CHLORAMPHENICOL 1% W/W EYE OINTMENT

PL 00156/0363

UKPAR

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LAY SUMMARY

On 10th May 2013 the MHRA granted Marketing Authorisation (licence) for the medicinal product Chloramphenicol 1% w/w Eye Ointment (PL 00156/0363). This is a Prescription-only medicine (POM).

Chloramphenicol Eye Ointment is used to treat acute bacterial conjunctivitis, which is an infection of the outer surface of eye that causes redness, discomfort and discharge from the affected eye. A doctor can provide further advice about these symptoms.

The active ingredient of Chloramphenicol Eye Ointment is chloramphenicol, which is an antibiotic.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of treatment with Chloramphenicol 1% w/w Eye Ointment outweigh the risks; hence a Marketing Authorisation has been granted.
CHLORAMPHENICOL 1% W/W EYE OINTMENT

PL 00156/0363

SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare products Regulatory Agency (MHRA) granted a Marketing Authorisation for the medicinal product Chloramphenicol 1% w/w Eye Ointment (PL 00156/0363) to Martindale Pharma on the 10th May 2013. This is a prescription-only medicine used for the treatment of bacterial conjunctivitis caused by chloramphenicol susceptible organisms.

This application was submitted as a simple abridged application according to Article 10c of Directive 2001/83/EC, as amended. The applicant is cross-referring to Tubilux Infected Eyes Eye Ointment (PL 17918/0004), originally granted to Tubilux Pharma SPA on 1st March 2007. The reference licence has undergone a Change of Ownership (COA) procedure and was authorised to the current Marketing Authorisation Holder, Martindale Pharma (PL 00156/0360) on 3rd October 2011.

Chloramphenicol exerts its antibacterial effect by binding to bacterial ribosomes and inhibiting bacterial protein synthesis at an early stage.

No new data were submitted nor were they necessary for this simple application, as the data are identical to those of the previously granted cross-reference product.

A pharmacovigilance system has been provided with this application and is satisfactory.

Suitable justifications for non-submission of the Environmental Risk Assessment (ERA) and Risk Management Plan (RMP) have been provided for this product.
PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00156/0363
PROPRIETARY NAME: Chloramphenicol 1% w/w Eye Ointment
COMPANY NAME: Martindale Pharma
E.C. ARTICLE: Article 10c of Directive 2001/83/EC, as amended
LEGAL STATUS: POM

1 INTRODUCTION
This is a simple, informed consent application for Chloramphenicol 1% w/w Eye Ointment, submitted under Article 10c of Directive 2001/83/EC, as amended. The applicant cross-refers to Tubilux Infected Eyes Eye Ointment (PL 17918/0004), originally granted to Tubilux Pharma SPA on 1st March 2007. The reference licence has undergone a Change of Ownership (COA) procedure and was authorised to the current Marketing Authorisation Holder, Martindale Pharma (PL 00156/0360) on 3rd October 2011.

2 MARKETING AUTHORISATION APPLICATION (MAA)
2.1 Name(s)
The proposed name of the product is Chloramphenicol 1% w/w Eye Ointment. The product has been named in line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
The product contains the active ingredient chloramphenicol 1.0% w/w.

The ointment is packed in aluminium tube with epoxy-phenolic-ureic resin internal coating and polyethylene screw cap and nozzle. The pack size is 4 g tube.

Specifications and Certificates of Analysis for all packaging components used have been provided and are satisfactory. The packaging and pack size are the same as those for the reference product.

The proposed shelf-lives are 2 years for unopened tube and 28 days after opening have been set. The proposed storage conditions are ‘Do not store above 25°C and Protect from light’. These are satisfactory.

The shelf-lives and the storage conditions are identical to those for the reference product and are satisfactory.

2.3 Legal status
This product is a prescription-only medicine (POM).

2.4 Marketing authorisation holder/Contact Persons/Company
The proposed Marketing Authorisation holder is Martindale Pharma, Bampton Road, Romford, RM3 8UG, United Kingdom.

The Qualified Person (QP) responsible for pharmacovigilance is stated and a Curriculum Vitae (CV) is included.
2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is consistent with the details registered for the reference product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the reference product and the maximum batch size is stated.

2.8 Finished product/shelf-life specifications
The proposed finished product and shelf-life specification are in line with the details registered for the reference product.

2.9 Drug substance specification
The proposed drug substance specification conforms to the current European Pharmacopoeia monograph for chloramphenicol, and is in-line with that for the reference product.

Chloramphenicol is the subject of a European Drug Master File (EDMF). A letter of access has been provided by the drug substance manufacturer. The active substance manufacturer is in line with that for the reference product.

2.10 TSE Compliance
No materials of human or animal origin have been used in the manufacture of this product. This is consistent with the reference product.

2.11 Bioequivalence
No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula utilising the same process as the reference product Tubilux Infected Eyes Eye Ointment (PL 00156/0360).

3 EXPERT REPORT
The applicant has included detailed expert reports in the application. Signed declarations and copies of the experts’ CVs are enclosed for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4 PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product is identical to that of the reference product.

5 SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The proposed SmPC is consistent with the details registered for the reference product.
6. **PATIENT INFORMATION LEAFLET (PIL)/LABELLING**
User testing of the package leaflet has been accepted, based on a bridging report provided by the applicant making reference to the user-testing of the PIL for Tubilux Infected Eyes Eye Ointment (PL 00156/0360). A critical analysis demonstrated that the key messages for safe and effective use for all leaflets were similar. The justification of the rationale for bridging is accepted.

The proposed artwork complies with the relevant statutory requirements. In line with current legislation, the applicant has also included the name of the product in Braille on the outer packaging and sufficient space for a standard UK pharmacy dispensing label.

7. **CONCLUSIONS**
The data submitted with the application are acceptable. The grant of a Marketing Authorisation is recommended.
NON-CLINICAL ASSESSMENT

No new non-clinical data have been supplied with this application and none are required for applications of this type.
CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for applications of this type.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application are consistent with those previously assessed for the reference product and, as such, have been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for applications of this type.

EFFICACY
This application is identical to the previously granted application for Tubilux Infected Eyes Eye Ointment (PL 17918/0004), originally granted to Tubilux Pharma SPA on 1st March 2007. The reference licence has under gone a Change of Ownership (COA) procedure and was authorised to the current Marketing Authorisation Holder, Martindale Pharma (PL 00156/0360) on 3rd October 2011.

Pharmaceutical, non-clinical and clinical expert statements have been provided, together with CVs showing that the experts are appropriately qualified. The experts confirm that the product is identical in composition, manufacture and pharmaceutical characteristics to the respective reference product and that there are no toxicological or clinical issues.

No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labelling are satisfactory and consistent with those for the reference product.

RISK BENEFIT ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the reference product. Extensive clinical experience with chloramphenicol is considered to have demonstrated the therapeutic values of the compounds. The risk benefit is, therefore, considered to be positive.
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STEPS TAKEN FOR ASSESSMENT

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<tbody>
<tr>
<td>1</td>
<td>The MHRA received the Marketing Authorisation application on 12\textsuperscript{th} December 2011</td>
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<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application is valid on 19\textsuperscript{th} December 2011</td>
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<td>3</td>
<td>Following assessment of the application the MHRA requested further information on 16\textsuperscript{th} March 2012, 30\textsuperscript{th} October 2012,</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s request, providing further information on 10\textsuperscript{th} September 2012 and 29\textsuperscript{th} November 2012</td>
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<td>5</td>
<td>The application was determined on 10\textsuperscript{th} May 2013</td>
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Module 2
Summary of Product Characteristics

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPC) for products that are granted Marketing Authorisations at a national level are available on the MHRA website.
Module 3
Patient Information Leaflet

In accordance with Directive 2010/84/EU the Patient Information Leaflets (PIL) for products that are granted Marketing Authorisations at a national level are available on the MHRA website.
Module 4

LABELLING