

INFLUENZA PANDEMIC

## Might oseltamivir be a mixed blessing?

From Dr H. Pickles and Mrs V. Tailor, MRPharmS

The antiviral oseltamivir (Tamiflu) is a mainstream of UK government policy for dealing with pandemic influenza.<sup>1</sup> As flu pandemic co-ordinators struggle to make viable local plans for its storage and distribution, the mixed blessing it creates becomes more apparent.

First, will it work at an individual level? The National Institute for Health and Clinical Excellence had doubts in relation to regular flu,<sup>2</sup> and it has yet to be tested for the pandemic strain. The adverse effects may be significant and resistance has been reported,<sup>3</sup> and the more widespread the use of oseltamivir, the more likely this becomes. The formula for children is not yet ready and is untested. Conditions may have to be optimum for it to have any effect. Even so, the individual benefit may not be great nor can it be relied upon. Deaths may still occur after treatment with oseltamivir.<sup>3</sup>

Secondly, there are all the logistic issues of ensuring those most in need access it when those optimum conditions can be met. The appropriate symptoms for less than 48 hours with a fever of at least 38C are said to be required, but how those requirements would be validated at a dispensing stage is unclear. In any event, for those ill at home, it makes sense for a third party to collect the medicines. Encouraging the infected to attend pharmacies or emergency treatment centres, and so spread disease to the pharmacist and to other customers, needs to be avoided.

None of this would matter if there were plenty to go round and resistance was not an issue. But neither is the case. Access will have to be limited. The DoH has said it should be available for all-comers, so being registered with the NHS cannot be a criterion for access. Will it require use of the drug to be directly observed to ensure supplies are not for stockpiling or selling on? Not all oseltamivir offered in bars or on e-Bay will be counterfeit.

However careful the central policy and local actions, there will be perceived to be insufficient supplies. Hence there is the need for secure storage and plans for dealing with those angry at being denied the drug. In a pandemic there will be plenty of media

## Letters to the editor

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images of the death toll worldwide, and if oseltamivir is "sold" as life-saving many will be desperate to get supplies.

Health care workers and other essential workers may quite reasonably assume stocks will be secure for them if needed, but many others may feel the same and use their muscle to ensure they have privileged status, too. Indeed, the business sector, on being informed of the threat of pandemic flu, will want to know how their workers can be designated as key and hence be privileged recipients of limited supplies.

This will become divisive, and lead to difficult rationing decisions. Prophylaxis of immediate contacts in the early stages in an attempt to stamp out the incipient pandemic will be rapidly abandoned when the full pandemic is on us. However, those with access to supplies may feel differently if occupationally exposed, and put what they think are their short-term personal interests first. Most nations do not have the stockpiles we have in the UK, risking others coming here for our supplies, infecting others en route. For good reasons, prisoners and their warders may need some priority, but this will not go down well with the public.

Presumably we can, and will, work through all the above issues. If infectivity is dampened down and complications reduced, at one level oseltamivir will have worked at a population as well as an individual level.

But at what price? The real outcome we are striving for is a cohesive society at peace as it tries to rebuild itself once the pandemic is over. The current emphasis on vaccines and antivirals may be necessary to justify the current

government spend, but channels thinking into a medical model. It would be far better to stress all the positive things<sup>4</sup> which can be done by those who will be without antivirals, either because they are ineligible or because the drugs are rationed or turn out to be ineffective. Of these, increasing social distance and handwashing are important, but wearing face masks is of little value. We must avoid recriminations over who did and did not receive oseltamivir becoming a running sore in the post-pandemic period.

A new consensus is needed, dampening down expectations of antivirals, and raising the profile of all the other measures available and seeing beyond the hype. Even if the worse fears materialise, the vast majority will emerge from the pandemic with full physical health. Life will and must go on after the pandemic.

### Hilary Pickles

Director of Public Health

### Vasundra Tailor

Head of Medicines Management  
Hillingdon Primary Care Trust

### References

1. UK operational framework for stockpiling, distributing and using antiviral medicines in the event of pandemic influenza. London: Department of Health; 2005.
2. NICE Technology Appraisal no 58. Guidance on the use of zanamivir, oseltamivir and amantadine for the treatment of influenza. London: NICE; 2003.
3. De Jong MD, Thanh TT, Khanh TH et al. Oseltamivir resistance during treatment of influenza (H5N1) infection. *New England Journal of Medicine* 2005;353:2667-72.
4. World Health Organization Writing Group. Non-pharmaceutical interventions for pandemic influenza, national and community measures. *Emerging Infectious Diseases* 2006;12:88-94.

PREREGISTRATION TRAINING

## Paying bonuses is not a sensible way to improve preregistration training

From Mr I. F. Cawthorne, MRPharmS

Riaz Firfirey argues that the lump sum paid to community pharmacies for training preregistration pharmacists should be reduced, with a bonus at the end of the year for giving the student a satisfactory report (*PJ*, 17 December 2005, p752).

In my view the preregistration year is about ensuring the student is a safe and competent practitioner. It is important that preregistration tutors are able to give an impartial verdict on the student's abilities. By linking a bonus for a satisfactory report it would be difficult to feel confident that students were not being signed off inappropriately merely for the cash; indeed for unscrupulous tutors it would be an incentive for them to sign off sub-standard students.

Recognition also needs giving to the fact that most community pharmacy preregistration grants are used to subsidise the salary of the student. Reducing the grant would lead to a reduction in the trainee's salary.

There may be tutors who might put more effort into training their students. However, in my experience, the best scenario is an enthusiastic and dynamic trainee, who will inevitably energise and stimulate the whole process.

The vast majority of preregistration trainees are knowledgeable and competent and they put as much into a pharmacy department as they get out. We do need to make sure though that those students who struggle are given the support they need, but providing a bonus only for passing students is not a sensible way to make the system work.

### Ian Cawthorne

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### Broad spectrum

The Broad spectrum feature is open to any reader. Contributions of around 1,100 words commenting on topical issues should be sent to [graeme.smith@pharmj.org.uk](mailto:graeme.smith@pharmj.org.uk) for consideration

 COX-2s

## What is the POEM evidence for celecoxib?

From Mr P. D. Burrill, MRPharmS

I wish to respond to the letter from Chris Walker, of Pfizer Ltd (*PJ*, 24/31 December 2005, p773). His letter is similar to one published in the *BMJ* of 17 December (p1473) from Joe Feczko, chief medical officer at Pfizer, New York. Both these letters claim that celecoxib has a lower risk of gastrointestinal complications than competitors. Unfortunately, they rely on observational studies to support their claim and appear to be ignoring the randomised controlled trial data. Observational studies occupy a lower place on the hierarchy of evidence than a large, prospective RCT measuring patient-oriented outcomes.

Our colleague from the National Prescribing Centre, Jonathan Underhill, responded to the letter from Dr Feczko (*ibid*, p1474) and, for the benefit of readers who may not have seen it, the following abstract should prove informative: "The only POEM evidence for celecoxib is the CLASS study. CLASS showed no significant difference between celecoxib and the comparators (diclofenac and ibuprofen) in terms of the primary outcome of the study — gastrointestinal ulcer complications. Only when a post-hoc sub-group analysis of these data was performed in those not taking aspirin was a significant benefit seen (with a *P* value of 0.04). This was one of over 34 post hoc analyses performed on this study (so, by chance, we would expect at least one of these to show a difference with a *P* value slightly less than 0.05). Others have recently highlighted the folly of post hoc subgroup analyses where the primary end point does not show a significant difference.

"The regulators in the USA and in Europe have concluded that the data from the CLASS study do not show a meaningful benefit for celecoxib . . . . That the prescribing of this drug continues to increase despite the lack of good quality evidence for its usefulness in providing a benefit to patients is disappointing.

"Perhaps we should stop arguing about the wording of the conclusions of hypothesis generating data (like those of Hippiusley-Cox *et al*). Although such data are interesting, they do

not inform our practice in the same way that a negative prospective randomised controlled trial does."

**Peter Burrill**

*Assistant Director of Public Health  
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 CAM

## A pragmatic answer to consumer protection can be found

From Dr R. J. Woodward,  
MRPharmS

Recent years have seen an upsurge in demand for complementary and alternative medicines. Concomitantly, CAM research in academic institutions has increased. Yet results have been disappointing, inconclusive and have done CAM no favours.

The high-profile academic department in Exeter and its publications run by Edzard Ernst have demonstrated that resources for research are meagre because the CAM industry and profession are no match for big pharmaceutical companies and modern medicine. The truth is they never will be and I am puzzled why anyone wastes resources in the hopeless cause of trying to let CAM endeavour to emulate its giant competitor. Strict judgement of CAM by the criteria designed for modern drugs and medical interventions can never succeed.

Professor Ernst and his cohorts are clear in their demands that CAM treatments must be evidence-based with clinical trials that are independently replicated and validated. Practitioners of CAM who do not rely on such evidence are described as dishonest. That is disgraceful but should signal to the CAM movement that he is no friend. Much modern medicine does not meet these standards but does he describe doctors as dishonest? Misguided is a better word when all one is expressing is an opinion. Professor Ernst describes himself as a wishful thinking idealist — I would call him a blinkered academic with no grasp of reality.

Not long ago the organisation Healthwatch used the word "fraud" in one of its publications in connection with CAM and, rightly, heavy libel damages had to be paid. My experience of CAM practitioners is that most are decent, dedicated people who are

passionate about what they are doing. Above all, their patients are usually satisfied.

Many advocates of CAM believe they can protect themselves by taking the regulatory route. Some demand a regulatory body for every area of CAM — resources for both regulators and researchers coming from where?

The philosophy behind CAM health care is different from modern medicine. The clinical treatment methods are too diverse even within each CAM group to make meaningful research results attainable with infinite financial and human resources. Since no patents are available for CAM treatments, the accumulation of significant research funds is impossible. The reference to the CHARM trial (*PJ*, 10 December, p714) showing adherence to medication, even placebo, improves outcomes is surely most relevant in the CAM context.

I believe a pragmatic answer to consumer protection could be found without hyper-regulation if all sides admitted that the resource problem was insoluble. If it is not then waste will continue to no avail except the benefit of Professor Ernst, bureaucrats and the army of CAM technical and legal advisers and consultants.

**Robert Woodward**

*Liss,  
Hampshire*

EDZARD ERNST replies: Robert Woodward argues in favour of double standards: "judgement of CAM by the criteria designed for modern drugs and medical interventions can never succeed" because "the philosophy behind CAM . . . is different". This seems a big step, albeit in the wrong direction. If we do not assess health care on the basis of reliable evidence, by what should we evaluate it? The answer probably is by belief.

Thus CAM becomes a belief system and not health care. In this case, we should place it in churches rather than hospitals. I am convinced that double standards, even though they may preserve the interests of certain CAM groups, are to the detriment of patients and the public.

Luckily this view is fast becoming accepted wisdom. The House of Lords Science and Technology Sixth Report (2000) states: "CAM practitioners and researchers should attempt to build up an evidence base with the same rigour as is required of conventional medicine."

 CONTROLLED DRUGS

## Clarification

From Mr R. A. Hancocks,  
MRPharmS

I think Priya Sejal (*PJ*, 10 December 2005, p719) has missed the point I was trying to make (*PJ*, 3 December 2005, p685). I was not referring specifically to amending computer-generated prescriptions but to any prescription, however written or generated.

The regulations, as I understand them, remove the need for a prescription to be written in the prescriber's own hand provided it is indelible, and signed and dated by the prescriber. Explanatory note 9 to the regulations (SI 2005/2864) elaborates as follows: "Regulation 9 amends regulation 15 of the 2001 Regulations to enable prescriptions to be written in any form, including typing, printing and any other mode of reproducing words in a visible form, with only the signature necessarily being handwritten."

"Any other mode of reproducing words in a visible form" is an interesting phrase. Does it not follow that it is lawful that a CD prescription might be written by another person provided it is written in indelible ink and it is then signed and dated by the prescriber. What is the difference between a prescription generated by a machine and one produced by a person?

I ask this question because I suspect many pharmacists will have interpreted the removal of the handwriting requirement to mean that they can add or alter the prescription when it does not fulfil the prescription requirements. This will be especially so in hospitals where junior doctors often have little idea how to prescribe a CD properly and much time is wasted trying to get the doctor to get it right. The guidance we need should clarify whether or not a pharmacist can add the strength or form when it is missing, change the strength when a non-existent strength has been prescribed, add the address, and add the total quantity in words and figures where necessary.

And, not that I would want to, because I believe we have better things to with our time, but could a pharmacist write the entire prescription for the doctor to date and sign? This brings me back to my original point: if all these examples are lawful then the regulations have turned prescription requirements into

endorsement requirements and this adds little to the secure management of Controlled Drugs.

**Roger Hancocks**

*Worksop  
Nottinghamshire*

PRIYA SEJPAL, pharmacist adviser, Royal Pharmaceutical Society, replies: As Mr Hancocks correctly states the recent changes to the Misuse of Drugs Regulations 2001 have removed the requirement for Controlled Drug prescriptions to be written in a doctor's own handwriting. However, this amendment does not allow pharmacists to make technical changes to CD prescriptions. It would be possible from the outset for a pharmacist to write the entire prescription, and then have a doctor sign it. However, after the prescription has been signed the pharmacist would be unable to make changes.

There are proposals to enable pharmacists to make technical changes to CD prescriptions where the prescriber's intentions are clear, however these amendments are not expected to occur until later in 2006. Pharmacists will be notified when this change takes place.

■ MEDICINES USE REVIEWS

**MURs take more than a few minutes**

From Mrs S. O. Howshall,  
MRPharmS

I have been conducting medicines use reviews (MURs) in an independent pharmacy for the past three months. I am a self-employed locum so patients do not know me before the appointment. The pharmacist manager gives written and verbal information to the patients, who have been referred by the GP or, more commonly, selected following primary care trust guidelines. Some patients initially decided they did not want a review because they thought it would criticise their regular pharmacist or doctor. However, they agreed once the procedure was properly explained. The new booklets produced by Medicines Partnership will help this process of understanding.

I have been conducting anonymous research after the review and so far comments have all been positive and patients have thought it has improved their knowledge or treatment, or both.

The GPs, although not wanting to receive more paperwork, have acted on recommendations to the benefit of patients.

I do not understand the comment about a review only taking "a few minutes" (*PJ*, 10 December 2005, p712). In my experience the shortest time in which I have conducted an MUR is 20 minutes; most average 30 minutes. One of the first questions on the form asks the patient what they would like from the process. The responses have been diverse: information about a new drug on the market, side effects, discontinuing drugs, herbal products, etc. MURs cannot be done in a few minutes.

**Sue Howshall**

*Wimborne, Dorset*

■ PHARMACY PRACTICE

**Common sense!**

From Mr G. D. Batey, MRPharmS

I have just realised how lucky we pharmacists are. For years I have worried about what to do (i) if a person with disabilities is unable to

remove tablets from a blister pack, (ii) if the same person cannot pour from a bottle into a 5ml spoon, (iii) if he or she cannot read normal labels and (iv) if he or she cannot understand why they need to take medicines.

But now all is made clear by the article (*PJ*, 17 December 2005, p747) explaining how to "make adjustments associated with dispensing services". We must all be grateful to the authors, who give the answers to the above difficulties: (i) remove the tablets, (ii) supply a 20ml measuring cup, (iii) use larger fonts and (iv) conduct a medicine review to explore what the patient does not understand (or, in layman's terms — talk to the patient about it).

I qualified some 55 years ago and so cannot set my mind to the difficult problems that confront modern pharmacy. But I cannot help thinking that my wife (who was a teacher of young children) would have considered herself a failure if her class could not have coped with problems such as these without help from an official journal.

**G. D. Batey**

*Wylam, Northumberland*

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