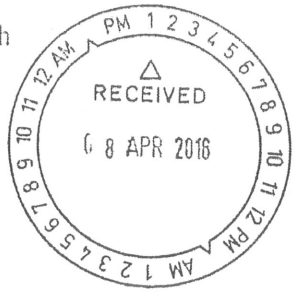
PaxVax

[redacted]
Assistant Director
Monitoring Section | Regulatory Practice and Compliance Branch
Office of the Gene Technology Regulator
Department of Health and Ageing
15 National Circuit
Barton ACT 2600
Australia



April 4, 2016

RE: DIR 126 PXVX0200 Cholera Vaccine
Annual Report

Dear [redacted]

Further to the conditions of the DIR 126 license issued on April 10, 2014 for PaxVax's PXVX0200 cholera vaccine, we wish to provide the following information.

Condition 50, Annual Report: The total number of trial participants inoculated with the PXVX0200 vaccine during the previous 12 months was 0 (zero), and there were no serious or significant adverse events linked to exposure to PXVX0200.

As discussed with [redacted] of your office on February 25, 2016, we wish to maintain DIR 126 as an active license at this time, in anticipation of potential future studies (e.g. a booster trial) and will submit a variation to the license to describe those studies prior to their conduct.

Should you or your staff have any questions regarding this submission or require additional information, please contact me via phone at [redacted] or [redacted] or via email at [redacted]

Sincerely,

[redacted]

[redacted]
[redacted] Regulatory and Pharmacovigilance
PaxVax, Inc.

Cc: [redacted]

900 Veterans Blvd., Suite #500; Redwood City, CA 94063
P: (650) 847-1075 F: (650) 720-4585 paxvax.com