

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA77: Zaleplon, zolpidem and zopiclone for the management of insomnia

This guidance was issued April 2004 with a review date of April 2010.

Background

At the GE meeting in April 2010 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	A review of the guidance should be transferred to the “static guidance list”.
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GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	A review of the guidance should be transferred to the “static guidance list”.
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Respondent	Response to proposal	Details	Comment from Technology Appraisal
NHS Quality Improvement Scotland	No comment		

Royal College of Nursing	No objection		
Sanofi Aventis	Agree	Sanofi Aventis confirmed that they have no new evidence that they can submit at this time.	Comment noted.
Welsh Assembly Government	No comment		
Loughborough University Sleep Research Centre	Disagree	<p>NICE has received a group response from this commentator, undersigned by members of SomnIA, a joint project on insomnia being carried out collaboratively between members of Loughborough, Surrey and Bath Universities, and King's College London.</p> <p>The group make no specific comments about the three agents which are the subject of TA77, however they point out that TA77 only looks at a limited set of options (three separate drug therapies) for the treatment of insomnia.</p> <p>The group believe that, without a wider piece of work on insomnia treatments, TA77 risks biasing clinicians towards pharmacological therapies, and note that the evidence base on non-pharmacological therapies has expanded significantly since the original publication of TA77.</p> <p>The group would prefer a wider appraisal to cover</p>	Comment noted. The topic selection team are currently considering the issue of a wider guideline on insomnia. If appropriate, consideration of the incorporation of a review of TA77 into a wider guideline on insomnia will take place.

		all insomnia treatments. This would include non-pharmacological treatments such as Cognitive Behavioural Therapy, and other pharmacological treatments, such as melatonin.	
Sleep Research Group, Section of Psychological Medicine, University of Glasgow	Disagree	The named respondent from this group points out that he is also a signatory to the response from the Loughborough University Sleep research Response. The only additional point the author raises is that he has recently (May 2010) suggested a topic on the effectiveness of Cognitive Behavioural Therapy for insomnia in adults/ older adults to NICE for further consideration.	Comment noted. The topic selection team are currently considering the issue of a wider guideline on insomnia. If appropriate, consideration of the incorporation of a review of TA77 into a wider guideline on insomnia will take place.

No response received from:

Consultees	Commentators (no right to submit or appeal)
<u>Manufacturers/sponsors</u> <ul style="list-style-type: none"> ▪ AAH Pharmaceuticals (zolpidem, zopiclone) ▪ Actavis UK (zolpidem, zopiclone) ▪ Almus Pharmaceuticals (zopiclone) ▪ Apotex UK (zopiclone) ▪ Arrow Generics (zopiclone) ▪ Genus Pharmaceuticals (zolpidem) ▪ Kent Pharmaceuticals (zopiclone) ▪ Meda Pharmaceuticals (zalepon) ▪ Mylan (zolpidem, zopiclone) ▪ Ratiopharm UK (zolpidem, zopiclone) ▪ Ria Generics (zopiclone) 	<u>General</u> <ul style="list-style-type: none"> ▪ Board of Community Health Councils in Wales ▪ British National Formulary ▪ Care Quality Commission ▪ Commissioning Support Appraisals Service ▪ Department of Health, Social Services and Public Safety for Northern Ireland ▪ Medicines and Healthcare products Regulatory Agency (MHRA) ▪ National Association of Primary Care ▪ Public Health Wales NHS Trust ▪ NHS Alliance

Consultees	Commentators (no right to submit or appeal)
<ul style="list-style-type: none"> ▪ Sandoz (zolpidem) ▪ Teva UK (zolpidem, zopiclone) ▪ Tilomed Laboratories (zolpidem) ▪ Winthrop Pharmaceuticals UK (zolpidem) <p><u>Patient/carer groups</u></p> <ul style="list-style-type: none"> ▪ Afiya Trust ▪ Black Health Agency ▪ Chinese National Healthy Living Centre ▪ Counsel and Care ▪ Council for Involuntary Tranquilliser Addiction ▪ Equalities National Council ▪ Muslim Council of Great Britain ▪ Muslim Health Network ▪ Sleep Council ▪ Sleep Matters, Medical Advisory Service ▪ South Asian Health Foundation ▪ Specialised Healthcare Alliance <p><u>Professional groups</u></p> <ul style="list-style-type: none"> ▪ Academy of Pharmaceutical Sciences ▪ British Association for Service to the Elderly ▪ British Geriatrics Society ▪ British Sleep Society ▪ Royal College of General Practitioners ▪ Royal College of Pathologists ▪ Royal College of Physicians ▪ Royal College of Psychiatrists ▪ Royal Pharmaceutical Society 	<ul style="list-style-type: none"> ▪ NHS Commercial Medicines Unit ▪ NHS Confederation ▪ Scottish Medicines Consortium <p><u>Comparator manufacturers</u></p> <ul style="list-style-type: none"> ▪ AAH Pharmaceuticals (diazepam, nitrazepam, lorazepam, lormetazepam, temazepam) ▪ Actavis UK (diazepam, lorazepam, nitrazepam) ▪ Almus Pharmaceuticals (diazepam, lorazepam, nitrazepam) ▪ Chanelle Medical UK (nitrazepam) ▪ Crescent Pharma (diazepam, nitrazepam) ▪ Cross-Pharma (diazepam) ▪ Focus Pharmaceuticals (temazepam) ▪ Genus Pharmaceuticals (lorazepam, lormetazepam, temazepam) ▪ Hameln Pharmaceuticals (diazepam) ▪ Kent Pharmaceuticals (lormetazepam) ▪ LPC Medical (UK) (nitrazepam) ▪ M & A Pharmachem (diazepam, nitrazepam) ▪ Metwest Pharmaceuticals (diazepam, lorazepam, nitrazepam) ▪ Mylan (lorazepam, lormetazepam, temazepam) ▪ Pfizer (lorazepam) ▪ Ranbaxy UK (diazepam, nitrazepam) ▪ Relonchem (diazepam) ▪ Rosemont Pharmaceuticals (temazepam) ▪ Sandoz (diazepam, lorazepam, nitrazepam, temazepam)

Consultees	Commentators (no right to submit or appeal)
<ul style="list-style-type: none"> ▪ Royal Society of Medicine, Sleep Medicine Section ▪ United Kingdom Clinical Pharmacy Association <p><u>Others</u></p> <ul style="list-style-type: none"> ▪ Department of Health ▪ NHS Buckinghamshire ▪ NHS East Lancashire 	<ul style="list-style-type: none"> ▪ Sovereign Medical (diazepam, ▪ Teva UK (diazepam, lorazepam, nitrazepam, lormetazepam, temazepam ▪ Winthrop Pharmaceuticals UK (loprazolam) ▪ Wockhardt UK (diazepam nitrazepam) <p><u>Relevant research groups</u></p> <ul style="list-style-type: none"> ▪ Health Anxiety, Pain and Insomnia (HAPI) Research Group ▪ MRC Clinical Trials Unit ▪ National Institute for Health Research ▪ Policy Research Institute on Ageing and Ethnicity ▪ Psychopharmacology Research Unit,, University of Oxford ▪ Research Institute for the Care of Older People <p><u>Assessment team</u></p> <ul style="list-style-type: none"> ▪ National Institute for Health Research (NIHR) Health Technology Assessment Programme ▪ tbc <p><u>Associated Guideline Groups</u></p> <ul style="list-style-type: none"> ▪ National Clinical Guideline Centre ▪ National Collaborating Centre for Mental Health

GE paper sign-off: Frances Sutcliffe, 16th July 2010

Contributors to this paper:

Information Specialist: Tom Hudson

Technical Lead: Scott Goulden

Technical Adviser: Eleanor Donegan

Project Manager: Adeola Matiluko