Scottish Medicines Consortium
Providing advice about the status of all newly licensed medicines
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adalimumab 40mg/0.8mL solution for injection (Humira®)

SMC No. (1143/16)

AbbVie Ltd

08 April 2016

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHS Scotland. The advice is summarised as follows:

ADVICE: following a full submission

adalimumab (Humira®) is accepted for use within NHS Scotland.

Indication under review: treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.

Evidence from two double-blind, randomised studies demonstrated significant reductions in inflammatory lesions and no worsening of abscesses and draining fistulas at 12 weeks with adalimumab compared with placebo.

Overleaf is the detailed advice on this product.

Chairman,
Scottish Medicines Consortium

Indication

Treatment of active moderate to severe hidradenitis suppurativa (HS) (acne inversa) in adult patients with an inadequate response to conventional systemic HS therapy.

Dosing Information

By subcutaneous injection, 160mg initially on day 1 (given as four 40mg injections in one day or as two 40mg injections per day for two consecutive days), followed by 80mg two weeks later on day 15 (given as two 40mg injections in one day). Two weeks later (day 29) continue with a dose of 40mg every week.

Antibiotics may be continued during treatment with adalimumab if necessary. It is recommended that the patient should use a topical antiseptic wash on their HS lesions on a daily basis during treatment with adalimumab.

Continued therapy beyond 12 weeks should be carefully reconsidered in a patient with no improvement within this time period.

Should treatment be interrupted, adalimumab 40mg every week may be re-introduced.

The benefit and risk of continued long-term treatment should be periodically evaluated.

Product availability date

February 2016

Summary of evidence on comparative efficacy

Hidradenitis suppurativa (HS) is a chronic, inflammatory, skin disease that usually presents with painful, inflamed lesions in the apocrine gland-bearing areas of the body, most commonly the axillary, inguinal, and anogenital regions. The lesions often progress to become chronic with purulent discharge, scarring and sinus formation. It is classified clinically according to Hurley Stages, which represent the severity of HS disease and are used to guide treatment. Hurley Stage I represents abscess formation (single or multiple) without sinus tracts and scarring: Hurley Stage II represents one or more widely separated recurrent abscesses with tract formation and scars and Hurley Stage III represents multiple interconnected tracts and abscesses throughout an entire area. [1,2,3]

Adalimumab is a recombinant human monoclonal antibody that binds to and inhibits tumour necrosis factor (TNF). It is licensed for a range of conditions including rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis, Crohn's disease and ulcerative colitis. The marketing authorisation has recently been extended to include the treatment of moderate to severe HS.[1,4]

The evidence to support the use of adalimumab in HS comes from two similar, randomised, double-blind, phase III studies (PIONEER I and II).[1,4-8] Eligible patients were aged 18 years or more with a history of HS for one year which was stable for at least two months. They had HS lesions in at least two distinct anatomic areas (one with Hurley Stage II or III), a total abscess and inflammatory nodule (AN) count of ≥3 and had had an inadequate response (or intolerance or contra-indication) to at least three months of oral antibiotics. An inadequate response was defined as: progression of Hurley stage; requiring at least one intervention; pain interfering with daily living with unsatisfactory relief from

ibuprofen or paracetamol; pain requiring opioids including tramadol; drainage interfering with daily living; increase in the number of anatomic areas affected by HS or at least one new abscess or new draining fistula.

Both studies included two treatment periods: A and B. In period A, eligible patients were randomised equally, with stratification according to baseline Hurley Stage, to receive subcutaneous adalimumab (160mg at week 0, 80mg at week 2, 40mg at week 4 and then weekly) or placebo to week 12. All continuing adalimumab-treated patients were re-randomised at week 12 for period B. In both studies, patients randomised to adalimumab in period A were re-randomised equally to adalimumab 40mg weekly, 40mg every other week or placebo to week 36 with stratification according to response and by baseline Hurley stage. In PIONEER I, placebo-treated patients in period A all received adalimumab 40mg weekly to week 36 and in PIONEER II, placebo-treated patients in period A all received placebo to week 36. Any patient who achieved a response at week 12 but experienced a loss of response (LOR) during period B (defined as an AN count greater than the average of the AN count at baseline and 12 weeks) or who did not achieve a response at week 12 but during period B experienced a worsening or absence of improvement (WOAI) from week 16 onwards (defined as an AN count greater than the average AN count at baseline on two consecutive visits at least 14 days apart) was discontinued from the study and could receive open-label adalimumab in the extension study. In PIONEER I, rescue antibiotic treatment (doxycycline or minocycline continued at a stable dose up to 100mg twice daily for the rest of the study) was allowed at week 4 or 8 if a patient experienced a ≥150% increase in AN count from baseline. In PIONEER II, patients were allowed to continue permitted oral antibiotics (doxycycline or minocycline) provided they had received a stable dose for ≥4 weeks before baseline. An acutely painful lesion could be treated immediately by intra-lesion injection with triamcinolone acetonide or incision and drainage. Analgesia with ibuprofen, paracetamol and tramadol was allowed for worsened pain from baseline.[1,4]

In both studies, the primary outcome was the proportion of patients achieving ≥50% reduction in AN count with no increase in abscess count and no increase in draining fistula count relative to baseline, the Hidradenitis Suppurativa Clinical Response (HiSCR), and this was measured at week 12. This was achieved by significantly more adalimumab than placebo patients in both studies. There were three ranked secondary outcomes: the proportion of patients with Hurley stage II disease at baseline achieving AN count of 0, 1 or 2 at week 12; at least a 30% reduction in HS-related skin pain assessed using a Numerical Rating Scale (NRS) of 11 points in patients with NRS≥3 at baseline and the modified Sartorius score (MSS) which assesses severity of HS by measuring anatomical region involved, number of lesions by region and type, longest distance between two relevant lesions and Hurley stage. These were achieved by significantly more adalimumab than placebo patients in the PIONEER II study only. Detailed results are presented in the table below.[1]

Table: Results of primary and key ranked secondary outcomes at week 12 from PIONEER I and II [1,4-8]

	PIONEER I		**PIONEER II**	
	Adalimumab (n=153)	Placebo (n=154)	Adalimumab (n=163)	Placebo (n=163)
HiSCR at week 12; (n/N)	42% (64/153)	26% (40/154)	59% (96/163)	28% (45/163)
Difference (95% CI), p-value	16% (5.3% to 26%) p=0.003		32% (21% to 42%) p<0.001	
AN count of 0, 1 or 2 at week 12 in those with Hurley stage II disease at baseline; % (n/N)	29% (24/83)	29% (24/84)	52% (44/85)	32% (28/87)

p-value	p=0.961		p=0.01	
NRS30 at week 12 in patients with baseline NRS ≥3; % (n/N)	28% (34/122)	25% (27/109)	46% (48/105)	21% (23/111)
p-value	p=0.628		p<0.001	
Change in MSS from baseline to week 12	-24.4	-15.7	-28.9	-9.5
p-value	p=0.124		p<0.001	

HiSCR: Hidradenitis Suppurativa Clinical Response defined as the proportion of patients achieving ≥50% reduction in AN count with no increase in abscess count and no increase in draining fistula count relative to baseline
CI: confidence interval
AN: total abscess and inflammatory nodule count
NRS30: Proportion of patients achieving ≥30% reduction and ≥one unit reduction from baseline in Patient's Global Assessment of Skin Pain at worst at week 12 among patients with baseline NRS ≥3.
MSS: modified Sartorius score which assesses severity of HS by measuring anatomical region involved, number of lesions by region and type, longest distance between two relevant lesions and Hurley stage.

In both studies, there were significantly greater improvements with adalimumab than placebo in the Dermatology Life Quality Index (DLQI) from baseline to week 12. There were also significantly greater improvements with adalimumab than placebo from baseline to week 12 in the overall Treatment Satisfaction Questionnaire for Medication (TSQM) and TSQM effectiveness in adalimumab patients than placebo patients. TSQM scores for satisfaction with side effects and convenience were similar between the treatment groups.[1]

During period B, efficacy outcomes were considered exploratory in patients who had received adalimumab in period A. The proportions of patients with an HiSCR reduced over time in period B. Pooled results of both studies found that in patients treated with adalimumub in period A and then re-randomised at week 12 to adalimumab weekly for period B, HiSCR reduced from 54% (53/99) at week 12, to 44% (44/99) at week 24 and 43% (43/99) at week 36. In patients treated with adalimumub in period A and then re-randomised at week 12 to adalimumab every other week for period B, HiSCR reduced from 52% (52/101) at week 12, to 37% (37/101) at week 24 and 31% (31/101) at week 36. In patients treated with adalimumub in period A and then re-randomised at week 12 to placebo for period B, HiSCR reduced from 53% (53/100) at week 12, to 30% (30/100) at week 24 and 28% (28/100) at week 36.[1]

Patients from PIONEER I and II who had achieved HiSCR, then experienced a LOR, or not achieved HiSCR then experienced WOAI, could enter an ongoing, open-label, phase III extension study evaluating the longer-term safety and efficacy of adalimumab. All patients received adalimumab 40mg subcutaneously every week regardless of previous treatment in the PIONEER studies, which, after at least 24 weeks, could be reduced to 40mg every other week if HiSCR relative to original baseline was achieved, an AN count of 0 or 1 was achieved on at least two consecutive visits and the physician and patient agreed. Interim results indicate that the primary outcome, HiSCR, was achieved by more than 50% of patients at week 36. Although initial results suggest that this was maintained to 72 weeks, the numbers of patients with longer term results remain limited.[1]

*Other data were also assessed but remain commercially confidential.**

Summary of evidence on comparative safety

The PIONEER I and II studies compared adalimumab with placebo only. The proportions of patients reporting adverse events were comparable between the adalimumab and placebo groups during period A (53% and 62% respectively in PIONEER I and 58% and 67% respectively in PIONEER II). Treatment to week 36 in period B of both studies revealed few differences in the safety profiles between the different dosing regimens.[1]

The most frequently reported adverse events during the 12-week period A in the adalimumab and placebo groups respectively were exacerbations of HS: 9.2% (14/153) and 13% (20/154) respectively in PIONEER I, and 4.3% (7/163) and 13% (21/163) respectively in PIONEER II; nasopharyngitis: 5.9% (9/153) and 11% (16/154) respectively in PIONEER I, and 5.5% (9/163) and 6.1% (10/163) respectively in PIONEER II and headache: 9.2% (14/153) and 9.9% (15/154) respectively in PIONEER I, and 13% (21/163) and 13% (21/163) respectively in PIONEER II. [5-8]

One patient, treated with adalimumab weekly to week 12 and then every other week, experienced a malignancy (nasal squamous cell carcinoma) which was considered by the investigator as at least possibly related to study drug.[1]

The safety profile for adalimumab for other indications is well established and no new safety concerns were identified in the PIONEER I and II studies.[1,4]

Summary of clinical effectiveness issues

Adalimumab is the first medicine to be specifically licensed for HS. Patients with Hurley Stage I disease are initially treated with topical or systemic antibiotics and those failing generally receive retinoid therapy, short-term corticosteroids or cryotherapy. Patients with Hurley Stage II and III disease often require long-term immunosuppression or surgical intervention.[2,3]

The pivotal studies, PIONEER I and II, found a significant reduction in inflammatory lesions and no worsening of abscesses and draining fistulas at 12 weeks with adalimumab compared with placebo. The primary outcome, HiSCR, was developed by the market authorisation holder after discussion with the regulatory authorities. The European Medicines Agency (EMA) concluded that it has been adequately described and validated for its intended purpose as the primary outcome in the pivotal studies.[1] Although, the primary outcome was met in both studies, the treatment effect was larger in PIONEER II than PIONEER I. In addition, the ranked secondary outcomes in PIONEER I failed to reach statistical significance. Some differences between the study populations may have contributed to this, including slightly heavier patients, higher mean draining fistula count, higher mean AN count and slightly worse mean pain score in PIONEER I.[1] There was a substantial placebo response in both studies.

There was a high dropout of patients during period B of both studies due to the methodology which required that HiSCR responders who lost response and non-responders who experienced a WOAI discontinue the study. Results from period B up to 36 weeks were considered exploratory and, given the small numbers of patients in each treatment group, they should be interpreted with caution.[1] Results from the open-label extension study are awaited.

Study patients were required to have had an inadequate response to at least three months of oral antibiotics and the market authorisation holder had initially proposed a first-line treatment indication. However, the licence was restricted to patients with an inadequate response to conventional systemic HS therapy.[1] Although some patients had also received previous systemic treatments, the study inclusion criteria may affect the generalisability of the study results to clinical practice. The studies excluded patients with very severe HS (eg draining fistula count greater than 20 at baseline) and so the efficacy and safety of adalimumab in these patients is unclear.[1]

Patients in PIONEER II were allowed to continue on stable doses of doxycycline or minocycline during the study and 19% of study patients did so.[1] During both PIONEER I and II, patients used a topical daily antiseptic wash and the summary of product characteristics (SPC) recommends that this is used on HS lesions during treatment with adalimumab.[4]

HS is a chronic condition; however, the primary outcome of HiSCR was assessed at week 12 and longer term controlled data are limited by small numbers of patients. The SPC states that "Continued therapy beyond 12 weeks is recommended except in those patients without any improvement for whom continued therapy should be reconsidered" and this is supported by post-hoc analyses in partial responders (those with improvement of ≥25% reduction in AN count compared with baseline but who were not HiSCR responders in the clinical studies) which found that a proportion of patients, particularly those treated with continuous weekly adalimumab, were able to reach HiSCR.[1,4]

The introduction of adalimumab would offer a licensed treatment option for patients with moderate to severe HS which has not responded to conventional systemic treatments. As well as significant reductions in inflammatory lesions and no worsening of abscesses and draining fistulas at 12 weeks, patients experienced significant improvement in quality of life compared with placebo. There may be implications for the patient to administer weekly subcutaneous injections. Patients can be taught to self administer or have the injection administered by nurses. The submitting company has indicated that a homecare service is provided. The recommended dosing of adalimumab for HS (160mg then 80mg two weeks later, then 40mg after a further two weeks and then 40mg weekly) is higher than for some other indications.[4]

Summary of comparative health economic evidence

The company submitted a cost-utility analysis comparing costs and outcomes of adalimumab against standard care when used to the treat active moderate to severe HS in adult patients with an inadequate response to conventional systemic HS therapy. Standard care was assumed represent the placebo arms of the PIONEER studies. The model adopted a lifetime horizon.

A Markov model was adopted, with a 4-week cycle length except for the first 2 cycles which were 2 weeks long. The five health states modelled were:

- High response: defined as at least 75% AN reduction, with no increase in abscesses or draining fistulas from baseline.
- Response: defined as at least 50% but less than 75% AN reduction, with no increase in abscesses or draining fistulas from baseline.
- Partial response: defined as at least 25% but less than 50% AN reduction, with no increase in abscesses or draining fistulas from baseline; or at least 25% AN reductions, with an increase in abscesses and/or draining fistulas.
- Non-response: defined as less than 25% AN reduction.
- Death.

In the model, patients started treatment with either adalimumab or standard care in the non-response health state and transitioned across health states, based on treatment response and background mortality rate. Responses for patients in the adalimumab arm were modelled using the observed changes in patient distributions across the four health states in the pooled randomised controlled trials (RCT) (PIONEER I and II) for patients receiving weekly doses of adalimumab. The non-responder imputation method was used for missing values. Patients receiving standard care were modelled using data for patients who received placebo in both induction and maintenance periods of the studies. Non-responders in the adalimumab arm (32%) were assumed to discontinue treatment at week 12. During weeks 12 to 36, patients receiving adalimumab discontinued at the rate observed in the studies, being 13% per annum for responders and 80% per annum for non-responders. The base case discontinuation rate for adalimumab from weeks 36 to 48 also used the extension study data, with non-responders assumed to discontinue the medication at a rate of 45% per year. After week 48, all patients who had not responded to adalimumab between weeks 36 and 48 were assumed to discontinue it.

Transitional probabilities for patients treated with adalimumab beyond week 36 were modelled using data for current and previous health states from week 0 to 24 of the extension study, with current state being a function of previous state. Transitional probabilities for those on standard care and for discontinuers were estimated from the placebo arms of the pooled PIONEER studies, again modelling current health state as a function of previous state. A sensitivity analysis estimated transitional probabilities for all groups after week 36 from mean values for weeks 12 to 36 data from the PIONEER studies rather than using values from the extension study.

PIONEER II used the EQ-5D measure and reported utility values for high response, response, partial response and non-response of 0.782, 0.718, 0.576 and 0.472 respectively. No disutilities were applied for adverse events on the basis that these would be reflected in the utility values measured in the studies.

Health state resource use was estimated from a survey of physicians (n=40) who treat moderate to severe HS patients in the UK. The key driver is the difference in admissions to surgery across the health states, particularly the assumption that non-responders are admitted 0.8 times a year for surgery compared to 0.22 times for responders and 0.13 times for high responders. The model included frequently reported (≥ 5%) treatment-emergent adverse events reported by the studies. Unit costs came from NHS Reference Costs.

The cost of adalimumab was based on the recommended dose regimen. No medication costs were included for standard care, which was a conservative assumption. No administration costs were assumed for adalimumab. Rather, the analysis assumes patients will self-inject adalimumab subcutaneously, following training provided by the company.

The base case results estimated that adalimumab, compared to standard care, would increase total costs per patient by £22,003, with a quality adjusted life year (QALY) gain of 0.98, giving an incremental cost-effectiveness ratio (ICER) of £22,519. All the QALY gain was from improved quality of life; no relative gain in life expectancy was modelled. The cost increase was associated with the additional treatment cost of £38,082 per patient, with the main saving being fewer surgical procedures (saving £12,755 per patient).

Deterministic sensitivity analyses showed the results were sensitive to:

- Changing discontinuation rate for adalimumab non-responders at week 36 after 12 more weeks of treatment from 100% to 45%, being the rate observed in the studies (ICER increased to £40,172).
- Changing resource usage and/ or unit costs to those reported in an unpublished retrospective cohort study of Hospital Episode Statistics (HES) data. This resulted in ICERs of between £26,668 and £30,529.

- Shorter time horizons (at 20 years ICER increased to £35,229).
- Using data from PIONEER II study only (ICER increased to £30,927).
- Extrapolating transitional probabilities beyond week 36 using data from the RCTs rather than using the extension study data (ICERs ranged from £6,401 to £19,282).
- The choice of statistical approach to missing data (adopting values using last observation carried forward in the studies, decreased the ICER to £17,079: using non-responder imputation method to report values from the extension study decreased the ICER to £12,078).

The company provided additional analysis comparing the modelled data to those from the studies, by health state, at week 36 and these showed a close relationship except for the percentage of high responders or responders at week 60. This was 42.7% in the model compared to 36.7% at week 24 from the extension study.

The main weaknesses were:
- Some concerns about the generalisability of the study results to clinical practice, given the indication requires an inadequate response to conventional systemic therapy, not just antibiotics. The indication is more consistent with anticipated clinical practice, with adalimumab likely to be introduced as a later line of therapy and hence to treat a more refractory patient group. The studies also excluded patients with the most severe forms of the disease who may be candidates for this treatment in Scotland.
- Some uncertainties regarding the stopping criteria in the model at 12 weeks (defined as less than 25% AN reduction) and how it aligns with the SPC. Assuming that only patients who show no reduction in AN (<0% reduction in AN) over weeks 0-12 discontinue treatment at week 12 increased the ICER to £25,879. Additionally, the results were sensitive to assumptions about discontinuation later in the model eg if discontinuation at week 48 is 45% (from the studies) not 100% (expert opinion) the ICER rose to £40,172. SMC expert responses indicated that treatment would be discontinued if patients were not responding.
- Some uncertainty associated with the source of resource use and costs used for the health states of the model.
- The model overstated the percentage of high responders or responders at week 60 compared to that observed in the extension study (43% versus 37%).
- Limited clinical data for treatment with adalimumab beyond 36 weeks.

Despite these issues, the economic case was considered demonstrated.

Summary of patient and public involvement

The following information reflects the views of the specified Patient Group.

- A submission was received from The HS Trust, which is a registered charity.

- The patient group has received 30% pharmaceutical company funding in the past two years, including from the submitting company.

- Hidradentis suppurativa (HS) has a profound and detrimental effect on adult life and the lives of family and friends of the patient. Difficulties experienced include: physical pain and disfigurement, lack of mobility, misunderstanding from family members, peers and medical professionals, problems with sleep, lack of social activities, loss of jobs and careers, low self esteem, low body image, no confidence, anger, frustration and feelings of hopelessness and depression.

- Currently there are few medicines available for treating HS. The majority of HS patients are generally prescribed antibiotics, which patients claim have little to no effect on HS. There is limited treatment choice which makes it extremely frustrating for patients.

An effective HS medication for adults with moderate to severe disease could improve quality of life drastically. The potential benefits of an effective medication may include: less pain, less leakage from abscesses, increase in mood, increase in mobility and more confidence enabling better coping mechanisms.

Additional information: guidelines and protocols

The European Academy of Dermatology and Venereology (EADV) published "European S1 guideline for the treatment of hidradenitis suppurativa/acne inversa" in 2015.[3] This consensus-based guideline recommends that the disease should be treated based on its individual subjective impact and objective severity. Locally recurring lesions can be treated by classical surgery or laser techniques, whereas medical treatment either as monotherapy or in combination with radical surgery is more appropriate for widely spread lesions. Medical therapy may include antibiotics (clindamycin plus rifampicin, tetracyclines), acitretin and biologics (adalimumab, infliximab).

Additional information: comparators

There are no other treatments licensed for HS.

Cost of relevant comparators

Drug	Dose Regimen	Cost per year (£)
Adalimumab	**160mg by subcutaneous injection on day 1 followed by 80mg on day 15, then 40mg every week from day 29.**	**19,016**

Doses are for general comparison and do not imply therapeutic equivalence. Costs from eVadis on 3 January 2016. The cost per year includes the initial loading doses of adalimumab; costs for subsequent years would be £18,311.

Additional information: budget impact

The submitting company estimated the population eligible for treatment to be 1,603 in year 1, falling slightly to 1,597 in year 5, with an estimated uptake of 1.5% in year 1, rising to 21.8% in year 5. An annual discontinuation rate of 32% was applied to give estimates of 16 treated patients in year 1 and 236 in year 5.

The gross impact on the medicines budget was estimated to be £301k in year 1 and £4.3m in year 5. As no other drugs were assumed to be displaced, the net medicines budget impact is equivalent to the gross impact.

References

The undernoted references were supplied with the submission. Those shaded in grey are additional to those supplied with the submission.

1. European Medicines Agency. CHMP extension of indication variation assessment report for adalimumab (Humira®). EMA/CHMP/364731/2015 25 June 2015. www.ema.europa.eu

2. Collier F, Smith RC, Morton CA. Diagnosis and management of hidradenitis suppurativa. Clinical Review. BMJ 2013;346:f2121

3. Zouboulis CC, Desai N, EmtestamL et al. European S1 guideline for the treatment of hidradenitis suppurativa/acne inversa. Journal of European Academy of Dermatology and Venereology 2015;29:619-44.

4. AbbVie Limited. Humira® pre-filled pen, pre-filled syringe and vial, summary of product characteristics, 25 November 2015.

5. Kimball A, Zouboulis C, Armstrong A et al. Safety and efficacy of adalimumab in patients with moderate to severe hidradenitis suppurativa: results from first 12 weeks of PIONEER I, a phase 3, randomised, placebo-controlled trial. J Am Acad Dermatol 2015; 72 (5) Supplement 1; AB60 abstract 570

6. Kimball AB, Zouboulis CC, Armstrong AW et al. Safety and efficacy of adalimumab in patients with moderate to severe hidradenitis suppurativa: Results from first 12 weeks of PIONEER I, a phase 3, randomized, placebo-controlled trial (poster). Advances in Cosmetic and Medical Dermatology (ACMD) Conference; 2015; Maui Hawaii.

7. Jemec G, Gottlieb A, Forman S et al. Efficacy and safety of adalimumab in patients with moderate to severe hidradenitis suppurativa: results from PIONEER II, a phase 3, randomised, placebo-controlled trial. J Am Acad Dermatol 2015; 72 (5) Supplement 1; AB45 abstract 631

8. Jemec GBE, Gottlieb A, Forman S et al. Efficacy and safety of adalimumab in patients with moderate to severe hidradenitis suppurativa: Results from PIONEER II, a phase 3, randomized, placebo-controlled trial (poster). Advances in Cosmetic and Medical Dermatology (ACMD) Conference; 2015; Maui Hawaii.

9. *Commercial in Confidence*

This assessment is based on data submitted by the applicant company up to and including 11 March 2016.

Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal: http://www.scottishmedicines.org.uk/About_SMC/Policy_statements/Policy_Statements

Drug prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after careful consideration and evaluation of the available evidence. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.