FROM THE GMSC

Parallel importing: proposed action to protect patients deferred

Because of the rapid increase in the number of parallel imported drugs being prescribed in the National Health Service the General Medical Services Committee is advising general practitioners to include on their prescription forms the words "UK licensed products only." When this term is used it is on the understanding that the transit and storage of the products have been authorised in a way that conforms to the manufacturer's requirements and that the manufacturer would be prepared to endorse the drug at the point of sale. The GMSC's action was subsequently deferred (see final paragraph in this section).

At its meeting on 19 April the chairman, Dr John Ball, agreed that he would draw the attention of consumer organisations to the threat to patient safety.

Parallel imported medicines are those purchased at a relatively low price in one country for sale in another in competition with similar products already being marketed there by the original licence holder. An exemption from licences order in 1978 was intended to apply "in circumstances in which small quantities of medicinal products are imported into the UK for the purpose of treatment of particular patients." It was drafted in wide terms and has been used to cover the import of much larger quantities of drugs identical with or similar to products already licensed and available in the UK.

In a statement to the committee Dr Ball said that it was inequitable to allow the continued import of goods that might be manufactured under lower quality standards than exist in the UK. There was the danger of counterfeit products or substitutes that might be less safe or less efficacious. Products might not be labelled in English, and there was concern over batch numbering, expiry dates, transportation, and repackaging. A retailer who purchased such imports had a responsibility to his customer to ensure that the products were of the nature and quality demanded by the purchaser or specified in the prescription. Dr Ball said that as the system now operated it permitted the importation and marketing of medicines from sources outside the European Community without a United Kingdom marketing authorisation—that is, a product licence.

Last month the government announced the introduction of measures to control the safety of parallel imports of medicinal products. The existing system of licensing under the Medicines Act will be extended to imported drugs from the European Community. The government's aim is to ensure that in future all drugs dispensed in this country, whatever their origin, comply with the United Kingdom's strict standards of safety control.

Dr Ball told the committee that more and more drugs were being dispensed that had the same name but differed in composition, dose ranges, and safety instructions. Effective patient care and safety were under threat. That was what the committee should be concerned about and not the financial or commercial considerations.

A few months ago, Dr Michael Wilson reported, the value of imported drugs was about a level of £10 million a year. Now it was anything between £50 million and £100 million. It was not just a question of one or two isolated drugs, he warned: two weeks ago an association of pharmaceutical importers had been formed. The Association of Pharmaceutical Distributors had advised its members against abusing the system, but Dr Wilson said that he thought that some might be tempted to do so. If prescriptions were endorsed Dr Wilson believed that it would have the support of the majority of pharmacists.

According to Dr David Pickersgill, 150 of the most commonly used drugs were being parallel imported. When he had taken the matter up with the Minister for Health, Mr Kenneth Clarke, the minister had said that any substitution by the pharmacist should be referred to the appropriate family practitioner committee for investigation. The minister did not think that there was anything to prevent the prescriber indicating that a United Kingdom version of the drug was required.

Several of the drugs, Dr D K Ray said, were manufactured in Third World countries at low cost and were not surplus to their needs.

Dr Simon Jenkins warned against breaching the Treaty of Rome, which he thought the DHSS was encouraging general practitioners to do. It might prove an expensive exercise. He suggested that the prescription form should state "UK licensed products only," and if the doctor did not agree he could score through the words.

"We must put the interests of our patients first," declared Dr John Noble. If the pharmacists were not going to put their house in order then the general practitioners should. Dr John Callander expressed disappointment with the Pharmaceutical Society, which was analogous to the GMC. What were the pharmaceutical inspectors doing? The proposal to stamp prescription forms was not the complete answer if British manufacturers could send their products abroad and wholesalers could purchase them more cheaply and bring them back to this country.

The committee decided that to ensure that general practitioners' patients received precisely the drugs that were properly prescribed for them it would advise doctors to stamp all prescriptions "UK licensed products only." After the GMSC's decision was announced the BMA received a letter from solicitors acting for the Association of Pharmaceutical Importers warning that the committee's advice might be contrary to the Treaty of Rome (p 1390). The GMSC is seeking legal advice and meanwhile has deferred any action on the matter.

Counselling service for sick doctors

The committee has agreed to continue its support for locally organised schemes for helping sick doctors that are centred on local medical committees. These schemes have been running for some time in many parts of the country (29 January 1983, p 410). At the same time the national counselling scheme that had been proposed by the royal colleges

BRIEFLY . . .

- The committee supported the views from the conference of medical royal colleges and their faculties within the UK given in a letter to *The Times* (21 March) expressing the fear that future NHS funding may not be sufficient to maintain the present standards of health care.

- The GMSC was disappointed that in its report on the NHS management inquiry (Griffiths report) the House of Commons social services committee had not supported the BMA's call for pilot studies.

- The committee approved revisions to the medical certificate of cause of death; these now include provision for identifying whether a person's occupation could have contributed to his or her death. There are new forms for certifying stillbirths and neonatal deaths.

- The committee criticised the DHSS's decision—taken on the advice of the Committee on Safety of Medicines—to restrict the supply of phenylbutazone to hospitals, with several speakers arguing that the decision was an infringement of the general practitioner's freedom to prescribe.

and the BMA could make a contribution to helping general practitioners if it could be made more applicable to the discipline.

Dr David Pickersgill said that he was anxious that the proposed national scheme did not interfere with the local schemes. He did not believe that it was applicable to general practice, and the national scheme did not include arrangements for young doctors and women doctors in its advisory machinery. As to the suggestion of including an observer from the General Medical Council, he did not approve: the national management committee had to be seen to be independent and not a branch of the disciplinary machinery. Dr Pickersgill agreed that the local medical committee schemes could be improved but he thought that most general practitioners would want to support them.

Two general practitioner members from the GMC took a different view. The national scheme, Dr Arnold Elliott said, had been proposed by him and other general practitioners on the GMC's health committee. They had been unhappy about the existing schemes and had seen the "failures," many of them general practitioners. He did not believe that the local schemes had been able to help most of the general practitioners who needed it. Of course, those local schemes that were working well should be retained, but a national scheme would help to discover the extent of the problem. He agreed that the GMC should not be a party to the arrangements.

"Every general practitioner who appears before the GMC is a failure of the present system," declared Dr John Marks, chairman of the representative body. In his view the position at local level was a disaster. No one knew the size of the problem because details were kept secret, but general practitioners felt isolated and did not know what action to take.

Postgraduate education: section 63 funding

Dr Ball reminded the committee that there were two separate exercises being conducted on section 63 arrangements for postgraduate education. Firstly, there were the restrictions that had been imposed for 12 months. These were, he said, set out in Health Notice NH(FP)(84)13—*Approved study courses for general medical practitioners, assistants, trainees, and ancillary staff travel and subsistence payments.*

This circular states that a general practitioner will not be able to claim travelling and subsistence for continuing education courses unless they have been approved and funded by the local postgraduate dean from section 63 funds. Claims for travel and subsistence when the travel is 100 miles or more each way will not be automatically reimbursed. Prior approval will need to be obtained from the family practitioner committee, after advice from the local medical committee. The committee has criticised these arrangements on more than one occasion (25 February, p 656).

The second exercise is an overall review of section 63 funding, which is being conducted in a working party established by the Chief Medical Officer and on which the GMSC is represented by Dr Ian Bogle.

The Chief Medical Officer has confirmed that doctors will not be able to claim part reimbursement for expenses incurred in travelling 100 miles or more to courses. In a letter to Dr Ball, Dr E D Acheson said, "Decisions on what applications for travel in excess of that distance should be approved will be entirely for family practitioner committees, in consultation with local medical committees, and there is no question of 'sanctions' being imposed. We have also written to postgraduate deans to ask them to remind course organisers that they should not refuse applications to attend a course on the grounds of distance of travel."

Selecting trainers

The trainees subcommittee had proposed the following motion for submission to the annual conference of local medical committees:

"That this conference believes that a trainer shall have the right to appoint as a trainee any fully registered medical practitioner he may choose. The trainer may wish to take into account any advice issued by the various regional training authorities."

The motion had arisen after a debate in the subcommittee when it had been reported that trainers in South East Thames Regional Health Authority had been sent guidelines for appointing trainees. These included such requirements as previous completion of the hospital component of training; that the trainee had a fair chance of obtaining a partnership on completion of the training; and that some trainee appointments should be considered by the regional adviser. The subcommittee had thought that trainers might be pressurised into following the guidelines by the threat of not being reappointed. The following policy statement had been issued by the subcommittee:

"There are no universally agreed criteria for the selection of young doctors to ensure that they will become good general practitioners. There is no evidence that appointing trainees centrally will lead to higher standards of trainees, only perhaps to a higher number of stereotypes. It is no more appropriate for the regional adviser to vet the appointment of a trainee than for the family practitioner committee to vet the appointment of a new partner."

Dr A C Allen said that the vast majority of trainees would be young doctors who had completed their senior house officer jobs. In his region there were 150 trainers and 120 trainees. About 90 of the trainees would get jobs; the rest would not fit into general practice. He reminded the committee that trainees cost a lot of money and that family practitioner expenditure was being curtailed. In some cases he believed that inappropriate people were being chosen as trainees. There was, he assured the committee, no threat to trainers.

Dr Alison Hill wanted to know what an inappropriate trainee was. Was it someone not intending to finish up as a general practitioner? She thought that it was the committee's policy that more hospital doctors should have some experience of general practice.

After Dr Ball had read out the following paragraphs from the GMSC's 1984 annual report, which the committee agreed covered its policy on the subject, the chairman of the trainees subcommittee, Dr Peter Holden, withdrew the motion.

"(144) During the year the committee has been disturbed to learn of the growing practice of regional education committees to demand too restrictive standards for those wishing to be appointed or reappointed as trainers. In particular, some regions were demanding that prospective trainers hold the membership of the Royal College of General Practitioners. The GMSC believes that these qualifications do not necessarily identify those doctors who make the best trainers. While accepting the value of the MRCGP, and of higher qualifications in general, it does not feel that the absence of such a qualification should automatically debar a principal from appointment as a trainer.

"(145) The GMSC has been actively involved within the Joint Committee for Postgraduate Training in General Practice in the compilation of new guidelines for the appointment and reappointment of trainers. The concern of the GMSC has been expressed to the Joint Committee for Postgraduate Training in General Practice following the circulation of a draft document under the joint committee's name without its authority, and has received an assurance that it will in future be consulted before the wider circulation of any other such document."

Training needs of practice nurses

A working group, chaired by Dr Peter Kielty, had prepared a response to the report on the training needs of practice nurses produced by the Royal College of Nursing.

The working group believed that for the time being the initial training of practice nurse in tasks not covered by basic training is best provided by the employing practice. The ideal trainer would be the senior registered practice nurse. When she was not available the doctors would provide the training. The group foresaw difficulties with further education courses designed to provide initial training. The duties to be learnt were always with patients, often invasive, and largely available only in the surgery.

The group suggested that the content and format of properly constructed courses for practice nurses should be based on:

(*i*) The professional learning needs of practice nurses as identified by the needs of local practices together with evaluation of previous courses, literature sources, and research evidence.

(*ii*) The practical applications of membership of a primary health care team.

(*iii*) The organisation of general medical services and its relation with the rest of the NHS.

(*iv*) The generally agreed need for continuing education for nurses.

The group recognised the outline curriculum in the report as a sound basis for further planning. It concluded that the report made a contribution to the debates on practice nursing in the medical and nursing professions but had failed to draw a distinction between initial and continuing training.