



MEMORANDUM

To Administrative file for STN 125819

Date February 6, 2025

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Applicant GlaxoSmithKline Biologicals

Subject Review of analytical methods PENMENVY (Meningococcal Groups A,B,C,W-135, and Y) vaccine.

Recommendation: Approval

Summary:

The following analytical methods used for lot release of PENMENVY (Meningococcal Groups A, B, C, W and Y Vaccine) drug substance (DS) and drug product (DP) from GlaxoSmithKline (GSK) Biologicals SA, and the associated validations and qualifications, were reviewed:

- 1 Identity (b) (4) /DP ((b) (4)
- 2 (b) (4)
- 3 (b) (4)
- 4 Identity (b) (4) /DP MenA,C,W,Y((b) (4) MenACWY
Lyo/Reconstituted Vial (RV)
- 5 (b) (4)
- 6 (b) (4)
- 7 (b) (4)
- 8 (b) (4)
- 9 (b) (4)

Conclusion: Based on the validation and transfer data reviewed in this submission, the analytical methods used for lot release testing for Meningococcal A,C,W-135, and Y and CRM conjugated (b) (4) and the methods for MenB liquid and MenABCWY lyophilized drug products (DP), are acceptable for their intended purposes.

Documents Reviewed and Referenced:

Information submitted and reviewed includes:

125819/0: Section-3.2.S.4.2 - Analytical Procedures (b) (4)

125819/0: Section-3.2.S.4.3 - Validation of Analytical Procedures (b) (4)

125819/0: Section-3.2.P.5.2 - Analytical Procedures – ID for MenB, MenACYW DP.

125819/0: Section-3.2.P.5.3 - Validation of Analytical Procedures – ID for MenB, MenACYW DP.

125819/0: Section- 3.2.R- (b) (4) transfer (b) (4) from GSK-V, Rosia to GSKV (b) (4) site by analytical method transfer report (AMTR) by (b) (4) report# TES-0000009384-PQ&PV Report for rp 936-741 of Bexsero.

125819/0: Section- 3.2.R- (b) (4) transfer (b) (4) transferred from Rosia to (b) (4), US site by AMTR # TES-0000009383-PQ&PV report for CRM-MenA and CRM-MenY of Menveo DP.

Previous references: STN125300/682 and STN125300/851- Menveo- for transfer of methods for CRM-(b) (4) transfer from (b) (4) to Rosia.

Previous references: STN125564/634 and STN125546/995- Validation and transfer from (b) (4) for (b) (4) Methods for MenB (b) (4) transferred from (b) (4) and release test performed at (b) (4)

Background:

On February 15, 2024 GSK submitted a BLA for Meningococcal groups A,B,C,W, and Y vaccine (PENMENVY) for prevention of invasive disease caused by *Neisseria meningitidis* in individuals 10 through 25 years of age. PENMENVY is supplied as a vial of lyophilized MenACWY components (Menveo) of *N. meningitidis* capsular oligosaccharides conjugated to CRM197 (*Corynebacterium diphtheriae* Cross Reacting Material-197) along with one prefilled syringe (PFS) of liquid MenB-aluminum hydroxide (BEXSERO) which are reconstituted together before injecting 0.5 mL intramuscularly in two doses six months apart. The MenACWY Lyophilized contains the same antigen in the same amount as the commercial Menveo vaccine previously approved (STN125300), and the MenB liquid PFS which was previously

approved as BEXSERO (STN125546). The MenB liquid has the same formulation as BEXSERO with the four components of recombinant polysaccharides (rps-287-953, rp936-741, rp961c, Outer Membrane Vesicles- OMV) adsorbed to aluminum hydroxide. The only difference between BEXSERO and the MenB liquid DP is a (b) (4)

In this BLA sponsor provided the analytical methods for quality control of Men B Liquid and MenABCWY reconstituted vial (RV) final container product (FC/DP) release testing to be performed at (b) (4), Rosia (b) (4) GSK at (b) (4). The analytical methods for release were also previously transferred from Building (b) (4) at (b) (4) to Building (b) (4), Rosia, Italy, submitted to *Bexsero* and *Menveo* on 10 February 2020 [(referred to in submission for *Bexsero* STN 125546/634, sequence 0305, approved 19 August 2020 (for DNA, OMV, 961c, 936-741, 287-953 (b) (4) by (b) (4), and (b) (4) on (b) (4) and *Menveo* STN 125300/682, sequence 415, approved 30 July 2020 (for CRM content by (b) (4) for MenB-OMV, (b) (4) of CRM197 by (b) (4)). The reports supporting the analytical transfer from Building (b) (4) at (b) (4), Italy to Building (b) (4) at (b) (4), for Bexsero (125546/995 for (b) (4) by (b) (4) for (b) (4) MenB) and Menveo (125300/851, for CRM (b) (4) by (b) (4) and (b) (4) MenAWY-CRM) BLAs were reported in Annual Report, 2023.

Review

1. Identity (b) (4)/DP (b) (4) by (b) (4)

The (b) (4) MenB (961c, 936-741, 287-953 and OMV) component of PENMENVY are same as in previously approved Bexsero vaccine (STN125546) and are manufactured via the same processes. The method for ID determination by (b) (4) was validated for Bexsero vaccine: the release test is performed at Rosia (b) (4) sites.

Method:

(b) (4)

(b) (4)

Method Validation:


(b) (4)

All assay acceptance criteria mentioned above were met.

The results demonstrated that the (b) (4), therefore met the test specifications/acceptance criteria. The ID method was therefore successfully transferred to (b) (4) site and is suitable for its intended use.

2. (b) (4)

(b) (4)



4. Identity (b) (4) /DP (b) (4) MenACWY Lyo/RV

The (b) (4) DP for Men A,C,W,Y and adjuvanted with CRM197 components of PENMENVY are same as in previously approved Menveo vaccine (STN125300) and are manufactured via the same processes. The method for ID determination by (b) (4) was validated for Menveo vaccine and is similar for ID determination on MenACWY (b) (4) DP: the release test is performed at Rosia and (b) (4) sites.

In current submission, the sponsor submitted SOP#9000073355-06, entitled- (b) (4) method for the (b) (4) of the CRM-MenA, CRM-MenC CRM-MenW135, CRM-MenY Glycoconjugates of the Men ACWY Lyo Formulation. The purpose of the (b) (4) method is to determine the MenACWY

polysaccharide (PS) in (b) (4) of meningococcal serogroup A, C W, Y -
Diphtheria toxoid (CRM) conjugate DP.

Method:

(b) (4)

