationship and trust between the pharmaceutical company and the NHS

* If no national guidelines exist, the parties should agree appropriate treatment at the outset in line with local guidelines. Both parties to the Joint Working agreement must be comfortable that the proposed objectives and measures are ethical and in the best interest of patients.

Case Study - Coronary Heart Disease Guidelines

An example of the benefits of a 'Joint Working project for the implementation of guidelines for the primary prevention of coronary heart disease (CHD)' might be:

- Patient benefit – improved access to screening tests for CHD and appropriate interventions in line with national treatment guidelines
- NHS benefit – improvements in meeting national targets, reducing hospital admissions for heart attack or heart surgery
- Pharmaceutical company benefit – a higher number of patients identified with CHD is expected to lead to an increase in the number of patients treated with CHD medicines, including the company's medicine, in line with national treatment guidelines

9. Deciding to Take Part in Joint Working

During the consultation leading up to the publication of the Joint Working Toolkit, it was recognised that companies should be open and transparent about why they want to take part in Joint Working, including any commercial return on investment (ROI). It is acceptable for pharmaceutical companies to calculate ROI provided that governance arrangements are in place to ensure that the arrangements are appropriate (see Section 6).

The impression that is created by the arrangements for any Joint Working project must be kept in mind. Where companies enter into Joint Working projects on the basis of favourable ROI calculations and/or with inadequate documentation, this may raise a presumption that the Joint Working project is, in fact, promotional and possibly in breach of the ABPI Code and/or UK law.

Therefore, companies should consider the following:

- If made by pharmaceutical companies, ROI calculations should be set out in the context of patient care. It is recommended, in the interests of transparency, that the outcome of these ROI calculations is shared. However, it is accepted that either party has a right to withhold information that it regards as sensitive or commercially confidential. Where more than one pharmaceutical company is involved in a Joint Working project, any disclosure must not breach competition law (see Section 15)
- The aim of conducting any ROI analysis should be made clear, for example, to make decisions on resource utilisation. The results of such analyses can be used to inform future project design decisions but companies should not terminate a project solely on the basis of a negative ROI for its medicine(s) (see Section 11)
- Analysis of, and decisions about, Joint Working projects should be made only by those individuals who have resource allocation responsibilities within their individual organisations i.e. senior managers. Representatives as defined in Clause 1.6 of the ABPI Code must not be involved in such analysis or decision making
- It is acceptable to target Joint Working geographically according to:
 - Identified patient need. This will frequently coincide with the best use of resources for the NHS and the best overall return for the pharmaceutical company but, if not, it is reasonable to exclude opportunities that do not produce benefits for the pharmaceutical company or which are not cost effective for the NHS
 - Availability, experience and commitment of relevant personnel (NHS and pharmaceutical company) to deliver the project
 - Areas where the NHS has expressed a need or desire to improve benefits to patients by working together with the pharmaceutical company/companies

10. Joint Working Agreements

Every Joint Working project should have a formal, written document in place setting out what each party has agreed before the project begins. The precise nature of such documents will be determined by the particular project and the parties involved. Depending on the complexity of the Joint Working project, the obligations of each party could be written in a number of ways, such as a memorandum of understanding, engagement letter or a written agreement. Templates for written agreements and Joint Working framework documents are contained in the Joint Working Toolkit, Wales Health Circular WHC(2005)0016 and in A Common Understanding. Attention is also drawn to the certification requirements under Clause 14.3 of the ABPI Code. Each company should seek its own advice regarding contractual arrangements with the NHS.

Any agreement should clearly state the following:

- The name of the Joint Working project, the parties to the agreement, the date and the term of the agreement
- The expected benefits for patients, the NHS and the pharmaceutical company (see Section 7). Patient benefits should always be stated first and patient outcomes should be measured
- An outline of the financial arrangements

- The agreement should clearly spell out the roles and responsibilities of the NHS and the pharmaceutical company and how the success of the project will be measured, when and by whom. All aspects of input from the company should be included such as training, support for service redesign, business planning, data analysis etc
- The agreement should specify criteria that result in high certainty that both parties can meet their commitments. For example, both parties should be able to demonstrate that they have the capability, resource or track record to deliver on the commitments they are making
- The planned publication of any data or outcomes
- Procedures for dealing with Freedom of Information Act requests
- For situations where a number of companies are working together, the newly developed ABPI 'model agreement for outreach projects' (Joint Working between NHS organisations and pharmaceutical companies – with accompanying guidance notes) could be used. Feedback is requested from users so that this model agreement can be improved with experience
- If a pharmaceutical company enters into a Joint Working agreement on the basis that its product is already included in an appropriate place on the local formulary, a clear reference to this should be included in the Joint Working agreement so that all the parties are clear as to what has been agreed. For instance, it might be acceptable to state: *“On the basis that the Primary Care Trust / Health Board has previously placed [company x’s] medicine appropriately in the treatment guidelines for the treatment of [the condition] in line with local / national guidelines, the PCT/Health Board and [company x] have agreed to work together and provide funding and other support for this project.”* Any exit or termination provision linked to a company’s medicine(s) should be clearly explained and agreed in the contract (see Section 11)
- The agreement should include contingency arrangements to cover possible unforeseen circumstances such as changes to summaries of product characteristics and updated clinical guidance. Agreements should include a dispute resolution clause and disengagement/exit criteria including an acknowledgement by the parties that the project might need to be amended or stopped if a breach of the ABPI Code is ruled
- Companies must make public an executive summary of their Joint Working agreements, for example on a clearly defined website or section of a website and the NHS organisation should also be encouraged to publish these

11. Disengagement / Exit Criteria

Clearly defined, mutually agreed exit criteria must be written into Joint Working agreements at the outset. Clear end points in relation to timings, resources and budget commitments and outcomes will facilitate the disengagement /exit from a project.

During the course of the Joint Working project, if either party fails to deliver on its commitments, the other party can either exit or renegotiate and take reasonable steps to recoup its investment. In practice it may be difficult to establish whether a party is meeting its commitments unless these are very tightly defined at the outset.

Either party should be free to exit an agreement if it is demonstrated that patients are not deriving benefit from the project and must do so forthwith if it is found that the project is detrimental to patients.

Joint Working agreements should not be terminated by a pharmaceutical company solely on the grounds of a negative return on investment for its medicine(s).

12. Joint Working Projects and Clinical Guidelines

It is legitimate for a pharmaceutical company to support the development and implementation of NHS or other accepted clinical guidelines provided the company is open and transparent about its involvement in the guideline development process. As with any Joint Working project, there must be no inducement, directly or indirectly, for individual prescribers to prescribe, supply, administer, recommend, buy or sell any particular medicine.

The following points are intended to provide guidance for companies engaging in Joint Working projects involving clinical guidelines.

- If a company has supported a process of guideline creation independently from the Joint Working project, then supporting the subsequent implementation of those guidelines through Joint Working is acceptable provided that decisions about the prescription, supply, administration, recommendation, sale or purchase of medicines can clearly be seen to be separated from inappropriate company influence by appropriate governance arrangements (see Section 6)
- If clinical guidelines already exist and a Joint Working project simply involves implementing them, it still needs to be clear through appropriate governance arrangements that the pharmaceutical company is not inappropriately influencing decisions about the prescription, supply, administration, and recommendation etc of its products
- If clinical guidelines implement national guidelines or NHS targets, then measuring changes to the use of particular product(s) may be legitimate. If the clinical guidelines include a specific company medicine, then implementation of those guidelines through Joint Working with that company should be acceptable, provided the requirements of this guidance are met
- Therapy update or therapy review or change programmes may be acceptable as Joint Working projects provided that any changes to medication are not inappropriately influenced by pharmaceutical companies and the requirements of this guidance are met. Therapy reviews must not be a simple switch service as these are prohibited by the ABPI Code

13. Communicating Joint Working Projects within the Company

Companies may need to consider how sales representatives and other personnel are briefed in areas where Joint Working projects are underway to ensure that the Joint Working agreement is not infringed and that the project is not used inappropriately by sales representatives to gain access to customers or to influence prescribing. The importance of consistent communication within a company regarding Joint Working initiatives should not be underestimated.

If a Joint Working agreement exists between an NHS organisation and a company, promotion of the company's product(s) associated with the Joint Working project by sales representatives might cause a problem if it was seen to be intensified or targeted to individual health professionals involved in the initiative.

The role of sales representatives and others could be agreed as part of the Joint Working agreement. Inappropriate instructions from head office to sales representatives to focus promotion on health professionals in an area where Joint Working was in place might be seen as cause for a complaint under the ABPI Code.

Care should be taken to ensure that there is a consistent message communicated within and outside the company as to the nature and details of a Joint Working project.

It may be helpful for the NHS organisation and the pharmaceutical company involved to provide a joint communication to staff affected by the Joint Working project in order to ensure that there is transparency about the activities that have been agreed.

A Joint Working project could be exemplary in all respects, but still leave the company vulnerable to a complaint if misunderstanding or miscommunication took place within the company. For example, statements such as "The company is supporting this initiative as the NHS body has agreed to place [product x] in the first-line position for all patients and this is therefore an excellent opportunity to increase the sales of [product x]" are unlikely to be acceptable.

14. Using Data Obtained From Joint Working Projects

The combined effect of a number of laws and regulations such as the ABPI Code and health professional codes in relation to NHS data is to require the NHS and companies to implement procedures and governance arrangements to ensure compliance with the law and all codes, e.g. the Data Protection Act 1998 and the NHS Code of Practice on Confidentiality. Each company engaged in Joint Working should seek its own advice on these issues and enter into appropriate arrangements. The following are some general points to note:

- Use of anonymised patient data is preferable for Joint Working projects. Effective anonymisation generally requires more than just the removal of a patient's name and address. Full postcodes can identify individuals, a NHS Number can be a strong patient identifier and other information, e.g. date of birth, can also serve as a patient identifier, particularly if looked at in combination with other data items. If the NHS Trust cannot provide anonymised datasets, then the use of identifiable patient information to support a Joint Working project may well be appropriate and necessary, but normally requires explicit patient consent
- Under the ABPI Code, neither a pharmaceutical company nor its medical/generic representatives may be given access to data/records that could identify or could be linked to particular patients. This does not preclude individual employees from accessing patient identifiable information provided they are an appropriately qualified person (e.g. a healthcare professional, statistician) and not employed in a promotional role. A company involved in Joint Working should ensure that it keeps in place suitable information barriers between the employee and the company so that it is clear the employee will not disclose identifiable patient data to the company. Ideally, the company employee should sign an NHS honorary contract and, if applicable, a secondment agreement
- Given that Joint Working will involve NHS patients, it would be preferable to make clear in the Joint Working agreement (and/or secondment/NHS honorary contract) that the NHS organisation is the "data controller", i.e. the person or entity that determines the purpose and the means of any data processing. The data controller is ultimately responsible for ensuring that patient confidentiality and/or privacy are adequately protected

In addition, parties to a Joint Working project should bear in mind the following principles and rules and seek their own guidance where necessary:

- NHS Code of Practice on Confidentiality:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253
- NHS Code of Practice on Confidentiality (Wales):
<http://www.wales.nhs.uk/sites3/home.cfm?orgid=702>
- NHSScotland Code of Practice on Confidentiality
<http://www.confidentiality.scot.nhs.uk/publications/6074NHSCode.pdf>.
- NHS Code of Practice on Information Security Management:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074142
- Re-use of Public Sector Information Regulations: <http://www.opsi.gov.uk/si/si2005/20051515>
- Data Protection Act 1998: http://www.opsi.gov.uk/Acts/Acts1998/ukpga_19980029_en_1
- National Health Service Act 2006 (section 251):
http://www.opsi.gov.uk/Acts/acts2006/ukpga_20060041_en_1
- Caldicott Principles(England):
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_062722
(within the Caldicott Guardian Manual)
- Caldicott Principles (Wales):
<http://www.wales.nhs.uk/sites3/Documents/783/Caldicott%20Manual%20Final%20041108.pdf>

- Caldicott Principles (Scotland)
<http://www.elib.scot.nhs.uk/portal/ig/pages/index.aspx/caldicott.htm>
- Freedom of Information Act 2000: http://www.opsi.gov.uk/Acts/acts2000/ukpga_20000036_en_1
- Human Rights Act 1998: http://www.opsi.gov.uk/ACTS/acts1998/ukpga_19980042_en_1
- ISO 27001:2005:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074142
http://www.iso.org/iso/catalogue_detail?csnumber=42103 (not available for free)
- Computer Misuse Act 1990: http://www.opsi.gov.uk/acts/acts1990/UKpga_19900018_en_1.htm
- ABPI Guidelines for the Secondary Use of Data For Medical Research Purposes:
<http://www.abpi.org.uk/Details.asp?ProductID=315>

This list is not exhaustive and additional requirements may apply to particular projects.

15. Competition and Commercial in Confidence Issues

Joint Working projects may involve more than one pharmaceutical company and so competition and commercial in confidence issues may arise. Anti-competitive agreements, decisions or concerted practices between companies (e.g. agreeing prices or discount schemes with competitors) are illegal. Each company should seek its own advice to ensure that that it complies with competition law and enters into appropriate confidentiality agreements and other safeguards to keep its commercially sensitive information confidential. Where competing companies need to discuss setting up a Joint Working project they should consider the following 'best practice' advice:

- Establish a written understanding of the purpose and scope of the discussions to ensure that they remain consistent with the parties' objectives and do not stray into areas that could raise competition law issues (e.g. pricing, market practices). This could be in the "terms of reference" of a Joint Working steering group
- Create a written agenda for meetings and have it reviewed and approved in advance by legal counsel
- Consider whether legal counsel from at least one of the companies should be present at the meetings
- Take detailed minutes of the meetings that are reviewed and kept by legal counsel
- Limit participation to appropriate personnel who are briefed about the potential competition concerns and the importance of keeping to the approved agenda
- Do not disclose or discuss confidential or commercially sensitive information. In particular do not discuss, disclose confidential information or enter into agreements in the following areas:
 - the pricing of products or any company's commercial strategies
 - individual company cost components or structures, or the relationship between cost and price in the industry generally
 - allocation of markets or market practices, either in relation to particular customers or geographical regions
 - actual or potential company-specific customer relationships
 - actual or potential bidding opportunities, and each other's responses to such opportunities

- individual company or industry production levels, capacities, or inventories, or individual company market shares or
- research and development activities or results
- Avoid discussions relating to any other business matters

16. Other considerations

In addition to the ABPI Code other legal and regulatory considerations may apply to any Joint Working project and each company should seek its own advice where necessary so that it complies with the law. Particular care must be taken if it is likely that an individual physician or NHS employee could benefit personally from any Joint Working arrangements. This is because UK corruption laws (including the Public Bodies Corrupt Practices Act 1889 and the Prevention of Corruption Acts 1906 and 1916) and comparable legislation in the United States (the Foreign Corrupt Practices Act), prohibit the “corrupt” offer, payment or gift of any money or thing of value to public body officials for the purpose of obtaining or retaining business or obtaining any improper business advantage. Please note that the Prevention of Corruption Act 1906 extends to bribery of private persons, e.g. healthcare professionals operating in the private sector.

Although the NHS as an organisation may benefit from Joint Working projects, this is unlikely to breach anti-corruption laws unless one or more public body officials (e.g. an individual NHS healthcare professional or NHS employee) is offered or receives a personal benefit from a particular Joint Working project. Companies should take particular care when entering into Joint Working involving GP practices, as the individual partners in these practices may receive an indirect personal benefit as a result of any benefit to the practice that they own. That is why it is preferable to agree primary care Joint Working projects at the PCT / Health Board level or above.