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## CLARIFICATION OF MEDIA REPORTS

Positive articles covering Probiomics' clinical trial using PCC<sup>®</sup> to enhance the effect of flu vaccines, appeared in Sydney's Daily Telegraph and Melbourne's Herald Sun last Thursday. The Daily Telegraph article appears below.

Several aspects of the report require clarification:

1. The opening paragraph of the report incorrectly implies that *Lactobacillus fermentum* is found in yoghurt. PCC<sup>®</sup> is the registered trademark of Probiomics' proprietary strain of probiotic – *Lactobacillus fermentum* VRI 003. PCC<sup>®</sup> is not found or used in yoghurt.
2. It is true that some species of *Lactobacillus* are found widely in yoghurts.
3. PCC<sup>®</sup> is currently available in capsules in the proTract<sup>®</sup> range of products for the relief of symptoms of Irritable Bowel Syndrome and other conditions and is sold in Australian pharmacies. Probiomics has produced data in human clinical trials demonstrating the effectiveness of PCC<sup>®</sup> in relieving symptoms of disease conditions such as Irritable Bowel Syndrome and Atopic Dermatitis and reduction of respiratory illness. PCC<sup>®</sup>'s immunomodulatory effect therefore warrants investigation of its application in a broad range of conditions – including the flu vaccine study.

The articles followed Probiomics' announcement on 23 November (refer to [www.asx.com.au](http://www.asx.com.au)) of a trial to test the use of PCC<sup>®</sup> to boost the immune response to influenza vaccine and its possible applications to H5N1 (avian flu) vaccine. The trial will recruit 300 healthy volunteers aged 18-49 through Good Health Solutions Clinics in Sydney and test two doses of PCC<sup>®</sup> against a placebo capsule in a double blind trial. The rationale is to test the ability of PCC<sup>®</sup> to enhance the response to vaccines in humans. If successful, this could have significant implications for improving the performance of poorly immunogenic vaccines, particularly the H5NI vaccines.

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# Culture battles bird flu

## Yoghurt the key

By EDITH BEVIN

A BACTERIA found in yoghurt may hold the key to protecting Australia from the deadly bird flu virus.

The bacteria — *Lactobacillus fermentum* — will be used as a booster to the existing flu vaccine.

It could make the vaccine up to 12 times more effective, said Professor Ron Penny — one of Australia's leading immunologists and the brains behind the trial.

The world's first trial of the new natural approach — called probiotic PCC — on 300 healthy volunteers aged between 18 and 49 is expected to start in Sydney by the end of the year.

If initial trials with influenza vaccine are successful, PCC will be tested using a vaccine for the H5N1 strand of the bird flu virus.

"This project will test whether oral consumption of a specific strain of PCC is able to significantly enhance the immune response to a vaccine for influenza," Professor Penny said.

"If the trial demonstrates significant efficacy of PCC in enhance-

ing the immune response to influenza vaccine, we would then seek to test it using an H5N1 [avian flu] vaccine."

To make a dent in a pandemic, vaccines and anti-virals will be needed in much greater quantities than current plans allow, he said.

The US National Institute of Allergy and Infectious Diseases earlier this year said that to gain the essential immune response, people needed to be given 90 micrograms of killed bird flu vaccine virus, in two doses four weeks apart.

That is 12 times as much virus as is needed to make an effective vaccine out of an ordinary influenza virus.

The high dose needed using existing vaccine technology would mean vaccine-manufacturers would only be able to produce 25 million doses a year.

"That's far below what would be required in a global pandemic," Professor Penny said.

"If effective, PCC would substantially increase the number of vaccine doses the world could produce per month."

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