## Minutes Massachusetts Department of Public Health Massachusetts Vaccine Purchasing Advisory Council (MVPAC) Meeting

Date: Thursday, May 6, 2021 Time: 4-6 PM Location: Virtual Meeting

#### **Council Member Attendees:**

Kevin Cranston, MDiv Leanne Barry, DCN, MPH, MBA Lloyd Fisher, MD Thomas Hines, MD Susan Lett, MD, MPH H. Cody Meissner, MD

#### **Additional Attendees:**

Susanna Bächle Eric Bevans George Coutros Kim Daly Edward Doherty Katherine Galarza Bill Hagan Alex Helleberg David Johnson David Norton, MD Ronald Samuels, MD, MPH Patricia Toro, MD, MPH Marissa Woltmann, MPP Zi Zhang

Larry Madoff Cynthia McReynolds Monica Mercer Stephen O'Brien Corey Robertson Sherry Schilb Shumethia Seal PejmanTalebian Pamela Worthington

#### Welcome

Kevin Cranston opened the meeting and welcomed attendees. Attendees introduced themselves.

#### **MDPH Updates**

Pejman Talebian presented a MDPH Update.

To date, 7.7 million COVID-19 vaccine doses have been received in Massachusetts. Of these doses, 5 million have been processed at MDPH.

Of the 7.7 million doses, 6.5 million have been administered. 2.7 million Massachusetts citizens are fully vaccinated.

With the anticipated EUA approval of Pfizer-BioNTech COVID-19 vaccine for children aged 12-15 years, planning for the rollout of the vaccine to primary care providers is well underway and should be similar to the traditional model (utilizing the Massachusetts Immunization Information System for vaccine management).

## Manufacturer Presentation: MenQuadfi<sup>TM</sup> Meningococcal (Groups A, C, Y, W) Conjugate Vaccine Corey Robertson, MD, MPH, Senior Director of Scientific and Medical Affairs, Sanofi Pasteur US

Despite its low incidence, invasive meningococcal disease (IMD) remains a health challenge, because it can strike quickly with devastating effects. Despite the significant decline in IMD in adolescent and young adults since the introduction of MenACWY-CRM vaccine in 2005 and MenACWY-D in 2010, there is room for improvement.

MenQuadfi was approved by the FDA in April 2020 in persons 2 years of age and older, MenQuadfi is a quadrivalent meningococcal vaccine, to help prevent IMD caused by serotypes A, C, W and Y.

MenQuadfi is conjugated to tetanus toxoid as a protein carrier, does not require re-constitution and is supplied in a single dose vial.

The clinical development program and results were reviewed. The results of all five clinical trials have been published. All Phase III clinical trials were randomized, blinded and active-controlled. MenQuadfi demonstrated to have an acceptable safety profile and to induce robust immune response against serotypes, A, C, W, Y and especially serogroup C.

MenQuadfi induced robust booster responses among persons previously primed with either MenACWY-D (Menactra) or MenACWY-CRM (Menveo).

Clinical trial data show that MenQuadfi can be safely co-administered with routinely recommended adolescent vaccines, such as HPV and Tdap vaccines.

MenQuadfi vaccine became available in the US in April 2021.

MenQuadfi is currently being evaluated in various III/IIIb clinical studies to seek expansion of the age indication to six weeks of age and to evaluate MenQuadfi according to different pediatric immunization schedules that exist worldwide.

## **Q&A/Deliberation**

Questions:

Is there a price difference per dose? *The CDC price per dose is the same for Menactra and MenQuadfi - \$105.05.* 

What is the argument for adding MenQuadfi other than offering choice for providers? In the event of supply chain issues, it is better to have more than one available vaccine.

Will Menactra be discontinued in the near future? A transition from Menactra to MenQuadfi will not happen until the age indication for MenQuadfi is down to six weeks.

Deliberation: Should the MDPH Immunization Division add MenQuadfi into its formulary as an additional meningococcal conjugate vaccine?

After discussion, there was Council consensus to recommend that the MDPH Immunization Division add MenQuadfi into its formulary as an additional meningococcal conjugate vaccine.

Deliberation: Should the MenQuadfi vaccine be offered under the consideration of provider choice?

After discussion, there was Council consensus to recommend that provider choice be allowed for meningococcal conjugate vaccine.

Manufacturer Presentation: VAXELIS<sup>TM</sup> Diphtheria and Tetanus toxoids and Acellular Pertussis, inactivated poliovirus, Haemophilus b Conjugate and Hepatitis B Vaccine David Johnson, MD, MPH, Associate Vice President in Global Medical Affairs, Sanofi Pasteur

Combination vaccines have helped to improve timeliness of and compliance to recommended vaccinations. Combination vaccines offer the potential benefits of fewer vaccinations, reduced, late or missed vaccinations, more convenience and higher vaccination rates. Higher vaccination rates can reduce disease likelihood among unvaccinated individuals.

CDC, AAP and AAFP strongly recommended the use of combination vaccines when possible. Hexavalent vaccines are the standard of care in many European countries.

Vaxelis vaccine components were reviewed.

Vaxelis Phase III clinical trials and integrated safety analyses were reviewed.

In anticipation of its launch in 2021, Vaxelis has been included in the Recommended Child and Immunization Schedule for ages 18 and younger – United States, 2021.

Vaxelis was reviewed in comparison to the other US combination vaccines recommended for children in the first six months. Three Vaxelis shots are required, as compared to 5 or 6 for the other US combination vaccines.

A timeline of Vaxelis milestones from licensure to launch was reviewed.

## **Q&A/Deliberation**

What happened when Vaxelis was introduced in European countries? Was it chosen over other combination vaccines? *The vaccine was licensed in Europe in 2016 and launched in 2017. The uptake in Europe has been very brisk and is one of the reasons for the lengthy pause from licensure to launch in the US. The demand for Vaxelis has been very strong in Europe with* 

additional countries coming on. With anticipated US demand being high, Sanofi/Merck have been working to ensure that a sustainable supply will be available. Sanofi expects to meet demand when the vaccine becomes available.

Will Pentacel be phased out? Pentacel will continue to be marketed.

Discussion:

Mr. Talebian noted that if added to the formulary, Vaxelis, as a combination vaccine, would not be administered to replace other vaccines.

Dr. Samuels noted a concern that providers using Vaxelis may stop recommending the Hepatitis B birth dose. Mr. Talebian noted that this already is an issue with providers who are using Pediarix.

There is a concern about Hepatitis B birth dose uptake. Messaging regarding the importance of the Hepatitis B birth dose needs to be reinforced.

## **Deliberation: Should Vaxelis be added to the MDPH Immunization Division vaccine formulary?**

# There was Council consensus that Vaxelis should be added to the MDPH Immunization Division vaccine formulary.

Deliberation on provider choice for this vaccine would not be needed.

Dr. Lett noted that CDC is working on guidance and tools for Vaxelis vaccine integration with other vaccines. Ms. Schilb noted that Sanofi transition materials would be available soon.

## Next Meeting

The next Council meeting is scheduled to be held on Thursday, October 14, 2021. Updates for this meeting will be sent as they become available.

The meeting was adjourned.

## **Future Meeting Dates:**

Thursday, October 14, 2021 Thursday, March 10, 2022 Thursday, June 9, 2022 Thursday, October 13, 2022

#### **MVPAC** webpage:

https://www.mass.gov/service-details/massachusetts-vaccine-purchasing-advisory-councilmvpac