Editorial

WHO SHOULD PAY FOR OUR LIFESTYLE?

In Britain, the cost of pharmaceutical drugs to the National Health Service (NHS) is being debated once again. Among the points which are being discussed in both the medical and the lay press are the contrast between the costs charged to the NHS by pharmaceutical companies and the annual profits made; and the imbalance between high costs in the development of new medicines incurred by them when assessed against the charges made: the latter feature has been given added dimensions on this occasion. The Prescription Price Regulation System (PPRS) is being re-negotiated and the Government has pledged to add legal stature to this previously voluntary arrangement in the recent Queen's Speech at this session's opening of Parliament. The PPRS is currently a non-compulsory scheme whereby pharmaceutical companies may negotiate a price for new medicines which is mutually acceptable to them and the NHS. Unfortunately the scheme has recently been ignored by a small number of pharmaceutical companies who have been selling drugs on to generic companies at a high price; these then add on a further mark-up to ensure profit margins - a practice estimated to have cost the NHS £25 million per annum against a recent overall drug budget of at least £5 billion.[1,2] Both parties (the UK government and the pharmaceutical industry) have made public opening remarks that can be seen as predictable in these discussions, but the final outcome is not known - a compromise may well suit both sides.

Another new player who is about to enter the arena of pricing and costs of drugs in the UK is the National Institute of Clinical Excellence (NICE).[3] NICE is being set up as part of the drug licensing machinery in Britain, and is to have influence specifically over England and Wales. As well as recommending guidelines for treatment, it will review the cost-effectiveness of medicines. It seems unlikely that NICE (which begins work in April 1999 under the chairmanship of Professor Michael Rawlins, who is currently Chairman of the Committee on Safety of Medicines) will be sufficiently resourced to review the cost-effectiveness of all the new drugs that are given marketing approval in the UK on an ongoing basis, let alone be able to review drugs which are already approved. The assumption must then be that only certain classes of drugs or therapeutic indications will be scrutinised by this new institute. This delegated remit leads one to ask other questions, such as: How will priorities be determined and by whom? What data will be used to enable such a review? What are envisaged as the practical outcomes of such decisions on cost-effectiveness upon patients, prescribers and the drug industry as a whole? What effect, if any, will there be on the NHS in Scotland (perhaps an analogous institution is envisaged)? Answers to these and other questions will, no doubt, be part of a divergent spectrum, and the situation will become clear in time. Overall, the NICE initiative must be welcomed by the NHS budget (and the taxpayers) in England and Wales at least. Its implications for the other parties involved are less clear.

The most potent recent issue which relates to drug costs in the UK has been the debate surrounding the availability of the new drug 'sildenafil' (Viagra, Pfizer Ltd). The major controversy does not concern the efficacy of the drug - it does effectively overcome erectile dysfunction in the majority of the appropriate patient population to whom it can be prescribed. Nor does it concern directly the media 'hype' which heralded its arrival in Europe - as with much coverage of the public media this 'hype' was in fact more of a hyperbole. Sildenafil is not an aphrodisiac - it requires sexual stimulation to be effective[4] - but it gained a reputation as such to the extent that it has become the fastest selling drug of all time in the USA, largely because sex-related stories in the lay press seem to attract massive public attention. The drug even became available in Europe on the 'black market', or by mail order over the internet, before its marketing approval. Neither does the attention of the media reflect growing concerns about its safe use. Newspaper reports in November 1998 gave a figure of at least 100 men dying after taking sildenafil - albeit against a background of more than 6,000,000 prescriptions written; it seems likely that many of these should not have used the drug at all.[2,5] The media interest has, however, highlighted and become focused on the question of rationing of resources in the NHS when it was dubious whether or not this drug would be available on an NHS prescription.

It has been clear for several years that the NHS can no longer boast of financial resources that provide a comprehensive, high-quality service for everyone which is free at the point of delivery. There is nothing wrong in admitting this. However, successive governments have chosen not to address this imbalance in budgetary matters head on, but rather concentrate attention on shorter-term issues such as 'inefficiencies' in health care delivery, as assessed by lengths of hospital waiting lists and by attempts to improve the prevailing situation by introducing the competitive 'internal market'. The current UK government has taken a stance on health care, specifically on drug costs, following the marketing approval of sildenafil - their wish may have been to concentrate on the issue of the use of and payment for 'lifestyle' drugs such as sildenafil and orlistat (Xenical, Roche Products Ltd), a new anti-obesity agent also recently approved for prescribing in the UK. However, what has happened is that the wider concern about rationing of resources has surfaced.

As an aside, it could be argued that sildenafil was not to be the first 'lifestyle' drug; that dubious honour may belong to fluoxetine (Prozac, Eli Lilly & Co. Ltd). Fluoxetine generated a sub-culture of well-being in those who used it, particularly in the USA, and it was prolifically used for this purpose rather than for its appropriate therapeutic indication.

The European-wide marketing approval of sildenafil was followed by a (temporary) 'ban' on its prescription

under the UK's NHS, unless under exceptional circumstances. It is available, according to 'interim guidance', on private prescription only from a General Practitioner who is not the patient's usual physician (or one of the practice partners). This issue was subsequently debated in the medical and lay press, and the rights and wrongs of these central decisions closely argued. Pfizer Ltd have halved the cost of each tablet to just under £5.00. The Government has not opened up a public debate; rather they have taken the line of discussions with experts and the manufacturers. An outcome of these deliberations is still awaited at the time of writing.

The UK government stance on the cost of sildenafil is not an isolated case: in other countries, cost reimbursement to pharmaceutical companies has to be negotiated separately to technical (quality, safety and efficacy) marketing approval (such as in France and Italy), and here the manufacturers have not applied for reimbursement. In Germany the drug can be prescribed by physicians but is not covered by private insurance plans; most notably, in the USA its use is now controlled by various prescribing policies on a state-by-state basis (for example by limiting the number of tablets allowed per month - typically a maximum of 4-6 tablets - or by requiring detailed proof of cost-effectiveness). Furthermore, the largest health maintenance organisation, Kaiser Permanente, has taken the unprecedented step of refusing to reimburse the costs of sildenafil to the patient - it usually reimburses 80% of drug costs).[6]

In an editorial in the *British Medical Journal*, Richard Smith expressed a wish that many must share in the debate on potential rationing of resources in the UK and that this discussion should be an open, pro-active, well-balanced and co-ordinated exercise, rather than a closed, 'on the hoof', reactive process.[7] Hopefully this is what the UK government intended to spark off, using sildenafil as a catalyst and NICE as a focus. The interval between the marketing approval of the former and the useful functioning of the latter is unfortunate, and the continuing silence from the Government is of concern. Recognition of a more general shortfall in the UK NHS resource will also have to be addressed in a positive, comprehensive and constructive fashion.

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