

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

Best Practice Guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations

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GUIDANCE ON JOINT WORKING WITH THE PHARMACEUTICAL INDUSTRY

Introduction

1. The NHS is now the largest health organisation in Europe and it is recognised as delivering one of the best health services in the world by the World Health Organisation. As described in the White paper entitled “***Our health, our care, our say: a new direction for community services***”, the strategic shift in services from secondary to primary care encompasses NHS partnership working with relevant partners such as the pharmaceutical industry as one of a range of options available to meet the needs of patients and achieve clinical excellence.
2. This guidance is to help the NHS to meet the challenges of a rapidly changing health service by highlighting the potential of joint working¹ to support the delivery of efficient and high-quality services that meet the healthcare demands of the 21st century. It replaces EL (94)94 ‘Commercial Approaches to the NHS Regarding Disease Management’ (1994) with immediate effect. Research and Development (R&D) partnerships are outside the scope of this guidance and dealt exclusively in other documents with an R&D emphasis.
3. NHS 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 NHS. 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 an NHS that is truly a beacon to the world.
4. NHS organisations and staff are encouraged to consider partnership approaches against the following criteria:
 - meet patient and NHS needs,
 - be most accessible,
 - provide sustainable clinical benefits,
 - as well being highly cost effective.

Purpose of this Guidance

5. The first purpose of this guidance is to assist staff in the NHS 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.

¹ Rather than using the narrower term *Partnership*, the term joint working has been used in this document to illustrate the wide variety of arrangements for joint activities between the NHS and the industry. Joint working differs from sponsorship, where pharmaceutical companies simply provide funds for a specific event or work programme.

6. 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, NHS organisations and staff are encouraged to consider joint working as a realistic option for the delivery of high-quality healthcare.
7. The second purpose of this guidance is to inform and advise NHS staff of their main responsibilities when considering entering into joint working arrangements with the pharmaceutical industry. Specifically, it aims to:
 - Assist NHS employers and staff in maintaining appropriate ethical standards in the conduct of NHS business
 - Highlight that NHS staff are accountable for achieving the best possible health care within the resources available
8. A selection of other underpinning and extant NHS guidance can be found in Annex A. Research and Development (R&D) partnerships are outside the scope of this guidance.

Joint Working with the Pharmaceutical Industry

9. Joint working between the pharmaceutical industry and the NHS must be for the benefit of patients or the NHS and preserve patient care. Any joint working between the NHS 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 NHS, together with the perceived benefits for all parties, should be clearly outlined before entering into any joint working.
10. For the purpose of this guidance, joint working is defined as follows:

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 sponsorship, where pharmaceutical companies simply provide funds for a specific event or work programme.

Core Values

11. An extract from the “*Code of Conduct: Code of Accountability in the NHS*” (2nd rev ed, 2004), states that: “There are three crucial public service values which underpin the work of the health service:
 - **Accountability** - everything done by those who work in the NHS must be able to stand the test of parliamentary scrutiny, public judgments of propriety and professional codes of conduct
 - **Probity** - there should be an absolute standard of honesty in dealing with the assets of the NHS: integrity should be the hallmark of all personal conduct in decisions affecting patients, staff and suppliers, and in the use of information acquired in the course of NHS duties

- **Openness** - there should be sufficient transparency about NHS activities to promote confidence between the organisation and its staff, patients and the public”

12. Further, based on relevant pieces of additional guidance which are still extant, when the NHS and its staff enter into a joint working 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 NHS Employers and Staff

13. There is already a range of information, relating to partnership working between NHS bodies and commercial organisations, provided in previous governmental circulars a list of which can be found in Annex A.

14. As described in *'Standards of business conduct for NHS staff, and Commercial Sponsorship – Ethical Standards for the NHS (2000)*, NHS employers and employees need to maintain and demonstrate certain general standards and behaviours, as defined, when dealing with commercial organisations.

15. All health professionals, including independent contractors and locum practitioners, working under NHS 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.

16. Whilst directed at NHS staff, this guidance will also be of relevance to anyone working in the health environment. This includes private and voluntary sector staff. NHS 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.

17. NHS 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. If NHS staff believe that an industry representative has 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

18. By applying all the above-mentioned values, NHS 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 NHS body is accountable. Specifically:

- All staff should be aware of NHS guidance, the legal position and appropriate and relevant professional codes of conduct as described in extant NHS guidance;
- Contract negotiations are conducted with the necessary ethos and values mentioned above and where there is evidence of an unauthorised or disadvantageous arrangement, NHS 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;
- NHS bodies which entered into joint working arrangements should register and evaluate their outcomes and share them on request with other NHS 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.

Support for Those Considering Joint Working Arrangements

Exit Agreements

19. When entering into an agreement for joint working, the NHS 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.

Best Practice Toolkit on Joint Working

20. A toolkit on joint working between the NHS and pharmaceutical industry, focusing on learning from useful examples with a view to recommending and spreading best practice, will be issued to augment this Guidance. The Toolkit, entitled *Moving Beyond Sponsorship: joint working between the NHS and pharmaceutical industry* is being designed to give potential partners a solid foundation on which to develop joint working initiatives and it is suggested that the content be adapted by local NHS staff to support their specific requirements. The toolkit is currently under development and is being piloted with a number of NHS organisations. Following evaluation it will be published in its final form on the Department of Health and the ABPI websites in March 2008.
21. This guidance will be reviewed and/or renewed if necessary in 5 years from its issuance.

Further advice

22. Further advice on this guidance can be obtained from The Medicines, Pharmacy & Industry Group, Industry Branch, Room 402, Skipton House, London (e-mail: MPI-Industry@dh.gsi.gov.uk).

**Medicines, Pharmacy and Industry Group
Department of Health**

January 2008

UNDERPINNING NHS GUIDANCE AND REFERENCES

The following documents contain information of relevance to joint working between NHS 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 NHS Staff (1993)**

This circular on *Standards of Business Conduct for NHS Staff* was issued in 1993 (HSG(93)5) regarding the general standards which should be maintained by staff working in the NHS.

[Link:http://www.dh.gov.uk/en/PublicationsAndStatistics/LettersAndCirculars/HealthServiceGuidelines/DH_4017845](http://www.dh.gov.uk/en/PublicationsAndStatistics/LettersAndCirculars/HealthServiceGuidelines/DH_4017845)

- **New NHS: Modern and Dependable (1997)**

The New NHS: Modern and Dependable requires the various parts of the NHS 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.

[Link:http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008869](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4008869)

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

The purpose of this guidance is to emphasise that NHS bodies and primary care contractor 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.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005135](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005135)

- **Confidentiality: NHS Code of Practice (2003)**

The NHS Confidentiality Code of Practice is a guide to required practice for those who work within or under contract to NHS organisations concerning confidentiality and patients' consent to use their health records. It replaces previous guidance. The Code is a key component of emerging information governance arrangements for the NHS.

[Link:http://www.dh.gov.uk/en/Policyandguidance/Informationpolicy/Patientconfidentialityandcaldicottguardians/DH_4100550](http://www.dh.gov.uk/en/Policyandguidance/Informationpolicy/Patientconfidentialityandcaldicottguardians/DH_4100550)

- **Our Health, our Care, our Say White paper (2006)**

The Our Health, our Care, our Say White Paper sets out a vision to provide people with good quality social care and NHS 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.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_4127552

Further background information:

Code of Conduct: Code of Accountability in the NHS (2nd rev ed, 2004)

As described in paragraph 9.

Link: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4116281

Document EL(94)40 – Codes of Accountability and Conduct

As described in paragraph 15. Updated by the Code of Conduct: Code of Accountability in the NHS (2nd rev ed, 2004).

Link: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4116281

Document HSG(96)48 – NHS Indemnity: Arrangements for Handling Clinical Negligence Against NHS Staff

This guideline describes the arrangements, which apply to handling clinical negligence claims against NHS staff (NHS Indemnity). It updates the guidance given in Health Circular HC(89134.)

Link: http://www.dh.gov.uk/en/PublicationsAndStatistics/LettersAndCirculars/HealthServiceGuidelines/DH_4018270

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

The ABPI Code of Practice for the Pharmaceutical Industry 2006

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_code2006.pdf