Massachusetts Vaccine Purchasing Advisory Committee Guiding Principles

Article II, Mission and Purpose, Section 2, Purpose, of the MVPAC Operating Guidelines state: "The Council shall take into account safety and efficacy, and may take into account provider input, vaccine characteristics, cost, availability and other factors as determined by the Council." Further, the Council has recommended that its deliberations be guided by the common goal of reducing barriers to optimal pediatric vaccination rates. In general, the recommendations of Center for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP) will serve as the guide to all Council deliberations

The purpose of this document is to further specify and clarify the principles that will guide the MVPAC when making recommendations to the Commissioner of Public Health regarding pediatric vaccine purchases. These guidelines are grouped into five distinct categories, with Category I being of greatest of importance and Categories II-V all being treated either equally or of variable importance based on the discussion at the time.

Category I: Safety and Efficacy

Safety, efficacy and data published in peer-reviewed literature and the recommendations of the ACIP and U.S. Food and Drug Administration will serve as a guide to the Council on these issues. Data from the federal vaccine safety surveillance system will also be considered.

Safety shall at all times be of paramount importance, and encompasses the health and well-being of the individual with regard to potential adverse reactions to specific vaccines and vaccine elements. To this end the Council shall take into consideration in a balanced way evidence of serious adverse events associated with specific vaccines weighed against their individual and collective disease prevention benefits.

Efficacy shall relate to the absolute protection afforded to individuals by specific vaccines or vaccine combinations as well as their relative protection compared to available alternatives. It is relevant to consider not only the protection afforded to the individual but also to the community surrounding the individual as improved rates of immunization may result in more substantial protection of the community.

Category II: Cost and supply issues

Vaccine cost both in absolute and relative terms shall be weighed against potential individual and collective benefit with the goal of maximizing limited public resources expended on pediatric vaccines. To the degree possible, relative cost shall not be considered in isolation, but in the context of other factors outlined in these guiding principles.

Supply issues shall be considered on an ongoing basis, with reference to historic and anticipated challenges at the national level in maintaining adequate and timely availability of specific vaccines. Interruptions in supply risk underimmunization, increased provider and patient burdens, and the potential for vaccine error. Historic supply issues shall be examined in light of

more recent data regarding current and anticipated supplies of specific vaccines. The Council may choose to recommend the purchase of more than one vaccine formulation to prevent a given infection or group of infections in order to ensure adequate supplies.

Category III: Provider and patient issues

Storage and administration: The Council shall consider the relative provider burden associated with the storage, preparation, dosing schedules, and administration of specific vaccines, giving weight to those formulations that simplify these processes for the clinical provider in service of the common goal of reducing barriers to optimal pediatric vaccination rates. No single provider issue shall exclude a vaccine from consideration, but the cumulative effect of multiple provider-side issues may be weighed against other factors outlined in these principles.

Patient issues: The Council shall consider patient preferences with regard to the administration of particular vaccines, including the relative convenience of various dosing schedules, routes of administration, and vaccine tolerability/adverse event profiles. In all cases, patient issues shall be weighed against other factors outlined in these principles, in particular considerations of safety and efficacy.

Category IV: Market share

The Council recognizes the importance of a robust vaccine manufacturing industry in the U.S. and internationally to the public's health and the important role the Commonwealth's resource investment in pediatric vaccines plays in this industry. Therefore, the relative pediatric vaccine Massachusetts market share of each manufacturer may be considered in the final recommendations of the Council, should all other factors outlined in these principles be assessed as reasonably equivalent.

Category V: Conservatism

The Council, in its goal to maximize vaccine coverage and minimize provider confusion, vaccine waste and administration errors, will avoid to the degree possible making significant changes to their periodic purchasing recommendations except as indicated by their careful assessment of the factors outlined in these principles.