

DoH issues guide to implementation of supplementary prescribing online

THE Department of Health has issued a guide for implementation of supplementary prescribing in England. The guide, which applies to pharmacists and nurses, explains how such prescribing will work and who can undertake it and covers legal, training and evaluation issues.

Gul Root, principal pharmaceutical officer at the DoH, reminded *The Journal* that it plans to introduce supplementary prescribing from April 2003. Nurses have already begun training, while pharmacists will begin to train from spring 2003.

The relationship between independent and supplementary prescribers is the key to safe and effective prescribing, says the guide. The two professionals must be willing and able to work together and communicate easily, share access to and keep a common patient record up to date. Both may work in more than one prescribing partnership.

Supplementary prescribers must prescribe in accordance with the clinical management plan (CMP). They must monitor and assess the patient's progress and work within their clinical competence. They have clinical responsibility for and must be pro-

fessionally accountable for their practice but must pass responsibility back to the independent prescriber if adequate reviews are not undertaken. The supplementary prescribing must be supported by regular clinical review of the patient by the independent prescriber at intervals no longer than one year, and much less if antibiotics are included.

The guide says that individual CMPs should be drawn up and agreed before supplementary prescribing begins. The DoH has drafted two sample templates. The independent prescriber is responsible for setting the parameters of the CMP although they do not need to draw it up personally.

Pharmacists are encouraged to record all details of monitoring and supplementary prescribing. Information should ideally be entered immediately on the common patient record. Pharmacists should not have a system of separate records. If not possible, separate records should be transferred to the common patient record within 48 hours.

For pharmacists prescribing with the consent of their employer, the employer is held vicariously liable for their actions. The guide says that all supplementary pre-

scribers should ensure they have professional indemnity insurance. Pharmacists are reminded that they should not prescribe any medicine outside their area of competence.

Pharmacists undertaking supplementary prescribing must have at least two years post registration experience and have completed an approved training programme (*PJ* 4 January p21).

The DoH says that dispensing and prescribing need not necessarily be separated provided clear accountability arrangements are in place to assure patient safety and probity. Rules for dispensing and reimbursement of supplementary prescribers' scripts will be the same as for GPs'.

Dispensing pharmacists will have to check the status of prescriptions received from supplementary prescribers. The guide advises them to have a local list of bona fide prescribers with a copy of their signatures. An individual's prescribing status will also be held by the Nursing and Midwifery Council and the Royal Pharmaceutical Society.

The guide can be downloaded as a PDF file from the Department of Health website (www.doh.gov.uk/supplementaryprescribing).

NICE says "no" to amantadine for influenza treatment

THE National Institute for Clinical Excellence has recommended that amantadine (Lysovir) should not be used for the treatment of influenza.

In new guidance issued this week, the institute also recommends that neither zanamivir (Relenza) nor oseltamivir (Tami-flu) should be used to treat a 'flu-like illness in people who are otherwise healthy (ie, unlikely to be at risk of developing complications).

The guidance supercedes recommendations made by NICE on the use of zanamivir in November 2000 (*PJ*, 25 November 2000, p777) and introduces guidance for amantadine and oseltamivir.

It states that when the number of people with 'flu reaches a high-enough level in the community, zanamivir or oseltamivir are recommended to treat 'flu-like illness in those considered to be at risk of developing complications, provided that they start treatment within 48 hours of the onset of symptoms.

People considered to be at risk include those aged 65 years or over, those with chronic lung disease, heart disease, long-term kidney disease, or diabetes and those with a compromised immune system.

At-risk patients over 12 years can be treated with either agent but oseltamivir is recommended to treat 'flu-like illness in children (aged over one year).

NICE says that it considered several points when developing its recommendations. These include the low probability that

people with 'flu-like illness actually have 'flu when the viruses are not circulating in the community. The institute also noted that the rate of GP consultations would increase if a 'flu drug was thought to be readily prescribable.

The cost of using zanamivir and oseltamivir in any year will depend on the severity of the outbreak, NICE says, and is estimated at between £2m and £15m. The drugs become increasingly cost effective as the severity of an outbreak rises, particularly in winter when there is pressure on use of hospital beds.

NICE emphasises that it considers vaccination the most effective way of preventing illness from 'flu and that the drugs for 'flu treatment should not be used instead of immunisation. It calls for 'flu monitoring schemes to be used to spot the start of an outbreak as quickly as possible.

The manufacturer of Lysovir, Alliance, expressed disappointment at the recommendations made by NICE, stating that much of its data, extending to over 36,000 patients, related to otherwise healthy patients, and had thus been discounted by NICE's "rigid methodology".

NICE says that, following appeals against draft guidance, it is reconsidering evidence on the use of the antivirals in 'flu prophylaxis. It expects to issue these recommendations in June, this year.

Insulin pump therapy Insulin pump therapy is recommended as one option for people with type 1 diabetes, says NICE in guidance

issued this week. It says pump therapy can be considered when multiple dose insulin has failed to manage a patient's diabetes provided the patient is willing and able to use such therapy. NICE adds that people beginning insulin pump therapy should be provided with training and ongoing support. Insulin pump therapy is not recommended for people with type 2 diabetes.

NICE has also issued guidance on the use of tension free vaginal tape for stress incontinence.

NICE guidance can be accessed via the internet (www.nice.org.uk).

Promising result for low-dose warfarin

A STUDY of low-dose warfarin treatment has been stopped early because of promising results in patients with recurrent venous thromboembolism.

The group carrying out the trial says that patients suffering clots of unknown origin in their legs or lungs (idiopathic venous thromboembolism) are usually treated for just three to 12 months with full-dose warfarin with a target international normalised ratio (INR) of 2 to 3.

No agent has, so far, been found to have an acceptable risk:benefit ratio for long-term management, they add. But in this trial, after around six months of standard treatment, 508 patients were randomised to receive either placebo or "low intensity" warfarin (target INR 1.5 to 2) long-term.

Patients had been treated for an average of two years when the trial was terminated following an interim analysis. Rates of recurrent venous thromboembolism were reduced from 7.2 to 2.6 per 100 person-years, a risk reduction of 64 per cent. Major haemorrhage occurred in two patients taking placebo and five taking warfarin. However, eight patients in the placebo group died compared with four in the warfarin group. This equated to a 48 per cent reduc-

tion in the composite end point of recurrent event, major haemorrhage or death.

The study is due to be published in the 10 April issue of *The New England Journal of Medicine* but has been published early online because of its therapeutic implications (<http://content.nejm.org>).

Dr Stephan Moll, of the University of North Carolina, one of the study's authors said: "Until now we had to accept that about 20 to 25 per cent of patients would go on and have another blood clot once blood thinners were stopped."

He continued: "We found the later [low intensity warfarin] maintenance dose to be not only safe in that it did not increase the risk of major bleeding but also effective in preventing a recurrence of clots. That means a maintenance dose should become the new standard of care for patients following a first blood clot and the current treatment."

In an accompanying editorial, Dr Andrew Schafer, University of Pennsylvania, Philadelphia, agrees that the new regimen could be used for patients requiring more than three months of anticoagulation after an initial event. But he warns of forthcoming data showing that a low-dose regi-

men (INR 1.5 to 1.9) was less effective than conventional warfarin (INR 2 to 3). He calls for a three-way trial of conventional, low dose and placebo therapy.

Fear of vascular disease should not stop HIV therapy

CONCERNS about possible cardiovascular complications of antiretroviral therapy should not prevent its use, say researchers.

Reports have hinted at an increased risk of cardiovascular disease, particularly among patients receiving protease inhibitors. Such reports have dampened enthusiasm for early treatment of HIV infection and have sparked interest in different treatment approaches, such as intermittent antiretroviral therapy.

However, Dr Samuel Bozzette of the University of California, San Diego, and colleagues, say that fear of accelerated vascular disease need not compromise antiretroviral therapy over the short term.

They conducted a retrospective study of 36,766 patients who received care for HIV infection between 1993 and 2001. They found that use of newer therapies for HIV was associated with a large benefit in terms of mortality that was not diminished by any

increase in the rate of cardiovascular or cerebrovascular events. "After the introduction of highly active antiretroviral therapy, the rate of admission for cardiovascular or cerebrovascular disease decreased from 1.7 per 100 patient-years in 1995 to 0.9 per 100 patient-years in 2001," they say. In addition, overall rate of death dropped steadily from 1995 to 2001.

The researchers say there was a reduced risk of death from any cause for each of the three classes of antiretrovirals (nucleoside analogue, protease inhibitor or non-nucleoside reverse transcriptase inhibitor) used by patients. They add that estimates of risk reductions for combination therapy were similar (*New England Journal of Medicine* 2003;348:702).

In an accompanying editorial (ibid p679), Dr Daniel Kuritzkes, of Harvard Medical School, Boston, and Dr Judith Currier, of the University of California, Los

Angeles, agree that for patients at immediate risk for AIDS or death from HIV infection, fear of cardiovascular complications of antiretroviral therapy should not prevent its use. However, they add: "For patients with earlier stages of HIV infection, the use of antiretroviral agents that are less likely to produce hyperlipidemia and insulin resistance still seems prudent." They suggest that efforts at prevention such as taking regular exercise and smoking cessation should also be recommended for all patients.

Liz Davies, principal pharmacist, HIV & GU medicine, Chelsea and Westminster NHS Trust, London, told *The Journal* that the benefits of HIV therapy certainly outweighed the risks. "But if patients start to live longer, we may see more complications," she said.

She also pointed out that HIV-infected patients may be at increased risk of cardiovascular disease because of the disease itself.

New eczema cream works well in young infants

PIMECROLIMUS (Elidel) cream is an effective treatment for atopic dermatitis in infants as young as three months, according to the authors of a new study (*Journal of Pediatrics* 2003;142:155).

They found that after six weeks of treatment, more than twice as many patients treated with pimecrolimus than a placebo cream (Elidel base without active ingredient) were rated as clear or almost clear of

eczema. The study, funded by Novartis, involved 186 infants, aged three to 23 months, with mild to moderate eczema.

The researchers say that in the first 15 days of treatment the proportion of patients in the pimecrolimus group rated as clear or almost clear of eczema increased rapidly to 37.4 per cent. After six weeks the proportion rose to 54.5 per cent, compared with 23.8 per cent for the control group ($P < 0.001$). By

day 43, pruritus "the most bothersome symptom of atopic dermatitis" was absent or mild in 72.4 per cent of pimecrolimus-treated infants compared with 33.3 per cent of control infants ($P < 0.001$).

Overall, there was a slightly higher incidence of adverse events in the pimecrolimus group compared with the vehicle group.

Elidel is currently licensed for use in adults and children over two years.

Politicians are petitioned

PETITIONS signed by pharmacy customers opposing the deregulation of pharmacy contracts have been presented to politicians in Scotland and England.

Elizabeth Roddick, chairman of the Glasgow Area Pharmaceutical Committee, presented a petition with over 500 signatures to her Member of the Scottish Parliament. Mike Watson, Scottish Minister for Tourism, Culture and Sport, visited Mrs Roddick's pharmacy on 21 February to receive the petition and discuss the issues raised by the Office of Fair Trading report. Later that day, a copy of the petition was presented to Tom Harris, Labour Member of Parliament for Glasgow Cathcart, at the pharmacy. The petition form was designed with assistance from the Scottish Pharmaceutical General Council and has been sent to all pharmacies in Glasgow.

Elliot Morley, Labour MP for Scunthorpe, was also presented with petitions on 21 February. He visited Moore's Chemist, at Battersford in his constituency, to receive a petition with over 400 signatures collected



Mrs Roddick hands over her petition to MSP Mike Watson

from two branches of a chain owned by Independent Pharmacy Care Centres.

Other action in response to the OFT report is summarised in the panel below.

Not too late to lobby MPs, says NPA V-C

PHARMACISTS should continue lobbying Members of Parliament until the April closure date for consultations on the Office of Fair Trading report, National Pharmaceutical Association vice-chairman Hemant Patel is urging.

"While the Department of Health has asked for formal responses to the OFT report by 28 February, it is not too late to lobby MPs," Mr Patel told *The Journal*. "MPs will have a vital role behind the scenes in deciding the outcome of the Government's response to the report. This will continue until the decision is announced. Pharmacists should keep up their hard work until then," he said.

Mr Patel said that MPs need to be made aware of some of the unintended consequences that could follow if pharmacy contracts were deregulated, including the creation of local monopolies if general practitioners are allowed to control all the medical, nursing and pharmaceutical services in an area.

Members of Parliament join in expressing concerns over OFT report

APPG The All-Party Pharmacy Group has sent its response to the Office of Fair Trading report on control of entry to ministers at the Department of Health and the Department of Trade and Industry following its meeting last month (*PJ*, 15 February, p215). The APPG report says that the group is not convinced that outright deregulation of the controls over pharmacy contracts would achieve the OFT's stated aims of improving access, choice, competition and quality. The APPG recommends a collaborative approach to achieving these aims and, as part of this process, suggests that ways of modifying the current control of entry arrangements are found. Such changes should take place alongside the introduction of a new contract for community pharmacy, it says, and a firm date for this should be set. Ministers are urged to make a decision on control of entry as soon as possible.

London Pharmacies in the areas covered by six local pharmaceutical committees (North East London; Hertfordshire; Lambeth, Southwark and Lewisham; Kensington, Chelsea and Westminster; Merton, Sutton and Wandsworth; and Croydon) have been sent 270,000 postcards to be signed by customers opposing the OFT recommendation. The postcards will be sent back to pharmacies for forwarding to ministers and Members of Parliament.

North east London North East London Local Pharmaceutical Committee is holding a dinner at the House of Commons on 28 March, hosted by Tony Banks (Lab, West Ham). The 15 MPs in its area, including the Leader of the Opposition (Iain Duncan-Smith), and primary care trust chief executives have been invited to hear about plans for improving health through pharmacies.

Numark Pharmacist members of Numark have been using geodemographic profiles of their areas to explain their cases in meetings with MPs. The profiles show localities in their area which have high numbers of older people, those on low incomes or who do not have access to a car. The maps also show current distributions of pharmacies and supermarkets.

Scotland The Scottish Parliament discussed its response to the OFT report on 20 February. First Minister Jack McConnell said that the Scottish Executive would aim to protect the community pharmacy network on behalf of the National Health Service in Scotland. He noted the health advisory role of pharmacists and the need to maintain access to pharmacies, particularly in rural areas. The Royal Pharmaceutical Society has sent a briefing note on the OFT report to all MSPs.

Generic manufacturer opposes changes to child-resistant packs

PACKAGING aspirin, paracetamol and iron preparations in blister packs that meet a new child-resistance standard will not improve patient safety, the United Kingdom's largest generics manufacturer claims.

Alpharma says making the packaging for these products more difficult to open will cause problems for patients who may well respond by having their medicines decanted into unlabelled containers, endangering themselves and putting children at risk.

The company says that there is no research to suggest that enforcing British

Standard BS8404 on child-resistant packaging will prevent the accidental taking of medicines by children. However, it says, the increased use of conventional blister packs has contributed to safety over and above the use of child-resistant reclosable containers.

Alpharma says that the increased costs of new packaging may lead to companies withdrawing unprofitable products. It is also calling for greater co-ordination in regulatory changes to packaging, such as the use of international non-proprietary names and barcodes.

BRIEFLY

UK medicines sales up in 2002

Sales of medicines in the United Kingdom grew by 10 per cent to \$10.8bn (£6.9bn) in the year to December 2002 — the biggest growth in Europe — according to figures from IMS Health. The UK regained its position as Europe's third largest market. World sales grew by 7 per cent to \$275.8bn, of which \$154bn were in the United States. The world's best-selling drugs were Lipitor (atorvastatin), Zocor (simvastatin), Losec (omeprazole), Norvasc/Istin (amlodipine) and Ogas-tro/Zoton (lansoprazole).

Tell quitters of increase in colds and mouth ulcers

SMOKERS trying to stop should be informed that they have an increased chance of developing mouth ulcers or cold symptoms, authors of a new study say.

They found that smokers have an increased chance of experiencing aphthous ulcers and cold symptoms, such as sore throat, coughing and sneezing, for up to two weeks after quitting. After six weeks all such symptoms had subsided.

The authors say that an increase in mouth ulcers could be related to the loss of the antibacterial effect of smoking, and the cold symptoms might be due to a transient depression in immune function after kicking the habit.

They suggest that people are more likely to take up the habit again if they are not psychologically prepared for the symptoms they might experience. "The body's backlash

could deter many ex-smokers from staying the course, unless they know what to expect," they say (*Tobacco Control* 2003;12:86).

Call to revive palliative care group

PHARMACISTS from four hospitals in the United Kingdom are hoping to revive a palliative care interest group and are calling on other pharmacists to register their interest.

Andrew Dickman, specialist principal pharmacist at the Whiston Hospital in Merseyside, told *The Journal* that the Hospice and Palliative Care Pharmacists' Association, of which he is a co-opted member, has been inactive for some time.

However, he believes it is important that pharmacists working within palliative care should not become isolated. "We therefore propose that the group will serve as a point of information exchange, provide educa-

tional support and act as a national voice." Mr Dickman said the group will organise at least one meeting per year and will develop a website to help information exchange between palliative care pharmacists.

"In order to proceed, we need to know how many pharmacists from both community and hospital would actually be interested in joining," he said.

Pharmacists interested in joining the group should e-mail their job titles and work addresses to hpccs@lineone.net or send them to Andrew Dickman, Specialist Principal Pharmacist, Palliative Care Team, Whiston Hospital, Merseyside L35 5DR.

PJ Online

PJ Online contains the editorial contents of *PJ* publications.

No Smoking Day

12 March is No Smoking Day. This page has articles, links and telephone numbers. www.pjonline.com/topics

Reunions

If you are planning a reunion, you can e-mail details to reunions@pharmj.org.uk www.pjonline.com/reunions

Statutory Committee reports

The "Society" section of the "Noticeboard" has links to Statutory Committee, Council meetings and other reports. www.pjonline.com/noticeboard

Surveys

This section has a list of current surveys and results of previous ones. www.pjonline.com/surveys

Education

There are education and development resources. As well as homepages for CPD and pharmacy students, links include:

- Postgraduate courses for pharmacists
- Credit for learning
- Exercises in clinical accuracy checking
- Learning styles

www.pjonline.com/education

Pharmacy Information Pointers

These articles are produced and updated by the Society's Information Centre.

- Identification of foreign medicines
 - Technical information service publications
 - Medicines requiring storage at low temperature in the pharmacy
 - Preparation of chloroform water and peppermint water
- www.pjonline.com/pip

BRIEFLY

More people quit smoking

Almost 55,000 smokers gave up smoking last year with help from National Health Service smoking cessation services. This was over half of those who set a date for quitting, according to the Department of Health. Nicotine replacement therapy on its own was used by 73 per cent of people attempting to give up, 12 per cent received bupropion (Zyban) only, and 2 per cent received both.

Improvement in 'flu vaccine uptake

An extra 350,000 elderly people were immunised against influenza this winter compared with last winter with over 5.5 million people aged 65 years and over being vaccinated, according to the Department of Health. Of 304 primary care trusts, more than half (154) achieved the Government's target uptake rate of 70 per cent or above. The lowest uptake rate for any PCT was 49 per cent.

Pregnant women should limit tuna

Pregnant and breast feeding women, and women who intend to become pregnant, should limit their intake of tuna to no more than two medium-sized cans or one fresh tuna steak per week, says the Food Standards Agency. This is because of the small risk to the child from mercury in certain species of fish. These women should also avoid eating shark, swordfish and marlin, it says.

Erectile dysfunction on the up

Recorded diagnoses of erectile dysfunction have more than doubled since the launch of sildenafil (Viagra) in the United Kingdom, researchers report. Using data from the UK general practice research database they found that the incidence of this condition increased gradually during the mid-1990s then rose two- to three-fold from 1998 to 2000 (*BMJ* 2003;326:424).

ROYAL PHARMACEUTICAL SOCIETY NEWS

Workforce census results

The Society has published a summary of the results of the census of members conducted between September and December 2002. Among the findings are that 21 per cent of respondents are from minority ethnic groups and 30 per cent of those working in community pharmacy are locums (pp313, 314).

Manchester to host BPC from 2004

The Manchester International Convention Centre is to be the long-term home for the British Pharmaceutical Conference from 2004. Bookings have been made until 2008 (p316).

Pharmacists must help to manage the use of amiodarone in primary care

COMMUNITY pharmacists must be alert to the possible unwanted effects of amiodarone, according to a consultant cardiothoracic pharmacist.

Mojgan Sani, consultant pharmacist, cardiothoracic centre, Guy's and St Thomas' Hospital Trust, spoke to *The Journal* in the light of a review of amiodarone safety published in the *Drug & Therapeutics Bulletin* last week (2003;41:9). The review outlines the drug's potential to cause unwanted effects, some of which can be fatal.

The bulletin emphasises that, though amiodarone is usually initiated and monitored under hospital supervision, responsibility for maintenance therapy often falls to

the general practitioner. In England, in 2001, around one million scripts for this drug were dispensed in primary care. "Most serious toxicity is seen with long-term use and may therefore present first to GPs. Prompt recognition and action usually reverses toxicity, although due to the drug's long half life, reversal may be slow," the DTB says.

Mrs Sani points out that first presentation may actually be to the pharmacist. She notes that awareness of the adverse effects of amiodarone is a good example of how community pharmacists can effectively be involved in medicines management and review. "Polypharmacy may be particularly important in this respect," Mrs Sani says.

She adds that a multidisciplinary approach is needed to ensure that patients taking amiodarone who experience unwanted effects are quickly referred back to the GP and, if necessary, their cardiologist.

The bulletin reminds doctors and pharmacists that amiodarone is licensed for the treatment of severe cardiac rhythm disorders where other treatments have failed or cannot be used. It has several dose-dependent or idiosyncratic adverse effects (see Table).

The DTB says that amiodarone's unwanted effects seem to occur less frequently with low-dose maintenance therapy (100–200mg) than with older, higher-dose regimens (above 400mg daily) but there are no direct comparisons. Patients should have careful clinical assessment and monitoring before starting therapy. Thereafter, measurements of thyroid function, liver enzymes and possibly potassium concentration should be monitored every six months.

Professor Joe Collier, editor of the DTB, says: "Supervision of patients in the community needs the GP to be alert and informed."

He cautions: "The decision to withdraw amiodarone or modify dosage should only be made in consultation with a specialist."

TABLE: DOSE-DEPENDENT OR IDIOSYNCRATIC ADVERSE EFFECTS OF AMIODARONE

| Unwanted effect | Signs |
|---------------------|---|
| Pulmonary toxicity | Cough, progressive shortness of breath |
| Thyroid dysfunction | Hyper or hypothyroidism may occur, may appear as worsening of existing cardiac disorder, hyperthyroidism may appear after treatment is discontinued — monitoring required |
| Liver damage | Elevated liver transaminases — monitoring required |
| Cardiac toxicity | Cardiac symptoms may develop or worsen — ECG required |
| Visual disturbances | Halos or blurred vision — may warrant discontinuation |
| Neurological | Tremor, ataxia, peripheral neuropathy associated with high loading doses, usually improve on maintenance |
| Skin toxicity | Photosensitivity or blue/grey skin discoloration |

DTB calls for more research on tiotropium in COPD

THE *Drug & Therapeutics Bulletin* has called for more research on tiotropium (Spiriva) to assess its place next to cheaper and older antimuscarinic agents in chronic obstructive pulmonary disease (COPD).

Tiotropium was launched in September 2002 as the first once daily anticholinergic bronchodilator for use in COPD.

In a review of the efficacy and safety of tiotropium published last week, the bulletin outlines trials of the agent versus placebo, ipratropium and salmeterol in the maintenance treatment of COPD (2003;41:15).

It concludes that tiotropium appears to be more effective than the four times daily anticholinergic ipratropium in reducing exacerbations. But the bulletin adds that it is unclear from trials whether tiotropium is more effective than ipratropium in improving bronchodilation as measured by trough FEV₁.

The DTB highlights a lack of trials comparing tiotropium with the twice daily antimuscarinic agent oxitropium. And it asks whether the new inhaler for tiotropium, the HandiHaler, is suitable for patients with poor dexterity or cognitive problems.

In addition, the review calls for confirmation of data suggesting that tiotropium may be more effective than the long-acting beta₂-agonist salmeterol.

"At £37 for 30 days treatment, tio-

trópium bromide is more costly for the NHS than alternatives such as ipratropium, oxitropium and salmeterol," the DTB says in an accompanying press release. Its 30-day cost compares to about £2–£7 for ipratropium, £4–£6 for oxitropium, and £29 for salmeterol.

Professor Joe Collier, editor of the DTB, adds: "Tiotropium's once daily dosage could represent an advantage. However, its place with respect to the cheaper, twice daily

oxitropium bromide is not clear. To determine tiotropium's place in practice, trials using clinically relevant endpoints are needed to compare it with ipratropium and with oxitropium."

Boehringer Ingelheim and Pfizer, co-developers of Spiriva, say that the DTB, despite containing many positive conclusions about tiotropium, has made significant omissions that have generated misunderstandings about the drug.

They point out that oxitropium is not widely used either in the UK or globally and hence was not included in the study programme. They explain that trough FEV₁ was agreed with licensing authorities to be the most appropriate parameter in comparisons of tiotropium with other bronchodilators as a measure of persistent bronchodilation over 24 hours.

Commenting on price, Boehringer Ingelheim and Pfizer say that reductions in exacerbations and admissions to hospital with tiotropium could reduce overall therapy costs to the local NHS economy. This would more than offset the drug acquisition cost of tiotropium and would help release capacity within the system.

The companies emphasise that many improvements in breathlessness and health related quality of life were not included in the review.