Is the current training of pharmaceutical industry staff adequate?

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Introduction

The Pharmaceutical Industry is often considered as an entity when it is praised for a major therapeutic breakthrough or maligned for its promotional practices. Yet, the Pharmaceutical Industry actually consists of the many individuals in various disciplines who work for it at any point in time. Why is the Pharmaceutical Industry so often maligned as a group whereas the individuals who make up the whole are usually regarded as trusted and respected colleagues?

There seems little doubt that better training would improve the Industry, as indeed, better training of doctors would almost certainly improve the practice of medicine. However, the optimum education will always be debated and in these times of rapid technological developments, the nature of training may also need consideration. The change is from providing an individual with a set of facts to a training designed to provide the ground rules to remain flexible, despite changes in knowledge and technology (Horder *et al.*, 1984). The Pharmaceutical Industry places the emphasis on continuing training to develop individuals to the full and allow them to utilise these relevant changes in knowledge.

It would be complacent to say that training in the Pharmaceutical Industry is adequate. However, before it is possible to even consider the question, it is important to know what sort of training exists at the moment. This article sets out to look at the basic functions and training of four groups of people within the Industry to provide a background for further discussion as to whether more training in the Industry would be beneficial.

Training can be carried out by individual companies; by commercially available courses run by people with a knowledge of the special needs of personnel within the Industry; and by scientific or professional bodies. Such courses cover much more than scientific matters and opportunities exist for personal development with courses, for

example, in management, planning, finance and public speaking.

The Association of the British Pharmaceutical Industry (ABPI) encourages and supports training by member companies, acting as a co-ordinating body to maintain the quality of the training courses available. It also acts as a central fund of information and advice.

Clinical pharmacologists

Clinical pharmacologists in the Pharmaceutical Industry are responsible for identifying pharmacokinetic and dynamic properties of a drug or new formulation, which helps determine the correct dosage and frequency of dosing. They act as an interface between the pharmacologists and chemists in development and the medical advisers who will be designing studies for the use of that product in clinical trials to establish safety and efficacy in a number of clinical indications. Clinical pharmacologists also form a strong link between the pharmaceutical company and academic clinical pharmacology. These links are essential to the continued development and knowledge of new methods and understanding but the relationship works in both directions. The new molecules brought to university departments often stimulate ideas and research which would not occur otherwise.

Many companies have facilities for carrying out studies in normal healthy volunteers and the recruitment of experienced doctors with an existing knowledge of clinical pharmacology is therefore essential. Clinical pharmacology training takes place at a specialist level before entry into the Industry and subsequent training is to maintain those standards as well as to broaden them. The British Pharmacological Society has many clinical pharmacologists from Industry amongst its members and acts as a very useful forum for interchange.

Medical advisers

Most doctors entering the Pharmaceutical Industry become medical advisers and roughly half of new recruits already have membership of the Royal College of Physicians or other higher qualifications. A few doctors join the Industry very soon after their house job, but to have most value they need a broad medical education of at least 3 years' experience and will often have already developed a major interest. Some doctors join the Industry at a much more mature stage of their career.

Medical advisers are the initiators of most of the therapeutic clinical trials in the U.K. They form links with doctors who have a special interest in a particular therapeutic area or who have a number of patients with a particular condition and design and monitor clinical trials to answer questions about a particular drug. These questions will, initially, be to establish efficacy in a given clinical condition, to confirm dosage and to develop a strategy of sustained efficacy. The answers to the questions should enable registration authorities to approve the drug for marketing.

Following this, there is a much more active phase of comparative studies to determine the actual usefulness of the drug to doctors. These subsequent studies may involve many more doctors and patients than the original studies. It is also at this stage that post-marketing surveillance begins to occupy the mind and companies either need to document formally the frequency of adverse events by specific studies or to keep a vigilant eye open and liaise with independent experts who may be monitoring the drug's progress.

Medical advisers are also responsible for monitoring the medical and technical detail of advertising material and have to approve all such material before it is used. They are also involved in the training of medical representatives. In general, a medical adviser should have a more detailed knowledge of a particular drug than any independent clinician and should be able to provide that information to the company and outside.

Because of the specialised nature of the work of medical advisers, an attempt has been made to create a speciality of pharmaceutical physicians, in line with the current system of accreditation. The initiative for this new speciality came from the ABPI and the Association of Medical Advisers in the Pharmaceutical Industry (AMAPI).

The Royal Colleges of Physicians of London, Glasgow and Edinburgh agreed in 1975 to set up

a new diploma to be called the Diploma in Pharmaceutical Medicine. The first examination took place in 1976 and there has been one examination each year since then. A course lasting 2 years and consisting of 4 weeks' residential study each year has been developed to train medical advisers for the Diploma. It is presently run by the University of Wales, Institute of Science and Technology within the Welsh School of Pharmacy. Courses are organised by Dr D. K. Luscombe, who invites speakers from academic medicine, clinical pharmacology and Industry to participate. The courses concentrate on clinical therapeutics and clinical trials but incorporate statistics, regulatory affairs and a general Pharmaceutical Industry training. A full description of the course can be found in a review by MacLeod & Goldberg (1981).

In addition, medical advisers will participate in training within the company and there are also a number of commercial courses catering for various aspects of the job. In particular, clinical trials methodology and statistics as well as features of adverse reaction monitoring.

The Association of Medical Advisers in the Pharmaceutical Industry holds a series of educational meetings which cut across company boundaries and continue a knowledge and understanding of medical developments of general interest.

Clinical research associates

The carrying out of clinical trials has become increasingly complex in terms of regulatory requirements and also sophistication. In order to obtain clear answers to questions, it is essential to create viable and appropriate protocols. However, for those answers to actually be arrived at, it is necessary for the protocols to be adhered to, the appropriate patients to be recruited and record forms to be filled in correctly. Clinical trials involve the investigator in a good deal of time and trouble and so the need for people to help solve day-to-day problems is useful.

A group of people in the Industry called clinical research associates (or similar titles) have this function. They are usually pharmacists or natural science graduates and work closely with medical advisers to monitor and co-ordinate clinical trials. They need a detailed knowledge of clinical trial methodology and statistics, as well as a fairly intensive understanding of the medical area they are investigating.

Many commercial courses exist to develop these skills and there is usually considerable training within the company. In addition, clinical

research associates have formed their own professional body, the Association of Clinical Research Associates in the Pharmaceutical Industry (ACRPI) which holds regular meetings to develop and maintain knowledge of topical matters in the clinical trials area.

Medical representatives

The main function of medical representatives is to sell drugs. They do this by conveying information about a particular drug to a doctor or group of doctors in a manner which should make them reconsider their current prescribing policy and encourage a better understanding of the companies' drugs. The communication is in both directions with doctors telling medical representatives about changes in patterns of drug prescribing and also about specific adverse reactions. General practitioners receive most of their specific drug knowledge from medical representatives and usually welcome the opportunity of seeing them.

According to Avorn & Soumerai (1983) the best way of changing prescribing patterns is on a face-to-face basis. Increasingly, audio-visual aids are used to convey information at these meetings and this encourages a group discussion.

There is an increasing number of science graduates being employed as medical representatives together with pharmacists, laboratory technicians and nurses. On joining the Industry they are likely to receive an intensive in-company course lasting about 8 weeks. This would provide a general overview of therapeutics as well as a basic understanding of anatomy and physiology related to the particular disease processes being treated, the pharmacology of the companies' drugs and similar alternative therapies, with particular attention to the indication, dosage and adverse reactions. The sales training techniques centre on identifying and discussing a doctor's needs in terms of the information available. Specialist training in audio-visual presentation and public speaking also form an important part of the communication skills which are developed.

Although representative training is carried out by individual companies, the ABPI has advised on the syllabus to be followed and an ABPI examination for medical representatives has been held since 1968. The standard of the examination is that of a State Registered Nurse and the examination must be passed within two years of becoming a representative. The pass mark is 60%.

The Pharmaceutical Industry believes strongly in continuing training and uses modern techniques

to achieve this. New drugs are usually presented to the representatives through self-teaching manuals backed up by audio and video tape presentations and finally lectures given by doctors from within the company, as well as independent authorities. Knowledge on older drugs is maintained through regular presentations of new articles or other information on the drug and occasional refresher courses. Representatives also need a detailed knowledge of the whole range of drugs used in a particular circumstance, so they can have a reasoned discussion with the doctor.

In addition, opportunities exist for more personal development in terms of management training, public speaking and financial affairs.

Whilst there may always be individuals who do not have a full grasp of a subject, the intention and opportunities for training are clearly adequate. Whether doctors should be trained more effectively in clinical pharmacology and therapeutics to assess the information presented to them more critically, may be a more pertinent question than the adequacy of representative training.

Other personnel

There are many other groups of people in the Industry with their own training needs which have to be met. Drug discovery involves chemists and pharmacologists working together; animal models have to be developed to test new drugs; animal toxicology has to be carried out to assess the potential risks; and drugs have to be produced and quality control assured. This is within a framework of a commercial environment with lawyers, accountants and administrators having their own special functions. Drugs are marketed and market research is carried out to find out what doctors are actually doing (often a very revealing exercise). All of these disciplines involve highly trained and motivated people who have their own liaisons across companies to ensure that standards are maintained.

Conclusions

The science of therapeutics and the art of using the appropriate drug in the correct indication at the optimum dose to obtain the greatest efficacy with the least risk are relatively new features of medical practice, going back perhaps only 40-50 years. Before this time medicine was largely a descriptive science based on observation and diagnosis. Now treatment is possible, it is important that doctors use the new opportunities wisely.

The Pharmaceutical Industry has provided doctors with a whole range of materials to treat and diagnose conditions more effectively. There is a responsibility on the Industry to ensure that standards are maintained at all levels of operation and across all disciplines. However, despite this there is often criticism of the Industry, sometimes with good reason, but often based on looking at the way doctors are using drugs.

As drug treatment has become more complicated, it seems obvious that right from the early clinical years at medical school, medical students should be given some insight into the complexities of drug discovery, clinical trials and practical therapeutics, as well as an understanding of the economics of the Industry. Yet these disciplines are hardly taught in most medical schools (Burley, 1984) and so it is no wonder that newly qualified doctors are bemused by the number of drugs available and their first contacts with the Industry.

This is sad because many of the courses available to Industry staff would enable a greater

insight if they were shared by doctors in the early years of their postgraduate training. This could be one way of developing greater understanding between prescribing doctors and the Pharmaceutical Industry.

A recent article suggested that doctors and nurses were losing sight of their respective functions and purpose (Mitchell, 1984).

It may be that some of the hostility between clinicians and the Pharmaceutical Industry is because of a failure to understand each others' purpose. It is more likely to be this than a failure of training within the Industry. However, if there is a perceived problem about the most appropriate use of drugs by doctors, it will be more readily solved by a greater attempt at educating doctors and medical students about therapeutics than by tampering with training in the Pharmaceutical Industry. Nevertheless, there is always a need to improve the standards of training and to ensure that the people within the Industry do not get complacent in a rapidly changing world.

References

- Avorn, J. & Soumerai, S. B. (1983). Improving drug-therapy decisions through educational outreach. A randomized controlled trial of academically based 'detailing'. *New Engl. J. Med.*, **308**, 1457.
- Burley, D. M. (1984). Medical student education. *J. Roy. Soc. Med.*, **77**, 81.
- Horder, J., Ellis, J., Hirsch, S., Laurence, D., Marinker, M., Murray, D., Wakeling, A. & Yudkin, J. S. (1984). An important opportunity. An open letter to the General Medical Council. *Br. med. J.*, **288**, 1507.
- MacLeod, H. M. & Goldberg, A. (1981). Diploma in Pharmaceutical Medicine. *Br. J. clin. Pharmac.*, **12**, 3.
- Mitchell, J. R. A. (1984). Is nursing any business of doctors? A simple guide to the 'nursing process'. *Br. med. J.*, **288**, 216.