

Drugs - From Manufacture to Patient

TODAY'S GREATER IMPORTANCE OF THE PHARMACIST'S COMPLETE SUPERVISION

This is based on the lecture given by Prof. D'Arcy to Pharmacists on 4th March 1988

Pharmacy for the Pharmacist — 'a controversial subject'

Pharmacy for the Pharmacist is a concept that is enshrined in the F.I.P. Budapest Declaration which was signed by 65 countries in 1984. It is not a new concept and Prof. D'Arcy quoted from the article 'An Outline of the History of Pharmacy' published in our journal 'The Pharmacist' in which Dr. P. Cassar writes about "state control of the exercise of Pharmacy which came into being about 1240 when Frederick II, the Holy Roman Emperor and King of Sicily, introduced the licensing of sellers of drugs by the Medical School of Salerno, rules prohibiting physicians, from owning a pharmacy and regulates fixing the prices of medicaments". From these initial legal enactments stemmed the various laws controlling the Pharmaceutical profession of our own days. What is 'Pharmacy for the Pharmacist?' asked Prof. D'Arcy ... "We claim it is our own ... we all know it is not just 'the Chemist shop' that changed in the post war years with the introduction of more complex drugs and the manufacture went away from the pharmacy into the pharmaceutical industry."

Drug — a four-letter word!

There are various roles which the pharmacist can play from the point of manufacture to the time the drug is taken by the patient, hopefully at the right time and in the right dose. However, Prof. D'Arcy added 'drug' is a four-letter word. It is preferable to use the word 'medicine' because all medicines are drugs but not all drugs are medicines. This message must reach the general public. Often patients when asked as to whether they take drugs, they say "no". On the other hand when asked whether they take medicines, they may come up with quite a list.

INDUSTRY

Research and development are areas in which the pharmacist has to compete with other scientists e.g. biochemists, biologists, toxicologists etc. The pharmacist getting involved in this field requires a higher degree and specialisation. An important aspect of this area is choosing the correct excipients as this can cause adverse reactions.

The term iatrogenic diseases literally means 'physician produced' diseases, however it has now come to mean drug induced diseases. These are not necessarily caused by the active ingredient. Table 1 shows four classical examples of drug formulation reactions. They have been well documented, well proven and all caused clinical hazard. They are probably just the tip of the iceberg in so far as these formulation reactions



are concerned. Many are probably not recognised as such. They are obviously a matter of potential concern especially since they may have important consequences in comparing the safety spectrum of generic and proprietary formulations of the same drug.

Table 1

iatrogenic disease: classical examples of drug formulation effects

1. 1968-9. Outbreak of phenytoin intoxication in Australia due to change in capsule filler from calcium sulphate to lactose. Increased bioavailability.
2. 1971. Intestinal absorption of rifampicin impaired by PAS. Later shown to be due to bentonite in PAS granules. Reduced efficacy of antitubercular treatment.
3. 1972-3. Bioavailability problems with digoxin (Lanoxin) due to particle size. Over digitalisation of standardised patients.
4. 1983. Indomethacin dumping in gut by Osmosin resulting in ulcers or perforation of gut.

These examples suggest that drug formulation is a pharmaceutical expert's job that can best be done by a pharmacist. So also is production, which involves getting quality assurance built into the product. Raw materials and excipients must be up to specification, good manufacturing practice followed to the letter of the law and checks carried out all along. At the end, when the drug is in the container, one doesn't need to do any quality control tests, as quality is assured throughout its production.

When a new drug is developed actual tests — clinical trials, human toxicology, animal tests are done on the final product in the container. Although other professionals e.g. chemical engineers, developing chemists, can get involved in production, it is the developing pharmacist who has a global view of the pharmaceutical problems.

Sales and Marketing. As drugs are not ordinary articles of commerce, one does not need detail men to go around to get a quick sale, but experienced, knowledgeable people who go around telling the doctor of the advantages of this new drug. Again, pharmacists are the best people for the job.

Management. Whereas years ago most of the managing directors of British Pharmaceutical companies were pharmacists, nowadays one finds lawyers and accountants in these posts. This has changed the orientation of Pharmaceutical Companies, and though they might be more efficient they have lost the ethical approach. Why is this? This has happened because none of the pharmacists become managers. Only through taking a management course and developing their skills can pharmacists attain a management post.

HOSPITAL PHARMACY

In Britain and in America, hospital pharmacy has developed into a number of specialisations and includes participation in the procurement, distribution and manufacture of small batches of drugs.

A patient goes into hospital to receive excellent medical or surgical care which the state pays for. What is the end product? It is the prescription. If the patient gets the wrong drug, or a drug that is expired, or stored under the wrong conditions one is wasting everything. Distribution of drugs should be totally under the control of the pharmacist though obviously not done completely by him. However in Britain, no

pharmacy technician works without the supervision of a pharmacist. In purchasing drugs one must be absolutely certain as to the quality of drugs, purchasing them from the right source at the right price and ensuring that they are of the required standard.

Hospitals which manufacture drugs themselves, are required by law to have the same standards as industry, i.e. they must meet good manufacturing practice requirements and other specifications. In particular I.V. fluids undergo the most stringent regulations and controls as in industry, because over the years many patients have died through contamination of these fluids.

Drug Information is the provision of interpreted information. Pharmacists undergo specialisation in drug information to prepare them for the interpretation of information.

Clinical and ward pharmacy are different names for the same thing. The Americans use clinical pharmacy while the British call it ward pharmacy.

Pharmacists are involved in the medication history taking of patients. Their knowledge of proprietary names and the ability to describe them is of tremendous help in identifying non-prescription medication taken by the patient. They can advise the physician which is the best drug to use and with their knowledge of pharmacokinetics, work out the correct dosage for a particular patient.

The pharmacist also has a special role to play in:—

- Drug therapy review Committee, which ensures that the patient is compliant.
- Drug therapy management, checking the patient and making sure treatment is continued.
- Educating the patient about their medication they are receiving and which they will be receiving in the community in the terminology they will understand.
- Preventing and detecting adverse drug reactions.
- Calculations for total parenteral nutrition.
- Anticoagulant monitoring of patients attending outpatient clinics.
- Ambulatory patient management to improve patient compliance in outpatient clinics.

Drug therapy review Committee, which is made up of pharmacists, who together with physicians and nurses look into the total drug usage within the hospital. Other committees govern the use of antibiotics.

COMMUNITY PHARMACY

This is the backbone of pharmacy. Certainly in the U.K. 75 per cent of registered pharmacists are working in the community practising clinical pharmacy without perhaps realising. In the U.K. community pharmacists dispense medicine prescribed within the N.H.S.

Advising patients on the use of prescribed medicines. The Pharmacist not only dispenses the medication but he dispenses advice and information on how best to take it. This might mean written information, helping patients fill a little diary, particularly in the case of elderly patients perhaps talking to them for 5 to 10 minutes. The Pharmacist must make sure that a patient does not leave the pharmacy until they have the full instructions.

Many patients come out of the doctor's clinic without remembering a word of what the doctor has said and it is especially so with young mothers who take a child to the doctor. Prof. D'Arcy recalled that in a survey done by students outside a doctor's clinic there was no relationship at all between what the doctor had said and what the mothers recalled. The pharmacist's job is very important to reinforce what the doctor said, and to check the prescription for any interactions.

Other important aspects of community pharmacy are:

— **Keeping medication records for patients and checking for compliance** might be impossible within a normal community pharmacy but one can do it for those patients at risk, the elderly, pregnant women and those on chronic medication. Some pharmacists in Britain are putting medication records on a small computer, others are producing their own medication cards where they keep an account of non prescription and prescription drugs, though they are not paid for doing this. The government is moving towards payment for this service.

Most of the elderly do everything the doctor tells them, they follow all the instructions and unfortunately end up with more medicine than they should have. Prof. D'Arcy mentioned the case of a 75 year old arthritic patient who could not cope because she was mildly confused, incontinent and unwilling to walk because she kept falling down. When she was visit-

ed by a pharmacist, she was pleased to tell her that she manages to take all the tablets — she was asking for praise. She was on 26 medications including liquid paraffin and herbal medicines. The pharmacist stopped all the medication and admitted her to hospital. Ten days later she was sent home, still arthritic but leading a better lifestyle.

Keeping medication records will prevent this sort of thing from happening.

— **Advising patients on the use of over the counter non prescription medicine** and ensuring that there is no interaction with other medicines they are taking. Campaigns are being done in journals, newspapers and other publications entitled 'if you want advice on medicine, go and see your pharmacist'.

The U.K. Government has produced the white list and the black list. The black list consists of pharmacist recommended medicines.

— **Assisting the general public in self care** by advising the patient on the treatment of minor ailments and if necessary referring them to the doctor or dentist.

— **Providing emergency first aid treatment** and follow up if necessary and advising on special dietary requirements.

Health Information and Education Centre.

Health education is being given its due importance in Britain. There is a Health Education Council and Government is using pharmacies as the place where general health information is displayed. 'Glue sniffing the breath of death' is one of these leaflets and pharmacists can give information to worried parents about how to spot glue sniffing.

Pharmacies are being turned into Health Information Centres, where one can find information on when to have children inoculated with vaccines, on how to stop smoking, on drug abuse etc.

Conclusion

"If a pharmacist is necessary, one can't do without one," concluded Prof. D'Arcy.

The Pharmacist is the drug expert, he must be used and utilised. In those areas where he is going to be in competition with others he must accept that competition and undergo further specialisation.