From: Stanley Plotkin

Sent: 30 Apr 2019 19:50:21 -0400

To: Wolfe, Skip (CDC/DDID/NCIRD/ISD)

Subject: RE: MMR VIS Update

Thanks, Skip, very clarifying. Indeed my first question is whether or not I can help. Perhaps a more general question is who has input? Do the manufacturers? FDA? How will these revisions be made? Stanley

From: Wolfe, Skip (CDC/DDID/NCIRD/ISD) [mailto:crw4@cdc.gov]

Sent: Monday, April 29, 2019 10:31 AM

To: Stanley Plotkin

Subject: RE: MMR VIS Update

Good morning Dr. Plotkin,

At the moment, there's a bit of uncertainty in the VIS world, and it's very likely that all VISs will be undergoing a transformation and emerge with a simplified, easier to read, format. Because of this potential wholesale change, it's uncertain whether individual VISs will be updated in the meantime, but I'll let you know when we know more ourselves.

Regarding the changes to MMR we've discussed, CDC's Immunization Safety Office and the MMR subject matter experts all seem to be on board with these, so they will almost certainly be incorporated. DTaP will also undergo review and updates, and the adverse event language will be clarified as necessary. The language (on both MMR and DTaP) that you question is most likely related to encephalopathy and goes back to the earliest VISs in 1994.

At any rate, we're discussing all these issues almost daily, and I'm hopeful that something will happen soon. I'm sorry I can't give you a definitive answer or timetable right now, but lots of people are involved in these discussions, which, as I'm sure you're aware, bogs down the process.

Skip

From: Stanley Plotkin <stanley.plotkin@vaxconsult.com>

Sent: Thursday, April 25, 2019 1:39 PM

To: Wolfe, Skip (CDC/DDID/NCIRD/ISD) <crw4@cdc.gov>

Subject: RE: MMR VIS Update

Dear Skip:

I have been busy with other things but now have time to return to the issues of VISs and Package Inserts. With regard to the email below, has anything happened since?

Thanks,

Stanley

From: Wolfe, Skip (CDC/DDID/NCIRD/ISD) [mailto:crw4@cdc.gov]

Sent: Friday, March 15, 2019 3:30 PM

To: Stanley Plotkin

Subject: MMR VIS Update