Ethics and the pharmaceutical industry: some ideas for general practitioners

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SUMMARY. This paper summarizes a report by a working party of the Royal College of Physicians on the relationship between physicians and the pharmaceutical industry. As a member of that working party, and a general practitioner, I have taken the report's points and widened the discussion to involve general practitioners in their relationship with the pharmaceutical industry. At present there are no guidelines specifically for general practitioners. Some of the problems general practitioners have found in their relationship with the pharmaceutical industry are described and some guidelines for general practitioners are suggested, which form a framework for discussion. The College would welcome feedback about the guidelines to help in the drawing up of a code of practice for general practitioners.

Introduction

IN recent years there has been concern about the relationship between doctors and the pharmaceutical industry, in particular the prescribing of drugs and the conduct of clinical research and trials. In February 1984 the President of the Royal College of Physicians of London called a meeting of fellows of the College. They agreed to set up a working party to examine the relationship between physicians and the pharmaceutical industry. The working party, of which I was a member, met 12 times from 1984 through to 1986. It received oral and written evidence from a wide variety of organizations and individuals and reported its findings and recommendations in October 1986, with a paper entitled 'The relationship between physicians and the pharmaceutical industry'.[1]

Strict guidelines on the correctness of the relationship between doctors and commercial companies have been given in the General Medical Council's booklet, *Professional conduct and discipline: fitness to practice*,[2] the Department of Health and Social Security's notice on the acceptance of gifts and hospitality in the public service,[3] and Association of the British Pharmaceutical Industry's (ABPI) *Code of practice for the pharmaceutical industry*.[4] Comments in the press, on television and by the Consumers' Association demonstrated that the public expect doctors' conduct in prescribing and investigating drug actions to be above criticism. The Royal College of Physicians' (RCP) report[1] reinforced these guidelines, and gave specific advice to physicians in their relationship with pharmaceutical companies.

The report was not an attack upon the pharmaceutical industry. Instead, it was designed to be a guide to help physicians in their complex relationship with the pharmaceutical industry. Throughout the meetings, the working party was careful to concentrate on advice to physicians (fellows and members of the RCP and physicians in training) rather than to general practitioners or other members of the medical profession. However, there are points in the report which are relevant to all doctors in their relationship with the pharmaceutical industry.

In this paper I will first summarize the evidence to the RCP working party and mention briefly its recommendations, then describe examples of situations where general practitioners relate to the pharmaceutical industry. Finally, I will give some suggested guidelines for general practitioners based on the RCP recommendations, so that both general practitioners and representatives of the pharmaceutical industry will know what is and what is not acceptable. I hope that these ideas will stimulate discussion, so that the College may reach agreement on a code of practice for general practitioners in their relationship with the pharmaceutical industry.

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Summary of the RCP report

Evidence to the working party

Drug prescribing. The evidence to the RCP working party showed that in some postgraduate centres almost every meeting is dependent on sponsorship by a pharmaceutical company. Some doctors demand hospitality for themselves and their spouses (such as lavish meals in restaurants) on a scale in excess of the ABPI code of practice for the pharmaceutical industry.[4] Some gifts are commonly given to doctors (such as diaries, pens, writing pads and calendars), but some doctors demand much more substantial gifts or cash payments for seeing representatives or starting patients on a new drug. Doctors often ask for funds to attend overseas meetings. One even wrote that he frequently prescribed the company's products and would stop doing so if his request was unsuccessful. Furthermore, promotional meetings sometimes take place in attractive overseas locations, with generous hospitality.

Clinical research and trials. The report found that many trials are carried out with high ethical and scientific standards. However, some have little scientific value and are largely promotional exercises. Large sums of money are paid for clinical trials, and research companies, partnerships and individual doctors may offer to arrange trials and recruit patients and healthy volunteers. In some cases, payments are made to individuals without proper recompense for National Health Service or university facilities used in such studies. Some researchers feel that their right to publish work is unduly restricted by pharmaceutical companies. Also, there is concern about the proceedings of symposia being published in supplements of a journal without proper peer review, and the reprints being used for promotional purposes.

Conclusions and recommendations

The RCP report concluded that the overriding principle was that any benefit in cash or kind must leave the doctor's independence of judgement unimpaired. Recommendations were made about the conduct of meetings at postgraduate centres, of meetings for resident medical staff in hospitals and of conferences organized by or with help from pharmaceutical companies; about hospitality, gifts, payments and consultancy fees; about the conduct of research projects and clinical trials; about declarations of interest by physicians; and about publishing of papers presented at sponsored meetings.

General practitioners and their relationship with the pharmaceutical industry

There is a need for a strict code similar to the RCP's code of conduct, with rules for the kind of activities which occur in

general practice. None of the reports or codes of conduct already mentioned[1-4] or the British Medical Association's ethical handbook[5] are very specific about what occurs in general practice. If we look at general practitioners' interactions with the pharmaceutical industry, this will provide some illustrations of the problems we as general practitioners may face. One way to look at these is to examine the problems under the same headings as the RCP report.

Drug prescribing

Postgraduate meetings. It is regrettable that so many postgraduate meetings are sponsored by pharmaceutical companies. Greater funding from the National Health Service via Section 63 should be available to develop and expand postgraduate education of general practitioners, without dependence on pharmaceutical company sponsorship. However, not all meetings for general practitioners are sponsored by pharmaceutical companies. Indeed, in the West Midlands region there has been no sponsorship of trainees' half day release courses, of many lunchtime meetings, or of group discussions such as research workshops and young principals' groups. Funding for these meetings is from Section 63 payments, or not at all.

The pharmaceutical industry has an impressive record of innovation and development of new products, and general practitioners must be informed of such advances. Many meetings are of educational or scientific value. What is concerning is the steady stream of invitations to attend promotional meetings organized by pharmaceutical companies in which a short film or lecture is preceded by sherry and followed by a lavish dinner. Some of these meetings occur in hotels, providing hospitality beyond the resources of clinical tutors, course organizers and general practitioner tutors.

Unlike hospital medicine with its clinical tutor in a postgraduate centre, there are general practitioners with a variety of appointments involved in postgraduate education. These include general practitioner tutors, college tutors, course organizers, associate advisors and regional advisors. All may have responsibility for a course of educational activity.

Hospitality. Again, there are regular invitations to general practitioners to view a short film of a promotional nature, and for the partners to be entertained to a meal in a restaurant. Sometimes ancillary staff are invited, sometimes spouses (in breach of the ABPI code of practice for the pharmaceutical industry[4]). One practice in my region built new premises, of which they were justly proud. They invited local general practitioner colleagues to an open evening, with catering provided by two named pharmaceutical companies.

Gifts and inducements. The receipt of pens, calendars, diaries, memo pads and other small items is commonplace. More recently general practitioners have been offered medical textbooks, audiovisual material (slides, audiotapes and videotapes) and items of medical and surgical equipment. These may be more welcome than free samples of medicines, but perhaps reflect the increasing sophistication of the industry's marketing managers. Some practices have microcomputers provided by pharmaceutical companies.

Visits abroad. General practitioners in the West Midlands region have attended meetings in the Channel Islands, Spain and Sweden, paid for by pharmaceutical companies. These meetings are claimed to be educational rather than promotional, but, if this is the case, one wonders why they cannot be held in the local postgraduate medical centre.

Clinical research and clinical trials

It is essential that clinical research and trials of drugs are carried out outside the hospital setting. The ABPI code of practice gives several reasons why medicines should be assessed in general practice[4] and to these should be added the fact that as general practitioners take on the clinical care of patients with chronic diseases (hypertension, diabetes and asthma, for example), such patients may attend hospitals to a lesser extent or not at all.

Many studies in general practice have been carried out to high scientific and ethical standards and have made major contributions to clinical practice. The ABPI does issue guidelines for the conduct of drug trials in general practice.[6] These are clear and correct in their statements. However, some so-called drug trials are merely promotional exercises designed to put more patients on a company's products, and have little or no scientific value. General practitioners often participate in these through an informal arrangement with a local company representative, and in return for a small number of patients studied, receive payments in cash or an item of medical equipment. Blood tests are sometimes requested and carried out by an unsuspecting local National Health Service hospital — without prior arrangement with the head of the laboratory or charge to the pharmaceutical company for such services. Some doctors doing such work have little knowledge of the study as a whole. The concept of ethical approval by the local ethical committee seems like language from another world.

Suggested code of practice for general practitioners in their relationship with the pharmaceutical industry

Sponsored meetings

In practice premises and postgraduate centres. Sponsorship is acceptable at postgraduate meetings and a lunch or supper meal is allowable providing: (1) the programme selection and choice of speakers is in the hands of the general practitioner organizer; (2) promotional material is kept apart from the educational and scientific part of the meeting; (3) the level of hospitality is appropriate and not out of proportion to the occasion. The cost should not exceed the level which the course members may normally adopt when paying for themselves. The hospitality should not extend beyond members of the medical profession.

The code of practice of the National Association of Clinical Tutors[7] is recommended as a useful guide — with due allowance for the fact that general practitioner organizers should be responsible for their own educational activities.

Meetings organized by pharmaceutical companies. General practitioners should attend only meetings of educational or scientific value. Meetings where the main purpose of the occasion is a lavish meal in a restaurant, with little or no educational or scientific content, are not acceptable.

Meetings abroad. There are occasions when general practitioners wish to accept sponsorship for attending overseas meetings. An exotic venue is not of itself a reason for attendance, and the same educational and scientific standards should apply as above. It is preferable for sponsoring companies to make donations to an organizing committee, who should then invite speakers to the meeting. It is acceptable for payment of travelling and subsistence expenses to be paid from such funds. Payment to the spouse of general practitioners attending a meeting is not acceptable.

Hospitality

Hospitality should always be secondary to the main purpose of a meeting. It should not extend beyond the medical profession. A reasonable lunch or supper meal is acceptable — at a level which the recipients might normally adopt when paying for

themselves. A lavish meal in a restaurant after a meeting in practice premises or a postgraduate centre is not acceptable. The invitation of spouses to such meetings and hospitality is not acceptable (unless, of course, they are practising general practitioners).

Gifts

It is not acceptable to accept gifts other than those defined in the code of practice of the pharmaceutical industry[4] as 'inexpensive and relevant to the practice of medicine'. Such acceptable gifts include pens, diaries, notepads, audiocasettes of a medical nature and appointment books. Unacceptable gifts include glassware, cameras and payments of cash.

Payments

General practitioners are independent contractors, and any professional work done (such as clinical trials or other investigative work) should attract a fee. Fees paid for such work must be realistically related to payments for comparable professional work and be in keeping with the time, effort and degree of skill required.

Such professional fees paid should be paid into the practice account as professional fees (as specified in many practice agreements) — rather than paid in cash to an individual general practitioner.

It is unacceptable for a general practitioner to ask for and be paid a fee for the following activities: (1) seeing a company's representative, (2) notifying an adverse reaction to a drug or (3) sending letters to medical journals.

Research projects and clinical trials

The code of practice for the clinical assessment of licensed medical products in general practice[6] sets out clear guidelines for such projects and trials. It has been agreed jointly by the British Medical Association, the Royal College of General Practitioners and the ABPI.

These guidelines for clinical trials may be summarized as follows:

- The medical department alone within the pharmaceutical company should have responsibility for the trial.
- All clinical trials must have the protocol approved by an independent and properly constituted ethical committee.[8]
- The protocol must be approved by a person with suitable medical qualifications. The purpose, design, supply of medication, controls, patient selection, consent, dosage, full prescribing information, duration, assessments, compliance, adverse reactions, withdrawals, record sheets, statistical analysis and trial coordination must be included in the protocol. In particular the medication must always be supplied by the company free of charge, and not prescribed by the general practitioner on FP10.
- To protect confidentiality no individual patient must be identified from data supplied for statistical or research purposes, except by written consent of the patient.
- Investigators should be able to see the results of the study on their own patients and of the study as a whole and be able to comment upon these. Publication of results must be encouraged.
- General practitioners should be selected to give a representative sample. No pressure should be put on a general practitioner to use a product contrary to his usual prescribing habits.
- An invitation to take part in the trial must only be made by the medical adviser responsible for the protocol or such persons possessing the necessary knowledge of the proposed study.
- The fees should be realistic to comparable professional work. Hospitality should be modest and secondary to the main purpose of any meeting.

Points for clinical trials and research

Formal arrangements for such trials in general practice are essential. Before agreeing to take part in an investigation a general practitioner must satisfy himself that:

- The code of practice[6] has been followed. In particular the general practitioner should check that ethical approval has been given. The name of the ethical committee, the date ethical approval was given and the protocol number should be provided.
- A formal contract with the company will be provided before the study begins and signed in agreement.
- The company will provide the medication for the study rather than the general practitioner prescribe it on FP10.
- Any laboratory tests or investigations required in the study will be paid for by the company, and not charged on National Health Service facilities.
- There is prior agreement for the general practitioner to publish results in journals of the general practitioner's choice (subject to patent rights of new products being jeopardized).
- Arrangements have been made for the company to indemnify subjects in the trial in the event of harm arising as a result of the trial.

Conclusions

Much of what is recommended in this report comes from existing guidelines and codes of practice. I believe that the recommendations here represent the views and practice of most pharmaceutical companies and most general practitioners. I believe that general practitioners will welcome these guidelines as having been written by a general practitioner for their special guidance. The College would be pleased to hear members' views about the guidelines to help in the drawing up of a code of practice specifically for general practitioners.

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