# Vaxchora

Procedural steps taken and scientific information after the authorisation

| Application number | Scope | Opinion/ Notification [1] issued on | Commission Decision Issued [2] / amended on | Product Information affected [3] | Summary |
|---|---|---|---|---|---|
| PSUSA/10862 /202406 | Periodic Safety Update EU Single assessment - cholera vaccine, oral, live | 16/01/2025 | n/a | | PRAC Recommendation - maintenance |
| R/0024 | Renewal of the marketing authorisation. | 14/11/2024 | 13/01/2025 | SmPC, Annex II, Labelling and PL | Based on the review of data on quality, safety and efficacy, the CHMP considered that the benefit-risk balance of Vaxchora in the approved indication remains favourable |

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

| | | | | | |
|---|---|---|---|---|---|
| | | | | | and therefore recommended the renewal of the marketing authorisation with unlimited validity. |
| IB/0027 | B.I.a.1.k - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - New storage site of MCB and/or WCB | 10/12/2024 | n/a | | |
| IA/0026 | B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process | 21/11/2024 | n/a | | |
| PSUSA/10862 /202306 | Periodic Safety Update EU Single assessment - cholera vaccine, oral, live | 11/01/2024 | n/a | | PRAC Recommendation - maintenance |
| IA/0023/G | This was an application for a group of variations.<br><br>B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure<br>A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient | 12/12/2023 | 13/01/2025 | Annex II | |
| T/0021 | Transfer of Marketing Authorisation | 16/08/2023 | 22/09/2023 | SmPC, Labelling and PL | |
| II/0020 | B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test | 14/09/2023 | n/a | | |

| | | | | | |
|---|---|---|---|---|---|
| | method at the site is a biol/immunol method | | | | |
| IB/0019/G | This was an application for a group of variations.<br><br>B.II.z - Quality change - Finished product - Other variation<br>B.II.e.2.b - Change in the specification parameters and/or limits of the immediate packaging of the finished product - Addition of a new specification parameter to the specification with its corresponding test method | 03/05/2023 | n/a | | |
| IB/0018/G | This was an application for a group of variations.<br><br>B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol<br>B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data | 27/02/2023 | n/a | | |
| PSUSA/10862 /202206 | Periodic Safety Update EU Single assessment - cholera vaccine, oral, live | 12/01/2023 | n/a | | PRAC Recommendation - maintenance |
| IB/0016 | B.I.z - Quality change - Active substance - Other variation | 22/12/2022 | n/a | | |
| IA/0017 | B.II.b.3.a - Change in the manufacturing process of the finished or intermediate product - Minor change in the manufacturing process | 16/12/2022 | n/a | | |

| | | | | | |
|---|---|---|---|---|---|
| II/0013 | Type II - C.I.4, to update Section 6.6 of the SmPC to add the use of carbonated bottled water to reconstitute the vaccine in addition to non-carbonated bottled water. The package leaflet and labelling are updated accordingly.<br><br>The applicant took the opportunity to submit a corrected Annex A in all languages, which currently presents an inconsistency in the way the strength was stated at MAA approval (as detailed in SmPC).<br><br>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data | 21/07/2022 | 04/07/2023 | SmPC, Labelling and PL | The SmPC section 6.6 has been updated as follows: to add the use of carbonated bottled water to reconstitute the vaccine in addition to non-carbonated bottled water<br><br>The PL have been updated accordingly. |
| PSUSA/10862 /202112 | Periodic Safety Update EU Single assessment - cholera vaccine, oral, live | 07/07/2022 | n/a | | PRAC Recommendation - maintenance |
| IB/0014 | C.I.11.z - Introduction of, or change(s) to, the obligations and conditions of a marketing authorisation, including the RMP - Other variation | 20/05/2022 | n/a | | |
| IB/0011/G | This was an application for a group of variations.<br><br>B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol<br>B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol | 10/02/2022 | n/a | | |

| | | | | | |
|---|---|---|---|---|---|
| PSUSA/10862 /202106 | Periodic Safety Update EU Single assessment - cholera vaccine, oral, live | 13/01/2022 | n/a | | PRAC Recommendation - maintenance |
| IB/0010 | B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data | 22/12/2021 | n/a | | |
| II/0009 | B.II.d.1.e - Change in the specification parameters and/or limits of the finished product - Change outside the approved specifications limits range | 16/12/2021 | n/a | | |
| PSUSA/10862 /202012 | Periodic Safety Update EU Single assessment - cholera vaccine, oral, live | 08/07/2021 | n/a | | PRAC Recommendation - maintenance |
| IA/0007 | A.7 - Administrative change - Deletion of manufacturing sites | 04/05/2021 | 02/08/2022 | Annex II and PL | |
| II/0003/G | This was an application for a group of variations.<br><br>C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data<br>C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one | 28/01/2021 | 26/02/2021 | SmPC, Annex II, Labelling and PL | Please refer to Scientific Discussion 'Vaxchora-H-C-003876-II-0003-G' |
| PSUSA/10862 /202006 | Periodic Safety Update EU Single assessment - cholera vaccine, oral, live | 14/01/2021 | n/a | | PRAC Recommendation - maintenance |
| IB/0005 | B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other | 05/01/2021 | n/a | | |

| | | | | | |
|---|---|---|---|---|---|
| | changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate | | | | |
| IB/0002/G | This was an application for a group of variations.<br><br>B.I.d.1.a.4 - Stability of AS - Change in the re-test period/storage period - Extension or introduction of a re-test period/storage period supported by real time data<br>B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol | 29/06/2020 | n/a | | |
| IAIN/0001 | A.5.a - Administrative change - Change in the name and/or address of a manufacturer/importer responsible for batch release | 20/05/2020 | 26/02/2021 | Annex II and PL | |