All Wales Medicines Strategy Group

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

Guidance for Partnership Working Between NHS Organisations, Primary Care Contractors, the Pharmaceutical Industry and Allied Commercial Sector in Wales

June 2004

(Reviewed and updated September 2016)

This document has been prepared by a multiprofessional collaborative group, with support from the All Wales Prescribing Advisory Group (AWPAG) and the All Wales Therapeutics and Toxicology Centre (AWTTC), and has subsequently been endorsed by the All Wales Medicines Strategy Group (AWMSG).

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EXECUTIVE SUMMARY BACKGROUND

NHS Wales wishes to develop prudent, innovative partnerships that benefit patients and achieve improved health outcomes for the people of Wales. This may be achieved through projects within short- and long-term partnership arrangements based on Prudent Healthcare Principles[1]:

- Principle 1 – Achieve health and well-being, with the public, patients and professionals as equal partners through co-production.
- Principle 2 – Care for those with the greatest health need first, making most effective use of all skills and resources.
- Principle 3 – Do only what is needed and do no harm, no more, no less.
- Principle 4 – Reduce inappropriate variation using evidence-based practices consistently and transparently[1].

This guidance aims to encourage an open and transparent approach to partnership working between NHS Wales, primary care contractors, the pharmaceutical industry and the allied commercial sector. In developing partnership arrangements, the following should be considered:

- 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.

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 project aims and strategy and there is a shared commitment to its successful delivery.

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[2]. Reports of breaches of this Code are encouraged and should be reported to the Prescription Medicines Code of Practice Authority (PMCPA)[3].

SUMMARY

All partnership working must be for the benefit of patients, following the principles of Prudent Healthcare[1].

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 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.

All collaborative partnerships which involve the pharmaceutical industry and/or allied commercial sector must comply fully with the appropriate UK and European legislation (i.e. Bribery Act 2010).

Partnership between one or more pharmaceutical company/companies and NHS Wales is acceptable provided that this is carried out in a manner which benefits patients and is compatible with the guidance in this document.

Whatever type of agreement is entered into, a prescriber should aim to deliver the best available care – their judgement should be based on the best available evidence of clinical effectiveness and cost-effectiveness in discussion with, and with the agreement of, the patient.

All patients' identification should be removed from data, in line with the Data Protection Act 1998, to respect and preserve confidentiality.

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

1.0 INTRODUCTION

1. This guidance may be applied to all healthcare professionals and non-healthcare professionals working in or contracted to 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 health boards, NHS trusts and educational providers to work together and in collaboration with other agencies to improve the health and health literacy 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 extensive UK and European law relating to the promotion of medicines (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 NHS Wales. Such relationships, if properly managed, may provide mutual benefit to the organisations involved (see Annex 2 for an example of good practice).

5. A Welsh Health Circular (WHC) on *'Guidance for partnership working between NHS organisations, primary care contractors, the pharmaceutical industry and the allied commercial sector in Wales'* was issued in 2005[4] and is extant. This and other papers[2,5,6] have informed this updated guidance. Its purpose is to emphasise that NHS Wales organisations and primary care contractors are accountable for achieving the best possible healthcare within the resources available, using the tenants of Prudent Healthcare, and to provide guidance for organisations and individuals – it advises to fully consider the implications of a proposed partnership before entering into any arrangement. In particular, it is important to seek advice, when necessary, from health boards and NHS trusts on any effect on other parts of the NHS.

6. For the purposes of this guidance, partnership arrangements may include, but are not limited to, funding of all or part of the costs of:

- a member of staff;
- NHS research;
- staff training;
- pharmaceuticals;
- equipment;
- gifts;
- meeting rooms and costs associated with meetings;
- hospitality, hotel and transport costs; or
- the provision of free services, such as speakers or premises.

[*]The pharmaceutical industry has strict governance in place around its activities, both through extensive UK and European law relating to the promotion of medicines and, beyond this, through individual companies adoption of the ABPI Code of Practice; however, this may differ from some of the guidance given here to NHS Wales staff on their partnerships with commercial sector organisations. For example, gifts to healthcare professionals are prohibited by the ABPI Code of Practice, whilst the pharmaceutical industry is committed to the transparency of its financial support to both healthcare professionals and healthcare organisations via Disclosure of Payments to Healthcare Professionals (HCPs), Other Relevant Decision Makers (ORDMs) and HealthCare Organisations (HCOs).

In all these cases, NHS organisations and primary care contractors should use local processes 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. Partnership arrangements as outlined in paragraph 6 do not apply to:
    - gifts from patients;
    - commercial arrangements on particular products;
    - personal gifts and sponsorship of less than £25 per gift.

    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.

8. Where partnerships involve the pharmaceutical industry and allied commercial sector, then the proposed arrangements must comply with the Human Medicines Regulations 2012 as amended (2014)[7].

9. Whatever type of agreement is entered into, a prescriber's judgement should always be based upon evidence that the product is clinically effective and cost-effective and is the most appropriate for their patients, in line with evidence-based practice and, in particular, guidance from the National Institute for Health and Care Excellence (NICE) and the All Wales Medicines Strategy Group (AWMSG).

    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.

2.0 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. General Medical Council (GMC), Nursing and Midwifery Council (NMC), General Pharmaceutical Council (GPhC), ABPI health professional codes.
    - Take responsibility for ensuring that they and their staff adhere to their professional codes and guidance. 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 for annual declaration of interest form 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, are taken on the basis of best clinical practice, value for money and with prudent principles in mind. Such decisions should take into account their impact on other parts of the healthcare 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 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 are at a corporate, rather than individual, level.
    - The costs and benefits of any agreement are understood (Guidelines for: Partnership Working Initiative Assessment Checklist; and a *Suggested Service Agreement Template* are contained at Annexes 6 and 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*[8] and the additional implications of the Freedom of Information Act.
    - 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 in accordance with local clinical and corporate governance procedures.
    - The use of patient data is subject to the Data Protection Act 1998.
    - Competition Law.
    - The Bribery Act 2010.

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.

3.0 HOSPITALITY AND MEETINGS

14. Pharmaceutical industry and allied commercial sector representatives should not be expected to provide hospitality to members of the health professions and other relevant decision-makers except in association with scientific meetings, promotional meetings, scientific congresses and other such meetings, and training. It should be expected that these meetings are held in appropriate venues conducive to the main purpose of the event.

15. It should be recognised that hospitality will be limited and secondary to the main purpose of the event. The level of subsistence offered must be appropriate and not out of proportion to the occasion; 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. Pharmaceutical industry should not be expected to provide the funding for, or provision of, rooms to be used for meetings.

17. 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.

4.0 MONITORING ARRANGEMENTS

18. 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 have been established under current policy and this should continue to be 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*[9].

19. Pharmaceutical companies should document and publicly disclose transfers of value made directly or indirectly to health professionals and healthcare organisations. These include transfers of value in relation to:
    - joint working;
    - donations, grants and benefits in kind to organisations;
    - contracts between companies and organisations;
    - sponsorship of attendance by healthcare professionals and other relevant decision makers at meetings;
    - fees and expenses paid to healthcare professionals or their employers;
    - contributions towards the cost of meetings paid to healthcare organisations, which may include sponsorship of healthcare professionals by way of registration fees, accommodation and travel.

5.0 RESEARCH AND DEVELOPMENT

20. Guidance on Research and Development is contained in Annex 4.

6.0 EXAMPLES OF POTENTIAL CONFLICT

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

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RELEVANT DOCUMENTS

Legislation

- The Human Medicines Regulations 2012 No. 1916
- The Human Medicines (Amendment) (No.2) Regulations 2014 No. 1878
- The Consumer Protection from Unfair Trading Regulations 2008 No. 1277
- Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended by Directive 2012/26/EU
- Bribery Act 2010

Other codes

International

- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) (2012) Code of Practice
- European Federation of Pharmaceutical Industries and Associations (EFPIA) (2014) Code on the Promotion of Prescription-Only Medicines to, and Interactions with, Healthcare Professionals
- EFPIA (2011) Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations
- EFPIA (2013) Code on Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations
- World Health Organization (WHO) (1988) Ethical Criteria for Medicinal Drug Promotion
- International Pharmaceutical Congress Advisory Association (IPCAA) Healthcare Congress Guidelines

United Kingdom

- Prescription Medicines Code of Practice Authority (PMCPA) (2016) The ABPI Code of Practice for the Pharmaceutical Industry
- Committee of Advertising Practice (2014) The UK Code of Non-broadcast Advertising and Direct and Promotional Marketing
- Proprietary Association of Great Britain (PAGB) (2016) Medicines Advertising Codes – Professional Code
- British Medical Association (BMA) (2016) Medical Ethics Today
- General Medical Council (GMC) (2013) Good Medical Practice
- General Pharmaceutical Council (GPhC) (2012) Standards of conduct, ethics and performance
- Nursing and Midwifery Council (NMC) (2015) The Code: Professional standards of practice and behaviour for nurses and midwives
- General Dental Council (GDC) (2013) Standards for the Dental Team
- Department of Health (2000) Commercial sponsorship – Ethical standards for the NHS
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Guidelines

- Medicines and Healthcare products Regulatory Agency (MHRA) (2014) Blue Guide: Advertising and Promotion of Medicines in the UK – includes Disease Awareness Campaigns Guidelines and Medicines which are promoted for use during pregnancy.
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- Pharmaceutical Information and Pharmacovigilance Association Guidelines on Standards in Medical Information
- British Healthcare Business Intelligence Association (BHBIA) (2016) Legal and Ethical Guidelines for Healthcare Market Research

Other

- The Critical Care Experience March 2004 – Forming Productive Partnerships with Industry. Modernisation Agency Critical Care Programme.
- Department of Health (1993) Standards of Business Conduct for NHS Staff
- Department of Health (2000) Commercial sponsorship. Ethical Standards for the NHS
- Code of Practice for Health Authority Staff Relationships with Pharmaceutical Companies (Final Draft), All Wales Medicines Forum, 2001.
- Scottish Executive (2003) A Common Understanding. Guidance on the Joint Working between NHS Scotland and the Pharmaceutical Industry
- 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 Pharmaceutical Industry was introduced in 1958. The Code can be downloaded from the PMCPA website (www.pmcpa.org.uk/thecode/Pages/default.aspx). 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 60 non-member companies have voluntarily agreed to comply with the Code and to accept the jurisdiction of the Authority.

The Code covers the promotion of medicines to health professionals and administrative employees/independent contractors, and also covers information about such medicines made available to the general public. The term 'promotion' covers:

- journal and direct mail advertising;
- the activities of representatives including any electronic or printed material used by them;
- the supply of samples;
- the provision of inducements to prescribe, supply, administer, recommend, buy or sell medicines by the gift, offer or promise of any benefit or bonus whether in money or in kind;
- the provision of hospitality for promotional purposes;
- the sponsorship of promotional meetings;
- the sponsorship of scientific meetings including payment of travelling and accommodation expenses in connection therewith;
- all other sales promotion in whatever form, such as participation in exhibitions, the use of audio or video recordings in any format, broadcast media, non-print media, the Internet, interactive data systems, social media and the like[3].

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, 7th Floor, Southside, 105 Victoria Street, London, SW1E 6QT (telephone: 020 7747 8880, email: complaints@pmcpa.org.uk). The Authority can also be contacted for informal advice.

Extract from The Human Medicines Regulations 2012

Inducements and hospitality

300. (1) A person may not, in connection with the promotion of medicinal products to persons qualified to prescribe or supply them, supply, offer, or promise any gift, pecuniary advantage or benefit unless it is:

(a) inexpensive; and

(b) relevant to the practice of medicine or pharmacy.

(2) A person may not provide hospitality at a meeting or event held for the purposes of the promotion of a medicinal product unless:

(a) the hospitality is strictly limited to the main purposes of the meeting or event; and

(b) the person to whom it is provided or offered is a health care professional.

(3) Nothing in this regulation shall prevent any person providing hospitality at an event held for purely professional or scientific purposes provided that:

(a) the hospitality is strictly limited to the main scientific objective of the event; and

(b) the person to whom it is provided or offered is a health care professional.

(4) A person qualified to prescribe or supply medicinal products may not solicit or accept any gift, pecuniary advantage, benefit or hospitality that is prohibited by this regulation.

(5) In this regulation "hospitality" includes:

(a) sponsorship of a person's attendance at a meeting or event; and

(b) the payment of travelling or accommodation expenses.

(6) This regulation does not apply in relation to measures or trade practices relating to prices, margins or discounts that were in existence on 1st January 1993.

ANNEX 2: Collaborative Partnerships

Exemplar 1:

Extract taken ABPI Cymru Wales Bulletin Autumn 2015:

World Arthritis Day: Guest comment by Dale Riley, Chair of the ABPI Wales Arthritis & Musculoskeletal therapy group

Arthritis and chronic musculoskeletal conditions are one of the main causes of disability in Wales and amongst the most frequently reported long-term illnesses affecting people of all ages. Many of these conditions are life-long and have a dramatic impact on the physical, psychological and social aspects of a person's life.

They can deprive people of their independence, disrupt the lives of family members and other carers, and restrict life opportunities.

Arthritis is one of the most frequently reported chronic conditions in Wales, affecting more than 30,000 people. Arthritis and musculoskeletal conditions are also the most common cause of severe long-term pain and physical disability. Approximately 50% of patients will give up work within a decade due to the illness.

Prompt assessment and diagnosis can help ensure that appropriate treatment and management are initiated and individual risk factors are identified at an early stage. This approach can help to reduce or prevent the progression of chronic musculoskeletal disorders and it can also avoid the development of complications. Early assessment and effective treatment can help those living with these conditions to maintain their independence. It can also help to reduce the associated significant social and economic costs.

The Wales Arthritis and Musculoskeletal therapy group was established to create a link between pharmaceutical companies and stakeholders, such as the Welsh Government, the NHS, clinicians and patient organisations with an interest in arthritis and musculoskeletal services in Wales.

Our vision is to promote and improve the health of people with arthritis and musculoskeletal conditions through shared expertise and integrated joint working with key stakeholders in Wales.

Our membership comprises representation from a number of pharmaceutical companies, ensuring a wide knowledge base with respect to the healthcare and social issues which affect people with arthritis and musculoskeletal conditions.

The principle aim of the Arthritis and Musculoskeletal therapy group is to work in partnership with all other relevant stakeholders to ensure that people have access to high-quality, up-to-date care, evidence-based medicines and relevant support.

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;
- declare and record material financial or personal interest (e.g. company shares, research grants) 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 agree 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*[10]. 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 Marketed Medicines (SAMM) which remain in force[11].

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 5: Annual Declaration of Interests in the Pharmaceutical Industry and Allied Commercial Sector

NHS organisation name:.....

Name: .....

Position within organisation: .....

Position within any other NHS organisation or primary care contractors organisation: (e.g. primary care team or practice)

Under the guidance of the Code of Practice on Declarations of Interests, I wish to declare to the ***(INSERT NAME OF ORGANISATION)*** that my only interests in the pharmaceutical industry and allied commercial sector are as follows:

1. Current Personal Interests

Name of Company	Nature of Interest (e.g. shares, fees, consultancy, salary, grants, retainers, etc.)	Duration of Interest

A 'personal interest' involves payment to the member personally. The main examples are:

- **Consultancies**: any consultancy, directorship, position in or work for the pharmaceutical industry and allied commercial sector that attracts regular or occasional payments in cash or kind.
- **Fee-paid work**: any work commissioned by the pharmaceutical industry and allied commercial sector for which the member is paid in cash or kind.
- **Shareholdings**: any material shareholding in, or other beneficial interest in, shares of the pharmaceutical industry and allied commercial sector. This does not include shareholdings through Unit Trusts or similar arrangements where the member has no influence on financial management.

2. Current Non-Personal Interests

Name of Company	Nature of Interest (e.g. shares, fees, consultancy, salary, grants, retainers, etc.)	Duration of Interest

A “non-personal interest” involves payments that benefit an employer but are not received by the member personally. The main examples are:

- **Fellowships**: the holding of a fellowship endowed by the pharmaceutical industry and allied commercial sector.
- **Support by the pharmaceutical industry and allied commercial sector**: any payment, other support or sponsorship in cash or kind which does not convey any pecuniary or material benefit to a member personally but which does benefit his/her position or parent organisation, for example:
  - A grant from a company for the running of a unit or department for which a member is responsible.
  - A grant or fellowship to sponsor a post or member of staff or student in the unit.
  - The commissioning of research or other work by, or advice from, staff that work in a unit for which the member is responsible.
  - Income generating schemes.

Members are under no obligation to seek out knowledge of work done for, or on behalf of, the pharmaceutical industry and allied commercial sector, within units for which they are responsible if they would not normally expect to be informed.

3. Any additional relevant information

- Please state if your interest is limited to a particular product or group of products.
- “Current” interests refer to involvement within the last 12 months.
- “Non-current” interests refer to involvement prior to the last 12 months.
- “Nil” returns are required.

ANNEX 6: Partnership Working Criteria – A Guideline (Taken from ABPI Joint Working)

All potential parties should review this checklist and satisfy themselves that each criterion would be met under the project. The parties should also establish that their respective organisations have the required structures in place to enable successful delivery in line with Clause 20 of the ABPI Code of Practice for the Pharmaceutical Industry. If the answer to any of Red Questions is *No*, the project is not a true partnership working arrangement and should not be viewed as such. Appropriate steps to address the outstanding areas should be taken before proceeding further under the heading of partnership working.

Red Questions	Yes	No
1) The main benefit of the project is focused on the patient		
2) All parties acknowledge the arrangements may also benefit the NHS and pharmaceutical partners involved		
3) Any subsequent benefits are at an organisational level and not specific to any individual		
4) There is a significant contribution of pooled resources (taking into account people, finance, equipment and time) from each of the parties involved		
5) There is a shared commitment to joint development, implementation and successful delivery of a patient-centred project by all parties involved		
6) Patient outcomes of the project will be measured and documented		
7) All partners are committed to publishing an executive summary of the Partnership Working Agreement		
8) All proposed treatments involved are in line with national guidance where such exists		
9) All activities are to be conducted in an open and transparent manner		
10) Exit strategy and any contingency arrangements have been agreed		

A negative response to the Amber Questions signals potential issues that may arise. These should be addressed as soon as possible to ensure successful and timely project delivery.

Amber Questions	Yes	No
11) Will the project be managed by a joint project team with pharmaceutical industry, NHS and any appropriate third party representation?		
12) Do all parties and their respective organisations have appropriate skills and capabilities in place to manage the project thus enabling delivery of patient outcomes?		
13) Have all partner organisations got clear procedures in place for reviewing and approving Partnership Working projects?		
14) Are all parties aware of and committed to using the Partnership Working Agreement Template (or equivalent) developed by the DH and ABPI?		
15) Are all partners clear on who within their organisation is the signatory to ensure Partnership Working agreements can be certified?		

If all the answers are ‘yes’ you should proceed with internal compliance discussions. Pharmaceutical partners must verify that the project complies with the ABPI Code of Practice.

Partnership 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 a 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 partnership 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.
- Who the organisation's 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.
- What purpose the data will be put to.

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, health board, 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.

3. ANNEX 6 (continued): 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. health board, 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: • 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 beinvolved; • 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:	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. Details of how the project will be taken forward, personnel to be involved and how the project will be managed must be stated.
Period of agreement:	The period or duration of agreement is to be specified.
Financial implications	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. 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. 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. 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. 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. Income and 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.
Methods of payment	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.

	The method for making payments or receiving funding must be identified and comply with Standing Orders and Standing Financial Instructions.
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 dispute resolution mechanisms must be stated.
Confidentiality:	A comprehensive Confidentiality Clause must be included (See *Data and Confidentiality Issues* in Annex 6).
Legality:	The agreement must state that appropriate consideration has been given to the legal implications of the partnership work (Note: pharmaceutical companies and the 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 'Conflicts of Interest' which may lead to poor practice

(Text adapted from *Commercial Sponsorship – Ethical Standards for the NHS*[6])

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/she has links, e.g. company shares, research grant, in the health board/trust formulary.* Health board/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 company wishes to present the case for a new product being included on a health board/trust 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 health board/trust*. The health board/trust should not accept the sponsorship if it would require the stoma nurse to recommend the sponsor's equipment in preference to other clinically appropriate appliances, nor if it requires the health board/trust to recommend patients to use a particular dispensing service or withhold information about other products.

e) *A company offers to provide discounted products to an NHS health board/trust.* This agreement is acceptable, but should be routinely declared to the NHS health board/trust.

f) *A high-tech home healthcare provider offers to supply equipment at a 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.

g) *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 health board/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.

Glossary of Terms

TERM	MEANING
ABPI	Association of the British Pharmaceutical Industry
ABPI Code of Practice	Code 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	Code setting out the basic principles underlying public access to information about the NHS
Collaborative working	Work together in a joint intellectual effort for mutual benefit
Commercial	Making or intending to make a profit, in this case by supplying a product or service to the NHS
Data Protection Act	Act of Parliament defining UK law on the 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	Act of Parliament that 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	A person who stands in temporarily for someone of the same profession
NHS Wales	NHS Wales is the structure providing comprehensive healthcare to people in Wales. The Welsh 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 health boards
Objectives	Aims or purposes that guide action
Partnerships	In the context of this document, 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 its successful delivery.
Pharmaceutical industry and allied commercial sector	Suppliers of products or services to NHS Wales for use in the treatment and care of patients
Prescription Medicines Code of Practice Authority (PMCPA)	See Annex 1
Probity	Unimpeachable honesty, integrity and virtue
Promote	Encourage the sale of something by advertising (directly and indirectly)
Sponsor	Provide funding for a project or event
Standing Financial Instructions	Instructions detailing responsibilities, policies and procedures for all aspects of financial management and control. Set out the rules that directors and employees must follow when taking action on behalf of the health board
Standing Orders	Prescribe the terms on which committees and sub-committees of the health board may have delegated functions, and should include the schedule of decisions reserved for the health board
Transparency	Full, accurate and timely disclosure of information