From: [redacted] 5.1.2e
Location: Res 525 - Video Conference Room
Importance: High
Subject: TIME CHANGE FOR WEBINAR: 18:15 - 19:15 CET - EU-EEA NITAG COLLABORATION WEBINAR: Follow-up Safety signal on AstraZeneca vaccine
Start Date/Time: Thur 3/18/2021 5:15:00 PM
End Date/Time: Thur 3/18/2021 6:15:00 PM
CASE DEFINITION OF THROMBOSIS AND THROMBOEMBOLISM_DRAFT.docx
SPEAC_D2.5.2.1 Thrombocytopenia Case Definition Companion Guide_V1.0_format.pdf

RESENDING TO MAKE ALL AWARE
PLEASE NOTE
NEW CHANGE OF TIME FOR WEBINAR TO ALLOW FOR ALL MEETINGS TO BE HOSTED BY EMA TODAY. EMA PHARMACOVIGILANCE RISK ASSESSMENT COMMITTEE WORK IS STILL ON-GOING.

Dear Colleagues,

Please be invited to a

Follow-up Webinar on the Safety Signal on the AstraZeneca vaccine

Thursday 18th of March 18:15 – 19:15 CET (line will stay open longer if needed)

This meeting follows the EMA PRAC meeting to be held earlier on the 18th of March. Please extend the invitation to all EU/EEA NITAG Members and colleagues in public health, ministries of health and regulatory agencies with responsibilities for the COVID-19 vaccination programmes.

Please find dial-in details below.

To facilitate the EMA PRAC assessments it is key that the ADR reports submitted from MSs are of highest possible quality. It all starts with the vaccinators investigations and their reports. We discussed on the 15th of March whether a case definition would be needed to ensure reported cases are properly investigated. Although reported cases may have an atypical presentation it is possible that we can learn a lot from the earlier and on-going work by the Brighton Collaboration on case definitions. Both EMA and ECDC therefore were invited to a dialogue yesterday where the Brighton Collaboration presented their DRAFT case definition for thrombosis and thromboembolism that they have been working on since autumn 2020. Yesterday, they agreed to share the draft case definition with the EMA, EU/EEA regulators and the EU/EEA NITAG network. At the time of sending this invitation it is unclear what the outcome of the EMA PRAC assessment will be but the draft case definition may be helpful for us moving forward so we decided to share them already today for you to have a first glance. Also adding an updated Brighton Collaboration case definition on thrombocytopenia.

A very warm welcome to all.

Programme

18:15 – 18:25	Welcome and objectives of the meeting	[redacted] 5.1.2e, ECDC
18:25 – 18:45	Update on discussions and conclusions in EMA Pharmacovigilance Risk Assessment Committee concerning the safety signal on the COVID-19 vaccine AstraZeneca	[redacted] 5.1.2e 5.1.2e 5.1.2e 5.1.2e
18:45 – 19:10	Discussion	All
19:10 – 19:15	Next steps	All

**Please note that the meeting will be recorded for the purpose of the minutes.*

With kindest regards,

[redacted] 5.1.2e
[redacted] 5.1.2e

EU/EEA NITAG COLLABORATION

Thursday, March 18, 2021

18:15 PM | (UTC+01:00) Brussels, Copenhagen, Madrid, Paris | 1 hr

Join meeting

More ways to join:

Join from the meeting link

5.1.2h

Join by meeting number

Meeting number (access code) 5.1.2h

Meeting password: 5.1.2h

Tap to join from a mobile device (attendees only)

5.1.2h Sweden Toll International Dial

5.1.2h Belgium Toll

Some mobile devices may ask attendees to enter a numeric meeting password.

Join by phone

5.1.2h Sweden Toll International Dial

5.1.2h Belgium Toll

Global call-in numbers

Join from a video system or application

Dial 5.1.2e @ecdc.webex.com

You can also dial 5.1.2h and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial 5.1.2e @lync.webex.com

Need help? Go to https://help.webex.com

Confidentiality Notice
If you are not the intended recipient of this message, you are hereby kindly requested, to, consecutively, refrain from disclosing its content to any third party, delete it, and inform its sender of the erroneous transmittal.