(1) Does the application adequately address the issue of the public health need for the medicine?

Yes ☒ No ☐

Please provide brief details:

The application contends that hypochlorous acid as a pH-neutral electrolysed water (NEW) is a preventative against the spread of nosocomial infections and multi-drug resistant bacteria within hospital and other healthcare and community settings. Hypochlorous acid is presented as a more effective, safe, and non-cytotoxic topical antimicrobial alternative to other antiseptic agents.

The proposal notes that the antimicrobial efficacy of NEW is essentially rapid osmotic shock, it is not believed to be susceptible to the development of antimicrobial resistance because of its extremely rapid physical mode of action and not cytotoxic mode of action. Furthermore, NEW has a broad biocidal effect against bacteria, viruses, fungi, spores, eukaryotes, and biofilms.

Industry-sponsored recommendations sited indicate HOCL for Diabetic Foot Ulcers, Venous Leg Ulcers, Pressure Ulcers, Postsurgical wounds, First-degree and second-degree burns and Grafted and donor sites (not all solutions)

(2) Have all important studies/evidence of which you are aware been included in the application?

Yes ☒ No ☐

Please provide brief comments on any relevant studies that have not been included:

(3) Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed use?

Yes ☒ No ☐

(a) Briefly summarise the reported benefits (e.g. clinical versus surrogate) and comment, where possible, on the actual magnitude of benefit associated with use of the medicine:
There is limited evidence presented from large randomised control trials in human subjects. The authors present several clinical trials and *in vitro* work demonstrating superiority to other antiseptic solutions in reducing, amongst other things, signs of infection, odour, and days of hospitalisation.

(b) Is there evidence of efficacy in diverse settings and/or populations? Please provide brief details:

Clinical trials and research findings have been conducted on surgical and medical patients in HIC and LMIC. Furthermore, *in vitro* and animal models have been presented.

(4) Has the application adequately considered the safety and adverse effects of the medicine? Are there any adverse effects of concern, or that may require special monitoring?

Yes ☒ No ☐

Please provide brief details:

The application presents evidence of several clinical trials and *in vitro* work. However, there is limited evidence of safety and adverse effects in human studies.

(5) Please comment on the overall benefit to risk ratio of the medicine (e.g., favourable, uncertain etc).

The application presents evidence that hypochlorous acid does not target cell nuclei, produces only limited damage to cell membranes, and does not induce DNA oxidation or accelerated ageing. It is contended that NEW presents no environmental hazard as well.

**ADDITIONAL CONSIDERATIONS:**

(6) Are there special requirements or training needed for the safe, effective and/or appropriate use of the medicine?

Yes ☐ No ☒

Please provide brief details:

(7) Are there any issues regarding the registration of the medicine by regulatory authorities? (e.g., recent registration, new indications, off-label use)

Yes ☐ No ☒

Please provide brief details:
(8) **Is the medicine recommended for use in a current WHO GRC-approved Guideline (i.e., post 2008)?**

Yes ☒ No ☐

Please provide brief details:

Antibiotic Guidelines 2015 edition for the Cook Islands and Western Samoa.

2016 International Wound Infection Institute (IWII) Consensus Guidelines published in the Journal Wound were supported by an educational grant from IWII and sponsored by a number of commercial organisational which did not include a manufacturer of NEW note that NEW (super-oxidised solution with hypochlorous acid) is the only wound care solution and hydrogel that penetrates biofilm and kills microbes from within while not promoting antimicrobial resistance.

(9) **Please comment briefly on issues regarding cost and affordability of this medicine.**

The authors contend that the cost per application of Electromicyn is significantly less than that of comparator antiseptic solutions and hydrogels. Furthermore, the duration of treatment with Electromicyn is significantly less than comparators making the cost per treatment even more affordable.

(10) **Any additional comments?**

None

(11) **Please frame the decisions and recommendations that the Expert Committee could make.**

It is recommended that the Expert Committee consider hypochlorous acid for inclusion in the Essentials Medicines List.

(12) **References (if required)**

Please see the applications for full references ([http://www.who.int/selection_medicines/committees/expert/21/applications/hypochlorous_acid_solution_ad/en/](http://www.who.int/selection_medicines/committees/expert/21/applications/hypochlorous_acid_solution_ad/en/)) and additional public comments.