

**Guidance for partnership working between NHS
organisations, primary care contractors, the
pharmaceutical industry and the allied
commercial sector in Wales**

August 2004

Contents

Executive Summary	3
Introduction	4
Considerations and Actions	5
Hospitality and Meetings	6
Monitoring Arrangements	6
Research and Development	7
Examples of Potential Conflict	7
References	7
Annex 1: Prescription Medicines Code of Practice Authority	8
Annex 2: Collaborative Partnerships	10
Annex 3: Model Code of Conduct	12
Annex 4: Research and Development	13
Annex 5: Annual Declaration of Interests in the Pharmaceutical Industry	14
Annex 6: Joint Working Initiative Assessment Checklist – A Guideline	16
Annex 7: Suggested Service Agreement Template Checklist	19
Annex 8: Examples of Potential Conflict	21
Acknowledgements	22
Glossary	23

Executive Summary

Background

NHS Wales wishes to develop innovative partnerships that benefit patients and achieve improved health outcomes for the people of Wales. This may be achieved through collaborative projects within short and long-term partnership arrangements based on the following set of core values:

- Patients needs come first;
- Openness and transparency;
- Mutual trust, honesty and respect;
- Responsibility and accountability;
- Alignment with healthcare priorities;
- A balanced whole systems approach to healthcare;
- Cost effectiveness.

This guidance aims to encourage an open and transparent approach to partnership working between NHS Wales, the pharmaceutical industry and allied commercial sector.

Partnership, in the context of this document, refers to situations where the organisations involved pool skills, experience and/or resources for the joint development and implementation of specific projects. Partner individuals or organisations have equal ownership of the projects aims and strategy and there is a shared commitment to it's successful delivery (1)

There is an interdependent relationship between the pharmaceutical industry, the allied commercial sector and NHS Wales and on occasions it may be in the interest of patients to explore and develop partnership arrangements within a clear ethical framework. Whilst the need for the pharmaceutical industry and allied commercial sector to maintain profitability and promote specific products is acknowledged this must not conflict with the requirement of NHS Wales to ensure evidence based decision-making, equity and cost effectiveness.

The pharmaceutical industry and allied commercial sector welcome the opportunity to form partnership arrangements with NHS Wales for the benefit of patients in Wales. For member

companies of the Association of British Pharmaceutical Industry (ABPI) such partnership arrangements should comply with the ABPI Code of Practice. Reports of breaches of this Code are encouraged and should be reported to the Prescription Medicines Code of Practice Authority.

Summary

All partnership working must be for the benefit of patients.

Partners are expected to behave professionally and comply with their own professional and or organisation's code of conduct.

Partnership arrangements should be recorded with a summary being made available to all on request.

Partnership arrangements should be open and transparent, have a signed agreement with declared objectives and a minimum of a start and finish date.

Where collaborative partnerships involve the pharmaceutical industry and allied commercial sector, then the proposed arrangements must comply fully with the Medicines (Advertising) Regulations 1994.

Whatever type of agreement is entered into, a prescriber's judgement should be based upon best available evidence that the product is appropriate for patients in line with evidence-based practice and cost effectiveness.

All patients' identification should be removed from data in line with the Data Protection Act to respect and preserve patient confidentiality.

A partnership agreement should not be seen as an on-going endorsement or promotion of a specific medicine or technology.

Introduction

1. This guidance applies to all health professionals and non-healthcare professionals working in NHS Wales. This includes independent contractors and locum practitioners, either working under NHS terms and conditions, or contracted to the NHS and their employees.
2. NHS Wales encourages Local Health Boards, NHS Trusts and educational providers to work together and in collaboration with other agencies to improve the health of the population they serve and the health services provided for that population.
3. The pharmaceutical industry and allied commercial sector in particular welcome the opportunity to function as a partner with NHS Wales to deliver improvements in health outcomes. The pharmaceutical industry and allied commercial sector support a professional basis for such arrangements. Probity and consistency of approach is assured for the ABPI member companies through enforcement of the ABPI Code of Practice which in turn complies with and supplements the Medicines (Advertising) Regulations 1994 (see Annex 1)
4. If a partnership is to work, there must be trust and reasonable contact between the pharmaceutical industry and allied commercial sector and the NHS. Such relationships, if properly managed, may provide mutual benefit to the organisations involved. Examples of collaborative partnerships are given in Annex 2. The NHSIF will produce and maintain a database of other collaborative partnerships.
5. A previous circular on *Standards of Business Conduct for NHS Staff* was issued in 1993 (2) and is extant. This and other papers (3-6) have informed this new guidance. Its purpose is to emphasise that NHS Organisations and Primary Care Contractors are accountable for achieving the best possible health care within the resources available. It advises them to consider fully the implications of a proposed partnership before entering into any arrangement. In particular it is important to seek advice when necessary from Local Health Boards and NHS Trusts on the effect on other parts of the NHS.
6. For the purposes of this guidance, partnership arrangements may include:
 - funding of all or part of the costs of: a member of staff, NHS research, staff training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, hotel and transport costs, or the provision of free services such as speakers or premises.In all these cases NHS organisations and Primary Care contractors should use local arrangements to publicly declare partnership arrangements particularly those linked to the supply of goods or services and be prepared to be held to account for it. A simple ledger may suffice to avoid any unnecessary paperwork.
7. The definition of partnership arrangements in paragraph 6 does not apply to:
 - personal gifts and sponsorship of less than £25 per gift e.g. gifts of post-it pads, pens etc. However gifts should be declared if several small gifts worth a total of over £100 are received from the same or closely related source in a 12 month period. (Note: The ABPI Code of Practice (6) permits the provision of a promotional aid, which costs the company no more than £6 plus VAT).
 - gifts from patients.
 - discounts on particular products.
8. Where partnerships involve the pharmaceutical industry and allied commercial sector then the proposed arrangements must comply with the Medicines (Advertising) Regulations 1994 (regulation 21 'Inducements and hospitality' attached at annex 1).

9. Whatever type of agreement is entered into, a prescriber's judgement should always be based upon clinical evidence that the product is appropriate for their patients in line with evidence-based practice and cost effectiveness.

A model code of conduct is attached at Annex 3, for use by those who do not have an existing professional code of conduct. Where an employer's code is used, this should be in addition to professional codes, or be for the benefit of those staff who are not regulated.

Considerations and Actions

10. NHS employers and Primary Care contractors should:

- make all staff aware of NHS guidance, the relevant legislation and appropriate professional codes of conduct and guidance, e.g. GMC, NMC, RPSGB, ABPI, HPC codes
- take responsibility for ensuring that they and their staff adhere to their professional code. The code should contain clear guidance on partnership working;
- ensure all partnership arrangements are documented through use of a register or simple ledger, held by the employer and which can be audited as appropriate. In order to demonstrate openness, it is essential that the register should be available on request to the public;
- be aware that arrangements whereby the partnership is linked to the purchase of particular products, or to supply from particular sources, are not allowed, unless as a result of a transparent tender for a defined package of goods and services, (see Annex 4 on research and development);
- ensure all staff record with their employer, in the interests of transparency, any material financial interest in organisations

(e.g. company shares or research grants) which impact upon funding, whether through contracts, sales or other arrangements that they may make with non NHS organisations. An official register should be established and maintained to demonstrate openness (see template at Annex 5).

11. Before entering into any partnership arrangements, NHS organisations and Primary Care contractors should satisfy themselves that:

- purchasing decisions, including those concerning pharmaceuticals and appliances, should always be taken on the basis of best clinical practice and value for money. Such decisions should take into account their impact on other parts of the health care system e.g. products dispensed in hospital which are likely to be required by patients regularly from their general practitioner;
- there are no potential irregularities that may affect a pharmaceutical company's ability to meet the conditions of the agreement or impact on it in any way e.g. checking financial standing by referring to company accounts;
- a cost benefit assessment has been made in relation to alternative options where applicable, and to ensure that the decision-making process is transparent and defensible;
- legal and ethical restrictions on the disclosure of confidential patient information, or data derived from such information, are complied with. Additionally, disclosure for research purposes should not take place without the approval of the appropriate research ethics committee;
- clinical and financial outcomes will be monitored;
- the partnership agreement has break clauses built in to enable the

partners to terminate the agreement if it becomes clear that it is not providing expected value for money/ clinical outcomes;

- partnership arrangements involving NHS bodies should be at a corporate, rather than individual level;
 - the costs and benefits of any agreement are understood; (Guidelines for: Joint Working Initiative Assessment Checklist; and a Suggested Service Agreement Template are contained at Annexes 6 & 7 respectively).
12. Existing contracts, which include any element of partnership, should be reviewed and any clauses, which do not follow the recommendations set out above, should, where possible, be renegotiated.

In particular note

- The Code of Practice on Openness in the NHS and the additional implications of the Freedom of Information Act both now and when access rights come into force on 1 January 2005;
 - Standing Orders and Standing Financial Instructions of NHS Organisations should be reviewed to ensure that this guidance does not conflict with locally agreed procedures. Where there is a conflict the Standing Orders could be amended;
 - Clinical accountability of projects must always be under local control;
 - Development of prescribing or clinical guidelines and protocols should be developed in accordance with local clinical and corporate governance procedures;
 - The use of patient data is subject to the Data Protection Act.
13. NHS organisations and Primary Care contractors should review their arrangements for working with the

pharmaceutical industry and allied commercial sector on an annual basis. This should include:

- a summary of all partnership arrangements reached;
- a summary of all pharmaceutical industry contacts and allied commercial sector contacts (in relation to partnership arrangements);
- a summary of any problems and difficulties encountered (in relation to partnership arrangements);
- a summary of ongoing partnership arrangements; and
- changes to the register of interests.

Hospitality and Meetings

14. Pharmaceutical industry and allied commercial sector representatives organising meetings are permitted to provide appropriate hospitality and/or meet any reasonable, actual costs, which may have been incurred. If none is required, there is no obligation, or right, to provide any such hospitality, or indeed any benefit of equivalent value.
15. Hospitality must be secondary to the purpose of the meeting. The level of hospitality offered must be appropriate and not out of proportion to the occasion; and the costs involved must not exceed that level which the recipients would normally adopt when paying for themselves, or that which could be reciprocated by the NHS. It should not extend beyond those whose role makes it appropriate for them to attend the meeting.
16. Where meetings are funded by the pharmaceutical industry or allied commercial sector that fact must be disclosed in the papers relating to the meeting and in any published proceedings.

Monitoring Arrangements

17. Employers should ensure that monitoring arrangements are

established to ensure that staff register any partnership working and are held accountable for it. This may be through scrutiny by an appropriate committee, e.g. local audit or ethics committees, as part of their normal activity, as well as through publication in the Annual Report, where this is practicable. An official Register of Interests should be established and maintained as part of the monitoring arrangements. At corporate level, employers should ensure that contract negotiations are conducted according to high ethical standards.

Employers finding evidence of unrecorded partnership arrangements should act swiftly to deal with the situation and bring it within their local arrangements. Records of partnership arrangements should be kept in accordance with WHC (2000)71, Managing records in NHS Trusts and Health Authorities.

Research and development

18. Guidance on research and development is contained in Annex 4.

Examples of Potential Conflict

19. Some examples of potential conflict which may lead to poor performance are set out at Annex 8.

References

1. The Critical Care Experience March 2004 - Forming Productive Partnerships with Industry. Modernisation Agency Critical Care Programme.
2. Standards of Business Conduct for NHS Staff, 1993. DGM (93) 84.
3. Commercial sponsorship. Ethical Standards for the NHS. Department of Health, November 2000
4. Code of Practice for Health Authority Staff Relationships with Pharmaceutical Companies (Final Draft), All Wales Medicines Forum, 2001.
5. A Common Understanding. Guidance on the Joint Working between NHS Scotland and the Pharmaceutical Industry, Scottish Executive, Edinburgh 2003.
6. Code of Practice for the Pharmaceutical Industry. ABPI 2003
7. R&D Funding in Wales: Treatment and Services Support Costs, DGM(97)87
8. SAMM Guidelines: Guidelines for Company Sponsored Safety Assessment of Marketed Medicines. London: MCA, 1993
9. NHS Indemnity: Arrangements for Handling Clinical Negligence Claims Against NHS Staff, WHC(98)8

ANNEX 1

Prescription Medicines Code of Practice Authority

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 ABPI itself.

The Code of Practice for the Industry was introduced in 1958. Copies of the code are available from the PMCPA, www.abpi.org.uk or www.emc.vhn.net/. It covers and extends beyond the legal requirements in the UK.

Compliance with the code is obligatory for ABPI member companies and, in addition, about 70 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 employees/independent contractors and also covers information about such 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, 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 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 and includes independent members from outside the industry.

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 should be sent to the Director of the Prescription Medicines Code of Practice Authority, 12 Whitehall, London, SW1A 2DY (telephone 020 7930 9677, facsimile 020 7930 4554). The Authority can also be contacted for informal advice.

Extract from The Medicines (Advertising) Regulations 1994

Inducements and hospitality

21. (1) Subject to paragraphs (2) and (4), where relevant medicinal products are being promoted to persons qualified to prescribe or supply relevant medicinal products, no person shall supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy.

(2) The provisions of paragraph (1) shall not prevent any person offering hospitality (including the payment of travelling and accommodation expenses) at events for purely professional or scientific purposes to persons qualified to prescribe or supply relevant medicinal products, provided that –

- (a) such hospitality is at a reasonable level,
- (b) it is subordinate to the main scientific objective of the meeting, and
- (c) it is offered only to health professionals.

(3) Subject to paragraph (4), no person shall offer hospitality (including the payment of travelling or accommodation expenses) at a meeting or event held for the promotion of relevant medicinal products unless –

- (a) such hospitality is reasonable in level,
- (b) it is subordinate to the main purpose of the meeting or event, and
- (c) the person to whom it is offered is a health professional.

(4) Nothing in this regulation shall affect measures or trade practices, relating to prices, margins or discounts, which were in existence on 1 January 1993.

(5) No person qualified to prescribe or supply relevant medicinal products shall solicit or accept any gift, pecuniary advantage, benefit in kind, hospitality or sponsorship prohibited by this regulation.

Any person who contravenes regulation 21(1) is guilty of an offence, and liable, on summary conviction to a fine not exceeding £5000, and on conviction on indictment to a fine, or to imprisonment for a term not exceeding two years, or both. Anyone contravening 21(5) is also guilty of an offence and liable, on summary conviction to a fine not exceeding £5000.

ANNEX 2

Collaborative Partnerships: Exemplar 1

Representatives from the Association of the British Pharmaceutical Industry (ABPI) Cymru Wales Industry Group have been invited by Welsh Assembly Government to join the National Service Frameworks' (NSF) project boards in Wales. Currently representation has been invited to the Diabetes NSF Project Board, Older People NSF Project Board, Proposed Respiratory NSF Project Board and Proposed Children's NSF Project Board.

Diabetes National Service Framework Delivery Strategy Roadshow

A collaboration project between the Welsh Assembly Government and the ABPI Cymru Wales Industry Group (WIG).

The Diabetes National Service Framework for Wales was launched in March 2003. A Diabetes National Framework Project Board was established and the pharmaceutical industry was invited to be represented.

It was decided that the Diabetes NSF for Wales would be launched at Roadshow meetings across Wales and members of the Diabetes Sub-Group of the ABPI Cymru Wales Industry Group (WIG) offered to be the main supporting partners. These workshops were arranged in collaboration with the Diabetes NSF Project Board and took place in Cardiff, Carmarthen, Newport, Mold, Swansea and Bangor during September 2003. An audience in excess of 700 had the opportunity to listen to almost 40 local speakers with regard to the challenges of managing diabetes and achieving the targets as outlined in the Diabetes NSF for Wales.

In addition, the Diabetes Sub-Group members are the main supporting partner and provide the necessary know-how to establish a diabetes specific web-site for patients and clinicians in Wales. This can be found at **www.diabetesnsfwales.com** and will include the presentations from the roadshow meetings and an edited video of certain presentations.

The Diabetes Sub-Group has also developed a compendium of currently available support resources designed to help implement the NSF in Wales. Copies of this compendium are available from the office of the ABPI Cymru Wales on 02920 454297.

ANNEX 2 (cont)

Collaborative Partnerships: Exemplar 2

There was a desire to maximise the resources available from the industry within a partnership framework in order to avoid unnecessary duplication of effort and to offer tools to assist in the management of heart disease in Wales.

Coronary Heart Disease (CHD) Compendium of Resources

Collaboration project between the Cardiac Networks of Wales and the ABPI Cymru Wales Industry Group (WIG).

The main objective of the CHD Compendium of Resources was to bring together materials to help Primary and Secondary care across Wales to implement the guidance found in *Tackling Coronary Heart Disease in Wales: Implementing through Evidence*.

The pack itself offers;

- Background to the Compendium
- Role and function of the CHD Sub-Group from ABPI Cymru Wales Industry Group in working with the Cardiac Networks of Wales
- How to establish a Partnership Framework
- A Partnership Summary Form

Utilisation and selection of resources from this compendium commenced in September 2003.

A copy of the compendium is available on the HOWIS website or from the office of the ABPI Cymru Wales on 02920 454297.

ANNEX 3

Model Code of Conduct

NHS staff and independent contractors working for the NHS should follow existing codes of conduct. Staff who are not covered by such a code are expected to:

- act impartially in all their work;
- refuse gifts, benefits, hospitality or sponsorship of any kind which might reasonably be seen to compromise their personal judgement or integrity, and to avoid seeking influence to obtain preferential consideration. All such gifts should be returned and hospitality refused;
- declare and register gifts, benefits, or partnership arrangements of any kind, in accordance with time limits agreed locally, (provided that they are worth at least £25), whether refused or accepted. In addition gifts should be declared if several small gifts worth a total of over £100 are received from the same or closely related source in a 12 month period. The ABPI Code of Practice permits the provision of promotional aids, which costs the company no more than £6 plus VAT.
- Declare and record material financial or personal interest (e.g. company shares, research grant) in any organisation with which they have to deal, and be prepared to withdraw from those dealings if required, thereby ensuring that their professional judgement is not influenced by such considerations;
- not misuse their official position or information acquired in the course of their official duties, to further their private interests or those of others;
- ensure professional registration (if applicable) and/or status are not used in the promotion of commercial products or services;
- beware of bias generated through partnership arrangements, where this might impinge on professional judgement and impartiality;
- neither agrees to practise under any conditions, which compromise professional independence or judgement, nor impose such conditions on other professionals.

ANNEX 4

Research and Development

1. Exceptionally, in the case of non-commercial research and development (R&D) originated or hosted by NHS providers, commercial sponsorship may be linked to the purchase of particular products, or to supply from particular sources. This should be in accordance with the guidance of *R&D Funding in Wales: Treatment and Services Support Costs (6)*. Where there is industry collaboration in such studies, companies may alternatively make a contribution towards the study's costs, rather than supply of product.
2. Any funding for research purposes should be transparent and have been approved by the local research ethics committee and multi-centre research ethics committee where appropriate. There should be no incentive to prescribe more of any particular treatment or product other than in accordance with the peer reviewed and mutually agreed protocol for the specific research intended. When considering a research proposal, whether funded in whole or part by industry, NHS bodies and the industry involved must consider how the continuing costs of any pharmaceutical or other treatment initiated during the research will be managed once the study has ended.
3. Separate Guidelines exist for pharmaceutical company Sponsored Safety Assessment of Market Medicines (SAMM) which remain in force (7).
4. Where R&D is primarily for commercial purposes, NHS providers are expected to recover the full cost from the pharmaceutical industry and/or allied commercial sector on whose behalf it is carried out.
5. The NHS should benefit from commercial exploitation of intellectual property derived from R&D that the NHS has funded, or for which it has been funded, even where the intellectual property itself is owned by people outside the NHS. NHS bodies should ensure that an agreement to this effect is included in any contracts concerning R&D.

ANNEX 6

Joint Working Initiative Assessment Checklist – A Guideline

1. General

A checklist is available to help NHS organisations and Primary Care contractors in Wales assess whether proposals/ requests for support from the pharmaceutical industry and allied commercial sector offer appropriate opportunities for partnership.

Partnership with the pharmaceutical industry and allied commercial sector should aim to support the overall objectives and requirements of the organisation and be in keeping with the objectives and priorities of the NHS.

These arrangements should demonstrate tangible benefits to individual patient management and to the organisation and support or, at minimum, not be in conflict with the activities and decisions of the NHS. Agreements to participate in these programmes should:

- Consider their overall purpose;
- Have reference to any issues of probity and transparency in respect of their objectives and compliance with relevant legislation;

Agreements should consider the proposed initiatives' clinical effectiveness, value for money and equity and take account of the requirements of patient confidentiality.

Any such agreement must be documented in the Register of Interests.

Questions in the checklist should be able to be answered positively. Organisations should discuss proposed joint working with pharmaceutical industry and allied commercial sector partners with their employer before proceeding with any agreement.

2. Data and Confidentiality Issues

A clinician should give written consent for his or her own patients to be involved or for their patients' data to be used in any way. If patient data is used, such use must be in compliance with the Data Protection Act 1998. This normally requires advance permission being sought from the patient and informing the patient in general terms about the proposed use of their data, including:

- How the data may be used;
- Who will have access to the data;
- The organisations data may be disclosed to;
- Who is responsible for the data;
- Their right to impose restrictions (where the patient is offered a choice about how information about them is to be used).

If practice/clinic or patient data are to be used, there must be a clear statement included in the Service Agreement regarding:

- Who will have access to those data and in what form (i.e. aggregation and anonymisation criteria)?
- How, where and by whom those data will be manipulated?

- To what purpose will the data be put?

In maintaining confidentiality, if direct contact with patients is required:

- It is the responsibility of the practice/clinic to identify patients who may be eligible;
- It is the responsibility of the practice/clinic to inform and invite patients to participate;
- Any invitation should indicate that the patient is under no obligation to take part;
- Prior to patient involvement in the programme, informed consent must be obtained;

If data are stored electronically then:

- Any patient-identifiable information must be retained for use solely within the practice/clinic except with prior express written agreement of the patient;
- Data must be password protected;
- There must be a clearly defined protocol for satisfactory data encryption;
- This should be at practice/clinic level with patient codes held within the practice/clinic (similar to a clinical trial). Encryption must not rely on identifiers such as patient name, NHS number, practice/clinic computer ID codes, addresses or postcode.

If data are to be aggregated, then:

- The practice/clinic must have a clear understanding of how the data are to be used;
- There must be a clearly defined protocol for data management, which includes information on the nature and “ownership” of the aggregated data and protocols to govern requests for access to that data;
- No practice/clinic -level data should be identifiable from the aggregated data set;
- The practice/clinic should have the option not to share their data as part of the aggregated data set if they wish;

Before any service is implemented, the following external issues will also need to be addressed:

All practice/clinic staff must be aware of, and have agreed to participate as appropriate, with the proposed service. They should:

- Agree clearly who is responsible for supervising, reporting and seeking approval for the partnership from the employer (e.g. Trust, LHB, independent contractor) and any other relevant healthcare person or organisation as appropriate, e.g. Hospital Consultants, Practice Manager.
- Be satisfied that any information or materials to support the proposed service is valid, evidence-based, balanced, contemporaneous, and non-promotional.
- Ensure that appropriate professional indemnity and liability arrangements are in place

Organisations should make arrangements to involve or make patients aware of the service as early as practically possible.

Organisations should agree a process for reviewing the service at appropriate intervals and assessing the success of the service in achieving its stated objectives. Organisations may wish to involve patients in this process.

ANNEX 6 (cont.) 3. Checklist		YES	NO
1	Is the organisation satisfied with its knowledge of the sponsoring organisation(s), -i.e. is there evidence of audited accounts, is the organisation and its ownership known, is it capable of being independently audited?		
2	Does the support on offer align with current views on evidence-based clinical practice?		
3	Is the service on offer consistent with organisation and NHS priorities?		
4	Has the organisation documented the service in any local register of interests?		
5	Is the organisation satisfied that the offer is independent of purchasing or prescribing decisions?		
6	Is this or a similar service available from another local source e.g. LHB, practice or NHS Trust? Can it be compared favourably with any other?		
7	Can participants confirm that there is no current or potential conflict of interest for the organisation or any others in relation to the service offered?		
8	Have all participants discussed the proposed service? Are the participants prepared for their registered patients to be involved and are they willing to sign any service agreement?		
9	Will the organisation be provided with a fully documented service agreement that covers: <ul style="list-style-type: none"> ▪ The aims and objectives of the service ▪ An outline of the accountability framework within which the service will operate ▪ The protocols to be used on the programme including a full description of the service(s) to be provided and the names and details of personnel to be involved ▪ The procedure to be followed in the event of any adverse incidents ▪ For clinical services, the professional indemnity and liability arrangements that the service provider has in place ▪ The option to modify or suspend the service in the light of any assessments, evaluations or adverse events ▪ The option for either party to withdraw, with agreed and clearly defined notice periods on both sides 		
10	Are the skills, competencies, professional status and qualifications of the named individuals who will be providing the service of a sufficient level to provide the service effectively, efficiently and reliably?		
11	Are the lines of accountability of that individual – clinical, professional and managerial – clearly documented and appropriate?		
12	If the service requires direct access to patients or to patients' information, is the organisation satisfied that both it and the service provider can meet the requirements outlined in the section on "Data and Confidentiality Issues"?		
13	Research Ethics Committee approval is not required for the service?		

The above questions in the checklist should be answered affirmatively. If not, participants should seek further advice from their employer.

The organisation and the service provider should hold copies of all Service Agreements. It would be best practice for the employer to hold copies of all Service Agreements.

ANNEX 7

Suggested Service Agreement Template Checklist

NHS Organisation:

Service agreement with:

Title of project:	Title by which the project will be known.
Aim of project:	Clearly define the aim/s of the project.
Project objectives:	List of clearly defined objectives describing exactly what the project has been established to achieve.
Service to be provided:	<p>Clear description of exactly what the pharmaceutical industry and allied commercial sector will do. This will identify all services to be provided by the company. It will also identify any areas or activities in which the company must not be involved or where approval by the employer must be obtained.</p> <p>Details of how the project will be taken forward, personnel to be involved and how the project will be managed must be stated.</p>
Period of agreement:	The period or duration of agreement is to be specified.
Financial implications:	<p>The amount and duration of any funding must be agreed in advance and mechanisms must be in place to amend or adjust the funding arrangements during the course of the project.</p> <p>There must be clear and unambiguous arrangements regarding the longer term funding for projects which may have a duration beyond that envisaged by the initial project.</p> <p>Funding must not be contingent upon any arrangement to use a specific product other than in circumstances where this is the basis of the project itself (for example, a clinical trial) or provide positive references about a company sponsoring, supporting or working in partnership with the NHS organisation.</p> <p>Financial arrangements should not be entered into with a single individual from the company but should be entered into with the company and approved by a senior member of the company, as appropriate.</p> <p>Funding must be kept in separate accounts and must comply with current accounting conventions adhered to by the NHS and be available for audit by both external and internal auditors and the organisation's Audit Committee.</p> <p>Income and of expenditure should be in balance at the end of the project and the initial agreement should ensure the NHS organisation is not left with any deficit as a result of project, unless as a result of its failure to perform appropriately.</p>

Methods of payment:	<p>Payment terms must be agreed in advance. The organisation should not commit to any start up costs for which no funding has been agreed and received in advance.</p> <p>The method for making payments or receiving funding must be identified and comply with Standing Orders and Standing Financial Instructions.</p>
Period of notice:	The period of notice by which the agreement may be terminated by either party must be stated.
Performance:	The performance monitoring methodology and arrangements must be clearly stated.
Variation:	Arrangements for any mutual variation of the contract must be specified.
Unsatisfactory performance:	The methods for dealing with unsatisfactory performance must be stated.
Arbitration:	Arrangements for arbitration or other disputes resolution mechanisms must be stated.
Confidentiality:	A comprehensive Confidentiality Clause must be included (See Annexe 4, paragraph 2: <i>Data and Confidentiality Issues.</i>)
Legality:	The agreement must state that appropriate consideration has been given to the legal implications of the joint work. (Note: Pharmaceutical Companies and allied commercial sector will usually be required to have appropriate sanction from their Legal Departments.)
Agreement:	The agreement must be signed by appropriate representatives from each organisation.

ANNEX 8

Examples of potential 'Conflict of Interest' which may lead to poor practice

It may be helpful to give some examples of potential conflict and how they could be dealt with.

A. *A prescriber wishes to include a new drug, manufactured by a company with which he has links e.g. company shares, research grant, in the Trust Formulary.* Trust committee (e.g. Drug and Therapeutics Committee) should require declarations of interest from prescribers 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 industry company wishes to present the case for a new product being included on a Trust or Board Formulary.* The Trust or Board should establish and adopt a policy on approaches from industry representatives. Industry representatives should be required to sign up to compliance with such a policy before being given access to any meetings.

C. *Offer from a company to provide training of staff.* Employers should be careful to ensure that staff are not pressurised by sponsors of training, to alter their own activity to accord with sponsors' wishes, where these are not backed up by appropriate evidence. Training provided by industry may be above board if it is unbiased has mutual benefit for both the NHS and the sponsoring company, is evidence based and the hospitality is appropriate. However participants should assess whether they may be influenced unduly and also bear in mind what benefits the company might derive.

D. *A manufacturer of ostomy equipment offers to sponsor a stoma nurse post in an NHS Trust.* The Trust should not accept the sponsorship if it would require the stoma nurse to recommend the sponsor's in preference to other clinically appropriate appliances, nor if it requires the Trust to recommend patients to use a particular dispensing service or withhold information about other products.

E. *A pharmaceutical company offers, as part of an approved partnership agreement, to provide starter packs at a discounted price.* This type of financial arrangement is acceptable, but should always be declared in order to avoid any suspicion that subsequent prescribing might be inappropriate and linked to the provision of starter packs.

F. *A company offers to provide discounted products to an NHS Trust.* This agreement is acceptable, but should be routinely declared to the NHS Trust.

G. *High tech home health care provider offers to supply equipment at reduced rate in return for business linked to a specific product.* NHS contract negotiators should advise the company that any contract will not prejudice the provision of the most appropriate service to patients, and will not bear any relation to other contracts.

H. *A manufacturer offers to pay the travelling costs or accommodation costs for clinicians invited to a conference to view medical products or a pharmaceutical company offers to pay the travelling costs, registration fee or accommodation costs for a clinician to attend a clinical symposium or conference.* Only clinicians with a specific interest in the products/therapy area should attend and the travel costs incurred should be paid for by the trust, unless the Chief Executive/Director of Finance (or one of their nominees) gives approval for the potential supplier to take responsibility for the costs. Such decisions should be taken at least at executive director level. A report on the benefits to patient care and/or service provision covered by the conference should be shared with interested colleagues.

Acknowledgements

The NHSIF is grateful to the following for help and advice in writing this partnership guidance:

- Gemma Nye, Welsh Assembly Government;
- Members, NHS Industry Forum;
- Members, All Wales Prescribing Advisory Group;
- Members, All Wales Medicines Strategy Group.

Full details on membership of above groups may be found at:
www.wales.nhs.uk/sites/home.cfm?orgid=371

Glossary of Terms

TERM	MEANING
ABPI	Association of British Pharmaceutical Industry
ABPI Code of Practice	To ensure that promotion of medicines to members of the health professions and to administrative staff is carried out in a responsible, ethical and professional manner. Also covers information about such medicines made available to the general public
Arbitration	Hearing and settling of a dispute by an impartial referee chosen by both sides
Code of Practice on Openness in the NHS	Sets out the basic principles underlying public access to information about the NHS.
Collaborative	Work together in a joint intellectual effort for mutual benefit.
Commercial	Supply of a product or service to NHS Wales for financial return.
Data Protection Act	Ensures appropriate handling of information according to eight principles.
Educational Providers	Organisations/institutions providing education material to/for NHS staff.
Ethical	Being in accordance with the accepted principles of right and wrong that govern the conduct of a profession.
Freedom of Information Act	Gives general right of access to all types of “recorded” information held by public authorities, sets out exemptions from that right and places a number of obligations on public authorities.
Hospitality	Provision of friendly and generous reception and entertainment of guests
Indemnity	Security against damage and loss, exemption from penalty, compensation for damage
Locum practitioners	Temporary person who practices a profession
Medicines (Advertising) Regulations 1994	See Annex 1
NHS Wales	NHS Wales is the structure providing comprehensive

	health care to people in Wales. The Welsh Assembly Government is responsible for policy direction and for allocating funds to the NHS in Wales. The NHS in Wales provides four levels of care – namely primary care, secondary care, tertiary care and community care.
NHS Organisations	Trusts and Local Health Boards
Objectives	Aims or purposes that guide action.
Partnerships	Partnership, in the context of this document, refers to situations where the organisations involved pool skills, experience and/or resources for the joint development and implementation of specific projects. Partner individuals or organisations have equal ownership of the projects aims and strategy and there is a shared commitment to it's successful delivery (1).
Pharmaceutical Industry and allied commercial sector	Supplier of product or service to NHS Wales used in the treatment and care of patients.
Prescription Medicines Code of Practice Authority	See Annex 1
Probity	Unimpeachable honesty, integrity and virtue.
Promotion	Encourage the sale of by advertising (directly and indirectly)
Royalties	Payment to an NHS body
Sponsorship	Provide funding for project or event.
Standing Financial Instructions	Covers all aspects of financial management and control. In effect they set the business rule which Directors and employees must follow when taking action on behalf of the board.
Standing Orders	Prescribe the terms on which committees and sub-committees of the Board may have delegated functions, and should include the schedule of decisions reserved for the Board.
Transparency	Full, accurate and timely disclosure of information.

End