



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

<b>Name of medicine (INN):</b>	<ol style="list-style-type: none"><li>1) Live attenuated rotavirus vaccine NLT <math>10^{6.0}</math> CCID<sub>50</sub> /1.5 mL oral suspension</li><li>2) Live attenuated rotavirus vaccine NLT <math>10^{6.0}</math> CCID<sub>50</sub> /mL freeze dried powder for reconstitution (oral administration) [human strain]</li><li>3) Rotavirus vaccine, live, oral, pentavalent G1 2.2 x 10<sup>6</sup> infectious units, G2 2.8 x 10<sup>6</sup> infectious units, G3 2.2 x 10<sup>6</sup> infectious units, G4 2.0 x 10<sup>6</sup></li></ol>
<b>Indication:</b>	<ol style="list-style-type: none"><li>1) For the prevention of gastroenteritis caused by Rotavirus</li><li>2) For active immunization of infants against gastroenteritis due to Rotavirus</li><li>3) Prevention of Rotavirus enteritis in infant and children caused by serotypes G1, G2, G3, G4 and G-serotypes that contain P1 (e.g. G9)</li></ol>
<b>Dates of deliberation:</b>	14 January 2015 05 June 2015
<b>Recommendation:</b>	<b>DISAPPROVAL</b>
<b>Clinical evidence:</b>	<p>The Council acknowledged the results of the economic evaluation conducted for rotavirus vaccine entitled, "Assessing the Cost-effectiveness of Universal Rotavirus Vaccination for the Philippines." The Council noted that monovalent and pentavalent types of rotavirus vaccines are currently available in the Philippine market. A Cochrane review reported that there is no significant difference between the efficacies of the two (2) vaccines in severe diarrhea, hence, equal level of efficacy was assumed in the economic evaluation. Using a dynamic transmission model for rotaviral disease in the Philippines, the results of the economic evaluation showed that both vaccines led to reduction in cases and prevention of disability-adjusted life years (DALY). However, the incremental cost-effectiveness ratios (ICERs) of both were not cost-effective.</p>
<b>Cost data:</b>	<p>The costs data for each vaccine used in the study were obtained from correspondence with pharmaceutical company and from the latest bid price of the manufacturer for the Philippine government. The monovalent vaccine follows a two-dose regimen at a regimen price of PhP 638 to 866. The pentavalent vaccine, on the other hand, follows a three dose regimen at PhP 849 for the full regimen. Taking into consideration administrative costs, a 5 year universal rotavirus vaccination program for a birth cohort of around 2 million infants would cost PhP 10.78 billion if the monovalent vaccine was used and PhP 10.82</p>



## OFFICE OF THE SECRETARY

billion if the pentavalent vaccine was used.

The economic evaluation for the vaccine showed that both vaccines are not cost-effective with ICERs of PhP 593,252 and PhP 532,620 per DALY prevented for the monovalent and pentavalent vaccines, respectively. These values are way much higher than the set cost-effective level of PhP 143,880 which is equal to the gross national income (GNI) per capita of the Philippines and even higher than the WHO cost-effective level of 3x the GNI per capita.

Cost-effective regimen prices for the two products were computed using a healthcare payer perspective following two cost-effectiveness definitions: WHO and Philippines. Following the WHO definition, the cost-effective prices are PhP 445.72 for monovalent (PhP 222.86 per dose) and PhP 458.92 for pentavalent (PhP 152.97 per dose). Following the Philippine standard, the cost-effective regimen prices are PhP 250.8 (PhP 125.4 per dose) and PhP 258.72 (PhP 86.24 per dose). These prices are 50-70% lower than the current prices offered to the DOH. Given these information, the Council discussed that even though vaccination provides herd immunity and can decrease rotaviral morbidity and mortality, universal vaccination with rotavirus vaccine is not likely to be cost-effective given the current estimated disease burden and vaccine prices. The vaccine can become cost-effective if the prices are lowered to around 50%.

### Review of Appeal

The arguments of the proponent in the request for reconsideration are summarized into five points, to wit: (1) rotavirus infection leads to a high burden of illness in the form of diarrhea; (2) The rotavirus vaccine is the only feasible way of preventing rotavirus infection as sanitation has largely no impact on transmission; (3) rotavirus vaccine has been found to be efficacious and effective in lowering rotaviral diarrhea in various countries where it has been used; (4) rotavirus vaccine has been found to be cost-effective in countries with similar socio-economic background; and (5) a published cost-effectiveness analysis found that a monovalent vaccine is cost-effective in the Philippines. The Evidence Review Group did not contest the first four (4) points and only disagreed with the last argument. The reviewers noted that the proponent was referring to an unpublished study which used a very high case fatality rate. It was emphasized that the range used in the economic model was a better estimate because it used data from PhilHealth and published literatures which were validated through expert opinion. Moreover, the Council discussed that despite this, the outcome still remains the same since the vaccine is too expensive.

The FEC acknowledged the response of the reviewers to the appeal and agreed with their findings that the cost of implementing a universal vaccination program at the current market prices exceed the benefits gained from decreasing the transmission of disease. It was likewise



Republic of the Philippines  
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## OFFICE OF THE SECRETARY

discussed that for the vaccine to be cost-effective, the price has to be lowered down. It was noted, however, that a new price offer was not given in the appeal. Therefore, the Council reaffirmed their decision not to recommend the inclusion of rotavirus vaccine in the Formulary given the current available evidence and price offer which showed that it is not cost-effective.

**Remarks:**

After considering the documents submitted for reconsideration, the Secretary of Health, upon the recommendation of the Formulary Executive Council (FEC), has officially disapproved the said request.