

**Public Assessment Report  
for paediatric studies submitted in accordance  
with Article 45 of Regulation (EC) No1901/2006, as  
amended**

**Dalacin C and Dalacin T  
(Clindamycin hydrochloride  
or palmitate hydrochloride  
or phosphate)**

**DK/W/009/pdWS/001**

<b>Rapporteur:</b>	Denmark
<b>Finalisation procedure (day 120):</b>	30 March 2011
<b>Date of finalisation of PAR</b>	27 April 2011

## ADMINISTRATIVE INFORMATION

Invented name of the medicinal product(s):	Dalacin, Cleocin, Dalacin C, Dalacin T, Dalacin V, Dalacine, Sobelin
INN (or common name) of the active substance(s):	Clindamycin
MAH (s):	Pfizer
Pharmaco-therapeutic group (ATC Code):	D10AF01, J01FF01, G01AA10
Pharmaceutical form(s) and strength(s):	Dalacin, 1% topical lotion Dalacin, 1% topical solution Dalacin (Cleocin, Sobelin), 2% vaginal cream Dalacin (Sobelin), 300mg/2ml (150mg/ml), 600mg/4ml and 900mg/6ml solution for injection (IV/IM) Dalacin, (Cleocin)100mg vaginal ovules Dalacin, 1% topical gel Dalacin (Sobelin), 75mg/5ml granules for oral solution Dalacin, 75mg, 150mg and 300mg capsules, hard.

## I. EXECUTIVE SUMMARY

No SmPC and PL changes are proposed.

## II. RECOMMENDATION<sup>1</sup>

## III. INTRODUCTION

MAH submitted 16 completed paediatric studies for clindamycin substance, in accordance with Article 45 of the Regulation (EC)No 1901/2006, as amended on medicinal products for paediatric use.

A short critical expert overview has also been provided, citing 36 published studies.

The MAH stated that the submitted paediatric studies does not influence the benefit risk for clindamycin and that there is no consequential regulatory action.

In addition, the following documentation has been included as per the procedural guidance:

- A line listing

## IV. SCIENTIFIC DISCUSSION

### IV.1 Information on the pharmaceutical formulation used in the clinical study(ies)

#### **Clindamycin is available in several pharmaceutical forms**

Clindamycin, topical (oral/injectable)

Clindamycin topical solution, lotion and gel

Clindamycin, vaginal (vaginal ovules and vaginal cream)

#### **The studies submitted with this application comprise**

14 MAH-sponsored studies (all are clinical). A further two were listed but not submitted.  
and

31 non-sponsored published studies (all are clinical)

### **Line listing of MAH-sponsored studies (all are clinical)**

#### **Systemic clindamycin**

##### **251F-INF-0496-001**

A DOUBLE-BLIND MULTICENTER COMPARATIVE STUDY OF TWO DOSE

---

<sup>1</sup> The recommendation from section V can be copied in this section.

REGIMENS OF ORAL CLINDAMYCIN HYDROCHLORIDE IN THE TREATMENT OF ACUTE TONSILLITIS/PHARYNGITIS DUE TO GROUP A BETAHEMOLYTIC STREPTOCOCCI.

**251F-INF-9052-0279**

A DOUBLE BLIND COMPARATIVE STUDY OF ORAL CLINDAMYCIN HYDROCHLORIDE 300 MG BID COMPARED AGAINST ORAL LARITHROMYCIN 250 MG BID IN THE TREATMENT OF ACUTE RECURRENT TONSILLITIS/PHARYNGITIS DUE TO GROUP A-B HEMOLYTIC STREPTOCOCCI.

**251F-INF-9052-0280**

A SINGLE-BLIND (EVALUATOR BLIND) COMPARATIVE STUDY OF ORAL CLINDAMYCIN HYDROCHLORIDE 300 MG BID COMPARED AGAINST ORAL AUGMENTIN 1G BID IN THE TREATMENT OF ACUTE RECURRENT TONSILLITIS/PHARYNGITIS DUE TO GROUP A-B HEMOLYTIC STREPTOCOCCI.

**251F-INF-9052-0281 – May need to be available on request TBC**

AN OPEN LABEL COMPARATIVE, RANDOMIZED STUDY ASSESSING USEFULNESS OF RAPID MICROBIOLOGICAL DIAGNOSTICS IN PATIENTS WITH TONSILLITIS/PHARYNGITIS TREATED WITH CLINDAMYCIN

**CLIND-9052-285**

EFFICACY & SAFETY OF DALACIN C (CLINIDAMYCIN) IN ACUTE OR RECURRENT PHARYNGO-TONSILLITIS

**M11000093**

A COMPARATIVE EVALUATION OF CLINDAMYCIN VS CLINDAMYCIN PLUS TOBRAMYCIN IN THE TREATMENT OF PELVIC INFLAMMATORY DISEASE

**M11200134**

A STUDY TO COMPARE THE EFFICACY AND TOLERANCE OF CLINDAMYCIN WITH ERYTHROMYCIN IN THE TREATMENT OF FEMALES WITH CONFIRMED CHLAMYDIA TRACHOMARIS CERVICITIS

**M11200178**

A DOUBLE-BLIND MULTICENTRE COMPARATIVE STUDY OF TWO ADMINISTRATION REGIMENS OF CLINDAMYCIN HYDROCHLORIDE IN THE TREATMENT OF ACUTE STREPTOCOCCAL TONSILLITIS/PHARYNGITIS

**M11200241**

EVALUATION OF TWO DOSE REGIMENS OF CLEOCIN HCL CAPSULES IN COMPARISON WITH DICLOXACILLIN IN THE TREATMENT OF MILD TO MODERATE SKIN AND SOFT TISSUE

**Clindamycin topical solution, lotion and gel**

**M11120001**

A COMPARISON OF CLEOCIN T TOPICAL GEL VS PLACEBO IN THE TREATMENT OF ACNE VULGARIS

Clindamycin  
DKW/009/pdWS/001

**M11120002**

A COMPARISON OF CLEOCIN T TOPICAL SOLUTION VS CLEOCIN T TOPICAL GEL IN THE TREATMENT OF ACNE VULGARIS

**M11120004**

A COMPARISON OF CLEOCIN T TOPICAL SOLUTION, CLEOCIN T TOPICAL GEL AND PLACEBO IN THE TREATMENT OF ACNE VULGARIS

**M11120005**

COMPARATIVE EFFICACY AND TOLERANCE OF CLEOCIN T GEL VS ORAL MINOCYCLINE IN THE TREATMENT OF ACNE VULGARIS

**Vaginal clindamycin****M11140001**

EFFICACY OF CLINDAMYCIN VAGINAL OVULE (3-DAY TREATMENT) VS. CLINDAMYCIN VAGINAL CREAM (7-DAY TREATMENT) IN BACTERIAL VAGINOSIS

**M11150023**

EFFICACY OF CLINDAMYCIN VAGINAL CREAM PROPHYLACTIC TREATMENT REGIMEN TO PREVENT RECURRENT BACTERIAL VAGINOSIS - A RANDOMIZED, PLACEBO CONTROLLED TRIAL

**M11150039– May need to be available on request TBC**

DOUBLE-BLIND RANDOMIZED COMPARISON OF 2% CLINDAMYCIN VAGINAL CREAM VS ORAL METRONIDAZOLE CAPSULES FOR THE TREATMENT OF BACTERIAL VAGINOSIS

**Line listing of non-sponsored published clinical studies**

- 1 Koren G, Zarfin Y, Maresky D, *et al.* Pharmacokinetics of intravenous clindamycin in newborn infants. *Pediatr Pharmacol* 1986;5:187–92.
- 2 Bell MJ, Shackelford P, Smith R, *et al.* Pharmacokinetics of clindamycin phosphate in the first year of life. *J Pediatr* 1984;105:482–6.
- 3 Rush DE, Abdel-Haq N, Zhu J-F *et al.* Clindamycin versus Unasyn in the treatment of facial cellulitis of odontogenic origin in children. *Clin Pediatr (Phila)*. 2007; 46:154-9
- 4 Borrmann S, Lundgren I, Oyakhirome S *et al.* Fosmidomycin plus Clindamycin for Treatment of Pediatric Patients Aged 1 to 14 Years with Plasmodium falciparum Malaria Antimicrobial Agents Chemotherapy 2006; 50(8): 2713–2718.
- 5 Miura MS, Saleh C, de Andrade M *et al.* Topical clindamycin in post-adenotonsillectomy analgesia in children: A double-blind, randomized clinical trial. *Otolaryngology–Head and Neck Surgery* 2009; 141: 509-515.
- 6 Bonfioli AA and Orefice F. Toxoplasmosis. *Seminars in Ophthalmology*. 2005; 20:129-141;

- 7 Centre for Disease Control and Prevention. Chapter 5. Other infectious diseases related to travel. Toxoplasmosis. <http://wwwnc.cdc.gov/travel/yellowbook/2010/chapter-5/toxoplasmosis.aspx#> . Accessed 11 March 2010.
- 8 Department of Health and Human Services Center for Disease Control and Prevention. Strategies for clinical management of MRSA in the community: Summary of an Expert's Meeting Convened by the Centre for Disease Control and prevention. March 2006
- 9 Martinez-Aguilar G, Hammerman WA, Mason EO Jr et al. Clindamycin treatment of invasive infections caused by and CA-MRSA and MSSA infection in children. *Pediatr Infect Dis J*. 2003;22:593-8.
- 10 David MZ, Crawford SE, Boyle-Vavra S et al. Contrasting pediatric and adult methicillin-resistant *Staphylococcal aureus* isolates. *Emerging infectious diseases*. 2006; 12(4):631-637.
- 11 Li F, Park SY, Ayers TL et al. Methicillin-resistant *S aureus* , Hawaii, 2000-2002. *Emerging diseases*. 2005;11(8): 1205-10.
- 12 Frank AL, Marcinak JF, Mangat PD et al. Clindamycin treatment of methicillin resistant *S aureus* infections in children. *Paediatric infectious diseases journal*. 2002; 21: 530-4
- 13 Siberry G, Tekle T, Carroll K et al. Failure of clindamycin treatment of methicillin-resistant expressing inducible clindamycin resistance in vitro. *Clin Infec Dis*. 2003;37:1257-60.
- 14 Marcinak JF and Frank AL. Treatment of community-acquired methicillin-resistant *Staphylococcus aureus* in children. *Curr Opin Infect Dis*. 2003; 16: 265-9.
- 15 Hussain FM, Boyle-Vavra S, Bethel C et al. Current trends in community- acquired methicillin-resistant *S. aureus* at a tertiary care paediatric facility. *Paediatr Infect Dis J*. 2000;19:1163-6.
- 16 Martinez-Aguilar G, Avalos-Mishaan A, Hulten K et al. Community-acquired, methicillin-resistant and methicillin-susceptible *S. aureus* musculoskeletal infections in children. *The Pediatr Infect Dis J*. 2004; 23(8):701-6.
- 17 Herold BC, Immergluck LC, Maranan MC et al. Community-acquired methicillin-resistant *S aureus* in children with no predisposing risk factors. *JAMA*. 1998; 279: 593-598.
- 18 Prepared by the EARSS Management Team, members of the Advisory Board, and national representatives of EARSS. EARSS Annual Report 2004. Bilthoven, The Netherlands, September 2005. Downloaded from [http://www.rivm.nl/earss/Images/EARSS%20annual%20report%202004%20webversie\\_tcm61-25345.pdf](http://www.rivm.nl/earss/Images/EARSS%20annual%20report%202004%20webversie_tcm61-25345.pdf) on 02 March 2010.
- 19 Vuopio-Varkila JK. Community-Acquired MRSA in Europe. *Interscience Conference on Antimicrobial Agents and Chemotherapy (43rd: 2003: Chicago, Ill.)*. 2003 Sep 14-17; 43: abstract no. 516.
- 20 Foote PA, Brook I. Penicillin and clindamycin therapy in recurrent tonsillitis. *Arch Otolaryngol Head Neck Surg* 1989 115: 856-6
- 21 Randolph MF, Redys JJ, Cope J et al. Streptococcal pharyngitis: posttreatment carrier prevalence and clinical relapse in children treated with clindamycin palmitate or phenoxymethyl penicillin. *Clinical pediatrics*. 1975; 14(2): 119-22

- 22 DeHaan RM and Schellenburg D. Clindamycin palmitate flavoured granules, multidose tolerance, absorption and urinary excretion study in healthy children. *J Clin Pharmacol.* 1972;12:74- 83
- 23 Kremsner PG, Radloff P and Metzger W et al. Quinine plus Clindamycin Improves Chemotherapy of Severe Malaria in Children. *Antimicrobial Agents and Chemotherapy* 1995; 39(7):1603–1605.
- 24 Collins MD, Dajani AS, Kim KS et al. Comparison of ampicillin/sulbactam plus aminoglycoside vs. ampicillin plus clindamycin plus aminoglycoside in the treatment of intraabdominal infections in children. *The Pediatric Infect Dis J.* 1998; 17(3)S1: S15-S18
- 25 Gallegos B, Rios A, Espidel A et al. A double-blind, multicentre comparative study of two regimens of clindamycin HCl in the treatment of patients with acute streptococcal tonsillitis/pharyngitis. *Clinical therapeutics.* 1995; 17(4):613-621
- 26 Kremsner PG, Winkler S, Brandts C et al. Clindamycin in combination with chloroquine or quinine is an effective therapy for uncomplicated plasmodium falciparum malaria in children from Gabon. *Journal of infectious diseases.* 1994; 169: 467-70.
- 27 Tuner K and Nord CE. Impact of phenoxymethylpenicillin and clindmycin on microflora in recurrent tonsillitis. *Ann Otol Rhinol Laryngol.* 1985; 94: 278-80
- 28 Metzger W, Mordmuller B, Graninger W et al. Sulfadoxine/pyrimethamine or chloroquine/clindamycin treatment of Gabonese school children infected with chloroquine resistant malaria. *Journal of antimicrobial chemotherapy.* 1993; 36: 723-8.
- 29 Jacobson S J; Griffiths K; Diamond S; et al. A randomized controlled trial of penicillin vs clindamycin for the treatment of aspiration pneumonia in children. *Archives of pediatrics & adolescent medicine.* 1997; 151(7):701-4.
- 30 Schropp KP, Kaplan S, Golladay ES et al. A randomized clinical trial of ampicillin, gentamicin and clindamycin versus cefotaxime and clindamycin in children with ruptured appendicitis. *Surgery Gynecology & Obstetrics* 1991;172(5):351-6
- 31 Orrling A, Stjernquist-Desatnik A, Schalen C et al. Clindamycin in persisteing Streptococcal pharyngitis after penicillin treatment. *Scand J infec Dis.* 1994; 26: 353-41
- 32 Kircik LH, Peredo MI, Bucko AD et al. Safety of a novel gel formulation of clindamycin phosphate 1.2%-tretinoin 0.025%. Results from a 52 week open label study. *Cutis* 2008; 82:358-66.
- 33 Judd PL, Sandor GKB. Management of odontogenic orofacial infection in the young child. *Ontario Dentist.* 1997. 39-45.
- 34 Brook I. Microbiology and management of endodontic infections in children. *The Journal of Clinical Pediatric Dentistry.* 2003;28(1): 13-17.
- 35 Morrow BM, Argent AC, Jeena PM et al. Guideline for the diagnosis, prevention and treatment of paediatric ventilator-associated pneumonia (VAP). *SAMJ.* 2009; 99(4): 255-267
- 36 Klein JO. Management of streptococcal pharyngitis. *Paediatr Infect Dis J.* 1994;13:572-5.

## **IV.2 Non-clinical aspects**

### **1. Introduction**

No non-clinical studies have been submitted.

### **2. Non clinical study(ies)**

No non-clinical studies have been submitted.

### **3. Discussion on non clinical aspects**

No non-clinical studies have been submitted.

## **IV.3 Clinical aspects**

### **1. Introduction**

The clinical studies submitted with this application comprise 16 MAH-sponsored studies and 31 non-sponsored published studies.

## **Clinical Aspects**

### **251F-INF-0496-001**

A double-blind multicenter comparative study of two dose regimens of oral clindamycin hydrochloride in the treatment of acute tonsillitis/pharyngitis due to group A betahemolytic streptococci.

We requested information about the number of children

MAH-response: "Of the 179 patients who received 150 mg QID clindamycin, 11 were < 18 years of Age (6.3%) and of the 179 patients who received 300 mg BID clindamycin, 10 were < 18 years of age (5.6%). The individual patient data is not available ..... meaning no further stratification of the data has been possible."

Assessor: This is accepted.

## **For the following studies we requested that the MAH clearly presents the numbers of children:**

### **251F-INF-9052-0279**

A double blind comparative study of oral clindamycin hydrochloride 300 mg BID compared against oral clarithromycin 250 mg BID in the treatment of acute recurrent tonsillitis/pharyngitis due to group A beta-hemolytic streptococci.

### **M11000093**

A comparative evaluation of clindamycin vs clindamycin plus tobramycin in the treatment of pelvic inflammatory disease

### **M11200134**

A study to compare the efficacy and tolerance of clindamycin with erythromycin in the treatment of females with confirmed *Chlamydia trachomatis* cervicitis

**M11120004**

A comparison of cleocin T topical solution, cleocin T topical gel and placebo in the treatment of acne vulgaris

**M11200241**

Evaluation of two dose regimens of cleocin HCl capsules in comparison with dicloxacillin in the treatment of mild to moderate skin and soft tissue

**M11140001**

Efficacy of clindamycin vaginal ovule (3-day treatment) vs. clindamycin vaginal cream (7-day treatment) in bacterial vaginosis

MAH-response, combined for these studies: "...has not been able to locate the original patient data.... The MHA are also unable to provide further stratification of the data"

Assessor: This is accepted. These studies can not be part of the evaluation.

**251F-INF-9052-0280**

A single-blind (evaluator blind) comparative study of oral clindamycin hydrochloride 300 mg bid compared against oral Augmentin 1g BID in the treatment of acute recurrent tonsillitis/pharyngitis due to group A beta-hemolytic streptococci.

We requested information about the number of children in the two groups.

MAH reponse: "... Of the 384 patients who received 300 mg BID clindamycin hydrochloride capsules, 70 were <18 years of age (18.2%) and of the 390 patients who received the augmentation [sic!] tablets (1 tablet = 1 g), 50 were <18 years of age (12.8 %)..."

Assessor: This is accepted.

**CLIND-9052-285****Efficacy & safety of Dalacin C (clindamycin) in acute or recurrent pharyngo-tonsillitis**

We requested presentation of the results ("This report includes only tables. There is no presentation of results, no discussion, and no conclusion. This should be provided").

MAH response: The MAH now states: "... Patients enrolled were between 13 and 74 yrs old. "

Assessor: The present response from the MAH does not add clarity. It is obvious that it is impossible for us to ascertain any paediatric issues of this study, as the number of patients 13-18 years of age is not informed. This study must be excluded from the Application and from the Assessment.

**M11200178**

A double-blind multicentre comparative study of two administration regimes of clindamycin hydrochloride in the treatment of acute streptococcal tonsillitis/pharyngitis

We requested information about the age composition of the patient population.

MAH response: Of the 82 patients who received 150 mg QID clindamycin, 20 were <20 years of age (24.4%) and of the 82 patients who received 300 mg QID clindamycin, 15 were <20 years of age (18.3 %)".

Assessor: It is not possible to ascertain how many of the 20 and 15 patients, respectively, that were <18 years or 18-20 years of age. Therefore, this study cannot be included in the Application of the assessment.

**For the following studies we concluded that the findings did not justify any changes to the SmPC.**

**M11120001**

A comparison of cleocin T topical gel vs placebo in the treatment of acne vulgaris

**M11120002**

A comparison of cleocin T topical solution vs cleocin T topical gel in the treatment of acne vulgaris

**M11120005**

Comparative efficacy and tolerance of cleocin T gel vs oral minocycline in the treatment of acne vulgaris

MAH response: "The MAH concur .."

Assessor: Issue resolved.

**M11150023**

**Efficacy of clindamycin vaginal cream prophylactic treatment regimen to prevent recurrent bacterial vaginosis – a randomized, placebo controlled trial**

This study did not include children. We therefore considered it to be irrelevant to the present submission.

MAH response: "Reference to this study has been removed..."

Assessor: Issue resolved.

**For the following studies we concluded that the findings supported the current SmPC.**

1, 2, 3 and 20.

MAH response: "The MAH concur .."

Assessor: Issue resolved.

**For the following studies we concluded that the findings did not justify any proposal for changes to the current SmPC.**

4, 5, 6, 8, 9, 10, 11, 12, 13, 16, 21, 22, 23, 26, 28, 29, 30, 33, 34, 35.

MAH response: "The MAH concur .."

Assessor: Issue resolved.

**For the following studies we concluded that the studies could be not be included in the present Application.**

15, 17, 19, 36

MAH response: "The MAH concur .... and reference to theses studies has been removed .."

Assessor: Issue resolved.

**For the following studies we requested information about the the number of children**

25, 31 and 32

MAH response: "... The MAH are unable to provided this information as requested"

Assessor: In that case, the studies must be excluded from an application about the use of clindamycin in children.

**Assessment of non-sponsored study reports that were not initially submitted:**

Five of the studies in the above line listing were not submitted as PDF files and had therefore not been taken into account (number 7, 14, 18, 24, and 27).

These have now been submitted.

**7 Centre for Disease Control and Prevention. Chapter 5. Other infectious diseases related to travel. Toxoplasmosis. <http://wwwnc.cdc.gov/travel/yellowbook/2010/chapter-5/toxoplasmosis.aspx#> . Accessed 11 March 2010.**

Assessor:

This section on toxoplasmosis from the website of CDC includes a subsection about the treatment of acute toxoplasmosis in children, but clindamycin is not mentioned.

The MAH states: "Thus, although clindamycin may be used for treatment of toxoplasmosis, the findings of this study do not justify any changes to the clindamycin SmPC as they report treatments [sic!] regimens that have not been verified by the MAH"-

Assessor's conclusion:

We agree that this report does not justify any changes to the current clindamycin SmPC.

**14 Marcinak JF and Frank AL. Treatment of community-acquired methicillin-resistant *Staphylococcus aureus* in children. *Curr Opin Infect Dis.* 2003; 16: 265-9.**

Assessor:

This is a review based on 23 literature references. Regarding clindamycin, it is concluded: "Clindamycin therapy is effective for the treatment of CA-MRSA [community acquired methicillin resistant *Staphylococcus aureus*], but resistance to clindamycin can develop if the isolate is also erythromycin resistant by the *erm* mechanism".

Assessor's conclusion:

This report does not justify any changes to the current SmPC

**18 Prepared by the EARSS Management Team, members of the Advisory Board, and national representatives of EARSS. EARSS Annual Report 2004. Bilthoven, The Netherlands, September 2005. Downloaded from [http://www.rivm.nl/earss/Images/EARSS%20annual%20report%202004%20webversie\\_tcm61-25345.pdf](http://www.rivm.nl/earss/Images/EARSS%20annual%20report%202004%20webversie_tcm61-25345.pdf) on 02 March 2010.**

Assessor:

The MAH states: "Review of the MRSA specific literature suggests that in areas where CA-MRSA is susceptible to clindamycin, that [sic!] clindamycin therapy may be an effective treatment for paediatric patients. However, clindamycin is not currently indicated for MRSA, and given that the prevalence of MRSA and resistance to antibiotics vary widely from country to country within Europe<sup>24</sup> and that the literature studies reviewed were US-specific, at this time it is

not possible to provide guidance in the labels for the use of clindamycin to treat paediatric patients with CA-MRSA in Europe”.

Assessor's conclusion:

This report does not justify any changes to the current SmPC

**24 Collins MD, Dajani AS, Kim KS et al. Comparison of ampicillin/sulbactam plus aminoglycoside vs. ampicillin plus clindamycin plus aminoglycoside in the treatment of intraabdominal infections in children. The Pediatric Infect Dis J. 1998; 17(3)S1: S15-S18**

Assessor:

This was a multicentre, prospective, randomized, comparative, open label study of parallel design. Hospitalized children 3 months to 11 years old requiring antibiotic therapy for established intraabdominal bacterial infections were enrolled. Study arms were: Ampicillin/sulbactam + aminoglycoside (ASA) and ampicillin + clindamycin+ aminoglycoside (ACA). Among 195 enrolled children, 145 were evaluable (75 of 131 in the ASA group, and 39 among 64 in the ACA group). The clinical success rate was 97% in both groups. The bacteriological cure rate at end of study drug therapy was 92% in the ASA group and 95% in the ACA group. At the final evaluation the clinical success rate was 92% in the ASA group and 95% in the ACA group, and the bacteriological eradication rate was 89%<sup>a</sup> and 92%, respectively. In both groups, 31% experiences adverse events, predominantly gastrointestinal.

Assessor's conclusion:

This report does not justify any changes to the current SmPC.

**27 Tuner K and Nord CE. Impact of phenoxymethylpenicillin and clindmycin on microflora in recurrent tonsillitis. Ann Otol Rhinol Laryngol. 1985; 94: 278-80**

Assessor:

A total of 75 patients (15 to 44 years of age; mean age 20 years) with recurrent tonsillitis were divided into three groups (n = 25), two of which were given antibiotics for nine days before the “operation” (it appears indirectly that the operation was a tonsillectomy). No difference between the three groups regarding age could be seen. One group was given clindamycin capsules 150 mg QID, one group was given phenoxymethylpenicillin 1 g BID, and one group was not given antibiotics at all. Clindamycin was more efficient than phenoxymethylpenicillin in diminishing the presence of *Staphylococcus aureus* and various anaerobic bacteria. However, no follow-up was performed, and there is no documentation that clindamycin may have a curative effect on recurrent tonsillitis in the absence of tonsillectomy. Furthermore, although a majority of the patients must have been ≤ 20 years of age, it is never-the-less impossible to ascertain how many were ≤ 18 years of age. Thus, the representativeness of this study for the paediatric population is limited.

Assessor's conclusion:

This report does not justify any changes to the current SmPC. The representativeness of this study for the paediatric population is limited, and it should therefore not have been part of the application.

## V. MEMBER STATES OVERALL CONCLUSION AND RECOMMENDATION

### ➤ Overall conclusion

The MAH has provided some of the supplementary data requested by us. However for historical reasons, such data were not retrievable in some cases. We acknowledge these circumstances.

After having reviewed all the hitherto submitted material we have concluded to agree with the MAH in that the study reports presented do not suggest that any changes to the clindamycin SmPC are warranted.

### ➤ Recommendation

No further action required.

## VI. LIST OF MEDICINAL PRODUCTS AND MARKETING AUTHORISATION HOLDERS INVOLVED

### MAH Pfizer:

Dalacin, 1% topical lotion

Dalacin, 1% topical solution

Dalacin (Cleocin, Sobelin), 2% vaginal cream

Dalacin (Sobelin), 300mg/2ml (150mg/ml), 600mg/4ml and 900mg/6ml solution for injection (IV/IM)

Dalacin, (Cleocin)100mg vaginal ovules

Dalacin, 1% topical gel

Dalacin (Sobelin), 75mg/5ml granules for oral solution

Dalacin, 75mg, 150mg and 300mg capsules, hard.