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Cost-Effectiveness Evaluation of a Quadrivalent Human Papillomavirus Vaccine in Belgium

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Acknowledgement

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References

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We read with interest the paper by Annemans et al.[1] describing a Markov model to estimate the cost effectiveness of a quadrivalent human papillomavirus (HPV) vaccine in Belgium.

The base-case model assumed that the vaccine would prevent 55% of cervical intraepithelial neoplasia (CIN)-2/3 lesions or all CIN-2/3 lesions caused by HPV-6, -11, -16 and -18. However, the most reliable estimate available for overall CIN-2/3 reduction after vaccination is 46% (95% CI 24, 62), as presented by the company that developed the quadrivalent HPV vaccine Gardasil®. This estimate was based on a pooled analysis after 3 years of follow-up of all subjects who tested negative at baseline for 14 high-risk HPV types and who were randomly assigned to receive Gardasil® or placebo.[2] We used this estimate in our own pharmacoeconomic model for Belgium[3] and found estimates for the ICER of €32 665 per QALY gained in the base-case scenario with a 95% credibility interval between €17 447 and €68 078 per QALY gained, which is clearly superior to the estimates resulting from the model of Annemans et al.[1] Although the differences between the results of the two models are not only attributable to the difference in the assumed effectiveness of the quadrivalent vaccine against CIN-2/3 lesions, we believe that data obtained in the context of randomized clinical trials provide the best currently available estimate of the population impact of the studied quadrivalent HPV vaccine Gardasil® in a truly susceptible population, rather than estimates based on theoretical projections. Therefore, we argue that the cost per QALY gained of HPV 6/11/16/18 vaccination is underestimated in this paper.

The Author's Reply

We thank Cleemput and Thiry[1] for their interest in our research[2] and are grateful for the opportunity to respond.

Since Gardasil® is a prophylactic quadrivalent vaccine that targets four human papillomavirus (HPV) types (6/11/16/18), the per protocol population (PPE) was used as the primary analysis population to evaluate the prophylactic efficacy of Gardasil® on the incidence of diseases caused by vaccine HPV types (PPE: received all three doses of vaccine, naive to the relevant HPV vaccine type at baseline and 1 month after complete vaccination). The measured prophylactic efficacy against cervical intraepithelial neoplasia (CIN)-2/3 related to HPV vaccine types 6/11/16/18 was almost 100% in the PPE population.

The figures reported by Cleemput and Thiry[1] correspond to another population (restricted, modified intent-to-treat-2 population: received at least one dose of vaccine, generally naive to all 14 HPV types tested and with negative Pap test at baseline) used in the clinical trials to evaluate the