Treating asthma

Clinical efficacy and safety of generic inhalers is well established

EDITOR,—Mike Pearson and colleagues advance the thesis that generic inhalers are therapeutically inequivalent and that this may not be “safe or desirable for patients.”¹ In support of their case they cite one *in vitro* study,² and they claim that five studies have shown biological inequivalence, though they cite only two of these. The first, from Finland, relates to a product made and sold in Finland but not in Britain³; the differences in lung function were significant but not clinically important, and the authors concluded that “both preparations proved to be effective.” The second paper, from Australia, showed small differences under laboratory conditions, but its authors concluded that “no clinical significant difference occurs between the bronchodilator effects of salbutamol and those of salbutamol sulphate which is administered as 200 µg of salbutamol equivalent, with different propellant mixtures, dispersal agents and inhaler systems.”⁴ These papers in no way provide evidence to challenge the clinical efficacy of generic inhalers, whose use is now well established.

Pearson and colleagues then refer to oral modified release preparations of theophylline and calcium antagonists, for which it is widely acknowledged that variations in bioequivalence may be clinically important. The issues here, however, are safety and a narrow therapeutic margin. These factors are not in question with inhaled steroids and bronchodilators; drawing comparisons with the biopharmaceutics of oral forms is irrelevant and serve only to confuse the issue.

In the north of England many practices have increased their rates of generic prescribing of inhaled salbutamol and some have converted completely. There have been no clinical problems, few problems concerning patients' satisfaction (provided proper explanation of the change is given), and considerable financial savings that release NHS funds to be used in other areas.⁵ Extending the use of generic inhalers is an important element in most regional and local prescribing strategies. It achieves substantial savings at no detriment to patient care, and the letter by Pearson and colleagues (most of whom declare a relationship with companies that have a vested interest) may be a measure of the success of this strategy.

J M SMITH
Regional pharmaceutical adviser
D N BATEMAN
Medical director

Northern and Yorkshire Regional Health Authority,
Regional Drug and Therapeutics Centre,
Newcastle upon Tyne NE1 4LP

- 1 Pearson M, Lewis R, Watson J, Ayres J, Ibbotson G, Ryan D, et al. Generic inhalers for asthma. *BMJ* 1994;309:1440. (26 November.)
- 2 Newman SP, Kenyon CJ. Asthma products bioequivalence. *Pharm J* 1994;253:42.
- 3 Saarelainen P, Sovijarvi ARA. Comparison of acute bronchodilation effects of two preparations of salbutamol aerosol in asthma. *Current Therapeutic Research* 1991;50:224-30.
- 4 Ruffin RE, Latimer KM, Crockett AJ, Blight MM. A comparative bronchodilator study of salbutamol and salbutamol sulphate that were administered by metered-dose inhalers. *Med J Aust* 1989;150:274-7.
- 5 Young JD. Prescribing generic drugs. *Br J Gen Pract* 1994;44: 139-40.

Advice to authors

We prefer short letters that relate to a recently published article and we are unlikely to publish letters longer than 400 words and containing over five references. Letters may be shortened. Your letters should be typed with double spacing and include a word count. All authors need to sign the letter and provide one current appointment and address. We encourage you to declare any conflict of interest. Please enclose a stamped addressed envelope if you require an acknowledgment.

Prescription pricing authority aims to promote high quality prescribing

EDITOR,—Dermot Ryan and Mark Levy, in their letter about the reports sent by the Prescription Pricing Authority, make three main comments about the centre page report on asthma sent to all general practitioners in England in August 1994.²

The Prescribing Research Unit and the General Practitioners in Asthma Group, of which Ryan and Levy are members, jointly undertook the research on which the comment from the Prescribing Research Unit was based. It would not have been appropriate to cite the level of statistical detail required by Ryan and Levy, but the points being made would have been more easily understood with a little more explanation. The words “should be” in relation to all three pointers on cost were intended in the sense of “are likely to be” rather than “have to be,” and we had hoped that these pointers would be of interest to practitioners.

The figure of £80-90 was not the cost of drugs for a year for a patient with asthma but the practice's total costs for respiratory drugs divided by its number of patients diagnosed as having asthma. For study practices with low diagnostic rates this cost could be up to £500; those whose diagnostic rate was at or above the generally accepted national rate of 7% had a figure of around £80 (at 1991 prices).

Ryan and Levy dispute our claim that “recent research indicates that all metered dose salbutamol inhalers now have similar performance.” All generic salbutamol inhalers have a product licence from the Medicines Control Agency, which is issued only after equivalent bioavailability has been demonstrated. Recent research by the Mersey quality control service has shown that all licensed products currently available in Britain comply with the *British Pharmacopoeia's* monograph for salbutamol pressurised inhalers and that there are probably no clinically significant differences between the various generic brands.³ Currently the Mersey quality control service is reviewing the performance of all beclomethasone inhalers.

We reject Ryan and Levy's allegations that “the Prescription Pricing Authority is being used to apply downward pressure on general practitioners' prescribing for patients with asthma.” Our aim is to promote high quality prescribing even if this involves extra costs. The topical commentary in the newly styled report giving prescribing analysis and cost (PACT) data is designed to encourage self

analysis and audit of individual and practice prescribing behaviour, an approach supported by the General Medical Services Committee.

JOHN FERGUSON*
Medical director

Prescriptions Pricing Authority,
Newcastle upon Tyne NE1 6SN

C M HARRIS*
Director

Prescribing Research Unit,
University of Leeds,
Leeds LS2 9NZ

G ENGLAND*
Director

Medical Advisers' Support Centre,
Liverpool L3 6AL

N HOUGH*
Director

Medicines Resource Centre,
Liverpool L3 6AL

M G LEE
Regional quality control pharmacist

North West Regional Health Authority,
Liverpool L3 6AL

D ARCHER*
Director

Management Services Information
Systems Development Unit,
Stockport SK1 3SH

T EWINGTON*
Senior principal

P CLAPPISON*
Senior medical officer

NHS Executive,
Leeds LS2 7UE

- 1 Ryan DP, Levy M. Unscientific assertions on treating asthma in general practice. *BMJ* 1994;309:1232-3.
- 2 Prescription Pricing Authority. *Asthma and inhaler therapy*. Newcastle upon Tyne: PPA, August 1994.
- 3 Lee MG, Ireland DS, Dwyer PJ, Weir PJ. Comparison of salbutamol inhalers available in the United Kingdom. *International Journal of Pharmacy Practice*. 1993;2:172-5.

*Members of the editorial board of PACT centre pages.

Oxygen is the first drug to use in acute asthma

EDITOR,—Simon A Evans and colleagues' survey of general practitioners' equipment for managing acute severe asthma highlights a common omission in management.¹ The British Thoracic Society's guidelines referred to in the paper suggest that the first drug to be used in acute severe asthma is oxygen.^{2,3} Unfortunately, the authors did not ask whether the general practitioners surveyed carried oxygen.

Hypoxia is universal in acute severe asthma and may be transiently exacerbated by bronchodilator treatment if compressed air rather than compressed oxygen is used to drive the nebuliser. Some studies suggest that as many as three quarters of deaths from asthma take place before the patient reaches hospital and that progression in these cases is rapid.⁴

Refillable portable oxygen cylinders are available and would be useful in many emergencies, including acute severe asthma. A question about oxygen would have made the survey complete and might have encouraged general practitioners to consider carrying a potentially lifesaving drug.

GRAHAM STEWART
Consultant paediatrician

Department of Paediatrics,
Royal Alexandra Hospital,
Paisley PA2 9PN