ALL-PARTY PHARMACY GROUP

The regulation of medicines

A report to Health Ministers

Background

The government's health strategy places growing emphasis on self-care. The logic for this development in policy is sound: in many cases, patients are able to treat a minor or common ailment with an over-the-counter (OTC) remedy. The benefits to all concerned are clear. Patients can quickly and conveniently relieve the symptoms and treat the condition; GPs can devote their time and effort to patients who need their expertise; and the NHS can make significant efficiency savings.

Yet medicines – including OTC products - are more potent, complex and numerous than ever before. If self-care is to be further progressed, issues arise concerning patient information, professional intervention and effective regulation.

These issues were brought to a head earlier in 2002 when a working party on the re-classification of medicines produced a strategy document containing proposals for moving various products from prescription-only (POM) to pharmacy sales (P) status. The working group included the Royal Pharmaceutical Society of Great Britain, the Medicines Control Agency, the Association of the British Pharmaceutical Industry, the Royal College of General Practitioners and the Proprietary Association of Great Britain.

Our deliberations

Against this background, we took the view that a number of issues need to be addressed in order to set the direction and pace of regulatory change. How best should the availability of medicines be regulated? Are the current regulatory classifications – prescription-only, pharmacy-only and general sales – appropriate for the future? How much scope is there for further de-regulatory change within those categories? In whose interests are medicines regulated and whose interests would significant de-regulatory change best serve? Does regulation ensure patients use

medicines safely and appropriately? Should the provision of more clear and accurate information mean less regulation?

We were fortunate to be joined at our meeting in March 2002 by two expert guest speakers: Nick Bosanquet, Professor of Health Policy at Imperial College, London, and Harry Cayton, Chief Executive of the Alzheimer's Society.

Professor Bosanquet put forward two propositions. First, that there should be a greater flow of information to patients, and in this respect he saw direct-to-consumer advertising (DTCA) as a desirable development. Second, that the range of OTC medicines should be extended to provide patients with greater choice and ability to self-medicate.

He argued that healthcare and the policy issues around healthcare had changed substantially over recent decades. New ways needed to be found of delivering fast, effective, high quality care for patients. Traditional, hospital-based solutions were being – and should continue to be – supplemented by innovative healthcare mechanisms.

Professor Bosanquet set out a strong case for increasing the availability of information about medicines. He argued that access to information was vitally important, and that DTCA – in the form of television, radio or printed media advertising – was only one way to increase the information flow, and it may not be the most appropriate. From a public interest and patient perspective, information posted on manufacturers' websites, for example, was likely to be preferable to a television advertisement. Using various media, an increased flow of information would not only empower patients but it would also enable health professionals to access more information and it was likely to promote a better understanding between health professionals and pharmaceutical manufacturers.

In considering the future range of OTC medicines, Professor Bosanquet argued that pharmacists should have an enhanced role in monitoring and advising on the use of such products. He saw encouraging developments in this regard already, notably in relation to smoking cessation and obesity. He identified the areas of dermatology and gastric conditions as opportunities for greater use of pharmacists' counselling skills.

Harry Cayton agreed that pharmacists played a vital part in helping people to use their medicines safely and effectively. He pointed out that, for many patients, speaking to the pharmacist in the relatively informal setting of the community pharmacy is easier than talking to their GP. He found that time spent waiting in a pharmacy for a prescription to be dispensed was time when patients could receive additional advice on ailments, medication and good health.

The NHS currently spends around £5 billion per year on medicines. A significant amount of that medicine is wasted through non-adherence, non-use and over-prescribing. Around 3% of all prescribed medicines are returned unopened. Failure to complete a course of medication is commonplace. Mr Cayton observed that this was often due to side effects that were of concern to the patient but regarded as of little consequence by the prescriber and the manufacturer. He also noted that the market in vitamins, supplements and herbal remedies has grown significantly.

Consumers were willing to spend money on medicines, and could presumably be encouraged to spend more. However, it was suggested to us that lifestyle changes could, in many cases, prove more effective. De-regulating medicines, and increasing the availability of a greater number of medicines, would not of itself lead to better medicines usage or improved therapeutic outcomes.

Mr Cayton reflected on the needs of those he represented. Patients suffering from Alzheimer's disease were major consumers of medication. But increasing their access to medicines was not to be equated with empowering them. More important is the availability of credible information and the ability to take responsibility for their own health. DTCA was unlikely to be a source of reliable and credible information about medicines. Existing patient information leaflets were generally poor. Were there to be a de-regulatory shift, it should be accompanied by improved information for health professionals.

He also argued that informed patients should be taking fewer medicines, not more. He therefore questioned whether the provision of more and better information to patients and health professionals sat easily with the interests of the pharmaceutical industry.

Our view

Our speakers offered sharply contrasting views on the current regulatory status of medicines and the way ahead. Nevertheless, there was common ground between them in relation to the role that pharmacists play in the supply of medicines. Not for the first time, we are struck by the degree of consensus that exists in relation to the value of the pharmacist's input into patient care, and – of equal importance – the potential to develop and increase that input. It is notable that this view applies across almost all of the issues we have considered in recent times, from medicines management to prescribing to reducing wasted medicines. Whilst the government has committed itself to realising that potential, it seems clear to us that the objective is still some way from being met.

Since our meeting the Medicines Control Agency has published its proposals to extend prescribing rights for health professionals other than doctors (MLX 284). Included in those proposals is supplementary prescriber status for pharmacists. We have indicated in a previous report to ministers (*Pharmacist Prescribing,* March 2001) our strong support for extending prescribing rights to pharmacists. We see this process as being directly linked to the issues we considered concerning the regulation of medicines. Prescribing by pharmacists could go a long way to achieving the desirable objectives of increasing the appropriate use of medicines, improving adherence to medication regimes, reducing waste, and educating and informing patients about their medicines. And, of course, pharmacists often already engage in 'counter prescribing' when they supply P medicines and other OTC products.

In our view, direct-to-consumer advertising is not the way to increase patients' knowledge of medicines, nor to promote their appropriate use. We therefore disagree with Professor Bosanquet on this point. We acknowledge, however that the internet provides a largely unregulated outlet for DTCA, and consumers in the UK who wish to do so may access such material.

We wish to see better access to effective medicines, but we wish to see that accompanied by better information for both patients and health professionals.

Recommendations

Recommendation One: The existing medicines classifications should be retained, but shifts from POM to P should be implemented wherever appropriate in order to increase access and reinforce the self-care message. Re-classification from POM to GSL should be viewed with caution.

Recommendation Two: The Department of Health should explore with the organisations representing pharmacists ways of recognising, formalising and developing the role that pharmacists play in advising on the use of medicines.

Recommendation Three: Progress towards pharmacist prescribing, as described in MLX 284 published by the Medicines Control Agency in April 2002, should be swift. Issues concerning training and skill mix should be addressed as a priority.

Recommendation Four: Active consideration should be given to ways in which patient information, and information available to health professionals, can be improved.

Recommendaiton Five: The current range of patient information leaflets should be reviewed for their practical effectiveness, their use of language, accuracy and completeness.

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