To: Camilla Riesbeck - 9744 DKMA[CARI@dkma.dk]
From: HENRIK G. JENSEN - 93590201 DKMA
Sent: Tue 19-01-2016 16:19:26
Importance: Normal
Subject: VS: Request for contribution from EMA (please reply by January the 15th 2016/February the 8th 2016) - Question from the Danish Parliament regarding EMA's assessment report on HPV-vaccines
MAIL_RECEIVED: Tue 19-01-2016 16:19:27

Fra: Labbe Sophie [mailto:Sophie.Labbe@ema.europa.eu]
Sendt: 19. januar 2016 17:16
Til: HENRIK G. JENSEN - 93590201
Cc: Benstetter Monika
Emne: Request for contribution from EMA (please reply by January the 15th 2016/February the 8th 2016) - Question from the Danish Parliament regarding EMA's assessment report on HPV-vaccines

Dear Mr Jensen,

As just discussed, please find below comments from EMA to respond to the first question from the Danish Parliament (letter from Vibeke Vind) regarding EMA's assessment report:

The PRAC carried out a detailed scientific review of all the available evidence. They reviewed the published research, data from clinical trials, reports of suspected side effects from patients and healthcare professionals, as well as data supplied by Member States.

The Committee also heard from independent leading experts on vaccine safety, cardiology, neurology and clinicians with specific expertise on CRPS/POTS, and took into account detailed information received from a number of patient groups that also highlighted the impact these syndromes can have on patients and families.

On the basis of this careful review of all available evidence, the PRAC concluded that the evidence available so far does not support a causal link between the vaccines and development of CRPS or POTS. The PRAC members agreed on these conclusions by consensus.

The PRAC noted that most symptoms of CRPS and POTS are unspecific, making them difficult to diagnose both in the general population and in vaccinated individuals. They noted also that some symptoms of CRPS and particularly POTS may overlap with chronic fatigue syndrome

(CFS or ME). Many of the reports considered in the review have features of chronic fatigue syndrome and some patients have been diagnosed with both POTS and chronic fatigue syndrome, an observation which was supported by recent publications (Brinth et al, 2015). Therefore, results of a large published study (Donegan et al, 2013) that showed no link between HPV vaccine and chronic fatigue syndrome were in the PRAC opinion relevant to be considered in the referral, although the study is conducted only for Cervarix. With the currently available data for both vaccines, there was no basis for differentiation according to the PRAC view.

Please kindly note that EMA cannot comment on the way that the different European countries diagnose and treat different conditions (including CFS/ME), as this is outside its remit.

Finally, we would like to emphasise that, regardless of the outcome of the referral, EMA will continue to carefully monitor the safety of these vaccines, as with all medicines, and will take into account any future new evidence of side effects that may become available, including any new evidence regarding POTS and CRPS.

Very sorry for the delay in replying to your request. We are working on questions 2 and 3 and will aim to respond within your deadline of 8 February.

Please don't hesitate to come back to us should you need any further information.

With kind regards,

Sophie

Sophie Labbé

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From: HENRIK G. JENSEN - 93590201 [mailto:HGJ@dkma.dk]
Sent: 06 January 2016 15:14
To: Benstetter Monika
Cc: Camilla Riesbeck - 9744
Subject: Request for contribution from EMA (please reply by January the 15th 2016/February the 8th 2016) - Question from the Danish Parliament regarding EMA's assessment report on HPV-vaccines

Request for contribution from EMA - Question from the Danish Parliament regarding EMA's assessment on HPV-vaccines

Dear EMA,

The Danish Medicines Agency is asking for your contribution in order to be able to answer the following questions from the Danish Parliament:

1. Question from the Danish Parliament regarding EMA's assessment report – letter from Vibeke Vind

In e-mail dated December the 7th 2015 we asked for your comments to a letter from Vibeke Vind regarding the assessment report. Please find enclosed a copy of our e-mail.

In order for us to answer the Parliament within our deadline, we would be very grateful to receive your comments by January the 15th 2016.

2. Question from the Danish Parliament regarding Louise Brinth's responsum to EMA's assessment report on HPV-vaccines

The Danish Parliament has asked the Danish Minister for Health to comment on the responsum from Louise Brinth to EMA's assessment report on HPV-vaccines. In the responsum Louise Brinth addresses the assessment report by EMA which according to Louise Brinth directly criticize three of her publications regarding her clinical experience with patients with suspected adverse reactions to quadrivalent HPV vaccine. Furthermore, Louise Brinth finds that the report indirectly criticize her clinical expertise and judgment as a substantial part of her adverse reactions reports are overruled. The responsum was sent to you by e-mail on December the 16th 2015 and is enclosed in this e-mail.

The Danish Medicines Agency is asking for EMA's comments to the responsum. In order for us to answer the Danish Parliament within our deadline, we would be very grateful to receive your comments by February the 8th 2016.

3. Question from the Danish Parliament regarding a blog from Sine Jensen, who participated in the SAG-meeting

The Danish Parliament has asked the Danish Minister for Health to comment on an article from Sine Jensen. Sine Jensen, who participated in the SAG meeting as a consumer representative, has published a blog in a Danish media with the title (our translation) BLOG: Gag about the HPV-vaccine - http://www.mx.dk/nyheder/hpv_blog/story/17207486). In the blog it is stated that Sine Jensen participated in the first scientific meeting, where the cornerstone to a possible connection between the vaccines and POTS/CRPS was investigated, but that she is not allowed to talk about it due to a lifelong obligation of confidentiality.

The Danish Medicines Agency would like EMA to explain what kind of obligations regarding confidentiality the participants from the SAG meeting have agreed to and the reasoning behind such obligations. Is it correct, that participants of the SAG meeting is not allowed to talk about any parts of the SAG meeting?

The answers from the SAG meeting are part of EMA's published assessment report on HPV-vaccines.

In order for us to answer within the deadline, we would be very grateful to receive EMAs comments by February the 8th 2016.

Should you have any questions regarding the matter, please do not hesitate to contact me.

Best regards,

Henrik G. Jensen

Director of Pharmacovigilance

Danish Medicines Agency