



Department of
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and Public Safety**

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AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÁNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

BEST PRACTICE GUIDANCE ON JOINT WORKING BETWEEN THE HSC AND THE PHARMACEUTICAL INDUSTRY AND OTHER RELEVANT COMMERCIAL ORGANISATIONS

**Prepared by: Pharmaceutical Advice and Services Branch
DHSSPS
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Best Practice Guidance on joint working between the HSC and the pharmaceutical industry and other relevant commercial organisations

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GUIDANCE ON JOINT WORKING WITH THE PHARMACEUTICAL INDUSTRY

Introduction

1. HSC employers and employees need to maintain and demonstrate certain general standards and behaviours when dealing with commercial organisations. This document updates previous policy issued by DHSSPS, HSS (GEN 1) 1/95. It is intended to replace the guidance previously provided by former HSSBs and Trusts to assist employers and staff in maintaining strict ethical standards in the conduct of HSC business.
2. HSC organisations and staff are encouraged to consider the opportunities for joint working with the pharmaceutical industry, where the benefits that this could bring to patient care and the difference it can make to their health and well-being are clearly advantageous. A philosophy of developing appropriate partnerships to help achieve high quality patient care could further enhance the objectives of a patient-centred HSC. Such initiatives should be managed in an effective and efficient way. The development of effective and clinically appropriate joint working with external stakeholders can contribute to building a best quality HSC.
3. HSC organisations and staff are encouraged to consider partnership approaches against the following criteria:
 - meet patient and HSC needs
 - be most accessible
 - provide sustainable clinical benefits
 - being highly cost effective

Purpose of this Guidance

4. The first purpose of this guidance is to assist staff in the HSC achieve their objectives and vision of a modern, dependable national health service delivering excellent healthcare, by building effective and appropriate working relationships with key partners, such as the pharmaceutical industry.
5. The learning from a number of partnership projects has confirmed that joint working can provide real benefits to patients whilst supporting the strategic objectives of the delivery partners. Accordingly, HSC organisations and staff are encouraged to consider joint working as a realistic option for the delivery of high-quality healthcare.
6. The second purpose of this guidance is to inform and advise HSC staff of their main responsibilities when considering entering into joint working and other engagements with the pharmaceutical industry (see paragraph 9 below).

Specifically, it aims to:

- assist HSC employers and staff in maintaining appropriate ethical standards in the conduct of HSC business

- highlight that HSC staff are accountable for achieving the best possible healthcare within the resources available
7. A selection of other underpinning and extant HSC guidance can be found in Annex A.

Joint Working with the Pharmaceutical Industry

8. Joint working between the pharmaceutical industry and the HSC must be for the benefit of patients or the HSC and preserve patient care. Any joint working between the HSC and the pharmaceutical industry should be conducted in an open and transparent manner. All such activities, if properly managed, should be of mutual benefit, with the principal beneficiary being the patient. The length of the arrangement, the potential implications for patients and the HSC, together with the perceived benefits for all parties, including the pharmaceutical companies, should be clearly outlined before entering into any joint working.
9. For the purpose of this guidance, joint working is specifically defined as:

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

Joint working agreements and management arrangements are conducted in an open and transparent manner. Joint working differs from a number of non-promotional and/or commercial practices that involve interaction with the HSC and healthcare professionals where pharmaceutical companies simply provide funds for a specific event or work programme eg pro-active offer or provision of medical and/or educational goods and/or services (MEGS). MEGS must comply with the ABPI Code of Practice, in particular Clause 18.4 and 18.5. For further information see ABPI Guidance Notes on Joint Working between Pharmaceutical Companies and the NHS and Others for the Benefit of Patients.

Core Values

10. Everything done by those who work in the HSC must be able to stand the test of parliamentary scrutiny, public judgments of propriety and professional codes of conduct.

An extract from the CODE OF CONDUCT FOR HPSS MANAGERS Circular HSS (SM) 4/2003 states that HPSS managers must;

- make the care and safety of service users their first concern and act to protect them from risk
- respect the public, service users, relatives, carers, HPSS staff and partners in other agencies
- be honest and act with probity and integrity

- accept responsibility for their own work and for the management of the performance of the people they manage
 - show commitment to working as a team by working constructively with all colleagues in the HPSS and in the wider community
11. When the HSC and its staff engage with the industry, their conduct should also adhere to the following values:
- transparency and trust
 - appropriateness of projects
 - patient focused
 - value for money
 - reasonable contact
 - responsibility
 - impartiality and honesty
 - truthfulness and fairness

Responsibility of HSC Employers and Staff

12. There is already a range of information, relating to principles of partnership working between NHS bodies and commercial organisations, provided in previous governmental circulars. A list of which can be found in Annex A.
13. All health professionals, including independent contractors and locum practitioners, working under HSC terms and conditions, are intended to be covered by this guidance. For the purposes of this document, the term ‘staff’ is used as a convenience to refer to all such people.
15. Whilst directed at HSC staff, this guidance will also be of relevance to anyone working in the health environment. This includes private and voluntary sector staff. HSC employers are responsible for ensuring that these guidelines are brought to the attention of all employees; also, that machinery is put in place for ensuring that they are effectively monitored and implemented
16. HSC staff should be aware that industry representatives must follow the “*ABPI Code of Practice for the Pharmaceutical Industry*”. It is a condition of membership of the Association of the British Pharmaceutical Industry (ABPI). The Code of Practice for the pharmaceutical industry is designed to ensure a professional, responsible and ethical approach to the promotion of prescription medicines in the UK through a self-regulatory system.

Further guidance to industry is provided by “*ABPI Guidance Notes on Joint Working between Pharmaceutical Companies and the HSC and Others for the Benefit of Patients.*” This provides companies with a framework and greater clarity about various aspects of joint working and the sort of issues that must be considered by them, prior to commencing joint working projects.

If HSC staff consider that an industry representative may have broken the Code, they can report their complaint to the Director of the Prescription Medicines Code of Practice Authority (PMCPA) at complaints@pmcpa.org.uk.

Additional Principles

17. By applying all the above-mentioned values, HSC staff will have met the majority of the relevant requirements of existing guidance (see Annex A).

However, employers should ensure that monitoring arrangements are established to ensure that staff record and monitor any joint working arrangement for which the HSC body is accountable. Specifically:

- all staff should be aware of HSC guidance, the legal position and appropriate and relevant professional codes of conduct as described in extant HSC guidance
- contract negotiations are conducted with the necessary ethos and values mentioned above and where there is evidence of an unauthorised or disadvantageous arrangement, HSC staff should act swiftly to deal with the situation and bring it within their local arrangements and patient and clinical needs
- all funding agreements either through joint working projects or other arrangements are recorded and monitored, and should also be conducted in a transparent and open way while the costs and benefits of it are properly measured and weighed with other proposals
- confidentiality of information received in the course of duty should be respected and should never be used outside the scope of the specific exercise
- HSC bodies which entered into joint working arrangements should register and evaluate their outcomes and share them on request with other HSC bodies
- local guidance and policy should take into account the ethical and contractual implications of commercial collaborations with external stakeholders while reviewing and amending its content when necessary
- joint working arrangements should be at a corporate, rather than individual level
- monitoring arrangements are established to ensure that staff register any sponsorship and are held accountable for it
- all joint projects propositions are officially documented and reviewed through use of a register as part of the monitoring arrangements
- establish how clinical and financial outcomes should be assessed through a risk assessment form

Exit Agreements

18. When entering into an agreement for joint working, the HSC should also consider the impact once these arrangements are concluded. An effective exit strategy should be in place at the outset of a given project detailing the responsibilities of each party. This should be capable of dealing with a situation where premature termination becomes necessary.

Support for Those Considering Joint Working Arrangements

19. A DH/ABPI toolkit on joint working between the NHS and pharmaceutical industry is available at

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082840

It provides learning from useful examples with a view to recommending and spreading best practice. The Toolkit, entitled *Moving Beyond Sponsorship: joint working between the NHS and pharmaceutical industry* provides potential partners with a solid foundation on which to develop joint working initiatives. It is suggested that the content be adapted by local HSC staff in Northern Ireland to support their specific requirements.

20. This guidance will be reviewed and/or renewed if necessary in 5 years from its issuance.

Further advice

21. Further advice on this guidance can be obtained from the Pharmaceutical Advice and Services Branch, Department of Health at pharmacyadvice@dhsspsni.gov.uk or Telephone 028 9052 3274

UNDERPINNING HSC GUIDANCE AND REFERENCES

The following documents contain information of relevance to joint working between HSC bodies and commercial organisations:

- **EL (94)94 - Commercial Approaches to the NHS Regarding Disease Management(1994)**

This EL explains the background to approaches from industry and gives preliminary advice on dealing with them. It is cancelled as of 1 November 2007 and replaced by **“The NHS Guidance on joint working with the pharmaceutical industry and other relevant commercial organisations”**.

- **Standards of Business Conduct for HPSS Staff. Management Executive Circular HSS (GEN 1) 1/95**

This circular on *Standards of Business Conduct for HSC staff* was issued in 1995 (regarding the general standards which should be maintained by staff working in the HSC).

- **Review of Public Administration (2002)**

The 18 Health trusts were reduced to 5 in April 2007 and new organisations were established in April 2009 which 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. The new HSC organisations are:

- a single Health and Social Care Board replaced the existing four Health and Social Services Boards
- 5 Local Commissioning Groups
- a Public Health Agency incorporating and building on the work of the Health Promotion Agency
- a Business Services Organisation providing a range of support functions for the whole of health and social care system. The Central Services Agency was dissolved and the majority of its services will be undertaken by the new organisation
- a single Patient and Client Council replaced the Health and Social Services Councils

Link:http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008869

- **Commercial Sponsorship – Ethical Standards for the HSC (2000)**

The purpose of this guidance is to emphasise to HSC bodies and primary care contractors that their staff are accountable for achieving the best possible health care within the resources available. It advises them to consider fully the implications of a proposed sponsorship arrangement before entering into any arrangement.

Link: <http://www.rpani.gov.uk/>

- **Confidentiality: Code of Practice on Protecting the Confidentiality of Service User information (2009)**

This Code of Practice aims to support all those staff involved in health and social care to make good decisions about the protection, use and disclosure of service user information.

Link: <http://www.northernireland.gov.uk/news/news-dhssps/news-dhssps-january-2009/news-dhssps-290109-department-of-health.htm>

- **A Healthier Future (2005)**

Sets out a vision to provide people with good quality social care and HSC services in the communities where they live. This paper will change the way services are provided, placing greater choice and control in the hands of the people who use them. Social care services are also changing to give service users more independence, choice and control.

Link: <http://www.dhsspsni.gov.uk/healthyfuture-main.pdf>

Further background information:

- **The Quality Standards for Health and Social Care (2006)**

The *Quality Standards for Health and Social Care* set out the standards that people can expect from Health and Personal Social Services (HPSS). The standards address

- Corporate leadership and accountability of organisations;
- Safe and effective care;
- Accessible, flexible and responsive services;
- Promoting, protecting and improving health and social well-being; and
- Effective communication and information quality of services
- In order to improve the health and social wellbeing of the people of Northern Ireland.

Link: http://www.skillsforhealth.org.uk/~media/Resource-Library/PDF/qpi_quality_standards_for_health___social_care.ashx

- **Medicines (Advertising) Regulations 1994**

This regulation concerns advertising and promotion of medicinal products to health professionals and to the public. Guidance on interpretation can be found in the MHRA Blue Guide, *Advertising and Promotion of Medicines in the UK*.

Link: http://www.opsi.gov.uk/SI/si1994/Uksi_19941932_en_1.htm

- **Moving Beyond Sponsorship – Joint working between the HSC and Pharmaceutical Industry**

Toolkit jointly developed by the Department of Health and the Association of the British Pharmaceutical Industry (ABPI) to enable HSC organisations and the pharmaceutical industry to work together in the interests of patients.

Link:http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082840

- **The ABPI Code of Practice for the Pharmaceutical Industry 2008**

The ABPI Code of Practice for the Pharmaceutical Industry is designed to ensure a professional, responsible and ethical approach to the promotion of prescription medicines in the UK through a self-regulatory system.

Link:http://www.abpi.org.uk/links/assoc/PMCPA/pmpca_code2008.pdf

- **ABPI Guidance Notes on Joint Working between Pharmaceutical Companies and the HSC and others for the Benefit of Patients.**

This provides companies with a framework and greater clarity about various aspects of joint working and the sort of issues that must be considered by them, prior to commencing joint working projects.

Link:http://www.abpi.org.uk/publications/pdfs/ABPI_Code_Guidance_Notes.pdf