REPUBLIC OF KENYA
EAST AFRICAN COMMUNITY

Reference no:

EVALUATION TEMPLATE FOR THE REVIEW OF SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

CTD number of the medicinal product: *CTD 8573*

Brand Name of the medicinal product: SENSOCAIN SPINAL 0.5%

Name and strength of the medicinal product: SENSOCAIN SPINAL 0.5%

Name of the manufacturer: BROOKES PHARMA PVT LIMITED

Name of Marketing Authorization Holder: BROOKES PHARMA PVT LIMITED

Name of the Local Technical Representative: HARLEYS LIMITED

Dosage Form: Solution For Injection

SmPC Version Reviewed: *[Specify the version or date of the SmPC being reviewed]*

Date of Review: 16/04/2024

Date of submission of dossier: Mon May 8 11:32:31 EAT 2017

Date of registration of the Product: 08/03/2024

CONCLUSION OF THE ASSESSMENT (*delete whichever is not applicable***): QUERIES RAISED /RECOMMENDED FOR CONDITIONAL APPROVAL, RECOMMENDED FOR REGISTRATION, RECOMMENDED FOR REFUSAL**

Evaluator: Assessor's full name Dr. Gitobu Kireran Date 16-04-2024

Review of Summary of Product Characteristics Template

Summary SmPC Information:

Purpose of Review: Update and publication of SmPC, complies with legal and regulatory requirements
Regulatory Compliance:
The SmPC is legible, clearly comprehensible, indelible and concise language.This is acceptable
Section 1: Product Description:
The applicant has provided the name and strength of the product.This is acceptable.

Section 2: Qualitative and quantitative composition
The applicant has provided the qualitative and quantitative composition of the active substances.
A standard statement is included at the end of the section, referring to section 6.1 for the full list of excipients.This is acceptable.

Section 3: Pharmaceutical form
A standard form has been used for the product.A visual description of the product has been used in a separate paragraph from the standard term.However,since the product is an injectable, information on the pH and osmolality should be included in this section.

Section 4. Clinical Particulars

4.1 Therapeutic indications and uses:
The indications provided are clear and consistent and align with marketing authorization.
4.2 Posology and method of administration:
The applicant has not provided the dosing units to be administered in different patient populations i.e adults, children and elderly.The details on the maximum recommended doses, dose titration and duration of use have not been included under this section. The route of administarton has also not been included.
You are requested to provide the dosing unit to be administered in the different patient population i.e adults, children and elderly. Additionaly, you are requested to include details on the maximum recommended doses, dose titration and duration of use. The route of administration should be also included.

Section 4.3 Contraindications:
Reviewed the section and found it to be satisfactory.

Section 4.4 Special warnings and precautions for use:
Reviewed the section and found it to be satisfactory.

Section 4.5 Interactions with other medicinal products and other forms of interaction.
Reviewed the section and found it to be satisfactory.

Section 4.6 Pregnancy and lactation:
Reviewed the section and found it to be satisfactory.

Section 4.7 Effects on ability to drive and use machines:
Reviewed the section and found it to be satisfactory.

Section 4.8 Undesirable effects:
It was noted that reporting of adverse reactions to Pharmacy and Poisons Board was not included under this section. You are therefore requested to include the following standard statement:
Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

Section 4.9 Overdose:
Reviewed the section and found it to be satisfactory
Section 5. Pharmacological Properties:

5.1 Pharmacodynamic properties:
Reviewed the section and found it to be satisfactory
5.2 Pharmacokinetic properties:
Reviewed the section and found it to be satisfactory
5.3 Preclinical safety data:
Reviewed the section and found it to be satisfactory
Section 6. Pharmaceutical Properties:

Section 6.1 List of excipients
Reviewed the section and found it to be satisfactory
Section 6.2 Incompatibilities:
N/A
Section 6.3 Shelf life:
The information aligns with that in the dossier and is acceptable
Section 6.4 Special precautions for storage:
The storage statement aligns with that in the dossier.
Section 6.5 Nature and contents of container:
Reviewed the section and found it to be satisfactory
Section 6.6 Special precautions for disposal and other handling:
Reviewed the section and found it to be satisfactory

Section 7. Marketing Authorisation Holder:
Information on the MAH was not provided.
Please provide information on the name and address of the MAH in this section.

Section 8. Marketing Authorisation Number(s):
N/A

Section 9. Date of First Authorisation/Renewal of the Authorisation:
N/A

Section 10. Date of Revision of the Text: [*Enter date of renewal*]
N/A

Comments and Recommendations:
SECTION 3: Provide information on pH and osmolality of the injection in this section.
SECTION 4.2: You are requested to provide the dosing unit to be administered in the different patient population i.e adults, children and elderly. Additionaly, you are requested to include details on the maximum recommended doses, dose titration and duration of use. The route of administration should be also included.
SECTION 4.8 It was noted that reporting of adverse reactions to Pharmacy and Poisons Board was not included under this section. You are therefore requested to include the following standard statement:
Reporting of suspected adverse reactions: Healthcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org
SECTION 7 Please provide information on the name and address of the MAH in this section

You are required to align the format of the SmPC (Section8-12) with that in the PPB guidelines for Summary of Product Characteristics (SmPC), Patient Information leaflet and labelling and submit for review.

Conclusion:
Queries have been raised.