Comments on the ACD Received from the Public Through the NICE Website

<table>
<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Role</td>
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<tr>
<td>Other role</td>
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<tr>
<td>Location</td>
<td>England</td>
</tr>
<tr>
<td>Conflict</td>
<td>No</td>
</tr>
<tr>
<td>Notes</td>
<td>I have provided advice to Basilea prior to their NICE submission.</td>
</tr>
</tbody>
</table>

### Comments on individual sections of the ACD:

#### Section 1
(Appraisal Committee's preliminary recommendations)

The DLQI is a very crude measure of severity of hand eczema and a necessary DLQI of 15 is high. I believe that data collection is important and DLQI should be measured. Perhaps a different cut off should be set.

I believe that Alitretinoin should be considered alongside therapies including Ciclosporin and Azathioprine. Both of these latter two treatments have much greater potential side effects and are used off licence. Most people would consider alitretinoin after potent topical steroids and perhaps after PUVA. In certain groups (young women) other systemics may be considered first.

Finally - most doctors do not stop a treatment as soon as it has had an effect. In particular with eczema (especially hand eczema) the healing process takes some time after the hands look normal. It is therefore normal for treatments to be continued for a short period of time after improvement - in order to minimise chances of rapid relapse.

#### Section 2
(the technology)

This looks fine.

#### Section 3
(manufacturer's submission)

There is unfortunately limited trial data on therapies in hand eczema.

#### Section 4
(consideration of the evidence)

I have a particular clinical interest in occupational contact dermatitis, which is often chronic hand eczema. In certain occupations, hand eczema can result in significant time off work. One of the benefits of this treatment is that patients may potentially return to work more rapidly.

Also, PUVA therapy involves two visits to hospital or clinic each week. Whilst some patients may choose this therapy ahead of other systemic treatments, some would prefer not to have the inconvenience of these multiple visits.

Finally, the side effect profile of ciclosporin and azathioprine is greater than with alitretinoin, so I would have thought that these might have been considered as potential therapies alongside each other, rather than ciclosporin and azathioprine first.

#### Section 5
(implementation)

Local audit is essential and we are already looking at implementing this locally.
### Comments on individual sections of the ACD:

**Section 1**  
(Appraisal Committee's preliminary recommendations)  
I do not feel that the DLQI is necessarily applicable to isolated hand eczema and am not aware that it has been a validated tool to measure disease severity for hand eczema.  
I do not think that alitretinoin should only be available to patients who have not responded to other second line treatments. Many of these other second line agents have a significantly higher side effect profile than alitretinoin particularly significant immunosuppression with all the attendant risks. Furthermore, these other agents do not have a formal license for this indication. I think the physician should be given the opportunity to pick a second line agent on an individual basis, based on each case, with no restriction in the order in which the agents are chosen.
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<tbody>
<tr>
<td>Role</td>
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<td>Conflict</td>
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</tr>
<tr>
<td>Notes</td>
<td>dermatology consultant</td>
</tr>
</tbody>
</table>

**Comments on individual sections of the ACD:**

**Section 1**  
(Appraisal Committee’s preliminary recommendations)  
I believe a DLQI of 15 is too, especially bearing in mind a DLQI of only 10 is recommended by NICE for pts with psoriasis to receive biologic therapies which are potentially much more risky to patients and expensive. The DLQI is not especially weighted towards occupational problems which is where pts with chronic hand eczema really suffer and this will deny many pts who need a safe effective therapy for their disease. I would prefer a lack of response to other drugs as indicator. Anyone who is not troubled by their hand eczema is not going to take ciclosporin or azathiaprine because of the risks involved.

**Section 2**  
(the technology)

**Section 3**  
(manufacturer’s submission)

**Section 4**  
(consideration of the evidence)

**Section 5**  
(implementation)

**Section 6**  
(proposed recommendations for further research)

**Section 7**  
(related NICE guidance)

**Section 8**  
(proposed date of review of guidance)

**Date**  
18/05/2009  09:30:00

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<td>Location</td>
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<tr>
<td>Conflict</td>
<td>No</td>
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<td>Notes</td>
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</table>

**Comments on individual sections of the ACD:**

**Section 1**  
(Appraisal Committee’s preliminary recommendations)  
I am surprised that non response to a drug like ciclosporin is required prior to considering alitretinoin as a treatment option. The toxicity of ciclosporin is far greater so I would have considered alitretinoin to be within the same cohort of second line treatments.
I have done a Medline search on azathiaprine and chronic hand eczema and could not find any literature regarding its use so am surprised that it is regarded as a prerequisite for use prior to consideration of alitretinoin. PUVA also requires multiple hospital visits (usually twice weekly) for 10-15 weeks which is an option many working patients with hand eczema cannot pursue.

I am not aware that any of the suggested first line systemic therapies (aza, ciclo, PUVA) have hand eczema as a licensed indication which may have medicolegal implications when a licenced agent is now available.

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**Section 4**  
(consideration of the evidence)

**Section 5**  
(implementation)

**Section 6**  
(proposed recommendations for further research)

**Section 7**  
(related NICE guidance)

**Section 8**  
(proposed date of review of guidance)

Date  
17/05/2009  16:56:00

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**Name**:  

**Role**: NHS Professional

**Other role**:  

**Location**: England

**Conflict**: No

**Notes**  
I have acted in an advisory capacity to Basilea and have taken part in symposia and educational events sponsored by the company.

**Comments on individual sections of the ACD:**

**Section 1**  
(Appraisal Committee's preliminary recommendations)

1 Â I accept that only patients with severe impairment should receive alitretinoin, but I have two comments:

A Â I am not sure how a DLQI of 15 was chosen nor what the impact of using this level would be it seems high (certainly when compared to the level required for the use of biologics in severe psoriasis) I suspect that many deserving patients who might benefit greatly from the drug would be denied it.

B Â Although I accept that this is not the remit of this appraisal to judge the use of DLQI and other such measures, I have concerns that new interventions for any skin disorder will be required to meet more exacting standards than existing approaches (licensed or not) it seems incongruous, and will gradually give rise to significant anomalies.

2 Â I have concerns that drugs that are not licensed for this indication, but with a significant toxicity profile, MUST be used before alitretinoin. If patients eventually move on to alitretinoin they will either have developed some complication or suffered some (potentially avoidable) adverse event, or would have failed on treatment and have experienced a longer period of distress and discomfort than might have been necessary.

**Section 2**  
(the technology)

I have never been convinced that the retinoids should be singled out for the "pregnancy prevention protocol". Many drugs used in dermatology are teratogenic, but are not subject to the same level of
attention doctors simply advised their patients on the risks. Furthermore, the process does not prevent pregnancy - only the patient can do that the process may detect pregnancies earlier than would otherwise be the case, but that is NOT the same and to suggest it is by using the word "prevention" is disingenuous.

The manufacturers will no doubt disagree, but I think this whole charade should be dropped.

Section 3
(manufacturer's submission)

Section 4
(consideration of the evidence)

Section 5
(implementation)

Section 6
(proposed recommendations for further research)

This looks like a good idea at first sight, but none of the other agents has yet been shown to work de facto by double-blind trial. Surely, comparator studies should follow proof that something actually works?

Section 7
(related NICE guidance)

These pieces of work are useful in clinical practice I think the restrictions on the calcineurin inhibitors were understandable, but I see no reason why either should not be used first-line as an option against topical steroids in some children, nor why there is a restriction on initiation in primary care.

Section 8
(proposed date of review of guidance)

Date 17/05/2009 07:28:00

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<td>Notes</td>
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<tr>
<td>Comments on individual sections of the ACD:</td>
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**Section 1**
(Appraisal Committee's preliminary recommendations)

The DLQI required for the prescribing of alitretinoin is in excess of that required to prescribe biologicals for patients with severe psoriasis (DLQI >10). This is unreasonable and puts these patients at a disadvantage to receive efficacious treatment.

The necessity to have already prescribed cyclosporin and azathioprine puts these patients at unnecessary risks. Firstly these drugs are not licenced for hand eczema and there is little evidence base supporting their use. Secondly these drugs increase the risk of skin cancers and possibly systemic malignancies. Synthetic retinoids do not have this risk and if anything protect against skin cancer and therefore there would be a logic to use alitretinoin before ciclosporin
and azathioprine.

<table>
<thead>
<tr>
<th>Section 2</th>
<th>(the technology)</th>
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<tbody>
<tr>
<td>Section 3</td>
<td>(manufacturer's submission)</td>
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<tr>
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<td>(proposed recommendations for further research)</td>
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**Date** 16/05/2009 12:57:00

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**Notes**

**Comments on individual sections of the ACD:**

**Section 1** (Appraisal Committee's preliminary recommendations)
I think the use of the DLQI is reasonable. However I am concerned by the suggestion that azathioprine or ciclosporin should be used before the prescription of alitretinoin. These are toxic drugs which are not licensed for severe chronic hand eczema and I feel this is unethical. Patient safety must be our prime consideration.

**Section 2** (the technology)

**Section 3** (manufacturer's submission)

**Section 4** (consideration of the evidence)

**Section 5** (implementation)

**Section 6** (proposed recommendations for further research)

**Section 7** (related NICE guidance)

**Section 8** (proposed date of review of guidance)

**Date** 15/05/2009 16:41:00
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**Comments on individual sections of the ACD:**

### Section 1
(Appraisal Committee's preliminary recommendations)

DLQI of 10 is considered severe for Psoriasis, why has committee recommended DLQI of 15?

### Section 2
(The technology)

### Section 3
(Manufacturer's submission)

### Section 4
(Consideration of the evidence)

### Section 5
(Implementation)

### Section 6
(Proposed recommendations for further research)

I use a cheaper alternative retinoid Acitretin for hyperkeratotic variant of hand eczema and I am sure other dermatologists do as well. Acitretin is approved for use in Psoriasis and other conditions. A Phase III trial should compare altretinoin with Acitretin for subgroup of patients with hyperkeratotic eczema where altretinoin is found to be most useful. I seldom use Ciclosporin or Azathioprine, while I do use PUVA often. I find it difficult to even consider Ciclosporin or Azathioprine for eczema limited to hands only.

### Section 7
(Related NICE guidance)

### Section 8
(Proposed date of review of guidance)

**Date**

15/05/2009 16:31:00

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**Name** | xxxxxxxxxxxx
---|---
**Role** | NHS Professional
**Other role** | |
**Location** | Wales
**Conflict** | No
**Notes** | |
**Comments on individual sections of the ACD:**

### Section 1
(Appraisal Committee's preliminary recommendations)

The advantage of Altretinoin is that it provides long lasting remission and lacks side effects associated with immunosuppressants such as Ciclosporin or Azathioprine. It therefore does not make any sense to me to make this treatment a third line agent after these other toxic treatments, especially given that the Altretinoin will be stopped if there is not improvement within 12 weeks.
### Notes

I am a Consultant Dermatologist with an extensive background of research on eczema, including clinical trials on alitretinoin, azathioprine, ciclosporin, methotrexate and topical steroids. I am an Editor of a textbook on dermatological therapeutics, author of a chapter on eczema in the Rook Textbook of Dermatology and author of a chapter on systemic treatment in a recently published textbook on atopic dermatitis. I am the Editor of Clinical and Experimental Dermatology.

I participated in a clinical of alitretinoin for treatment of hand eczema sponsored by Basilea pharmaceuticals.

### Comments on individual sections of the ACD:

**Section 1**

(Appraisal Committee's preliminary recommendations)

I have concerns about the requirement to use the other drugs first.

Ciclosporin is significantly more toxic than alitretinoin and its use is constrained, in particular, by nephrotoxicity. Both azathioprine and ciclosporin are immunosuppressant, and PUVA is carcinogenic. Alitretinoin has none of these disadvantages.

Evidence for efficacy of the other drugs in chronic hand eczema is not satisfactory.

In current practice, ciclosporin is very rarely used in this indication, and azathioprine rarely. PUVA is used more often but provides only a short term benefit. Prednisolone can be highly effective but is really only suitable for very short term use and its use is usually followed by prompt relapse. Methotrexate and acitretin are also very occasionally used but on insubstantial anecdotal evidence (retinoid molecules are not interchangeable, and exhibit different
efficacy/toxicity profiles).

There is, therefore, no established satisfactory treatment for severe hand eczema, unless it responds to topical corticosteroids. Existing systemic treatments are probably not very effective and are certainly hazardous.

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**Section 2**
(the technology)

**Section 3**
(manufacturer's submission)

**Section 4**
(consideration of the evidence)

**Section 5**
(implementation)

**Section 6**
(proposed recommendations for further research)

**Section 7**
(relate NICE guidance)

**Section 8**
(proposed date of review of guidance)

**Date** 13/05/2009 18:07:00

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**Name**

**Role** NHS Professional

**Other role**

**Location** England

**Conflict** No

**Notes**

**Comments on individual sections of the ACD:**

**Section 1**
(Appraisal Committee's preliminary recommendations)

I do not feel it is appropriate to have a higher DLQI score (15) to start allitretinoin than for biologic use in psoriasis (10). I also feel it is v inappropriate to suggest we use cyclosporin and azathioprine pre-allitretinoin which I dont think even have licenses for use in treating hand eczema. Both these oral agents have significant side effects such that I v rarely would ever use ciclosporin for eczema or psoriasis. I do not have an issue with use of PUVA pre allitretinoin.

**Section 2**
(the technology)

**Section 3**
(manufacturer's submission)

**Section 4**
(consideration of the evidence)

re 4.5, do ciclosporin and azathiprine have a license to treat hand eczema- if not how could the manufactureres of allitretinoin do a legitimate trial gainst these agents?

**Section 5**
(implementation)

**Section 6**
(proposed
Section 1
(Appraisal Committee's preliminary recommendations)

1. The DLQI value of 15 required for consideration for this treatment exceeds that recommended by NICE by patients with psoriasis (namely 10) for use of a biologic drug (a group of drugs with more serious side-effects than alitretinoin). This is inconsistent and unfair to patients with hand dermatitis. I suggest you should alter the DLQI requirement in this context to 10.

2. The second line treatment drugs suggested for use before alitretinoin can be considered have more serious potential side effects than alitretinoin. These must be familiar to you- hypertension/kidney disease with ciclosporin, liver disease/blood dyscrasias with azathioprine. As regards topical PUVA- it rarely has any effect at all in severe hand dermatitis and is a poor comparator.
**Comments on individual sections of the ACD:**

**Section 1**
(Appraisal Committee's preliminary recommendations)

 Confirmation on whether alitretinoin is suitable for prescribing in primary care in England would be useful in light of the SMCs recommendation that alitretinoin is dispensed by a hospital-based pharmacy in Scotland. Cost pressures can stimulate requests from acute trusts for high cost drugs to be prescribed under shared care where suitable.

**Section 2**
(the technology)

**Section 3**
(manufacturer's submission)

**Section 4**
(consideration of the evidence)

**Section 5**
(implementation)

**Section 6**
(proposed recommendations for further research)

**Section 7**
(related NICE guidance)

**Section 8**
(proposed date of review of guidance)

**Date** 12/05/2009 09:30:00

**Comments on individual sections of the ACD:**

**Section 1**
(Appraisal Committee's preliminary recommendations)

 Unclear as to the justification of recommendation 1.1.

 A DLQI of 10 - as required for biologics for psoriasis would be more appropriate

 Other systemic treatments such as cyclosporin are as expensive and perhaps more toxic than alitretinoin. This should therefore be offered as a second line treatment, along with the other treatments mentioned.

**Section 2**
<table>
<thead>
<tr>
<th>Section</th>
<th>Comments on individual sections of the ACD:</th>
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<tbody>
<tr>
<td>Section 1</td>
<td>It is not appropriate to consider alitretinoin oral therapy only after a patient has been treated with oral immunosuppressants and/or PUVA/UVB. These treatments have no firm evidence base for chronic hand eczema nor are they licensed. Alitretinoin is not immunosuppressant and should be considered as the first systemic therapeutic option once topical treatment has failed. Chronic hand eczema is a disabling condition, especially for manual workers, causing much time to be lost from work. It is therefore not in the patients best interest to have to proceed through unlicensed medications requiring further time off work for monitoring, before alitretinoin is prescribed. I have prescribed alitretinoin and found it to be highly effective, safe and well tolerated at 30mgs/day for 12 weeks.</td>
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<tr>
<td>Section 2</td>
<td>From experience well tolerated at 30mgs/day for 12 weeks.</td>
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<tr>
<td>Section 3</td>
<td>Confirms that there is no firm evidence of superiority of the comparator therapies in the treatment of CHE.</td>
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<tr>
<td>Section 4</td>
<td>Alitretinoin is clinically much more effective than current best supportive care. As a result fewer appointments in secondary care are likely to be needed and so alitretinoin is also more cost effective.</td>
</tr>
<tr>
<td>Section 5</td>
<td>No comment</td>
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<tr>
<td>Section 6</td>
<td>Do not support the proposal for comparison phase 111 trials using unlicensed immunosuppressants with poor evidence base.</td>
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</table>
### Comments on individual sections of the ACD:

#### Section 1
(Appraisal Committee's preliminary recommendations)
I agree that alitretinoin should be used only in severe cases. I am concerned, however, about the DLQI of 15. Why is that when in other conditions, such as psoriasis, you accept a DLQI of 10?

It also feels wrong to demand that we use unlicensed drugs before trying it. I agree that in many cases I may use some of those drugs first, but it should be a clinical decision, as all other treatments are unlicensed. I am sure if any of the suggested first line systemics submitted their case for a license or nice guidelines, they would not be approved, so how can we justify the decision in this guidelines?

#### Section 2
(the technology)

#### Section 3
(manufacturer's submission)

#### Section 4
(consideration of the evidence)
same comments as in section 1

#### Section 5
(implementation)

#### Section 6
(proposed recommendations for further research)

#### Section 7
(related NICE guidance)

#### Section 8
(proposed date of review of guidance)
If the nice guidelines are going to put first non-licensed treatments, then the review date should be sooner, ie 2years

### Notes

NO. Â I have no conflicts of interest. I have funded the toctino
treatment myself.

**Comments on individual sections of the ACD:**

<table>
<thead>
<tr>
<th>Section 1 (Appraisal Committee's preliminary recommendations)</th>
<th>I am concerned that the recommendation is to use this drug as third line after immunosuppressive drugs considering that the allitretinoin side effect profile looks so innocuous. Also Â I see no reason that dermatologists would have to be those with specialist expertise in CHE as the condition is easily diagnosed and has defined Â treatment options.</th>
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<tbody>
<tr>
<td>Section 2 (the technology)</td>
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<td>Section 3 (manufacturer's submission)</td>
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<td>Section 5 (implementation)</td>
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**Date** 11/05/2009 10:54

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| Name | [Redacted] |
| Role | NHS Professional |
| Other role |  |
| Location | England |
| Conflict | No |
| Notes |  |

**Comments on individual sections of the ACD:**

| Section 1 (Appraisal Committee's preliminary recommendations) | A DLQI of 15 or more is unreasonable. A patient only needs a DLQI of 10 or more for treatment with the more expensive biologics for psoriasis, why should this be even higher for allitretinoin?  

I feel as a consultant dermatologist we should be able to make the decision when to start a systemic agent and in which order. Allitretinoin is a licensed treatment for hand eczema is is not an immunosupressant unlike the other options, I feel therefore that it should be a second line option not third. I would like to be able to use it prior to submitting the patient to unlicensed immunosuppressive treatment options such as ciclosporin, if I felt it was appropriate to that patient.  

There are only a limited number of patients that fall into the severe hand eczema category that require systemic agents, certainly nothing compared to the numbers requiring biologics for psoriasis. |
| --- | --- |
I agree that a period of 12 weeks to show response is adequate is sufficient.

Section 2
(the technology)

Section 3
(manufacturer's submission)

Section 4
(consideration of the evidence)

Section 5
(implementation)

Section 6
(proposed recommendations for further research)

Section 7
(related NICE guidance)

Section 8
(proposed date of review of guidance)

Date 10/05/2009 14:13:00

Name 

Role Other

Other role Consultant Dermatologist and Senior Lecturer in Occupational Dermatology at The Institute of Occupational Health, University of Birmingham

Location England

Conflict No

Notes I have run a dedicated regional occupational dermatology service for the West Midlands for more than 25 years and have dealt with many cases of Dermatitis resistant to treatment. Where dermatitis fails to respond to potent steroids, it rarely responds to Azathioprine, occasional responds to cyclosporin. PUVA treatment can be a useful therapy but relapse is common even when it is effective. In addition patients attending for a 2 hour treatment session three times a week has a major impact upon their ability to remain or return to gainful employment. Toctino with its safety profile would allow the rapid return of this difficult group to their workplace. There is a need for specialist centres to be able to use this treatment for such selected cases who have been properly investigated from a contact allergy point of view, had appropriate potent topical therapy, rather than trying months of cyclosporin or azathioprine.

Comments on individual sections of the ACD:

Section 1
(Appraisal Committee's preliminary recommendations) Severe hand eczema in my experience of 30 years never responds to Azathioprine. There is no published evidence of hand eczema responding to this when it has not responded to potent topical steroids. 30% may respond to PUVA but relapse is common. PUVA with attendances 3 times a week, usually for 1 to 2 hours to allow application of topical psoralens is usually not compatible with gainful
employment and takes at least 12 weeks for any response to be obtained. Unfortunately PUVA treatment is rarely available outside normal working hours. Ciclosporin works in about 20% of severe cases, with relapse common on discontinuation and side effects often limit its long term use. There really is a need for specialist centres to be able to prescribe Alitretinoin for those who cannot work because of their dermatitis in preference to the current second line treatments, as efficacy and safety appears to be superior. There is also a need for patients to be thoroughly investigated to exclude any missed allergens, and therefore patients with severe hand dermatitis should be referred on to regional centres for further investigation. Returning people back to work needs to be a priority.

Section 2
(the technology)

Section 3
(manufacturer's submission)

Section 4
(consideration of the evidence)

Section 5
(implementation)

Section 6
(proposed recommendations for further research)

Section 7
(related NICE guidance)

Section 8
(proposed date of review of guidance)

Date 08/05/2009 12:57:00

Name

Role  NHS Professional

Other role

Location  Scotland

Conflict  yes

Notes  Involved as advisor on advisory board- no other conflict of interest

Comments on individual sections of the ACD:

Section 1
(Appraisal Committee's preliminary recommendations)

DLQI is not well validated in CHE, and if included should be reduced DLQI >10 to be consistent with guidance for use of biologics in severe psoriasis

Medicolegal concerns- why should unlicensed treatments be used ahead of licensed preparations?

Clinicians should choose therapies based on needs of patients- the SMC guidance on this subject is far more practical and allows for better quality of patient care

Section 2
(the technology)

Section 3
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<tr>
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**Date** 08/05/2009 10:13